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CLINICAL REPORT

Photobiomodulation self-treatment at home after rotator cuff arthroscopic repair accelerates improvement in pain, functionality, and quality of life: A double-blind, sham-controlled, randomized clinical trial

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Abstract

Objective: To determine whether self-applied photobiomodulation (PBM) therapy at home, following rotator cuff arthroscopic surgery (RCAS) can accelerate improvement in patient-reported outcomes within the first 6 months postsurgery.

Methods: This study was a prospective, double-blind, sham-controlled, randomized clinical trial (NCT04593342). Patients ($n = 50$, age 55 ± 7 years, male:female 29:21) who underwent primary RCAS were randomized to receive active ($n = 22$) or sham ($n = 28$) PBM devices (B-Cure Laser Pro, Erica B-Cure LASER Ltd., Haifa, Israel) in addition to standard care. Patients self-applied the treatments (808 nm, 15 min, 16.5 J/cm^2) at home for 3 months postsurgery. Evaluations were conducted before the surgery (baseline) and at 1–3 and 6 months post-RCAS (FU-1M, FU-3M, FU-6M), and included Constant–Murley score (CMS), range of motion (ROM), subjective pain by visual analogue scale (VAS), disability by QuickDASH, and quality of life (QOL) by SF-12. The difference from baseline to follow-up (ΔFU), %patients achieving minimal clinical important difference (MCID), and patient acceptable symptom score (PASS) were calculated. Comparisons were conducted with superiority 2-sample t test and χ^2.

Results: Baseline values were not significantly different between groups. Both groups had similar improvements in CMS and ROM. However, compared to Sham, PBM significantly accelerated subjective pain reduction at 3 and 6 months (VAS mean ± SD, PBM-vs-Sham: ΔFU-3M 32 ± 33 vs. 16 ± 27, $p = 0.040$; ΔFU-6M: 41 ± 36 vs. 23 ± 26, $p = 0.038$), with a significantly higher proportion of patients achieving MCID at 3 months (76% vs. 48%, $p = 0.027$) and PASS at 6 months (48% vs. 23%, $p = 0.044$). PBM also significantly accelerated improvement in functionality and QOL at 6 months (QuickDASH ΔFU-6M: 30 ± 24 vs. 18 ± 14, $p = 0.029$; SF-12 physical component 6.8 ± 12.5 vs. 0.4 ± 8.6, $p = 0.031$; SF-12 mental component 8.5 ± 9.1 vs. 2.2 ± 12, $p = 0.032$).

Conclusions: Self-applied photobiomodulation following RCAS significantly accelerates decrease in pain and disability, and improves QOL. This nonpharmacologic add-on therapeutic modality is easy to use and encourages active patient involvement. Its potential use in rehabilitation following other surgeries should be considered.

Level of evidence: Level I, high-quality RCT.

Rabie Abufoul and Lilach Gavish contributed equally to this study.

Portions of this project were presented at the 42nd and 43rd Annual Meeting of the Israel Orthopedic Association (IOA) conference, Tel Aviv, Israel, March 14, 2022 and January 25, 2023, and at the 23rd EFORT Congress, Lisbon, Portugal, June 22–24, 2022.

KEYWORDS
arthroscopy, low-level-laser, photobiomodulation, rotator cuff

INTRODUCTION

Rotator cuff tears are a major cause of pain and disability of the upper extremity and are the most common tendon injury in adults. Patients who fail conservative treatments are offered surgical rotator cuff repair, most commonly via rotator cuff arthroscopic surgery (RCAS).[1] Depending on the size of the tear, recovery time may vary between 3 and 6 months and up to 1 year for massive tears,[2,3] with the majority of patients returning to work approximately 8 months after surgery.[4] The standard of care during the recovery period includes physiotherapy, exercise and pain medication, with the latter contributing to the overall opioid crisis.[5,6] An effective, nonpharmacological therapeutic modality for rehabilitation may reduce the postsurgical opioid burden and accelerate return to work and functionality.

