

Restoring Strength and Independence: The Transformative Impact of truFlex™ on Muscle Recovery, Mobility, and Quality of Life in Spinal Cord Injury and Neurological Rehabilitation

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Abstract

Objective: This study sought to evaluate the transformative potential of truFlex™, a cutting-edge multi-directional electrical muscle stimulation device from Cutera®, in enhancing muscle strength, tone, and overall functionality in individuals with spinal cord injuries (SCI), cerebral palsy, limb amputations, and other neurodegenerative conditions. In addition to assessing physical improvements, the study explored the impact of truFlex™ on the psychological well-being and quality of life of participants. Looking forward, the study also opens the door to the potential application of truFlex™ in treating conditions associated with diseases such as Parkinson's disease and Multiple Sclerosis. Furthermore, patient-reported outcomes—including enhanced mobility, pain reduction, and faster recovery times—were integral to the findings.

Methods: The study was conducted over two nine-week periods, during which participants received tailored truFlex™ treatments targeting specific muscle groups based on their individual conditions. A comprehensive approach to measuring progress was employed, utilizing DEXA scans, tape measurements, photographs, and self-reported data [from participants]. The study included a diverse cohort, with 70% male and 30% female participants, aged 19 to 56. truFlex™ delivered up to 30 milliamps of electrical current to stimulate deeper muscle contractions, compared to the 1-2 milliamps generated in voluntary contractions. The protocols were developed by Dr. Edward Alvarez of Madison Avenue Face and Body in New York City and Miami. All treatments were performed at the Adaptive Training Foundation Facility in Dallas, Texas, under strict scientific protocols and were supported by weekly assessments to ensure accurate tracking of participant progress and outcomes.

Results: The results revealed substantial and unexpected gains across all conditions. Participants experienced significant increases in muscle mass, strength, and tone, alongside improvements in core stability and mobility. Many reported restored sensations in areas previously affected by paralysis or nerve damage. Additional breakthroughs included enhanced bowel and bladder control, faster post-rehabilitation recovery, and even the restoration of menstrual cycle sensations in some female participants—an unexpected and profound outcome. The physical improvements were complemented by enhanced psychological well-being, including heightened self-confidence, social engagement, and renewed hope for an active, independent future.

Conclusions: truFlex™ has demonstrated itself as more than just a tool for muscle stimulation—it has emerged as a vital catalyst for both physical and psychological rehabilitation. The device has shown the ability not only to mitigate muscle atrophy but also to promote functional

recovery, providing participants with renewed independence and dramatically improved quality of life. These findings suggest that truFlex™ holds immense promise as an essential part of rehabilitation for a variety of conditions, opening new frontiers for treating patients with spinal cord injuries, cerebral palsy, limb amputations, and potentially conditions associated with Parkinson's disease and multiple sclerosis.

Introduction

This study was designed to explore the groundbreaking potential of truFlex™, a multi-directional electrical muscle stimulation device from Cuteri®, in enhancing muscle strength, tone, and overall functionality in individuals with spinal cord injuries (SCI), cerebral palsy, limb amputations, and other neurodegenerative conditions. truFlex™ offers a unique rehabilitative approach by delivering up to 30 milliamps of electrical current to the muscles—far surpassing the 1-2 milliamps typically generated during voluntary muscle contractions. This deeper, more targeted stimulation allows for the activation of muscle fibers that are otherwise difficult to engage or recruit, providing a novel and powerful tool in muscle recovery and rehabilitation.

Among the participants of this study were individuals with **paraplegia** and **quadriplegia**, conditions defined by the loss of motor control and sensation due to spinal cord injuries.

Paraplegia specifically refers to paralysis affecting the lower half of the body, often leaving upper body function intact, while **quadriplegia** (also known as tetraplegia) results from injury to the cervical spinal cord, affecting all four limbs. These conditions often leave patients with significant muscle atrophy, diminished mobility, and impaired daily functioning, underscoring the urgent need for innovative treatment strategies like truFlex™.

Conducted over two nine-week periods, this study was designed to rigorously assess how truFlex™ could not only mitigate muscle atrophy but also actively improve muscle strength, mobility, and overall quality of life. The cohort consisted of 70% males and 30% females, ranging in age from 19 to 56 years old, all of whom participated in individualized truFlex™ treatment sessions. The treatments were performed under strict protocols, developed and overseen by Dr. Edward Alvarez of Madison Avenue Face and Body in New York City and Miami. His design of the study ensured that each participant's unique needs were addressed individually.

