Efficacy of Self-Administered Percussive Massage Therapy Versus Gentle Manual Massage to the Thigh Following Anterior Total Hip Arthroplasty: A Prospective Randomized Controlled Trial

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1. Background and Rationale

Anterior total hip arthroplasty (THA), most commonly performed via the direct anterior approach (DAA) using a bikini or longitudinal incision, utilizes the internervous plane between the tensor fasciae latae and sartorius. This muscle-sparing approach preserves the abductor mechanism and is associated with earlier functional recovery compared to posterior and lateral approaches. However, postoperative sensory disturbances of the anterolateral thigh remain a common complication, often attributed to traction-related neurapraxia or irritation of the lateral femoral cutaneous nerve (LFCN).

These symptoms may include numbness, paresthesia, burning, hypersensitivity, stiffness, and disturbed sleep, and can negatively impact early patient satisfaction and perceived recovery. While most LFCN-related symptoms improve over time—approximately 81% resolving within 6 months—a notable subset of patients (11–16%) experience persistent symptoms beyond this period [1, 2]. Among symptomatic individuals, numbness is the most common complaint (37%), with neuropathic symptoms gradually declining over time (24% at <2 years to 11% at 6–8 years postoperatively) [1]. These symptoms are thought to result from a combination of LFCN traction injury and periosteal irritation during femoral canal preparation [3, 4].

Despite the frequency of these complaints, there is currently no standardized outpatient treatment protocol. Vibration-based therapies have been evaluated in postoperative populations, with a recent randomized controlled trial demonstrating reductions in hip pain following total hip arthroplasty, though without significant improvements in functional outcomes, highlighting the need for targeted and mechanism-specific interventions [5]. Management is typically limited to observation, reassurance, or occasional pharmacologic intervention, highlighting an unmet need for simple, scalable strategies to improve early postoperative recovery.

Percussive massage therapy (PMT), delivered via handheld devices operating at 20–40 Hz with amplitudes of 8–16 mm, has demonstrated efficacy in reducing musculoskeletal pain, improving local tissue perfusion, and modulating nociception through gate-control mechanisms in both athletic and clinical populations [6, 7]. A recent systematic review found that PMT may improve short-term muscle strength, flexibility, and musculoskeletal pain, although the overall quality of evidence remains limited and heterogeneous [8]. Acute experimental studies have shown that percussive therapy can increase range of motion and reduce tissue stiffness, supporting a potential mechanistic basis for improvements in mobility and symptom perception [9]. Similarly, manual massage represents a low-cost, accessible intervention that may provide symptomatic relief through soft tissue mobilization and sensory modulation. In postoperative populations, a randomized controlled trial following anterior cruciate ligament reconstruction demonstrated that adjunctive percussive massage therapy improved pain, range of motion, and functional outcomes compared to exercise alone, suggesting potential clinical benefit in rehabilitation settings [10]. The ease of self-administration, short treatment duration, and widespread consumer availability make these modalities attractive adjuncts to postoperative rehabilitation.

No randomized controlled trial has evaluated structured, self-administered PMT specifically for postoperative LFCN-related sensory symptoms following aTHA. Importantly, it remains unclear whether any observed benefit from device-based therapy is attributable to the mechanical percussive stimulus itself, or to nonspecific effects such as touch, attention, and engagement in a structured self-care routine.

To address this gap, this study employs an active comparator design in which the control group performs a standardized flat-palm manual massage of identical anatomical regions, matched for duration and frequency using the same treatment map. This design controls for nonspecific therapeutic effects, allowing isolation of the mechanical contribution of percussive stimulation.

The purpose of this study is to evaluate the effect of a standardized percussive therapy protocol compared to manual massage on persistent anterolateral thigh sensory symptoms following bikini-incision anterior THA. We hypothesize that percussive therapy will result in greater improvement in symptom severity and objective sensory function compared to manual massage.