Photobiomodulation (PBM), also known as low-level laser therapy, is a nonionizing, nonthermal optical irradiation in the red to near-infrared range of the electromagnetic spectrum.[7] This low-risk, noninvasive technology is widely used for pain reduction and acceleration of wound healing, and for treating a variety of inflammatory-related conditions.[8,9] On the cellular level, PBM mechanisms of action include mitochondrial activation,[10,11] stimulation of collagen synthesis and cell proliferation, as well as a reduction of pro-inflammatory cytokines. Important for surgical applications, PBM has been shown to improve lymph drainage, accelerate postsurgical wound healing and reduce musculoskeletal pain.[12–16] In shoulder tendinopathis, such as subacromial impingement syndrome or rotator cuff tendinitis, PBM was shown to relieve pain and accelerate functional improvement when used as an add on to conservative therapy such as exercise, heat therapy, TENS, or ultrasound.[17–20] However, treatment protocols require multiple sessions administered in the clinic, which poses a logistic difficulty for patients after surgery and requires additional time from the clinical team. Thus, the use of a home-use PBM device following surgery may be useful for patients in the community and preferable over clinic-based treatment.[21] In a recent double-blind, randomized, sham-controlled study, focusing on rehabilitation after distal radius fracture repair, PBM was provided after cast removal as an add-on to a home-based exercise rehabilitation program. The PBM group achieved significant superiority in subjective functional score and significantly reduced consumption of analgesic medication.[22] We hypothesized that the same could be achieved after RCAS.

The purpose of this study was to determine if self-applied PBM using a consumer home-use device (Erica B-Cure LASER Ltd., Haifa, Israel) following RCAS could accelerate improvement in patient-reported outcomes (PROMs) including pain, disability, and quality of life within the first 6 months postsurgery.

METHODS

Study design

This was a prospective, single-center, randomized, double-blind, sham-controlled clinical trial. Patients with rotator cuff tears scheduled to undergo RCAS were randomized to receive active or sham PBM devices in addition to standard care (scheduled physiotherapy and pain medication) and were required to self-apply the treatment at home for 3 months. Patients were evaluated by a single orthopedic surgeon before surgery and at 1–3 and 6 months post-RCAS. Clinical evaluations included the Constant-Murley score and range of motion (ROM). PROMs included subjective average and worst pain by VAS, disability by QuickDASH, and quality of life by SF-12. The primary outcome was the reduction from baseline in level of subjective pain.

Ethical approval

This clinical trial was approved by an IRB (#HFH-219-2020) and prospectively registered at ClinicalTrials.gov (NCT04593342). All patients provided written informed consent before entering the study.

Setting and participants

Patients were recruited at the orthopedic outpatient clinic of the Holy Family Hospital from November 2020, with the last follow-up conducted on March 2022. *Inclusion criteria*: age 40–65 years of age, full or partial RC tear confirmed by imaging, scheduled to undergo RCAS due to failure of conservative therapy (injections, medication, physiotherapy). *Exclusion criteria*: osteoarthritis, rheumatoid arthritis, avascular necrosis, other chronic pain conditions: fibromyalgia, failed back surgery, back pain, has any PBM device at home or has previously used PBM for shoulder pain, use of medications that may affect sensitivity to light.

Randomization and blinding

Randomization was performed at the baseline visit, before surgery. Allocation to groups was done by block randomization. The devices arrived in carts of four (two active and two sham) and the patient chose a device from

the cart. When all four devices were dispensed, the next cart of four was opened.

Patients and evaluators were blinded to group allocation. The near-infrared wavelength of the device is invisible to the human eye. Both the active and sham devices were externally identical, emitted the same sound every 3 s, and glowed with a green light when they operated. However, in the active laser, due to the infrared emission, a sense of subtle warmth developed after several minutes of use, while in the sham laser, the infrared diode was electrically disconnected. Nonetheless, since the treatments were self-administered by each patient at his/her home, the risk of patients comparing devices during the treatments was estimated to be very low. Finally, the evaluators were blinded even to possible immediate effects of the treatment.

