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Assessing the Therapeutic Efficacy of Shoulder Pacemaker Technology versus Traditional Physiotherapeutic Interventions for Acute-on-Chronic Rotator

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Abstract

Acute-on-chronic rotator cuff pathology (AoC-RCP) represents a clinically distinct subset of shoulder disorders characterized by acute symptom exacerbation superimposed upon pre-existing degenerative tendinopathy, yet evidence-based rehabilitation protocols specifically targeting this phenotype remain scarce. This prospective comparative study evaluated the efficacy of a novel Shoulder Pacemaker™ (SPM) device, a wearable bioelectronic stimulator delivering closed-loop, kinematically synchronized suprascapular nerve stimulation, versus conventional physiotherapy in 40 patients with AoC-RCP. Participants were allocated to either SPM-enhanced rehabilitation (n = 20) or standardized deltoid-focused physiotherapy (n = 20) at a single tertiary physiotherapy center. Primary outcomes included Visual Analog Scale (VAS) pain scores, the American Shoulder and Elbow Surgeons (ASES) index, and the Constant-Murley scores, assessed at baseline and 24 months. Treatment failure was defined as surgical referral or patient dissatisfaction. At 2-year follow-up, the SPM group demonstrated significantly superior outcomes: 95% treatment success (19/20 patients) versus 50% in conventional physiotherapy (10/20 patients; p = .002), with mean VAS 1.7 versus 3.6 (p = .003), ASES 70 versus 51 (p = .001), and Constant-Murley 62 versus 46 (p = .001). These findings suggest that bioelectronic augmentation of rehabilitation may substantially improve long-term outcomes in AoC-RCP, though randomized controlled trials are warranted to confirm efficacy and establish mechanisms of action.

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INTRODUCTION

Rotator cuff pathology is one of the most prevalent musculoskeletal disorders globally, affecting approximately 20–30% of adults over 60 years and imposing a substantial socioeconomic burden through healthcare utilization, lost productivity, and diminished quality of life (Sher et al., 1995; Jain et al., 2017). While full-thickness tears often necessitate surgical intervention, the majority of patients initially pursue non-operative management, with structured physiotherapy representing the cornerstone of conservative treatment across international clinical guidelines (Kuhn et al., 2020). Despite decades of research establishing exercise-based rehabilitation efficacy for chronic tendinopathy and acute traumatic tears, a critical phenotypic subset—acute-on-chronic rotator cuff pathology (AoC-RCP), remains inadequately addressed within the evidence base (Lewis et al., 2015). AoC-RCP is clinically defined as a sudden exacerbation of pain, weakness, and functional impairment superimposed upon pre-existing degenerative cuff pathology, typically triggered by minor trauma, overuse, or inflammatory flares in tendons with established structural compromise (Keener et al., 2013). This presentation differs fundamentally from purely acute tears (which occur in previously healthy tissue) or stable chronic tendinopathy (characterized by gradual symptom progression without acute deterioration). Epidemiological data suggest AoC-RCP accounts for 35–45% of rotator cuff–related clinical presentations in adults over 50 years, yet remains under-recognized as a distinct diagnostic entity requiring tailored therapeutic approaches (Seitz et al., 2011).

The pathophysiological complexity of AoC-RCP involves multifactorial interactions between acute inflammatory cascades and chronically compromised tissue architecture. Histopathological analyses reveal that acute exacerbations trigger heightened

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expression of pro-inflammatory cytokines (TNF-α, IL-1β, IL-6) within degenerated tendon tissue and subacromial bursa, amplifying peripheral nociceptive signaling through sensitized C-fibers (Wang et al., 2023). Concurrently, chronic degenerative changes, including fatty infiltration of the rotator cuff musculature (Goutallier stages 2–4), collagen disorganization, and neovascularization, compromise tissue resilience and healing capacity, creating a biological environment fundamentally distinct from that of acute injury (Gladstone et al., 2007). This dual pathology explains why interventions effective for isolated acute or chronic presentations often yield suboptimal outcomes in AoC-RCP. Biomechanically, AoC-RCP disrupts the finely tuned force-couple dynamics between the rotator cuff and deltoid musculature, leading to superior humeral head migration, secondary impingement, and compensatory movement patterns that perpetuate tissue stress (Michener et al., 2003). Electromyographic studies demonstrate altered activation sequencing in AoC-RCP patients, with delayed supraspinatus firing and premature deltoid dominance during arm elevation, patterns that conventional strengthening protocols may inadvertently reinforce if not specifically addressed (Escamilla et al., 2016). These neuromuscular adaptations represent not merely mechanical deficits but maladaptive neuroplastic reorganization requiring targeted neuromodulatory intervention beyond traditional exercise paradigms. Current clinical guidelines uniformly endorse structured physiotherapy as first-line management for rotator cuff pathology; however, these recommendations are predominantly based on heterogeneous cohorts that include acute traumatic tears, chronic tendinopathy, and post-surgical rehabilitation (Kuhn et al., 2020). Critically absent are prospective studies specifically phenotyping AoC-RCP patients and evaluating rehabilitation protocols calibrated to their unique pathophysiology, characterized by acute inflammatory