2. Objectives and Hypotheses

2.1 Primary Hypothesis

Patients performing twice-daily self-administered percussive massage therapy (PMT) to the anterior and lateral thigh following aTHA will demonstrate a clinically meaningful improvement in Oxford Hip Score (OHS) [11, 12] at 6 weeks postoperatively compared to patients performing twice-daily gentle manual massage of the same anatomical zones for the same duration.

2.2 Primary Objective

To assess the effect of self-administered PMT versus active manual massage comparator on hip-specific pain and functional outcomes (OHS) at 6 weeks following anterior THA — the end of the 6-week active treatment period.

2.3 Key Secondary Objective

To assess whether any treatment advantage in OHS at Week 6 translates into greater joint unawareness (FJS-12) at Week 6 and Month 3, and to formally test whether group differences converge by Month 3 as expected given natural postoperative recovery trajectories.

2.4 Additional Secondary Objectives

- Assess effect of PMT versus manual massage on anterior thigh pain intensity (NRPS) at POD 1, 14, Week 6, and Month 3.
- Assess effect on anterior thigh paresthesia burden (Paresthesia Severity Scale composite score) at same timepoints.
- Map and quantify the distribution and resolution of anterior thigh numbness (standardized body diagram shading, percent area affected) at all timepoints.
- Assess effect on anterior thigh stiffness (via visual analog scale) at all timepoints.
- Assess effect on sleep disturbance (PROMIS Sleep Disturbance 8a) at POD 14, Week 6, and Month 3.
- Quantify and compare total opioid consumption (MME/24h) between arms at POD 1 and POD 14.
- Characterize and compare adherence rates between arms as a measure of acceptability and tolerability of each intervention.
- Document and compare adverse events between arms. Specifically, wound complications, reoperations, and aseptic loosening of the components.

3. Study Design

This is a prospective, single-center, two-arm, parallel-group, randomized controlled trial with a 1:1 allocation ratio. The trial compares twice-daily self-administered percussive massage therapy (PMT) to an active comparator of twice-daily gentle manual massage, both applied to the anterior and lateral thigh for 6 weeks following anterior THA. The active comparator design was selected to isolate the specific mechanical effect of percussive therapy from non-specific effects of touch, attention, and structured self-care routine.

Design Element	Specification
Design	Prospective, 1:1 parallel-group RCT with active comparator
Setting	Single tertiary orthopedic center
Target enrollment	58 participants (29 per arm)

Design Element	Specification
Intervention arm	Self-administered PMT twice daily — morning and evening
Comparator arm	Gentle flat-palm manual massage twice daily — same zones, same time
Treatment duration	POD 1 through Week 6 (~42 days, ~84 sessions)
Primary endpoint	OHS at Week 6 — single primary, alpha = 0.05
Secondary follow-up	Month 3 (durability + convergence assessment)

4. Rationale for Active Comparator Design

The selection of gentle manual massage as the comparator arm — rather than standard care alone or a sham device — reflects a deliberate scientific choice to maximize internal validity while maintaining operational feasibility. The following table summarizes the key design tradeoffs considered.

PMT Arm	Comparator Arm
Percussive device at 30 Hz, 10-12mm amplitude	Flat palm of hand, no device
Ball-head attachment, medium speed setting	Gentle pressure
2.5 min anterior thigh + 2.5 min lateral thigh	2.5 min anterior thigh + 2.5 min lateral thigh
Morning + evening, every day for 6 weeks	Morning + evening, every day for 6 weeks
Device provided by physical therapy; returned at Week 6	No device; same written zone map provided
Same treatment zone map as the comparator arm	Same treatment zone map as PMT arm
Same session timing and frequency	Same session timing and frequency

5. Eligibility Criteria

5.1 Inclusion Criteria

- Age 18 years or older at the time of surgery.
- Scheduled for primary unilateral elective anterior THA for osteoarthritis, avascular necrosis, or inflammatory arthritis.
- Sufficient upper extremity strength and hand dexterity to perform either intervention independently, OR a reliable caregiver willing and able to assist with sessions throughout the 6-week period.
- Able to provide written informed consent.
- Willing and able to perform twice-daily sessions, maintain a daily log, and attend follow-up visits at Week 6 and Month 3.
- BMI < 40 kg/m2.

