Improving ACL Reconstruction Outcomes with NeuroBrace: A Clinical and Economic Framework

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ABSTRACT

Nearly 200,000 individuals in the United States undergo Anterior Cruciate Ligament (ACL) reconstruction annually Still, the standard post-surgery recovery methods have not changed in decades. Conventional braces stabilize the joint but do not address e arthrogenic muscle inhibition (AMI), which is a reflex mechanism that lowers the activity of the quadriceps after injury, resulting in rapid quad atrophy and secondary rupture rates in more than 20% young athletes. Here, we propose NeuroBrace, which is a closed-loop orthotic pairing surface EMG (sEMG) sensors with targeted neuromuscular electrical stimulation (NMES) to detect and correct activation deficits, while equipping clinicians with objective compliance data. By implementing conceptual meta-synthesis of published sEMG, NMES, and landing-biomechanics studies , we model how consistent use of the feedback loop could accelerate quad hamstring co-activation symmetry and reduce risk of re-injury, and pair that with a cost model built on Remote Therapeutic Monitoring reimbursement codes to estimate savings from shifting rehab out of the clinic and into an AI guided home protocol.

INTRODUCTION AND HEALTH ECONOMIC CONTEXT

The Epidemiological and Macroeconomic Burden

ACL tears are one of the most common injuries among young athletes [1]. In the United States (US), the number of surgical and non-surgical procedures performed on patients is as high as 200,000 annually [1, 3]. For many of them, this single injury means a lost season, a jeopardized scholarship opportunity, and in some cases, giving up the sport they have spent years training for . Beyond the immediate effects of ACL injuries on the wellbeing of patients, the macroeconomic burden of ACL injuries is also prominent: the US spends $1-2 billion annually merely on ACL management [3]. The national lifetime expenditure associated with ACL injury is an estimated $7.6 billion annually considering the full lifetime cost of surgical treatment, including the index procedure, months long intensive physical therapy, post-operative bracing, and long-term consequences of joint degradation [2].

The Modern Market Failure of Passive Bracing

Despite the magnitude of the problem, the dominant tool in post-operative ACL rehabilitation has remained unchanged for decades: a passive and static, knee brace. These braces provide mechanical stabilization, holding the joint in place and preventing the knee from buckling under load. However, the braces fail to address the effects of arthrogenic muscle inhibition (AMI). Following injury and/or surgery, the knee joint is traumatized, stimulating AMI , which is a well-documented neurological response. The nervous system reflexively suppresses voluntary activation of the quadriceps as a protective mechanism [4]. As a result, the patient loses the ability to fully recruit their quad, increasing the risk of atrophy and recurrence of injury. Traditional orthotics represent a reactive care model that fails to address underlying neuromuscular deficits.

Studies suggest that AMI can persist for months, or even years, after reconstruction and is not a short-term post-operative side effect One of the key pieces of evidence is that motor unit firing rates remain measurably altered in the surgically treated limb at twelve months post-surgery [6]. The incidence of AMI among patients who undergo ACL reconstruction is estimated to be 56% at six weeks post-surgery [5]. This suggests that more than 50% of post-surgical patients are living with a functionally suppressed quad, and the prescribed standard-of-care orthotic does not adequately address these complications. .

The High Financial Risk of Secondary Re-Injury

AMI has a measurable and devastating consequence: secondary ACL rupture. A systematic review and meta-analysis found a pooled re-injury rate of 23% in young athletes who returned to sport following ACL reconstruction [1], and compared to uninjured age-matched peers, the athletes experience a 30 to 40 times increased risk of re-injury [1]. The secondary tears are the direct mechanical consequence of the neuromuscular deficits unaddressed by passive bracing, including deficient quadriceps activation, poor hamstring co-contraction, and the asymmetric landing mechanics due to a lack of proper firing patterns [7]. Paterno et al. demonstrate that athletes who experience a second ACL injury exhibit measurably greater inter-limb asymmetries in knee loading during landing tasks. [7]. The athletes were cleared

based on time elapsed since surgery and not on objective neuromuscular competency. Following the recurrence of ACL injury,, the financial and physiological penalties of secondary graft failure demand a proactive intervention strategy. Revision surgical costs compound, career prospects in competitive sport diminish substantially, and the risk of early-onset osteoarthritis climbs sharply in a joint that needs to last another six or seven decades [1, 2].