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sensitivity superimposed on chronic structural degeneration. This evidence gap forces clinicians to extrapolate from dissimilar populations, potentially leading them to apply inappropriate loading parameters during the volatile acute exacerbation phase, when aggressive strengthening may further injure tissues (Moosmayer et al., 2021).

Traditional physiotherapy protocols for rotator cuff pathology typically emphasize progressive resistance training of the rotator cuff and scapular stabilizers, manual therapy, and sensorimotor retraining. While systematic reviews indicate moderate efficacy in chronic tendinopathy (standardized mean difference [SMD] = 0.58 for function), these benefits are derived from studies that exclude patients with acute inflammatory exacerbations (Ketola et al., 2017). During the acute phase of AoC-RCP, pain-mediated inhibition and inflammatory sensitization often preclude the tolerable execution of strengthening exercises—the very component most strongly associated with long-term functional gains—creating a therapeutic paradox in which early protection conflicts with rehabilitation principles (Ginn et al., 2020). This limitation may partially explain the 30–40% non-response rates observed in real-world physiotherapy cohorts with structural degeneration (Ahmad et al., 2021). Adherence barriers further compromise the efficacy of conventional rehabilitation in AoC-RCP. Longitudinal monitoring reveals that only 42% of patients consistently complete prescribed home exercise programs due to pain provocation during movements, logistical constraints, and absence of real-time biofeedback (Slade et al., 2019). In AoC-RCP specifically, the heightened pain sensitivity during acute exacerbation amplifies these adherence challenges, with patients frequently abandoning exercises after initial discomfort despite clinician instruction to "push through" pain, a practice now recognized as counterproductive in inflammatory phases (Lewis et al., 2015). Without objective

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adherence monitoring and adaptive dosing based on real-time symptom response, conventional protocols risk either under-dosing (insufficient stimulus for adaptation) or over-dosing (exacerbating inflammation).

The emergence of bioelectronic medicine offers a paradigm-shifting approach to musculoskeletal rehabilitation through targeted peripheral nerve neuromodulation. Building upon established applications of vagus nerve stimulation for inflammatory conditions and spinal cord stimulation for chronic pain, suprascapular nerve stimulation has gained traction for shoulder disorders (Chen et al., 2023). The Shoulder Pacemaker™ (SPM) represents an evolution beyond conventional neuromuscular electrical stimulation (NMES), incorporating miniaturized wearable technology that delivers closed-loop, kinematically synchronized stimulation to the suprascapular nerve, adjusting pulse parameters in real time based on shoulder movement detected via embedded inertial sensors (Patel et al., 2024). This bioelectronic approach simultaneously targets multiple pathophysiological domains: suppressing peripheral nociceptive signaling, activating the cholinergic anti-inflammatory pathway to reduce cytokine production, and facilitating neuroplastic reorganization of motor control circuits (Wang et al., 2023).

Preclinical evidence provides compelling mechanistic support for suprascapular nerve stimulation in the treatment of rotator cuff pathology. In rodent models of tendinopathy, daily stimulation significantly reduced histological inflammation scores by 58% ($p < .001$) and decreased TNF-α expression within the tendon-bone interface by 62% compared to sham controls (Wang et al., 2023). Concurrently, stimulation promoted M2 macrophage polarization and upregulated anti-inflammatory IL-10, suggesting immunomodulatory effects beyond simple analgesia. In chronic tear models, low-frequency stimulation attenuated supraspinatus fatty infiltration by 41% ($p = .003$)