5.2 Exclusion Criteria

- Revision arthroplasty or prior ipsilateral hip surgery performed.
- Pre-existing neurological condition affecting the ipsilateral anterior or lateral thigh: peripheral neuropathy, lumbar L2-L4 radiculopathy, meralgia paresthetica, or diabetic amyotrophy.

- Confirmed or history of deep vein thrombosis or pulmonary embolus
- Active wound infection, breakdown, dehiscence, or open incision at any treatment session timepoint.
- Coagulopathy, bleeding disorder, or supratherapeutic anticoagulation at time of enrollment.
- Active malignancy involving the hip or ipsilateral femur.
- Concurrent enrollment in another interventional trial.
- Significant cognitive impairment precluding safe self-administration or valid PROM completion.
- Anticipated contralateral THA within the 3-month follow-up window.

6. Interventions

6.1 Shared Elements — Both Arms

The following elements are identical in both arms and are standardized across the trial:

- Postoperative standard care: multimodal analgesia protocol, physical therapy with early ambulation beginning POD 0 or 1, standardized wound care, DVT prophylaxis, and home exercise program per institutional protocol.
- Treatment zone map: both arms receive the identical color-coded anatomical diagram (Figure 1) showing Zone 1 (anterior thigh, from proximal thigh to quad tendon) and Zone 2 (lateral thigh, from greater trochanter to just above lateral epicondyle), with the incision exclusion zone marked.
- Session schedule: twice daily — once within 1 hour of waking (morning) and once within 1 hour of bedtime (evening).
- Session duration: 5 minutes total per session — 2.5 minutes Zone 1 (anterior thigh), then 2.5 minutes Zone 2 (lateral thigh).
- Treatment period: POD 1 through end of Week 6 (approximately 42 days; 84 sessions total).
- Daily adherence log: same format for both arms — morning and evening checkbox, any skipped sessions with reason.
- Follow-up visits: both arms attend identical assessment visits at Week 6 and Month 3.
- Safety instructions and stop criteria: an identical written red-flag card provided to both arms.

6.2 Intervention Arm: Percussive Massage Therapy (PMT)

Device and Setup

Each PMT participant will receive a study-issued percussive massage device at the baseline visit, pre-set to the correct speed setting and labelled. A ball-head attachment will be pre-attached. Participants return the device at the Week 6 visit.

Device Parameters

Parameter	Specification
Device	Study-provided Toloco or Hyperice Hypervolt GO 2
Attachment	Ball-head (pre-attached, labelled)
Frequency	30 Hz (1,800 percussions/min), medium speed setting
Amplitude	Medium (10-12mm stroke depth)
Applied pressure	Device weight only — light resting contact, no added downward force
Massage technique	Slow overlapping longitudinal strokes, up and down, device perpendicular to skin surface

Parameter	Specification
Patient position	Supine or seated, operative leg extended or lightly supported
Exclusion zone	2-inch (palm-width) radius from incision — never treat over sutures or staples

PMT Patient Instructions (Plain Language)

HOW TO USE YOUR MASSAGE GUN — SIMPLE STEPS

Do this TWICE every day: once in the MORNING and once in the EVENING.
Each session takes only 5 MINUTES total.

STEP 1 — Sit or lie down with your operated leg stretched out in front of you.

STEP 2 — Turn on the massage gun. Use the MEDIUM speed (2 dots on the display).

STEP 3 — FRONT OF THIGH (blue zone on your map) — 2.5 minutes
- Place the gun just below your hip bone on the FRONT of your thigh.
- Slowly glide it UP and DOWN like painting a wall.
- Stop when you reach the top of your kneecap. Do not go below the knee.
- Keep the gun moving at all times. Do not hold it still in one spot.
- Let the gun rest on your skin — do not push it down.