Introducing the NeuroBrace and the Dual Hypothesis

NeuroBrace is a closed-loop, data-driven orthotic system that merges surface electromyography (sEMG) tracking with localized Neuromuscular Electrical Stimulation (NMES), which are two clinically validated technologies that create a bidirectional neuromuscular feedback loop. With the advantage of a wearable orthotic format, the sEMG sensors continuously monitor real-time quadriceps and hamstring motor unit activity. Following the detection of AMI-related activation deficits, the brace delivers targeted corrective micro-stimulation pulses to the relevant muscle group.

Here, we evaluate two interconnected hypotheses. The Clinical Hypothesis is that the NeuroBrace closed-loop architecture will measurably accelerate the restoration of proper muscle pre-activation during high-impact landing tasks, directly reducing the biomechanical risk factors that predict secondary ACL rupture. The Economic Hypothesis is that transitioning from the current high-cost, clinic-dependent rehabilitation model to an autonomous, artificial intelligence guided home protocol will significantly compress total per-patient healthcare delivery costs, generating savings for patients, providers, and insurance payers simultaneously.

Interdisciplinary Literature Review

Sensorimotor Control and Biofeedback Mechanics

The underlying mechanism of NeuroBrace is based on the principles of how the nervous system works. The nervous system runs a continuous feedback loop: the motor cortex in the brain generates a signal, the muscles and joints integrate and re-send signals to the brain , and the brain fine tunes the next motor command. This feedback loop allows motor patterns to be built, refined, and stored over time [4]. When an ACL injury and subsequent surgery disrupt the input from the knee joint, the motor cortex loses the feedback. Without accurate incoming signals, the brain upregulates compensatory pathways through cortical reorganization, which leads to abnormal, protective muscle recruitment patterns that persist long after the tissue has healed [4]. The solution, according to both basic motor learning science and ACL-specific clinical research, is to supplement the nervous system with an artificial substitute to make up for the lost sensory feedback in real time.

Electromyographic biofeedback is based on the same principles. It captures the electrical activity in the muscle and feeds it back to the patient as a visual or auditory signal, allowing them to observe at their quad activity and consciously adjust their activation (change this to something else; not clear) in the moment. The embedded sEMG sensors in the NeuroBrace aim to substitute for the sensory input disrupted by surgical procedures, continuously reading quadriceps and hamstring activation and feeding the signals into the brace's onboard processor.

Instead of relying on the patient to consciously interpret a readout and self-correct, NeuroBrace would close the loop mechanically. Upon the detection of a deficit by the processor, the brace would fire a corrective NMES pulse directly into the underactivating muscle, while simultaneously relaying the data to an AI coaching app as the visual biofeedback signal. NeuroBrace would effectively run a fast, sub-conscious hardware loop (sense to stimulate) that corrects the muscle in real time, and a slower, conscious software loop (sense to display) that retrains the patient's own voluntary control. The two would reinforce each other resulting in biofeedback and NMES integration into a single system instead of two separate features combined together.

The first systematic review and meta-analysis specifically on EMG biofeedback in ACL rehabilitation, published in *Physiotherapy* in 2023, found clinically meaningful improvements in quadriceps strength, knee extension range of motion, and overall functional outcomes in patients who received EMG biofeedback compared to standard rehabilitation controls [8]. Current clinical literature recommends EMG visual biofeedback as an early post-operative intervention, with researchers noting that it allows patients to adjust their muscle activation patterns during exercise in a way that isolated electrical stimulation alone does not achieve [9]. This distinction matters enormously for the NeuroBrace design: biofeedback does not just stimulate the muscle, it teaches the brain how to recruit it voluntarily, which is an outcome that transfers to real athletic movement.

Efficacy of Neuromuscular Electrical Stimulation (NMES)

In the early post-operative window, when AMI is at its most severe and the patient may have almost no voluntary quad activation to, there is a need for a solution that y acts on the muscle directly. One solution is that NMES can deliver externally generated electrical impulses through surface electrodes directly to the motor units of the quadriceps, producing a muscle contraction without requiring active signal input from the motor cortex. This helps ensure the cellular architecture of the muscle is intact during the period when AMI could lead to atrophy.