Study device and photobiomodulation treatment protocol

The device used in this study was a lightweight, handheld, consumer home-use PBM GaAlAs laser (B-Cure Laser Pro; Erica B-Cure LASER Ltd., Haifa, Israel) that is approved as a medical device and sold over-the-counter without prescription in Europe, Canada, and Israel. The energy parameters of the device are 808 nm (near-infrared) wavelength, 250 mW peak power (55 mW/cm^2), 15 KHz in 33% duty cycle, 1.1 J/cm^2/min with a ray size of 4.5 × 1.0 cm^2, enabling the simultaneous irradiation of a relatively large area in a short time compared to single laser pointers. The treatment protocol is in accordance with the World Association for Laser Therapy (WALT) recommendations.[23] The method and location of treatment is based on recommendations by Hode and Turner[24] and previous studies focusing on accelerated wound healing[25] and stimulation of the microcirculatory flow.[26,27] The patients were required to self-administer the treatment daily for the first month, and every other day for the second- and third-month postsurgery. The duration of each treatment session was up to 15 min. The treatment included stimulation of regional lymph nodes to reduce inflammation and edema, accelerating soft tissue injury over the area of surgery, and inducing analgesia over the brachial plexus. See Figure 1 for the treatment protocol illustration.

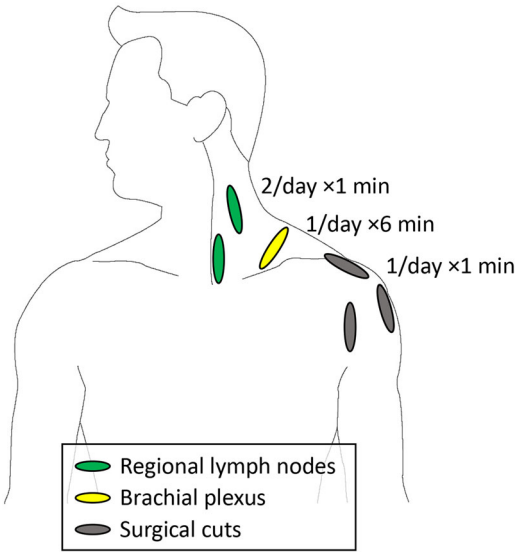

FIGURE 1 Photobiomodulation treatment protocol. Photobiomodulation therapy was self-administered by the patients at home following surgery—daily for the first month, and three times a week for the second- and third-month postsurgery. The protocol included stimulating the regional lymph nodes (cervical and subclavicular) to reduce inflammation and edema, healing soft tissue injury over the surgical cuts and area of tear, and analgesia via the brachial plexus. The duration per location is indicated in the illustration. Energy density per minute was approximately = 1 J/cm^2.

Rotator cuff arthroscopic surgery and standard of care

Participants with partial (>50%) or complete rotator cuff tear and normal glenoid and humeral cartilage, as confirmed by diagnostic arthroscopy under general anesthesia, underwent arthroscopic rotator cuff repair. After debridement and preparation of the tear, 2–3 anchors were inserted, followed by wire fixation using the double row technique. Tenodesis or tenotomy of the long head of the biceps tendon and subacromial bursectomy with or without acromioplasty were performed as indicated.

Postsurgery standard-of-care management included physiotherapy according to a custom rehabilitation program and pain and anti-inflammatory medication according to the hospital regulated protocol. These included 10 mg of Percocet (oxycodone) twice daily for the first week, Rocacet plus (contains codeine and paracetamol) as needed during the first 2 weeks, and 20 mg of Brexin (Piroxicam), a nonsteroidal anti-inflammatory drug (NSAID), for the first 2 weeks. No additional opioids or NSAIDs were prescribed as part of this study. Patients were advised to use nonopioid pain medication such as paracetamol and metamizole (dipyrone) for analgesia.

Study evaluations

Demographic and medical history data were collected and physical findings on examination of the painful shoulder were documented at the baseline visit. Additional data were collected from the surgical records.

Shoulder function was evaluated with the Constant-Murley score[28] that ranges from 0 (lowest) to 100 (highest) quality of the function. The overall score was

calculated using a free online calculator.[29] The active and passive range of motion was measured using goniometry. Since active and passive measurements were very similar, only active measurements are presented.