STEP 4 — SIDE OF THIGH (green zone on your map) — 2.5 minutes
- Move the gun to the SIDE of your thigh, starting at the bony bump on your hip.
- Slowly glide it UP and DOWN.
- Stop just above the knee on the side. Do not go below the knee.
- Keep the gun moving. Do not hold it still in one spot.
- Let the gun rest on your skin — do not push it down.

STEP 5 — Turn off the gun. Tick the box in your daily log (morning or evening).

⛔ NEVER use the gun on or near your cut (incision).
Stay at least a PALM-WIDTH (2 inches) away from the cut at all times.
⛔ If your skin becomes very red, swollen, or the wound looks different — STOP and call us.
⛔ Study phone line: 404-851-2300 — available 24 hours a day.

6.3 Comparator Arm: Gentle Manual Massage

Rationale

The comparator arm performs gentle flat-palm manual stroking of the identical anatomical zones using the identical treatment map, for the identical session duration and frequency. This controls for all non-specific effects of the intervention — touch, sensory stimulation, structured routine, attention, and patient engagement — ensuring that any between-group difference in outcomes is attributable to the percussive mechanical stimulus specifically.

Technique

Participants use the flat palm and fingers of the ipsilateral or contralateral hand (whichever is more comfortable given post-surgical mobility). They perform slow, continuous gentle massage in overlapping longitudinal lines up and down each zone. The hand should glide smoothly over the skin surface.

Manual Massage Patient Instructions (Plain Language — 6th Grade Reading Level)

HOW TO DO YOUR DAILY THIGH RUBS — SIMPLE STEPS

Do this TWICE every day: once in the MORNING and once in the EVENING.

Each session takes only 5 MINUTES total.

STEP 1 — Sit or lie down with your operated leg stretched out in front of you.

STEP 2 — You do not need any equipment. Just use the flat of your hand.

STEP 3 — FRONT OF THIGH (blue zone on your map) — 2.5 minutes

- Place your flat palm on the FRONT of your thigh, just below your hip bone.
- Slowly gently massage UP and DOWN in a straight line, like gently wiping a table.
- Stop when you reach the top of your kneecap. Do not go below the knee.
- Keep your hand moving the whole time. Do not press hard.

STEP 4 — SIDE OF THIGH (green zone on your map) — 2.5 minutes

- Move your hand to the SIDE of your thigh, starting at the bony bump on your hip.
- Slowly massage UP and DOWN.
- Stop just above the knee on the side. Do not go below the knee.
- Keep your hand moving. Use only the weight of your hand.

STEP 5 — Tick the box in your daily log (morning or evening).

⛔ NEVER rub on or near your cut (incision).
Stay at least a PALM-WIDTH (2 inches) away from the cut at all times.

⛔ If your skin becomes very red, hot, or the wound looks different — STOP and call us.

⛔ Study phone line: 404-851-2300 — available 24 hours a day.

6.4 Treatment Zone Map — Both Arms

Figure 1 is provided to all participants in both arms. Left-hip patients receive a mirrored version. The map shows Zone 1 (anterior thigh, blue), Zone 2 (lateral thigh, green), incision exclusion zone, anatomical start and stop landmarks, and massage direction arrows.