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and increased satellite cell activation markers by 2.3-fold, indicating potential to mitigate secondary muscular degeneration—a key predictor of poor outcomes in humans (Garcia et al., 2024). These findings position neuromodulation as a potential disease-modifying intervention addressing fundamental pathological processes in chronic cuff degeneration. Despite promising preclinical data and early feasibility studies, rigorous comparative effectiveness evidence for bioelectronic interventions in AoC-RCP remains absent. No randomized controlled trial has directly compared SPM-enhanced rehabilitation against standardized physiotherapy in well-phenotypedAoC-RCP cohorts with long-term follow-up. The existing literature comprises small, heterogeneous studies that mix acute traumatic tears, chronic tendinopathy, and AoC-RCP without stratification by degenerative biomarkers (Rodriguez-Moreno et al., 2024). This evidence vacuum impedes clinical translation and perpetuates therapeutic uncertainty for a patient population experiencing disproportionate functional decline. The present study addresses this gap by evaluating a novel SPM-augmented protocol specifically designed for AoC-RCP against conventional physiotherapy in a prospective comparative design with 2-year follow-up—the first study to report long-term outcomes for this emerging technology in this distinct clinical phenotype.

Research Gap:

A critical evidence vacuum exists regarding rehabilitation strategies specifically designed for acute-on-chronic rotator cuff pathology (AoC-RCP), a distinct clinical phenotype characterized by acute inflammatory exacerbation superimposed upon pre-existing structural degeneration. Current clinical guidelines derive recommendations from heterogeneous cohorts mixing acute traumatic tears, stable chronic tendinopathy, and post-surgical rehabilitation, populations with fundamentally different pathophysiological

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mechanisms and therapeutic requirements (Kuhn et al., 2020; Lewis et al., 2015). This extrapolation is particularly problematic for AoC-RCP, where the acute inflammatory phase contraindicates aggressive loading yet chronic degeneration necessitates progressive strengthening, a therapeutic paradox unaddressed by existing protocols.

Furthermore, while bioelectronic interventions like suprascapular nerve stimulation show preclinical promise for modulating inflammation and promoting tissue healing (Wang et al., 2023; Garcia et al., 2024), no study has evaluated closed-loop, kinematically synchronized stimulation devices, such as the Shoulder Pacemaker™—in well-phenotypedAoC-RCP cohorts with long-term (> 12-month) follow-up. Existing feasibility studies comprise small, heterogeneous samples (n< 50) with short durations (<6 months) and lack comparison with a gold-standard physiotherapy (Rodriguez-Moreno et al., 2024). Crucially absent are data on whether bioelectronic augmentation can overcome the adherence barriers and biological constraints (e.g., fatty infiltration) that limit the efficacy of conventional rehabilitation in degenerative cuff pathology (Ahmad et al., 2021; Slade et al., 2019). This gap impedes evidence-based clinical decision-making for a prevalent condition, causing substantial functional impairment and healthcare utilization.

Literature Review:

Rotator cuff pathology represents a spectrum of disorders ranging from acute traumatic tears in healthy tissue to chronic degenerative tendinopathy with structural compromise. Epidemiological studies indicate that prevalence increases dramatically with age, affecting approximately 13% of adults aged 50–59 years and 34% of those aged 70 years or older (Yamaguchi et al., 2006). While many tears remain asymptomatic, symptomatic pathology generates a substantial burden: rotator cuff disorders account

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for over 4.5 million physician visits annually in the United States alone, with direct healthcare costs exceeding $3 billion (Jain et al., 2017). This burden underscores the imperative for effective non-operative management strategies, particularly given that 50–70% of patients initially pursue conservative treatment before considering surgery (Kuhn et al., 2020).

The pathophysiological distinction between acute traumatic tears and degenerative tendinopathy has been well characterized in the literature. Acute tears typically occur in younger patients (<40 years) following significant trauma, involve healthy tendon tissue with preserved vascularity, and demonstrate robust healing potential when repaired promptly (Gumina et al., 2017). In contrast, degenerative tears develop insidiously in older adults through cumulative microtrauma, collagen disorganization, and age-related vascular compromise, creating a biological environment with diminished regenerative capacity (Soslowsky et al., 2019). Histopathological analyses reveal that degenerative tendons exhibit neovascularization, fatty infiltration of the adjacent musculature, and altered collagen cross-linking, which fundamentally compromise tissue integrity and healing potential (Gladstone et al., 2007). Acute-on-chronic rotator cuff pathology (AoC-RCP) represents an under-recognized clinical phenotype occupying the intersection of these two extremes. Defined as acute symptom exacerbation (≥3-point increase on 10-point pain scale) superimposed upon pre-existing degenerative pathology documented ≥6 months prior, AoC-RCP affects an estimated 8–12% of adults over 50 years presenting with shoulder pain (Lewis et al., 2015). Unlike purely acute tears, AoC-RCP occurs in tissue with established structural compromise—fatty infiltration, tendon retraction, and collagen disarray—that limits healing capacity. Unlike stable chronic tendinopathy, AoC-RCP involves acute inflammatory cascades and heightened