The most rigorous clinical evidence for this comes from a randomized, sham-controlled, blinded trial by Toth et al. published in the *American Journal of Sports Medicine* in 2020, which the authors described as the first study to examine NMES effects at the cellular level in ACLR patients [10]. Patients randomized to NMES starting within days of surgery showed significantly reduced atrophy in fast-twitch MHC II muscle fibers and preserved contractile function in slow-twitch MHC I fibers compared to the sham group, three weeks post-operatively [10]. A systematic review in the *Journal of Orthopaedic and Sports Physical Therapy* established that NMES protocols initiating as early as the third post-operative day and continuing through the 12th week consistently supported quadriceps function recovery, with electrode placement over the vastus medialis and proximal vastus lateralis producing the most reliable recruitment [11].

In a prospective trial in professional soccer players, NMES combined with standard exercise produced measurable gains in both quadriceps muscle mass and isometric strength at one and three months post-ACLR compared to exercise-only controls [12]. And a 2025 randomized crossover trial in martial artists post-ACLR found that NMES during single-leg hop testing significantly optimized muscle activation timing and coordination patterns as measured by high-density EMG analysis [13], which is directly relevant to the kind of dynamic, high-load

movements where secondary ACL tears most commonly occur. Taken together, this research suggests early NMES does more than slow atrophy, it keeps the neural side of the quadriceps responsive at exactly the point where passive bracing would otherwise let it go quiet.

Biomechanical Risk Factors in Landing Tasks

The specific movement where secondary ACL tears most commonly occur is landing, particularly during single leg landings from jumps and during deceleration cuts. The injury mechanism follows a well documented kinematic sequence: the knee is insufficiently flexed at the moment of ground contact, the tibia rotates inward, and the knee collapses into valgus, generating anterior shear forces that the reconstructed ligament cannot absorb [14].

The muscular root cause of this sequence is a failure of coordinated pre-activation. Prior to ground contact, the hamstrings and quadriceps must co-contract to pre-load the joint and prepare it for the incoming force. When the hamstrings fail to activate early enough or with sufficient magnitude, the quadriceps become the dominant force across the joint without the counterbalancing tension of the hamstrings, and the biomechanics collapse into the injury pattern described above [14]. Research has consistently identified delayed hamstring recruitment and quadriceps-dominant activation, particularly under neuromuscular fatigue, as the primary drivers of the asymmetric muscle responses that set up a second ACL tear [14]. In the landmark Paterno et al. prospective study following 56 ACLR athletes for 12 months post-clearance, those who went on to sustain a second ACL injury showed significantly greater inter limb asymmetries in knee loading forces during landing at the exact time they were cleared to return to sport [7]. A 2025 systematic review of biomechanical assessment tools confirmed that reduced quadriceps strength symmetry and compensatory movement deviations remained the strongest measurable predictors of re-injury risk [15].

This indicates that these movement deviations occur within a 100-millisecond window before foot contact, faster than any patient or clinician can consciously observe or correct, which limits the effectiveness of observation-based correction methods. The NeuroBrace closed-loop system is specifically designed to detect and respond within that pre-landing window in real time, which is precisely what no passive device and no human therapist can do.

The Convergence of Digital Therapeutics and Wearable Technology

The clinical case for a device like NeuroBrace does not exist in a vacuum. It sits inside a broader transformation happening across the entire healthcare delivery landscape, one that is moving care out of clinics and into patients' homes, and replacing periodic subjective check-ins with continuous objective data. The global digital therapeutics market is currently valued at $9.94 billion and is projected to grow at a compound annual growth rate of 22.4%, reaching $61.29 billion by 2034, driven by AI-powered personalization, remote monitoring integration, and payer demand for evidence-based software-delivered interventions [17]. The telerehabilitation market specifically is projected to reach $15.4 billion by 2032 at a CAGR of 14.1%, with orthopedics commanding the single largest application segment at over 30% of total revenue [18]. NeuroBrace sits squarely in that commercial lane. The Digital Health for Musculoskeletal Care market, which captures the hardware-plus-software model most analogous to the NeuroBrace platform, is projected to surpass $11.5 billion by 2030 at a CAGR of 17.7%, with

software and services representing 62.6% of revenue [16], reflecting the market reality that recurring digital revenue from connected platforms is where the long-term value lives, not one-time hardware sales.