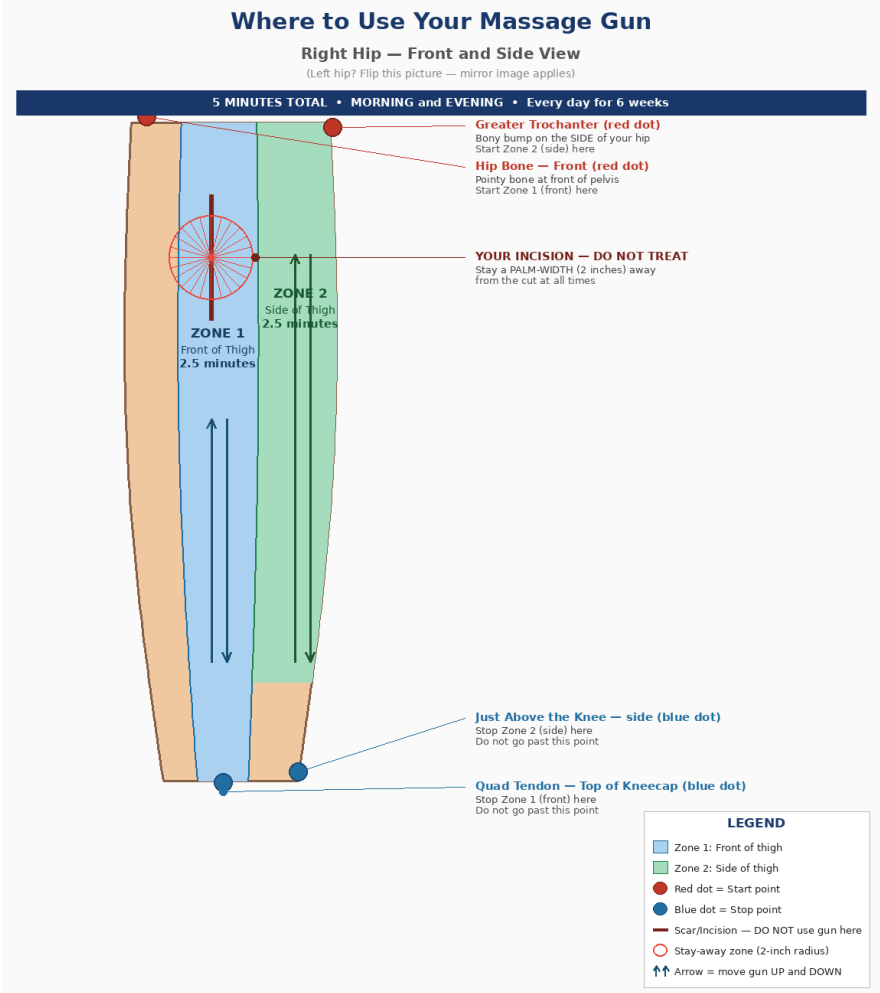


Figure 1. *Self-Administration Treatment Zone Map (both arms). Zone 1 (blue): anterior thigh, quad tendon to proximal thigh, short of incision. Zone 2 (green): lateral thigh, just below greater trochanter to just above lateral epicondyle. Red zone: incision — maintain 2-inch clearance at all times. Arrows indicate up-and-down stroke direction for both arms.*

6.5 Training — Before Discharge

Both arms receive an identical 5-minute in-person training session by a research coordinator prior to their surgery. Training covers: reading the zone map, identifying anatomical landmarks, performing the assigned technique (PMT or manual massage), timing each zone, and recognizing stop criteria. PMT participants also receive device operation training. All participants practice their technique on their own thigh before leaving.

6.6 Contamination Prevention

Given that percussive massage devices are commercially available consumer products, contamination of the comparator arm is a recognized operational risk. The following measures will be implemented:

- At enrollment, comparator participants are asked whether they currently own a percussive device. Current device owners who intend to use the device on the operative limb during the study period will be excluded.
- All participants are asked to refrain from using percussive devices on the operative limb for the full 3-month follow-up period and are reminded of this at each contact.
- Comparator participants are not told the specific identity of the intervention arm, only that they are in a comparison group receiving a different type of thigh therapy.
- Any reported device use in the comparator arm will be documented as a protocol deviation and analyzed in sensitivity analyses.

7. Outcome Measures

7.1 Primary Outcome: Oxford Hip Score (OHS) at Week 6

The OHS is a 12-item patient-reported outcome instrument developed and validated specifically for the assessment of outcomes following hip arthroplasty. Each item is scored 0-4; total score ranges 0-48 with higher scores indicating better hip function and less pain. The instrument covers pain at rest and with activity, walking distance, ability to perform activities of daily living (dressing, putting on socks, using transport, climbing stairs, shopping), and sleep disturbance due to hip pain.