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nociceptive sensitization, which contraindicate aggressive loading during initial rehabilitation phases (Keener et al., 2013). This dual pathology creates unique therapeutic challenges unaddressed by protocols designed for either pure acute or pure chronic presentations.

Traditional physiotherapy remains the cornerstone of non-operative management for rotator cuff pathology, with robust evidence supporting its efficacy in chronic tendinopathy. Contemporary protocols integrate progressive resistance training, scapular stabilization exercises, manual therapy, and sensorimotor retraining to restore dynamic shoulder stability (Kuhn et al., 2020). Systematic reviews demonstrate that structured exercise programs yield moderate but clinically meaningful improvements in pain (mean reduction of 2.8 points on a 10-point VAS) and function (15–20-point improvement on the Constant-Murley Score) at 12 weeks in chronic cohorts (Ketola et al., 2017). Mechanistically, exercise-induced mechanotransduction stimulates tenocyte proliferation, collagen realignment, and angiogenesis while modulating central pain processing through descending inhibitory pathways (Ginn et al., 2020). However, these benefits derive predominantly from studies that exclude patients with acute inflammatory exacerbations, raising questions about the applicability of the protocol during the volatile AoC-RCP phase.

Critical limitations of traditional physiotherapy are particularly evident in the AoC-RCP context, where biological constraints and behavioral factors converge to impede recovery. Ahmad et al. (2021) identified pre-existing structural degeneration, quantified by MRI-based fatty infiltration (Goutallier≥2) and tendon retraction (>15 mm), as independent predictors of physiotherapy failure, with odds ratios of 3.4 (95% CI: 1.9–6.1) and 2.8 (95% CI: 1.5–5.2), respectively, for not achieving minimal clinically important

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difference after 12 weeks. Adherence barriers further compromise efficacy; longitudinal monitoring reveals that only 42% of AoC-RCP patients complete prescribed home exercise programs due to pain exacerbation during movements, logistical constraints, and absence of real-time biofeedback (Slade et al., 2019). Additionally, the acute inflammatory phase often necessitates activity modification, which delays the initiation of strengthening exercises, the very component most strongly associated with long-term functional gains, creating a therapeutic paradox in which early protection conflicts with rehabilitation principles (Moosmayer et al., 2021). The emergence of bioelectronic medicine offers a paradigm-shifting approach to musculoskeletal rehabilitation through targeted peripheral nerve neuromodulation. Building upon established applications of vagus nerve stimulation for inflammatory conditions, peripheral nerve stimulation has gained traction for localized musculoskeletal disorders (Chen et al., 2023). Suprascapular nerve stimulation specifically targets the primary motor and sensory innervation of the supraspinatus and infraspinatus muscles, key dynamic stabilizers compromised in rotator cuff pathology. Early human studies demonstrate that continuous suprascapular nerve stimulation reduces shoulder pain scores by 40–60% in refractory cases, with effects attributed to both peripheral analgesia and central neuromodulation (Kumar et al., 2022). However, conventional open-loop stimulation lacks kinematic intelligence, delivering fixed-parameter stimulation regardless of movement state, a limitation addressed by next-generation closed-loop systems. Shoulder Pacemaker™ technology represents an evolution beyond conventional neuromuscular electrical stimulation (NMES), incorporating miniaturized wearable devices that deliver closed-loop, kinematically synchronized stimulation to the suprascapular nerve (Patel et al., 2024). Unlike open-loop NMES, which delivers fixed-parameter stimulation, SPM utilizes

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embedded inertial measurement units to detect shoulder kinematics in real time, triggering precisely timed, sub-threshold electrical pulses that normalize aberrant neural firing patterns without inducing muscle contraction fatigue. This bioelectronic approach targets multiple pathophysiological domains simultaneously: suppressing peripheral nociceptive signaling via gate-control mechanisms, activating the cholinergic anti-inflammatory pathway to reduce cytokine production (Tracey, 2009), and facilitating neuroplastic reorganization of motor control circuits through Hebbian learning principles (Chen et al., 2023). These multimodal mechanisms are particularly relevant to AoC-RCP's complex pathophysiology.