This trend reflects a fundamental shift in the priorities of both providers and payers: What is driving all of this is a fundamental shift in what both providers and payers want: not episodic snapshots of patient health during scheduled clinic visits, but continuous streams of objective biometric data that enable intervention before problems escalate. The NeuroBrace AI coaching application and cloud-based clinician dashboard are designed to generate exactly that kind of data natively.

Virtual reality integration represents the next layer of this convergence, with VR-based movement rehabilitation environments capable of embedding the sEMG feedback loop inside immersive motor retraining tasks, increasing patient engagement while simultaneously capturing richer biomechanical performance data than any traditional clinic exercise can provide. Beyond its clinical relevance, NeuroBrace is also positioned within this same market trajectory.

CONCEPTUAL METHODOLOGY & VALUE PROPOSITION FRAMEWORK

Conceptual Meta-Synthesis Study Design

This study does not collect primary data. It operates instead as a rigorous conceptual framework and meta-synthesis: a methodological approach that extracts established quantitative baselines from existing peer-reviewed clinical trials, systematic reviews, and biomechanical outcome studies, then maps those validated data points directly onto the proposed NeuroBrace platform architecture to model projected clinical and economic outcomes.

The clinical inputs driving this framework are drawn from the highest-quality evidence across three convergent domains. From the biofeedback literature, we extract EMG motor activation timing baselines and post-operative recovery trajectories documented in controlled ACLR rehabilitation trials, including the functional outcome improvements quantified in Howells et al. [8] and the early post-operative integration protocols outlined in Grooms et al. [9]. From the NMES literature, we extract muscle atrophy prevention thresholds and quadriceps recruitment efficiency metrics validated in the randomized controlled cellular-level trial by Toth et al. [10] and the post-operative electrode placement and protocol parameters established in the JOSPT systematic review [11]. From the biomechanical literature, we extract the inter-limb asymmetry thresholds and hamstring pre-activation timing windows identified in Paterno et al. [7] and confirmed in Patel et al. [15] as the primary measurable precursors of secondary ACL rupture risk. These three streams of quantitative data are not treated in isolation. They are synthesized into a unified injury prevention and cost-efficiency model, with the NeuroBrace closed-loop architecture serving as the conceptual mechanism through which each domain of clinical evidence is translated into a projected, real-world intervention outcome.

Cohort Selection & Target Demographics

The target cohort for this framework is young athletes between the ages of 14 and 22 who are recovering from a primary ACL reconstruction. This age range was selected deliberately: no other patient population carries a higher re-injury risk, a longer lifetime cost exposure, or a greater need for neuromuscular retraining in the specific context of return to competitive sport. Wiggins et al. established that the re-injury rate in this age group reaches 23% after returning to sport, with those athletes facing a 30 to 40 times greater risk of tearing their ACL again compared to uninjured peers [1]. Lepley et al. further reported re-injury risks as high as 33% within just two years of return to sport in young reconstructed athletes [6]. That's a huge concentration of preventable risk sitting inside one age range.

From an economic standpoint, this cohort also carries the highest lifetime value for early intervention. The MiACLR protocol data identifies peak injury incidence at age 16, meaning a successful rehabilitation and re-injury prevention at that age could protect five to six more decades of healthy joint function, drastically reducing the individual and systemic costs associated with post-traumatic osteoarthritis, revision surgeries, and long-term functional decline [2]. Finally, this population is the most prepared to engage with the digital interface that makes NeuroBrace work. Athletes in the 14 to 22 age range have grown up with smartphones, wearables, and real-time performance feedback platforms. For this group, the coaching app isn't a hurdle to clear, it's closer to something they'd already expect and want.

System Architecture and Closed-Loop Intervention

The NeuroBrace system is built around three integrated hardware and software layers that operate together in a continuous closed loop. The first layer is sensing. A network of surface electromyography sensors is embedded directly into the brace along the quadriceps and hamstring muscle groups, capturing the real-time electrical activity of both muscle systems simultaneously and continuously throughout every movement the patient makes.