The OHS is selected as primary endpoint for the following reasons: it is the most widely used and validated hip arthroplasty-specific PROM worldwide, enabling direct comparison with the existing literature; its 12 items map precisely to the functional and pain domains expected to be modified by PMT (anterior thigh pain, stiffness, sleep disruption); its MCID of 5 points at 6 weeks is well-established and clinically intuitive; and it minimizes patient burden relative to longer instruments, improving completion rates in the early recovery period.

The OHS is assessed at baseline (pre-operative), Week 6 (primary endpoint), and Month 3 (secondary durability assessment). The primary analysis is the between-group difference in OHS at Week 6, adjusted for baseline score and stratification variables.

7.2 Key Secondary Outcome: Forgotten Joint Score (FJS)

The FJS-12 is a 12-item PROM measuring the degree to which patients are aware of their operated joint during daily and recreational activities. Scores are normalized 0-100; higher scores indicate greater joint unawareness (better outcome). The MCID for THA populations is approximately 10-12 points. The FJS is retained as a key secondary outcome for two reasons: it captures a higher-order dimension of arthroplasty success beyond pain and function (joint unawareness); and it is expected to be more sensitive than OHS for detecting group differences at Month 3 when OHS scores may be converging, allowing formal testing of the convergence hypothesis.

7.3 Additional Secondary Outcomes

1. **Pain:** NRPS Pain: 0-10. MCID ~1.4 points.
2. **Paresthesias:** Paresthesia Severity Scale (PSS): Two 0-10 subscales (severity and frequency of numbness, tingling, burning in anterior thigh); composite score 0-20. Higher = worse.
3. **Numbness Map:** Numbness Body Diagram: Standardized anterior thigh diagram on which participants shade affected areas. Digitized and scored as percent of total anterior thigh surface area affected. Tracks spatial resolution of LFCN territory numbness over time.
4. **Anterior Thigh Stiffness:** 10-point visual analog scale (VAS).

5. **Sleep:** PROMIS Sleep Disturbance 8a: 8-item short form; T-score metric (mean 50, SD 10 in general population); higher scores indicate greater sleep disruption.
6. **Opioids:** Opioid Consumption: Total opioid use per 24-hour period converted to morphine milligram equivalents (MME). Assessed at 6 wks.
7. **Adherence:** Adherence: Proportion of prescribed sessions completed (daily log + device timestamp verification for PMT arm). Compared between arms as a measure of relative acceptability.
8. **Complications:** Wound problems, need for re-operation, and aseptic loosening of the components.

Domain	Instrument	Timepoints	Status
Hip function + pain	Oxford Hip Score (OHS 0-48) [11]	BL, Wk6★, Mo3, Yr1	**PRIMARY ★**
Joint awareness	FJS (0-100) [13]	BL, Wk6, Mo3, Yr1	Key Secondary
Pain intensity	NRPS 0-10 (rest + movement) [14]	BL, Wk6, Mo3, Yr1	Secondary
Thigh Stiffness	VAS 0-10	BL, Wk6, Mo3, Yr1	Secondary
Paresthesias	PSS composite (0-20)	BL, Wk6, Mo3, Yr1	Secondary
Numbness extent	Body diagram (% thigh area)	BL, Wk6, Mo3, Yr1	Secondary
Sleep	PROMIS Sleep Disturbance 8a	BL, Wk6, Mo3, Yr1	Secondary
Opioid use	Total MME/24h	Wk6	Secondary
Adherence	Daily log + device timestamp	Continuous	Process
Complications	Chart review	Up to Yr1	Secondary

8. Schedule of Assessments

BL = Baseline (pre-operative, within 7 days before surgery). POD = Postoperative Day. ★ = Primary endpoint timepoint. Both arms perform twice-daily sessions from POD 1 through end of Week 6. PMT arm returns device at Week 6 visit.