Subjective average and worst pain level were reported by the patients using the visual analogue scale (VAS) with the words "no pain" and "intolerable pain" on the left and right extremes of the scale, respectively. The position of the mark with respect to the entire scale was then calculated as percent. The criteria for pain, Minimal Clinical Important Difference (MCID) and Patient Acceptable Symptom Score (PASS), were 15 and 17 according to Kim et al.[30]

The QuickDASH questionnaire was used as the disability subjective measure specifically for the upper limb.[31] The overall score was calculated by summing scores of all answers, dividing by the number of questions (minimum answers = 10 of 11), subtracting 1, and multiplying by 25. The criterion for QuickDASH MCID was 8 points according to Minteken et al.[32]

The SF-12 questionnaire was used to assess the impact of health on an individual's everyday life, which is commonly used as a quality-of-life measure.[33] The physical and mental components of the score (PCS and MCS) were calculated using a free online calculator.[34]

The ease of use of the PBM device was determined with a VAS with the words "very easy" and "very difficult" on the left and right extremes of the scale, respectively. A score of <40 was interpreted as "easy to use." The patients were asked how likely they were to recommend the device to family and friends using an ordinal 6-step scale (1 = extremely likely to 6 = extremely unlikely).

Study outcomes

The primary outcome measure was the mean change from baseline in subjective pain. Secondary outcomes included mean change in CMS, ROM, disability, quality of life and frequency of MCID and PASS.

Statistical analysis

Sample size justification

Sample size was based on the mean change from baseline in pain by VAS for active PBM versus Sham over physiotherapy as standard care for rotator cuff tendinitis reported by Elsamian et al.[18] using $\mu_0 = 3.3$ versus $\mu_1 = 5.0$ (SD = 2.4). A sample size of 21 participants per group was calculated to achieve 81% power to reject the null hypothesis with a significance level (α) of 0.050. Sample size was calculated with PASS-15.0.4 software (NCSS Statistical Software, Kaysville, UT).

Data analysis

Statistical analysis was performed using intention-to-treat principles for all outcomes attributed to the assigned group. Variables are presented as mean ± SD or counts [%] as appropriate. Within-group comparisons between time points (baseline vs. 1, 3, or 6 months) were conducted by superiority paired t tests with Bonferroni's correction for three comparisons. Direct comparisons of the mean change over baseline between groups were conducted with superiority 2-sample t test, and change in frequencies (MCID and PASS) with superiority χ^2. $p < 0.05$ was considered significant. Statistical analysis was conducted using Systat-13 (Systat Software, Inc., San Jose, CA).

RESULTS

Participant flow and baseline data

Patients ($n = 63$) with partial or full thickness RC tear scheduled for arthroscopic repair were recruited and randomized from November 2020 through September 2021. Thirteen patients were excluded after randomization but before entering the study: nine did not undergo surgery and four withdrew before receiving the device. Thus, 50 randomized participants were included in the intention-to-treat analysis, with 22 allocated to PBM and 28 to Sham, of whom 42 (84%) completed the 6-month evaluation (despite COVID-19-related lockdowns). See Figure 2 for the CONSORT diagram of the participant flow.

The groups were similar at baseline. Participants were middle-aged, mostly overweight men and women (mean [95% CI]: age = 55 [53,57] years, 58% males, BMI = 28.8 [27.6,30.1] kg/m^2), of whom 26% had diabetes type II and 26% were current smokers. Medical history included one (2%) patient with hyperthyroidism, one (2%) with celiac and three (6%) with cardiovascular diseases. The etiology of the tears was either trauma or degeneration (44% and 56%, respectively) (Table 1).

Shoulder function and range of motion (Figure 3, Table 2)

Before surgery, patients had considerable limitations in shoulder function represented by Constant–Murley score and range of motion. At 3 months postsurgery, both groups showed significant improvement in CMS (PBM: $p = 0.003$ and Sham: $p = 0.006$), but only the PBM group was significantly improved in forward flexion (PBM: $p = 0.009$ and Sham: 0.186). At 6 months, both groups showed significant