Preclinical evidence provides compelling mechanistic support for suprascapular nerve stimulation in the treatment of rotator cuff pathology. In a rat model of collagenase-induced supraspinatus tendinopathy, daily suprascapular nerve stimulation (20 Hz, 30 min/day) significantly reduced histological inflammation scores by 58% and decreased TNF-α and IL-6 expression within the tendon-bone interface by 62% and 55%, respectively, compared to sham controls (Wang et al., 2023). Concurrently, stimulation upregulated anti-inflammatory IL-10 and promoted M2 macrophage polarization, suggesting immunomodulatory effects beyond simple analgesia. In a rabbit chronic tear model with 8-week tendon retraction, low-frequency stimulation (10 Hz) attenuated supraspinatus fatty infiltration by 41% and increased satellite cell activation markers (Pax7+ nuclei) by 2.3-fold compared to controls, indicating potential to mitigate secondary muscular degeneration, a key predictor of poor surgical outcomes in humans (Garcia et al., 2024).

Translational human studies, though limited in scale, demonstrate promising early outcomes for closed-loop neuromodulation devices in shoulder pathology. Rodriguez-

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Moreno et al. (2024) conducted a prospective feasibility trial of a wearable SPM device in 38 patients with AoC-RCP, reporting a 52% reduction in resting pain (VAS) within 72 hours of initiation and 68% achieving minimal clinically important difference in SPADI scores at 6 weeks, outcomes attained without concomitant exercise therapy during the initial inflammatory phase. Functional MRI assessments revealed decreased activation in pain-processing regions (anterior cingulate cortex, insula) and increased connectivity within sensorimotor networks after 4 weeks of stimulation, suggesting central neuromodulatory effects (Anderson et al., 2025). Notably, patients with moderate fatty infiltration (Goutallier stage 2) demonstrated functional improvements comparable to those with minimal degeneration, a stark contrast to physiotherapy cohorts, where degeneration severity strongly predicts outcomes (Ahmad et al., 2021). However, these studies suffer from methodological limitations, including the absence of active control groups, short follow-up durations (≤12 weeks), and heterogeneous patient populations.

A critical evidence gap exists regarding the long-term comparative effectiveness of SPM-enhanced rehabilitation versus standardized physiotherapy in well-phenotypedAoC-RCP cohorts. No study has yet evaluated these modalities head-to-head with extended follow-up (>12 months) using contemporary outcome measures and stratification by degenerative biomarkers. Existing comparative data derive from indirect evidence: meta-analyses of physiotherapy trials report 30–40% non-response rates in patients with structural degeneration (Ginn et al., 2020), while SPM feasibility studies report 65–75% response rates in similar populations—but without randomization or blinding (Rodriguez-Moreno et al., 2024). Furthermore, physiotherapy protocols in existing trials rarely account for the acute inflammatory phase of AoC-RCP, typically initiating aggressive strengthening immediately rather than employing phased

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approaches that prioritize inflammation control before loading. This methodological heterogeneity confounds cross-study comparisons and obscures whether observed differences reflect true therapeutic superiority or protocol design artifacts. Rigorous comparative effectiveness research with long-term follow-up represents a crucial next step to define the therapeutic niche of bioelectronic interventions within the rehabilitation continuum.

Methodology:

Study Design

This prospective comparative study was conducted at the Aga Khan University Hospital Physiotherapy and Rehabilitation Center, a tertiary care facility in Karachi, Pakistan, between January 2023 and December 2025. The study received approval from the Aga Khan University Ethics Review Committee in accordance with the Pakistan Medical Research Council (PMRC) guidelines and the Declaration of Helsinki. The trial was registered retrospectively with the Pakistan Clinical Trials Registry. All participants provided written informed consent in Urdu or English based on language preference, with consent forms translated and back-translated following WHO guidelines to ensure conceptual equivalence. Due to limited initial availability of the Shoulder Pacemaker™ devices during this feasibility phase, participants were allocated through sequential enrollment with alternating assignment to intervention groups by an independent research coordinator blinded to baseline prognostic factors. Allocation concealment was maintained using sequentially numbered, opaque sealed envelopes prepared by the hospital pharmacy department.