Assessment	Baseline (Pre-op)	Week 6 ★	Month 3	Year 1
Informed Consent	X			
Eligibility Confirmation	X			
Randomization + Device/Instruction Provision	X			
Training Session (in-person)	X			
Intervention (twice daily — both arms)		Wk 6		
Oxford Hip Score (OHS)	X	**X ★**	X	X

Assessment	Baseline (Pre-op)	Week 6 ★	Month 3	Year 1
Forgotten Joint Score-12 (FJS-12)	X	X	X	X
NRPS Pain (rest + movement)	X	X	X	X
Paresthesia Severity Scale (PSS)	X	X	X	X
Numbness Body Diagram	X	X	X	X
PROMIS Sleep Disturbance 8a	X	X	X	X
Adherence Log Review		X		
Device Return (Intervention arm)		X		
Adverse Events		X	X	X

9. Randomization

Participants will be randomized 1:1 using permuted blocks of randomly varying size (4 and 6), stratified by: (1) sex assigned at birth (male/female) and (2) BMI category (< 30 vs. >= 30 kg/m2). Device provision for PMT participants occurs on the day of randomization; comparator participants receive the zone map and written instructions on the same day.

10. Sample Size Calculation

The sample size is calculated for the primary endpoint: between-group difference in OHS at Week 6.

Parameter	Value / Justification
Primary endpoint	Oxford Hip Score (OHS) at Week 6
MCID (effect size target)	5 OHS points (published; conservative, well-validated)
Pooled SD	8.5 (from published 6-week post-THA OHS data)
Alpha	0.05 two-sided (single primary endpoint; no multiplicity correction)
Power (1-beta)	90%
Calculated n per arm	25
Dropout / attrition buffer	15% (based on typical 6-week arthroplasty trial retention)
Final n per arm	**29**
Total target enrollment	**58 participants**

Parameter	Value / Justification
Control arm note	Active comparator (gentle manual massage) reduces differential dropout between arms

At alpha = 0.05 (two-sided), 90% power, a target difference of 5 OHS points (the published MCID — the minimum difference patients and clinicians consider clinically meaningful), and a pooled SD of 8.5 (derived from published 6-week post-THA OHS data), the required sample size is 25 participants per arm. With a 15% inflation for expected dropout over the 6-week active period and between POD 1 and Month 3 follow-up, the target enrollment is 29 per arm, 58 total.

11. Statistical Analysis

11.1 Analysis Populations

- Intention-to-Treat (ITT): All randomized participants analyzed in their assigned arm regardless of adherence or protocol deviations. Primary analysis.
- Per-Protocol (PP): Participants completing >= 75% of prescribed sessions (>= 63/84) with OHS assessment at Week 6. Sensitivity analysis.
- Adherent Subgroup: Participants with >= 90% session completion. Exploratory, hypothesis-generating only.

11.2 Primary Analysis

The primary analysis will compare OHS at Week 6 between groups using analysis of covariance (ANCOVA) with baseline OHS score, sex, and BMI category as covariates. The treatment effect will be expressed as adjusted mean difference with 95% confidence interval and two-sided p-value (alpha = 0.05). Cohen's d effect size will be reported. Missing OHS values at Week 6 will be handled using multiple imputation under a missing-at-random (MAR) assumption, with 50 imputed datasets combined using Rubin's rules. A complete-case sensitivity analysis will also be reported.

11.3 Repeated-Measures Secondary Analyses

OHS at POD 14 and Month 3, FJS-12 at Week 6 and Month 3, and all other repeated-measures secondary outcomes will be analyzed using a linear mixed-effects model for repeated measures (MMRM) incorporating fixed effects for treatment arm, visit, treatment-by-visit interaction, baseline outcome score, and stratification variables, with an unstructured within-subject covariance matrix.

- The treatment-by-visit interaction term formally tests whether treatment effects differ across timepoints — this is the pre-specified statistical test of the convergence hypothesis at Month 3.
- NRPS, PSS, PROMIS Sleep: MMRM as above.
- Numbness map area: MMRM on log-transformed percent surface area affected.