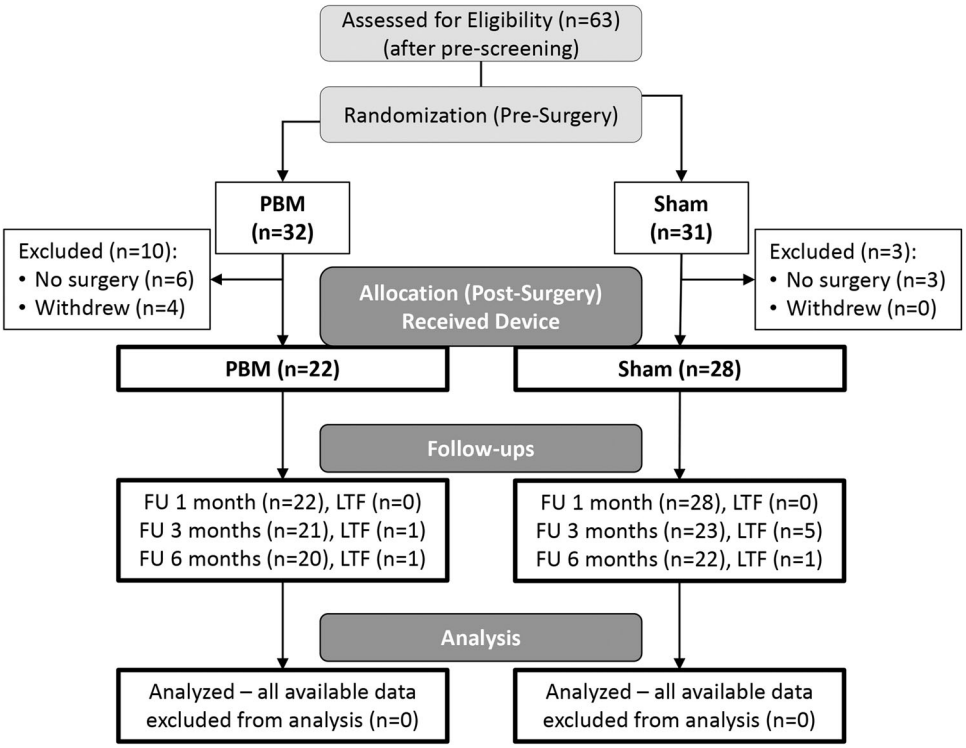

FIGURE 2 CONSORT patient flow diagram. PBM = Photobiomodulation; FU = follow up; LTF = lost to follow up.

improvements in CMS, forward flexion and abduction ($p \leq 0.006$ for all). There was no significant difference between the groups ($p > 0.2$) at any of the time points.

Subjective pain (VAS) (Figure 4, Table 3)

At 1 month postsurgery, significant average and worst pain reduction was reported only by the PBM group ($p < 0.05$), while both groups reported significant pain reductions at 3 and 6 months postsurgery ($p \leq 0.015$ for all). At these time points, the PBM group reported significantly larger pain reductions compared to Sham ($p \leq 0.04$). Moreover, at 3 months postsurgery, 76% of the patients from the PBM group achieved MCID while only 48% of the sham group achieved the same ($p = 0.027$). At 6 months postsurgery, compared to Sham, twice as many patients of the PBM group achieved an acceptable symptom state (48% vs. 23%, $p = 0.044$).

Subjective disability (QuickDASH) (Figure 5, Table 3)

At 3 months postsurgery, reduction in disability score was reported to be significant only in the PBM group (PBM: $p = 0.002$ and Sham: $p = 0.129$), of whom twice as many patients achieved MCID compared to Sham (86% vs. 45%, $p = 0.003$). At 6 months postsurgery, both groups reported significant reductions in disability score ($p < 0.001$ for both) but reduction reported by the PBM was significantly greater compared to Sham ($p = 0.029$).

Quality of life (Figure 6, Table 3)

At 6 months postsurgery, only the PBM group reported significant improvements in the quality of life as represented by the SF-12 physical and mental components (PCS: $p = 0.036$ and MCS: $p < 0.001$, PBM vs. Sham $p \leq 0.032$ for both).

Patient experience

Most participants (43 of 50 [86%]) thought the device was easy to use after 1 month of self-treatments at home, and 77% were very likely or extremely likely to recommend the device to friends and family at the end of the 3-month treatment period.

Adverse events

No device-related adverse events were reported.