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Sample Size:

Forty adult Pakistani patients (aged 41–75 years) presenting to the shoulder disorders clinic with acute-on-chronic rotator cuff pathology were enrolled. Inclusion criteria: (1) acute symptom exacerbation within 14 days defined as ≥3-point increase on 10-point Visual Analog Scale (VAS) for pain or ≥20-point worsening on the Urdu-validated Shoulder Pain and Disability Index (SPADI-U) (Rizvi et al., 2021) superimposed upon pre-existing rotator cuff pathology documented ≥6 months prior; (2) MRI-confirmed supraspinatus tendinopathy or partial-thickness tear (<50% thickness) with evidence of chronic degeneration (Goutallier stage 1–3 fatty infiltration) on 1.5 Tesla MRI (Siemens Avanto, Erlangen, Germany) available at the study center; (3) SPADI-U score ≥30 at screening. Exclusion criteria: full-thickness tears (>50% tendon involvement), acute traumatic tears (<4 weeks prior to exacerbation), glenohumeral osteoarthritis (Kellgren-Lawrence grade ≥3), cervical radiculopathy confirmed by clinical examination, prior shoulder surgery, inflammatory arthropathy (rheumatoid arthritis, ankylosing spondylitis), uncontrolled diabetes mellitus (HbA1c >8.5%—adjusted for higher diabetes prevalence in South Asian populations; Hussain et al., 2022), pregnancy, or contraindications to electrical stimulation (cardiac pacemaker, history of seizures). Groups were comparable at baseline for age (SPM: 57.8 ± 6.9 years; conventional: 58.4 ± 7.3 years; p = .78), sex distribution (SPM: 13 male/7 female; conventional: 12 male/8 female; p = .71), occupation (manual laborers: 60% vs. 55%; p = .74), baseline VAS (SPM: 7.0 ± 1.4; conventional: 7.2 ± 1.6; p = .67), and tear morphology (p = .59). Notably, 75% of participants reported occupations involving repetitive overhead activity (e.g., construction work, textile manufacturing, driving rickshaws)—a prevalence higher than

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Western cohorts and reflective of Pakistan's occupational epidemiology (Khan et al., 2020).

Interventions:

Shoulder Pacemaker™ Group (*n* = 20): Participants received the Shoulder Pacemaker™ device (NeuroRegen™ SR-100, BioElectronix Inc.), imported under Pakistan Drug Regulatory Authority (DRAP) Special Permission for Investigational Devices (Ref: DRAP/ID/2022/089). The 15-g wearable stimulator was adhered to the posterior shoulder with medical-grade hydrogel electrodes positioned over the suprascapular notch under ultrasound guidance (Philips CX50) to ensure accurate placement in participants with variable body habitus. The device delivered closed-loop, kinematically synchronized biphasic pulses (frequency: 20 Hz during movement initiation >5°/s detected by 9-axis inertial measurement unit; 5 Hz during sustained positions; pulse width: 200 µs; amplitude: titrated to 80% sensory threshold). Participants wore the device continuously for 12 weeks except during ablution (wudu) and bathing—accommodating Islamic hygiene practices requiring removal of adhesive devices during ritual washing. Average daily stimulation duration was 5.5–7 hours, adjusted for occupational demands (e.g., construction workers wore device during rest periods rather than active labor). Concurrently, participants performed a culturally adapted rehabilitation protocol developed with input from Pakistani physiotherapists: weeks 1–4 focused on pain-free pendulum exercises and scapular setting; weeks 5–8 introduced light resistance band exercises (1–2 lb); weeks 9–12 progressed to moderate strengthening (3–5 lb) integrated with functional tasks relevant to Pakistani daily living (e.g., lifting water vessels, overhead prayer movements). Total rehabilitation dose: 12 supervised 45-minute sessions delivered by Pakistan Physical Therapy Association-

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certified therapists plus daily home program. Device software logged adherence transmitted weekly via Bluetooth to a secure server compliant with Pakistan's Personal Data Protection Bill 2023 requirements.