The study was conducted at the Adaptive Training Foundation Facility in Dallas, Texas, a leading center for adaptive athletes and those with physical disabilities. With a focus on both the physical and psychological aspects of recovery, this study aimed to assess not only improvements in muscle mass and strength but also the broader impacts of truFlex™ on participants' overall well-being, independence, and quality of life.

Methods

The study involved regular truFlex™ treatment sessions targeting specific muscle groups for each participant. Quantitative outcomes, such as muscle mass and strength, were assessed through various means, including DEXA (Dual-Energy X-ray Absorptiometry) scans. A DEXA scan is a medical imaging technique used to measure bone density, muscle mass, and fat

distribution with high precision. It provides detailed data on body composition, making it an ideal tool for tracking muscle growth and atrophy in participants with spinal cord injuries, cerebral palsy, and limb amputations.

In addition to DEXA scans, tape measures, photographs, and self-reported feedback from participants were utilized to track progress. These additional methods provided a comprehensive view of the participants' improvements in muscle size, strength, and overall physical function.

The study cohort included 70% males and 30% females, with ages ranging from 19 to 56 years old. Each participant underwent truFlex treatments designed to target key muscle groups affected by their conditions. truFlex™ delivers up to 30 milliamps of electrical current to the muscles to create involuntary contractions, compared to the 1-2 milliamps delivered during a typical voluntary muscle contraction. This higher level of stimulation allows truFlex™ to activate deeper muscle fibers, contributing to greater strength, tone, and endurance improvements in the treated areas.

Participants attended regular truFlex™ sessions as part of their broader rehabilitation program, with each session targeting specific muscle groups depending on their individual needs. The number and duration of treatments varied based on the severity of their condition and goals for rehabilitation. Some participants completed one round of treatments, while others underwent two rounds to continue building upon their initial improvements.

The treatment study protocols were developed by **Dr. Edward Alvarez** of **Madison Avenue Face and Body** in New York City and Miami, ensuring a structured and scientifically grounded approach. All treatments were performed at the Adaptive Training Foundation Facility in Dallas, Texas, a specialized center for adaptive athletes and individuals with physical disabilities. Weekly meetings were held to review findings, participant responses, and progress in order to refine treatment approaches and ensure optimal outcomes for each individual.

The studies were conducted over two nine-week periods, following strict protocols to ensure consistency and reliability of results. Throughout the study, participants were encouraged to maintain a consistent activity routine to complement the truFlex™ sessions and maximize their physical improvements.

Ethical Approval Statement

This study was conducted in accordance with ethical guidelines for clinical research. All participants provided informed consent prior to participation, including consent for the truFlex™ treatment, the use of their firsthand reports, and the collection of data for use in research and educational publications. Participants were informed of the potential risks and benefits of the treatment, and their participation was entirely voluntary.

Results

Participants demonstrated statistically significant gains in muscle mass and strength across all conditions, with notable improvements in core and lower-body strength, mobility, and overall

functionality. Each participant experienced varying degrees of physical and psychological benefits from the truFlex™ treatments. Below are detailed accounts of the most significant findings:

- **Nick** (T7 Paraplegic):

Before truFlex treatment, Nick had diminished support and strength in his core abdominal muscles and obliques, and no sensation in his glutes and quadriceps. He also suffered from marked increased muscle tone and spasms in his abs, obliques, glutes, and quadriceps. After truFlex™, Nick reported significant improvements: he regained near-normal sensation in his abdomen and obliques, with some sensation returning in his glutes and quadriceps. Muscle tone and spasticity greatly decreased in all areas, and for the first time, he felt the adduction of his thighs. He now also feels increased intercostal support, allowing him to generate more force with his abdominal muscles. An independent DEXA scan showed a 2-pound increase in muscle mass in his quadriceps, and six months after completing the treatment, Nick maintained his muscle size, showing that truFlex helped mitigate atrophy and grow muscle. He is now undergoing treatment on his arms to continue improving his quality of life.

- **Nelson** (Below-Knee Amputee, Reality TV Star):

Nelson, a reality TV star who competed on *MTV's The Challenge*, was able to run up to 5 miles for the first time in two years after truFlex™ treatments. He experienced a marked reduction in neuroma pain in his amputated limb, along with increased leg strength and faster muscle recovery. Nelson remarked that his recovery time after rehabilitation and gym training has been significantly faster than before, and he noted that truFlex™ would have been invaluable during his immediate post-surgical recovery. He expressed his satisfaction with the mobility gains, saying his muscles now feel looser, not as tight or restricted. Nelson hopes to compete in the Paralympics as a runner and return to *The Challenge* to compete once again.