The second layer is processing. A localized microcontroller embedded within the brace receives that raw EMG signal stream and runs it through an onboard algorithm that analyzes muscle firing sequencing in real time, comparing the patient's current activation pattern against established clinical thresholds for healthy pre-activation timing. Grooms et al. confirmed that this kind of real-time analysis of motor output is now considered a best-practice standard in post-operative ACL rehabilitation, noting that systems capable of detecting deviation from normal quadriceps firing patterns can override inhibitory signals before they translate into faulty movement [9].

The third layer is actuation. When the processing layer detects a pre-activation deficit or an asymmetric co-contraction pattern, the brace delivers a targeted micro-NMES pulse to the underactivating muscle group before and during the landing motion, correcting the imbalance in real time without requiring any conscious input from the patient. Electrode placement follows the protocol parameters established in the JOSPT systematic review, targeting the vastus medialis near the knee and the proximal vastus lateralis for the most consistent quadriceps recruitment response [11]. Simultaneously, the full biometric data stream is transmitted wirelessly to the NeuroBrace AI coaching application, where both the patient and their supervising clinician can monitor activation symmetry, compliance trends, and functional progression over time. Together, these three layers distinguish NeuroBrace from passive braces and standalone NMES units currently on the market: the system senses, interprets, responds, and reports.

The Health-Economic Evaluation Matrix

Measuring the success of this framework requires more than tracking clinical milestones in isolation. It requires a dual-axis evaluation model that captures both what the patient gains physiologically and what the healthcare system saves economically. This framework evaluates NeuroBrace performance against two primary metrics. The first is Time-to-Gait-Symmetry, defined as the number of weeks from the date of surgery to the point at which the patient achieves a limb symmetry index of 90% or greater across quadriceps strength, hamstring co-activation timing, and single-leg landing kinematics. This composite benchmark is grounded in the biomechanical outcome thresholds established in Patel et al. [15] and Paterno et al. [7], both of which identify these specific measurable variables as the strongest predictors of safe return to sport.

The second metric is Total Rehabilitation Cost Efficiency, defined as the total per-patient cost of reaching those clinical benchmarks, accounting for the number of required in-person physical therapy sessions, imaging costs, and physician follow-up visits. The core hypothesis is

that by compressing Time-to-Gait-Symmetry through continuous closed-loop neuromuscular correction at home, the NeuroBrace protocol will simultaneously compress Total Rehabilitation Cost Efficiency by reducing the frequency and duration of clinic-dependent care. Success is defined not as the elimination of in-person therapy, but as achieving equivalent or superior clinical outcomes with a meaningfully smaller number of billed clinic encounters, generating measurable savings for patients, commercial and government insurance payers, and the broader healthcare delivery system. This dual-axis matrix is what allows NeuroBrace to be evaluated not just as a clinical device, but as a value-based healthcare intervention with a defensible return on investment.

DISCUSSION: TRANSLATIONAL BIO-ENTREPRENEURSHIP & MARKET VIABILITY

Clinical Risk Mitigation & Regulatory Pathway

The clinical case for NeuroBrace centers on risk reduction, a conclusion supported directly by the epidemiological data A 23% pooled re-injury rate in young athletes returning to sport after ACL reconstruction [1], driven by the same neuromuscular deficits that passive bracing never addresses, represents a massive and preventable source of both human suffering and downstream healthcare cost. By correcting quadriceps and hamstring co-activation patterns in real time during the exact high-risk movement window identified by Paterno et al. and Patel et al. [7, 15], the NeuroBrace closed-loop system attacks the biomechanical root cause of secondary rupture directly, rather than waiting for re-injury to happen and then paying to fix it twice.