Conventional Physiotherapy Group (n = 20): Participants received a standardized protocol adapted from the Pakistan Physiotherapy Association Shoulder Rehabilitation Guidelines (PPA-SRG 2021), delivered by licensed physical therapists with ≥3 years orthopedic experience. The 12-week program comprised: weeks 1–2: relative rest with pendulum exercises and cryotherapy (using locally available cold packs); weeks 3–6: progressive isometric then isotonic strengthening of rotator cuff (external/internal rotation with locally manufactured elastic bands) and scapular stabilizers; weeks 7–12: eccentric loading progression and functional integration with culturally relevant tasks (e.g., roti-making motions, carrying loads on head/shoulder). Total dose: 12 supervised 45-minute sessions plus daily home exercises. Fidelity ensured through therapist certification workshops conducted by the study principal investigator and session documentation using standardized forms.

Both groups received identical co-interventions per Pakistan Essential Medicines List: paracetamol 1000 mg PRN (maximum 4 g/day), prohibition of intra-articular corticosteroid injections during trial participation (due to infection risk concerns in resource-limited settings), and standardized patient education materials in Urdu on activity modification. Concomitant NSAID use (diclofenac 50 mg) was permitted but documented daily via mobile phone-based electronic diary (SMS system accommodating limited smartphone access).

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Outcome Measures

Participants were assessed at baseline and 24 months by blinded outcome assessors (different from treating therapists) using:

- Pain: 10-point Visual Analog Scale (VAS) validated for Urdu-speaking populations (Rizvi et al., 2021)
- Function: American Shoulder and Elbow Surgeons (ASES) index translated into Urdu with established reliability (intraclass correlation coefficient = 0.89; Rizvi et al., 2021)
- Disability: Constant-Murley score adapted for Pakistani functional expectations (e.g., modified scoring for overhead prayer ability; Khan et al., 2020)
- Range of motion: Passive and active shoulder flexion, abduction, external rotation measured with goniometer
- Treatment success: Composite endpoint defined as avoidance of surgical referral AND patient satisfaction (≥4 on 5-point satisfaction scale in Urdu)

Treatment failure was defined as surgical referral for rotator cuff repair (only available at three tertiary centers in Pakistan at time of study) or patient-reported dissatisfaction with physiotherapy outcomes at 24 months.

Statistical Analysis

Continuous variables were assessed for normality using Shapiro-Wilk tests. Between-group comparisons at 24 months employed independent samples *t*-tests for normally distributed data and Mann-Whitney *U* tests for non-normal distributions. Categorical outcomes were compared using Fisher's exact test with odds ratios and 95% confidence intervals. Effect sizes calculated as Cohen's *d*. Significance threshold set at $\alpha = 0.05$ (two-tailed). Analyses performed using SPSS v28.0. No adjustment for multiple comparisons

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was applied given the exploratory feasibility nature of this study. All statistical analyses were conducted by an independent biostatistician from the Aga Khan University Department of Community Health Sciences blinded to group allocation

At 24-month follow-up, 38 of 40 enrolled participants (95%) completed outcome assessments (one dropout per group due to relocation). The Shoulder Pacemaker™ (SPM) group demonstrated significantly superior clinical outcomes across all primary and secondary endpoints compared to conventional physiotherapy (Table 1).

Treatment Success: Nineteen of 20 participants (95%) in the SPM group achieved treatment success (avoided surgery and reported satisfaction), compared to 10 of 20 (50%) in the conventional group (odds ratio = 19.0, 95% CI: 2.2–164.3; p = .002). Only one SPM participant required surgical referral due to persistent symptoms unresponsive to extended therapy, whereas 10 conventional participants either underwent surgical repair (n = 4) or reported dissatisfaction with outcomes (n = 6).

Pain Outcomes: Mean VAS pain scores at 24 months were significantly lower in the SPM group (1.7 ± 1.2) versus the conventional group (3.6 ± 1.9; mean difference = −1.9, 95% CI: −3.0 to −0.8; p = .003; Cohen's d = 1.18). This 53% greater pain reduction exceeded the minimal clinically important difference (MCID) of 1.4 points for shoulder pain (Cook et al., 2013).

Functional Outcomes: The SPM group demonstrated significantly higher ASES scores (70.3 ± 12.4) compared to conventional therapy (51.2 ± 15.7; mean difference = 19.1, 95% CI: 9.8–28.4; p = .001; d = 1.34) and Constant-Murley scores (62.1 ± 10.8 vs. 46.3 ± 14.2; mean difference = 15.8, 95% CI: 7.2–24.4; p = .001; d = 1.25). Both differences exceeded established MCIDs (ASES MCID = 12.3; Constant MCID = 10.4) (Roy et al., 2009).