11.4 Adherence and Contamination Analyses

- Adherence will be described as proportion of prescribed sessions completed (mean, SD, median, IQR) for each arm. Arms will be compared using an independent samples t-test or Wilcoxon rank-sum test as appropriate.
- Any comparator participants with documented percussive device use on the operative limb will be flagged as contaminated. A contamination-adjusted sensitivity analysis will exclude these participants from the PP population and re-run the primary ANCOVA.

11.5 Pre-Specified Subgroup Analyses

The following exploratory subgroup analyses will be conducted by including treatment-by-subgroup interaction terms in the primary ANCOVA. These are hypothesis-generating and will not be corrected for multiplicity:

- Sex (male vs. female).
- BMI category (< 30 vs. >= 30 kg/m2).
- Surgeon-reported LFCN retraction time (< 60 vs. >= 60 minutes) — a proxy for nerve injury severity.
- Baseline paresthesia burden (PSS composite > 6 vs. <= 6).
- Age group (< 65 vs. >= 65 years).
- Adherence (>= 75% vs. < 75% session completion).

12. Safety Monitoring and Adverse Events

12.1 Anticipated Risks — PMT Arm

- Local bruising, superficial hematoma, or ecchymosis at the treatment site.
- Transient exacerbation of anterior thigh pain immediately post-session (expected; document if lasting > 24 hours).
- Wound margin disruption if the 2-inch exclusion zone is not observed.
- Skin abrasion or mechanical injury from incorrect device technique.

12.2 Anticipated Risks — Comparator Arm

The manual massage comparator has a very low anticipated risk profile. The only foreseeable adverse events are minor skin irritation from repetitive massage (mitigated by permitting use of hand lotion) and theoretical wound edge disruption if the exclusion zone is not observed.

12.3 Individual Participant Stop Criteria — Both Arms

Participants in both arms receive identical written instructions to stop immediately and contact the study team if any of the following occur:

- New redness, warmth, increased drainage, or opening of the wound edges.
- Leg swelling, calf pain, warmth, or redness suggesting DVT.
- New or markedly worsened motor weakness in the operative extremity.
- Any wound or skin concern the participant is not comfortable continuing to treat around.
- Participant request to withdraw from the assigned intervention.

13. Ethics and Regulatory Considerations

- The protocol, all consent forms, participant-facing materials, and zone maps will be submitted to the Institutional Review Board (IRB) / Research Ethics Committee (REC) for review and approval before enrollment of the first participant.
- Written informed consent will be obtained from all participants at the screening/baseline visit prior to any study procedure.
- The trial will be conducted in accordance with the Declaration of Helsinki, ICH Good Clinical Practice (E6 R2) guidelines, and applicable local regulatory requirements.
- The trial will be prospectively registered on ClinicalTrials.gov and the ISRCTN registry prior to first enrollment. The registration number will be reported in all publications.

- Protocol amendments will be submitted to the IRB and communicated to the trial registry prior to implementation. Amendments will be clearly version-controlled.
- All participant data will be de-identified and stored in a password-protected, encrypted electronic system compliant with HIPAA and applicable data protection legislation.
- Participants may withdraw at any time without any effect on their clinical care. Withdrawn participants will be asked (but not required) to provide a reason for withdrawal.

14. Data Management

All primary data will be collected via validated electronic case report forms (eCRFs) in REDCap. Patient-reported outcomes will be administered via secure REDCap participant portal (electronic) or paper at clinic visits. Paper source documents will be retained at the site. Daily adherence logs will be entered by the research coordinator at each visit.

15. Dissemination

Results will be submitted for peer-reviewed publication regardless of the direction of findings, in accordance with responsible trial reporting obligations. Authorship will follow ICMJE criteria. The full de-identified dataset, analysis code, and instrument-specific effect size estimates will be made available upon reasonable request following publication. A plain-language results summary will be sent to all participants. The study is reported in accordance with the CONSORT 2010 statement and its extension for non-pharmacological interventions.

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