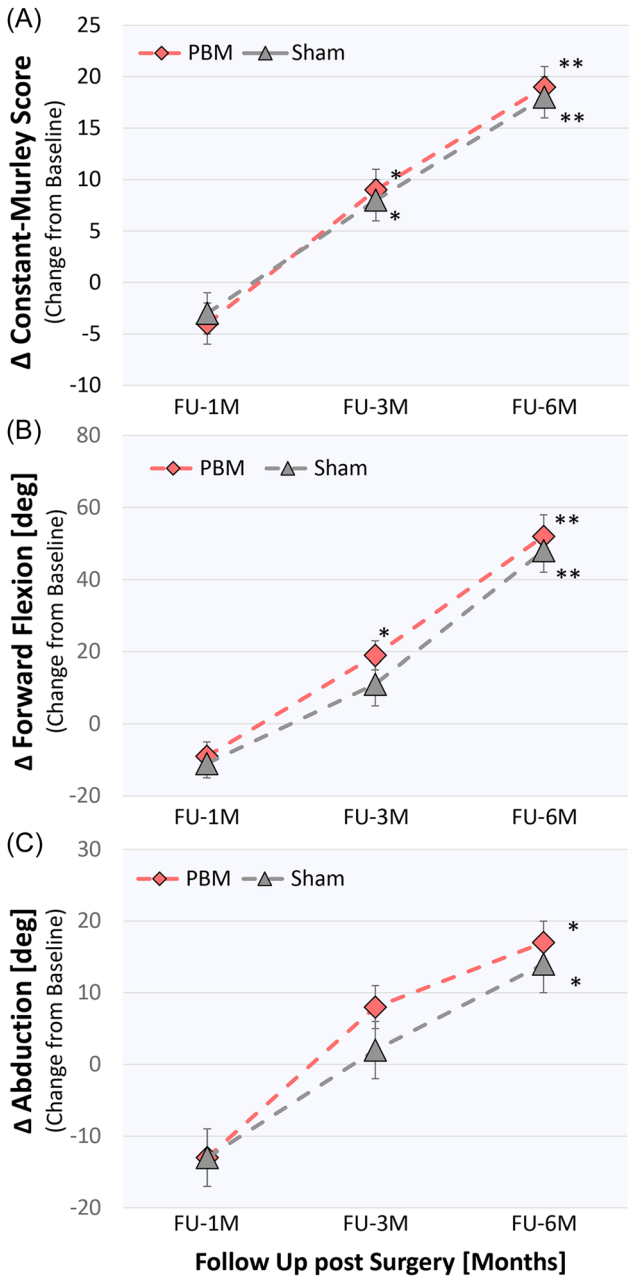

FIGURE 3 Effect of photobiomodulation on clinical outcomes. The average improvement from baseline in (A) shoulder function evaluated by the Constant–Murley score, and (B) and (C) range of motion (mean ± SEM) is depicted for the photobiomodulation (PBM) group (red diamonds, $n = 22$) and sham group (gray triangles, $n = 28$) at follow-ups 1–3, and 6 months (FU-1M, FU-3M, FU-6M). Dashed line added for visualization. Note significant improvement in both groups across all outcomes regardless of PBM. $*p < 0.05$, $**p < 0.001$ by superiority paired t test with Bonferroni's correction for three comparisons.

DISCUSSION

The goal of rotator cuff arthroscopic surgery (RCAS) is to decrease pain and reduce shoulder-related disability. A variety of surgical techniques and rehabilitation methods are constantly developed and tested to ensure better biomechanical outcomes and quality of rehabilitation.[35] Nonetheless, new therapeutic modalities that accelerate recovery, encourage patient involvement and reduce work load from the clinical staff are desirable.

PBM, a nonpharmacological, nonthermal optical irradiation is used clinically to accelerate wound healing and reduce pain and inflammation. Previous studies evaluated PBM for shoulder tendinopathies as an add-on to conservative therapy.[19] Abrisham et al.[17] reported that addition of PBM treatment (pulsed 890 nm laser, 6 min) to a 10-session exercise program was more effective than exercise therapy alone in the improvement of pain and range of motion (ROM) in patients with subacromial syndrome ($n = 80$). Eslamian et al.[18] reported that addition of PBM (GaAlAs 830 nm laser, 5 min) to a combination therapy of 10 exercise sessions with heat therapy, ultrasound and TENS was superior in pain reduction compared to the combination therapy alone in patients with rotator cuff tendinitis ($n = 50$). Martins et al.[20] reported that addition of PBM (850 nm laser or 640 nm light-emitting diodes [LEDs], 2 min) to 12 sessions of ultrasound was superior to ultrasound alone in pain reduction, and improvement in ROM and quality of life in patients with rotator cuff tendinitis ($n = 75$). Overall, these PBM treatments were determined to be effective and easy to perform, but they took place at the clinic and were done by the clinical team.