This clinical logic also forms the foundation of the device's regulatory strategy. NeuroBrace will pursue FDA clearance through the 510(k) pathway as a Class II Medical Device, which requires demonstrating that the device is substantially equivalent in intended use and technological characteristics to legally marketed predicate devices already cleared by the FDA. The two predicate categories are standalone clinical NMES units, which already carry clearance for post-operative muscle rehabilitation applications validated extensively in the literature [10, 11], and passive post-operative knee orthoses, which are standard-of-care cleared devices. Because NeuroBrace combines these two already-cleared functional categories into a single integrated platform rather than introducing a wholly novel biological or physiological mechanism, it does not require the multi-year clinical trial process that would be mandated under the PMA pathway for Class III devices. By pairing biomechanical risk mitigation with an FDA 510(k) regulatory framework, the device bypasses traditional commercialization bottlenecks, compressing the timeline from prototype to prescribable clinical product while keeping early-stage development costs well within what a seed-stage medtech venture can realistically absorb.

Insurance Reimbursement & Scalable Venture Monetization

Regulatory compliance represents only one component of commercial viability. The second is a sustainable financial model, and the reimbursement infrastructure required to support the one that already exists. The Centers for Medicare and Medicaid Services have established Remote Patient Monitoring CPT codes specifically designed for connected, data-generating devices prescribed and monitored by licensed clinicians. CPT code 98975 covers the initial setup and patient education for a remote therapeutic monitoring device, and CPT code 98977 covers the monthly supply of the musculoskeletal data monitoring service itself. This means that once an orthopedic surgeon prescribes the NeuroBrace, they can monitor the patient's real-time activation symmetry data through the cloud-based clinician dashboard and bill insurance directly for that monitoring service on a recurring monthly basis.

That reimbursement structure transforms the NeuroBrace from a one-time hardware sale into a Hardware-as-a-Service model where the physical brace is the entry point and the recurring monthly AI coaching subscription is where the long-term revenue lives. This is a B2B2C model: the business sells to the orthopedic surgeon and hospital system, who then prescribe the device to the patient, creating a scalable acquisition channel that does not require direct-to-consumer marketing spend.

The broader market is clearly moving in this direction. The Digital Health for Musculoskeletal Care market is projected to surpass $11.5 billion by 2030 at a CAGR of 17.7%, with software and services representing 62.6% of total revenue [16], confirming that payers and providers are already building the infrastructure for exactly this kind of connected, subscription-driven clinical model. The digital therapeutics market overall is on track to reach $61.29 billion by 2034 [17], and orthopedics commands the single largest application segment in the telerehabilitation market at over 30% of total revenue [18]. Leveraging established RPM reimbursement codes transforms a clinical asset into a highly scalable, recurring-revenue digital health ecosystem, one where every new surgeon partner becomes a distribution channel and every active patient brace becomes a monthly revenue-generating data node.

CONCLUSION & FUTURE FRONTIERS

Toward Intelligent Orthopedics

Calling NeuroBrace a better brace undersells it, it's really solving a different problem than a brace typically solves. Traditional post-operative orthotics solved one problem well, which is keeping the joint mechanically stable, while ignoring the deeper neurological crisis unfolding inside the patient's nervous system. The result has been a rehabilitation paradigm that discharges athletes back to sport based on time elapsed rather than real neuromuscular readiness, and then absorbs the compounding human and financial costs when secondary rupture rates exceed 20% [1] and lifetime national expenditures approach $7.6 billion per year [2]. This framework has demonstrated that the clinical tools to fix this already exist, that EMG biofeedback accelerates voluntary motor relearning [8, 9], that early NMES preserves the muscle fiber integrity of the quadriceps at the exact moment AMI would otherwise let it degrade [10, 11], and that the biomechanical signature of a future re-injury is measurable and detectable in the pre-landing window long before the second tear ever happens [7, 15]. NeuroBrace's

contribution is combining those validated mechanisms into a single closed loop wearable system that operates continuously, autonomously, and at home, inside the daily life of a 16-year-old athlete trying to get back to the sport they have trained their entire life for.

By intersecting artificial intelligence, wearable biotechnology, and data-driven health economics, this framework proves that intelligent orthotics can democratize elite-level sports medicine, accelerating recovery for young athletes while systematically driving down the macroeconomic costs of healthcare worldwide. NeuroBrace shifts the orthopedic paradigm from static restriction to intelligent, value-based neuromuscular restoration, and in doing so, it redefines what a brace is supposed to do in the first place.

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