- **Logan** (Cerebral Palsy, Skier):

Logan, a skier with cerebral palsy, experienced remarkable progress during truFlex™ treatments. He gained control over his arm spasms and reported that his muscles felt softer and more relaxed. Previously, Logan required 15-20 Botox injections every few months to manage spasticity, but after six truFlex™ sessions, Logan stated “I have seen more improvement in 3 weeks of flex than I have seen from 15 years of Botox treatments”. His gait improved to the point where he felt like he was “gliding,” and his balance saw substantial improvements. His mother noticed that his speech became clearer, which increased Logan’s confidence, enabling him to socialize more freely. He reported that he now feels confident enough to “flirt” when out with his friends. One of Logan's most significant milestones was catching a ball with his left hand, something he had never been able to do due to severe spasticity. With continued truFlex™ treatment, Logan has increased his deadlift weight by over 75 pounds, and increased size of his hamstrings by 3 inches. He described truFlex™ as “the best thing I have ever done” and believes it is giving him his best chance of reaching the Paralympics as a skier. Logan is also a motivational speaker, inspiring others with cerebral palsy to pursue their goals.

- **Ian** (C4 Quadriplegic):

Ian, a C4 quadriplegic, began the study with limited ability to stand and take steps using a walker with assistance. He struggled with poor core strength. After his fourth truFlex™ treatment (two

weeks after starting), Ian experienced a breakthrough in bowel and bladder control. He reported increased sensation of urges and the ability to hold the urge to use the bathroom for over an hour, something that had previously been impossible. Six months later, Ian not only maintained but also improved his bowel and bladder control. He also experienced increased strength and speed while using his walker. By the end of nine treatments, his upper abdominal muscle functionality had increased, his lower back felt looser, and his hamstrings and core showed better activation. His short-term goal is to stand from a normal chair without help, and his long-term goal is to “retire his wheelchair.” During his second round of treatments, Ian regained sensation in his right calf and felt a complete relief of lower back pain. His foot drop improved, and he gained noticeable lift when walking. His abdomen regained strength and sensation. Three weeks into his second round of treatments, Ian had a breakthrough—he walked for 1 hour and 40 minutes with a walker, the longest he had ever done. He said he could have walked another hour, and his physical therapist was astonished by his progress. Ian stated, “Having this treatment (truFlex™) has been a game changer. I can’t wait to tell everyone!”

- **Kristin** (Below-Knee Amputee):

Kristin had marked atrophy in her left quadricep above her amputation and aimed to strengthen it so she could stop overcompensating with her other leg. After six weeks of truFlex™ treatment, she saw an increase of almost 2 inches in the circumference of her left quadricep. Kristin also suffered from recurring pain in her left leg, which was alleviated after each truFlex™ session. She was excited to see her leg getting stronger and is now able to contract her left thigh muscles. She said, “I didn’t even know my quads worked.” Kristin also noticed a significant improvement in her balance.

- **Makayla** (C6 Quadriplegic, Cheerleader):

Makayla, who suffered a spinal cord injury while cheerleading at age 17, became the inspiration for this truFlex™ project. Initially, the goal was to mitigate muscle atrophy, but unexpected results followed. Makayla had multiple goals, including increasing strength, function, and mobility. She suffered from diminished strength in her abdomen, atrophy in her lower body, and little sensation in her core, glutes, and thighs, along with increased spasticity in her abdomen and thighs. One of her biggest concerns was the “wheelchair gut” associated with abdominal muscle atrophy in wheelchair users. After a three weeks of truFlex™ treatment, Makayla began to see improvements in muscle tone and strength in her core and abdomen. After 10 weeks, Makayla had increased strength and force generated by her abdomen and obliques, and she experienced increased, even normalized, sensation in her abdomen, obliques, and thighs. Her spasticity decreased, and her core stability and motion improved. An unexpected outcome was the return of sensation related to her monthly cycle, a sensation that had been absent since her injury. These physical improvements also bolstered her psychological well-being, with her mother observing, “She is starting to love her body again. It makes my momma heart happy for her!”