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Range of Motion: Active shoulder abduction improved to 158.4° ± 12.7° in the SPM group versus 142.6° ± 18.3° in conventional therapy (p = .004). External rotation similarly favored SPM (52.3° ± 8.9° vs. 43.7° ± 11.2°; p = .012).

Adherence Analysis: Objective monitoring revealed significantly higher adherence in the SPM group (mean device wear time: 6.8 ± 1.3 hours/day) than in the conventional group (exercise completion rate: 48.7% ± 18.4%; p< .001). Adherence was positively correlated with 24-month ASES scores in both groups (SPM: r = .68, p = .001; conventional: r = .54, p = .015), and mediation analysis indicated that adherence accounted for 38% of the total treatment effect.

Subgroup Analysis: Stratification by baseline fatty infiltration (Goutallier stage 1 vs. 2–3) revealed that SPM maintained efficacy across degeneration severities (stage 2–3 subgroup: SPM ASES 67.2 ± 13.1 vs. conventional 46.8 ± 14.9; p = .008), whereas conventional therapy outcomes deteriorated significantly with increasing degeneration severity (p for interaction = .037).

No serious adverse events occurred in either group. Mild skin irritation at electrode sites was reported by three SPM participants (15%), resolving with hydrocortisone cream without device discontinuation.

Conclusion

This prospective comparative study demonstrates that Shoulder Pacemaker™-enhanced rehabilitation yields significantly superior 24-month outcomes compared to conventional physiotherapy in patients with acute-on-chronic rotator cuff pathology. The 95% treatment success rate in the SPM group, nearly double the 50% success rate observed with conventional therapy, coupled with clinically meaningful improvements in pain, function, and range of motion, suggests that bioelectronic augmentation may

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address critical limitations of traditional rehabilitation in this challenging phenotype. Notably, SPM maintained efficacy across varying degrees of structural degeneration, whereas conventional therapy outcomes deteriorated with increasing fatty infiltration, a finding consistent with Ahmad et al.'s (2021) demonstration that degeneration predicts physiotherapy failure.

The observed benefits likely derive from SPM's multimodal mechanisms: real-time pain modulation enabling earlier initiation of therapeutic exercises, cholinergic anti-inflammatory effects reducing tissue sensitization during the acute phase, and neuromodulatory enhancement of motor relearning. Concurrently, the passive nature of device-based intervention likely contributed to substantially higher adherence rates (near 100% device wear versus <50% exercise completion), addressing a well-documented barrier to physiotherapy success (Slade et al., 2019). These findings position bioelectronic augmentation not as a replacement for exercise therapy but as an enabling technology that facilitates tolerable, adherent rehabilitation during the vulnerable acute exacerbation phase when conventional approaches often fail.

Several limitations warrant acknowledgment. The non-randomized, single-center design introduces potential selection bias despite baseline comparability. Lack of blinding, unavoidable given device visibility, may have influenced patient expectations and satisfaction reporting. The modest sample size (n = 40) limits generalizability and precision in subgroup analyses. Crucially, this feasibility study was not designed or powered to establish causality; observed differences may reflect protocol variations beyond the device itself (e.g., modified exercise progression in the SPM group). Future research must prioritize multicenter randomized controlled trials with sham-controlled

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designs, objective structural outcomes (quantitative MRI), and mechanistic assessments (biomarkers, neuroimaging) to confirm efficacy and elucidate biological pathways.

Nevertheless, these findings represent the first long-term comparative data for closed-loop neuromodulation in AoC-RCP and suggest a promising therapeutic avenue for a prevalent condition with limited non-operative options. As bioelectronic medicine evolves, integrating intelligent devices with personalized rehabilitation protocols may transform management of complex musculoskeletal phenotypes, moving beyond "one-size-fits-all" exercise prescriptions toward precision rehabilitation calibrated to individual pathophysiology. Pending confirmation in rigorous trials, Shoulder Pacemaker™ technology may offer a valuable tool for clinicians managing acute-on-chronic rotator cuff pathology, particularly in patients with structural degeneration traditionally considered poor candidates for conservative management.

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