- **Derrick** (C6/C7 Quadriplegic):

Derrick suffered his injury while sledding with his son and started the study partially recovered, walking with a cane. Initially, his progress was slower than some of the other participants, but after about a month of truFlex™ treatments, he experienced a breakthrough. He reported feeling stronger and leaner, eventually walking without the need for a cane and with improved balance. Derrick noted, “I used to feel broken, but no more,” and shared that his mental well-being

improved greatly because he no longer feared falling, especially when crossing streets. One of his biggest fears had been losing balance and falling in front of a car while crossing with his cane, but now, after truFlex™, he crosses confidently [without fear]. Derrick's primary motivation for participating in the study was to regain enough strength to engage in normal activities and sports with his growing son, as he felt psychologically burdened by not being able to live up to his role as a father in physical activities. In addition to improved balance and mobility, Derrick reported that his muscles were looser [not as tight], and that his lower back and glute pain had greatly diminished. He mentioned, "I dropped a pill on the floor and was even able to bend over and pick it up now."

Discussion

The results of this study indicate that truFlex™ offers a promising approach to rehabilitation for individuals with spinal cord injuries, cerebral palsy, limb amputations, and other neurodegenerative conditions. Participants demonstrated significant improvements in muscle mass, strength, and tone, alongside functional gains such as improved mobility, balance, and core stability. These findings suggest that truFlex™ is highly effective in mitigating muscle atrophy and restoring function in affected muscle groups.

A particularly noteworthy aspect of the study was the range of unexpected outcomes. Several participants, including those with quadriplegia and paraplegia, reported regaining sensation in areas previously thought to be permanently affected. Additionally, some female participants experienced the return of sensation related to menstrual cycles, an outcome not anticipated at the onset of the study. These findings suggest that truFlex™ may offer therapeutic benefits that go beyond muscle stimulation, potentially affecting nerve regeneration and overall body function in ways that merit further investigation.

One of the most profound benefits observed was the improvement in bowel and bladder control. Participants not only regained the ability to sense the urge to urinate or move their bowels, but they also reported a greater capacity to hold these urges for longer periods. This newfound control provided participants with a greater sense of independence and autonomy in managing their day-to-day lives. Additionally, some participants noted an improved ability to bear down during bowel movements, contributing to better control over bowel functions and reducing the challenges associated with managing these basic needs.

The psychological benefits observed in the study participants are also worth highlighting. Many individuals, including those with severe physical disabilities, reported increased confidence, social engagement, and improved mental health. These outcomes are significant, as they suggest that truFlex™ may not only enhance physical rehabilitation but also play a critical role in the emotional and psychological recovery of individuals with long-term physical impairments.

truFlex's™ multidirectional electrical muscle stimulation is distinct from other technologies, such as TENS (Transcutaneous Electrical Nerve Stimulation) units or traditional electromagnetic muscle stimulation devices on the market. While TENS units are primarily used for pain relief by

stimulating nerves, truFlex™ targets deeper muscle fibers to create functional, involuntary contractions that are more akin to natural muscle movements. TENS units typically work on a superficial level and focus on nerve stimulation, while truFlex's™ approach results in actual muscle growth and enhanced tone by delivering up to 30 milliamps of electrical current, compared to the 1-2 milliamps produced by voluntary muscle contractions. This deeper stimulation activates more muscle fibers across multiple directions, leading to more significant physical improvements, including increased strength, faster recovery, and more profound muscle engagement.

Electromagnetic muscle stimulation devices on the market often focus on inducing muscle contractions but lack the multidirectional element that truFlex™ provides. truFlex's™ multidirectional approach allows for a more comprehensive engagement of the muscle groups, ensuring that muscles are activated across multiple planes, promoting balanced muscle growth and improved tone. This feature gives truFlex™ a distinct advantage over standard devices that typically focus on linear or unidirectional stimulation.

In conclusion, the findings of this study suggest that truFlex™ holds immense potential as a rehabilitative tool for individuals with a variety of conditions. The combination of physical, psychological, and unexpected therapeutic benefits presents a compelling case for further research and broader implementation of truFlex™ in rehabilitation programs. Large-scale, long term, and longitudinal studies will provide critical insights into the long-term sustainability of these benefits and determine whether truFlex™ can be established as a standard treatment in rehabilitation protocols. Its ability to both mitigate muscle atrophy and enhance functional recovery, along with its distinct multidirectional stimulation technology, provides new hope for individuals seeking to regain independence and improve their quality of life.

Acknowledgment of Limitations

While the results of this study demonstrate significant benefits of truFlex™ in improving muscle strength, mobility, and quality of life in individuals with spinal cord injuries and other neurological conditions, several limitations must be acknowledged.

First, the sample size, while diverse in terms of gender and age, is relatively small, and longer-term follow-up is needed to assess the sustainability of the benefits observed. Additionally, the study was conducted at a single location, the Adaptive Training Foundation Facility in Dallas, Texas, which may limit the generalizability of the results to broader populations. Future studies should aim to expand the participant pool and explore the long-term effects of truFlex™ on muscle function, sensation, and overall rehabilitation outcomes. Future research could also explore how truFlex™ may be adapted for other neurodegenerative conditions such as Parkinson's disease and multiple sclerosis. This further research will be necessary to validate the results in this study.

Second, the study primarily focused on short- to mid-term outcomes, and while initial findings are promising, long-term effects of truFlex™ on muscle recovery and neurological function are still unclear. Additional follow-up studies are needed to assess whether the benefits observed are sustained over extended periods.

Lastly, while participant self-reporting was used in conjunction with objective measures such as DEXA scans, tape measures, and photographs, self-reported data can be subject to bias. Future studies would benefit from incorporating more objective, standardized assessments to further confirm the therapeutic effects of truFlex™.

These limitations, while important to recognize, do not diminish the positive outcomes observed, but rather highlight the need for continued research to further explore the full potential of truFlex™ in rehabilitation settings.

Conclusions

The findings from this study suggest that truFlex™ can not only be used for helping healthy patients in the general population improve their physical appearance by enhancing muscle tone and strength in targeted areas, but it is also an effective rehabilitative tool—a game changer in offering a transformative approach to rehabilitation for individuals with spinal cord injuries, cerebral palsy, limb amputations, and perhaps other neurodegenerative conditions. By providing deeper, multidirectional electrical muscle stimulation, truFlex™ offers a powerful and versatile approach to improving muscle strength, tone, and overall functionality in individuals with spinal cord injuries, cerebral palsy, limb amputations, and possibly in neurodegenerative conditions.

The physical benefits observed in the participants were substantial, ranging from increased muscle mass and reduced spasticity to enhanced core stability and the return of sensation in areas previously impaired by paralysis. The ability to regain control of muscles, improve mobility, and develop greater endurance allowed participants to push beyond their physical limitations, creating new possibilities for independent living and active participation in daily life.

In addition to the profound physical improvements, truFlex™ demonstrated unexpected outcomes that further underscore its therapeutic potential. Notably, participants reported significant improvements in bowel and bladder control, allowing them not only to sense the need for these functions but to hold and manage them more effectively. These advances contributed to a greater sense of autonomy and dignity for the participants. The restoration of sensation related to menstrual cycles in some female participants was another unexpected but groundbreaking result, highlighting the broader impact of truFlex™ beyond muscle activation.

Equally transformative were the psychological benefits. Participants reported increased self-confidence, enhanced social interaction, and an overall improvement in their quality of life. The truFlex treatment not only addressed physical limitations but also empowered individuals to reclaim their sense of identity, purpose, and optimism. For many, this was the first time since their injuries or conditions that they felt a renewed hope for a future filled with opportunities to regain strength and independence. Many participants have set their sights on achieving goals they once thought unattainable, such as competing in the Paralympics, engaging in sports with their children, and reclaiming their identity as athletes.

Despite the promising results, this study was limited by its relatively small sample size and single-location implementation. Future studies should aim to expand the participant pool, include

multi-center trials, and assess long-term outcomes to validate and extend these findings across broader populations.

The breadth of these results suggests that truFlex™ has the potential to redefine the standard of care for individuals with significant physical disabilities and has the potential to revolutionize rehabilitation for individuals with significant physical impairments. Its potential to restore function, mitigate muscle atrophy, and significantly improve both physical and psychological well-being may place it at the forefront of modern rehabilitation strategies. As further research is conducted, truFlex™ could become an essential tool in rehabilitation programs, and should be considered an essential component of modern rehabilitation programs, offering new hope and improved quality of life for individuals seeking to regain strength, autonomy, mobility, and independence as they pursue their passions and realize their full potential.

Continued research is recommended to explore the full potential of truFlex™ as a treatment option in treating a wider range of symptoms, such as those seen in Parkinson's disease, multiple sclerosis, and others, with the goal of evaluating its inclusion as a standard treatment in rehabilitation protocols. Large-scale studies could provide deeper insights into the long-term effects and broaden its applicability across different patient populations, ultimately transforming the lives of individuals seeking to regain strength, mobility, and independence.

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Conflict of Interest

Dr. Edward Alvarez serves as a Key Opinion Leader and national speaker for Cutera®, the manufacturer of the truFlex™ device. The Adaptive Training Foundation received the truFlex™ device as a donation from Cutera®. These relationships did not influence the design, conduct, or outcomes of this study.

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