This double-blind, randomized, sham-controlled study was designed to evaluate the usefulness of PBM for accelerating recovery post-RCAS. Patients received the device at postoperative Day 1 before going home and were expected to return for evaluations at the usual 1-month checkup. Any therapeutic modality requiring additional visits at the clinic would have been difficult for these post-op patients due to pain and limited functionality. Moreover, this study took place at the height of the COVID-19 pandemic, including several national and regional lockdowns. Arriving at the hospital for nonemergency treatments was discouraged and social distancing required minimal interaction with clinical personnel. In the current study, this was not necessary because the treatments were self-administered at home, thereby both encouraging patient involvement and reducing clinical staff work load.

The addition of self-administered PBM (808 nm, up to 13 min) resulted in earlier and greater improvements in patient-reported outcomes throughout the 6-month recovery period. Specifically, the proportion of patients of the PBM group achieving pain MCID and disability MCID at 3 months was similar to that achieved by the sham group at 6 months. Furthermore, although improvements in ROM and shoulder function (Constant–Murley score) were similar in both groups, the PBM group reported significantly greater improvement in physical and mental quality of life, with a greater proportion of patients reaching an acceptable symptom state (PASS) at 6 months postsurgery.

TABLE 1 Baseline data—Demographics, medical history, etiology, and shoulder tests.

Category	Variable	PBM ($n = 22$)	Sham (28)	All ($n = 50$)
Demographics	Age (years)	56 [52,60][a]	54 [52,57]	55 [53,57]
	Male:Female (% Male)	13:9 (59%)[b]	16:12 (57%)	29:21 (58%)
	BMI (kg/m^2)	28.4 [26.8,30.0]	29.2 [27.2,31.1]	28.8 [27.6,30.1]
Smoking	Never	14 (64%)	10 (36%)	24 (48%)
	Former	2 (9%)	11 (39%)	13 (26%)
	Current	6 (27%)	7 (25%)	13 (26%)
Medical history	Diabetes (Type 2)	6 (27%)	7 (25%)	13 (26%)
	Cardiovascular	1 (5%)	2 (7%)	3 (6%)
	Gastrointestinal	0 (0%)	1 (4%)	1 (2%)
	Thyroid	1 (5%)	0 (0%)	1 (2%)
Etiology	Trauma	10 (45%)	12 (43%)	22 (44%)
	Degenerative	12 (55%)	16 (57%)	28 (56%)
Tear extent	Complete:Partial	10:10	15:13	25:23
Shoulder tests	Jobe's test	22 (100%)	26 (93%)	48 (96%)
	Speed's test	22 (100%)	25 (89%)	47 (94%)
	Hawkin's test	12 (55%)	17 (61%)	29 (58%)

Abbreviation: PBM, photobiomodulation.
[a]Mean [95% CI].
[b]Counts (%).

TABLE 2 Clinical outcomes.

Clinical outcomes	Timepoint	PBM	Sham	PBM versus sham (p Value)
Constant–Murley score	Baseline	32 [28,36]	34 [30,37]	0.575
	FU-1M	29 [25,33]	31 [27,35]	0.609
	FU-3M	41 [36,46]*	43 [38,48]*	0.442
	FU-6M	52 [44,60]**	53 [47,60]**	0.463
Forward flexion	Baseline	72 [65,80]	77 [68,85]	0.449
	FU-1M	63 [53,72]	66 [53,78]	0.426
	FU-3M	92 [80,103]*	91 [78,103]	0.225
	FU-6M	125 [110,140]**	127 [114,141]**	0.330
Abduction	Baseline	67 [58,76]	69 [61,76]	0.738
	FU-1M	51 [43,58]	55 [46,63]	0.518
	FU-3M	75 [68,81]	74 [65,82]	0.239
	FU-6M	84 [79,89]*	86 [81,91]*	0.307

Note: Mean [95% CI]; comparisons within group between time points by superiority paired t test with Bonferroni's correction for three comparisons.
Abbreviation: PBM, photobiomodulation.
*$p < 0.05$ and **$p < 0.001$ comparison between groups by 2-sample t test (2-tailed for baseline, superiority for change from baseline at follow-ups).

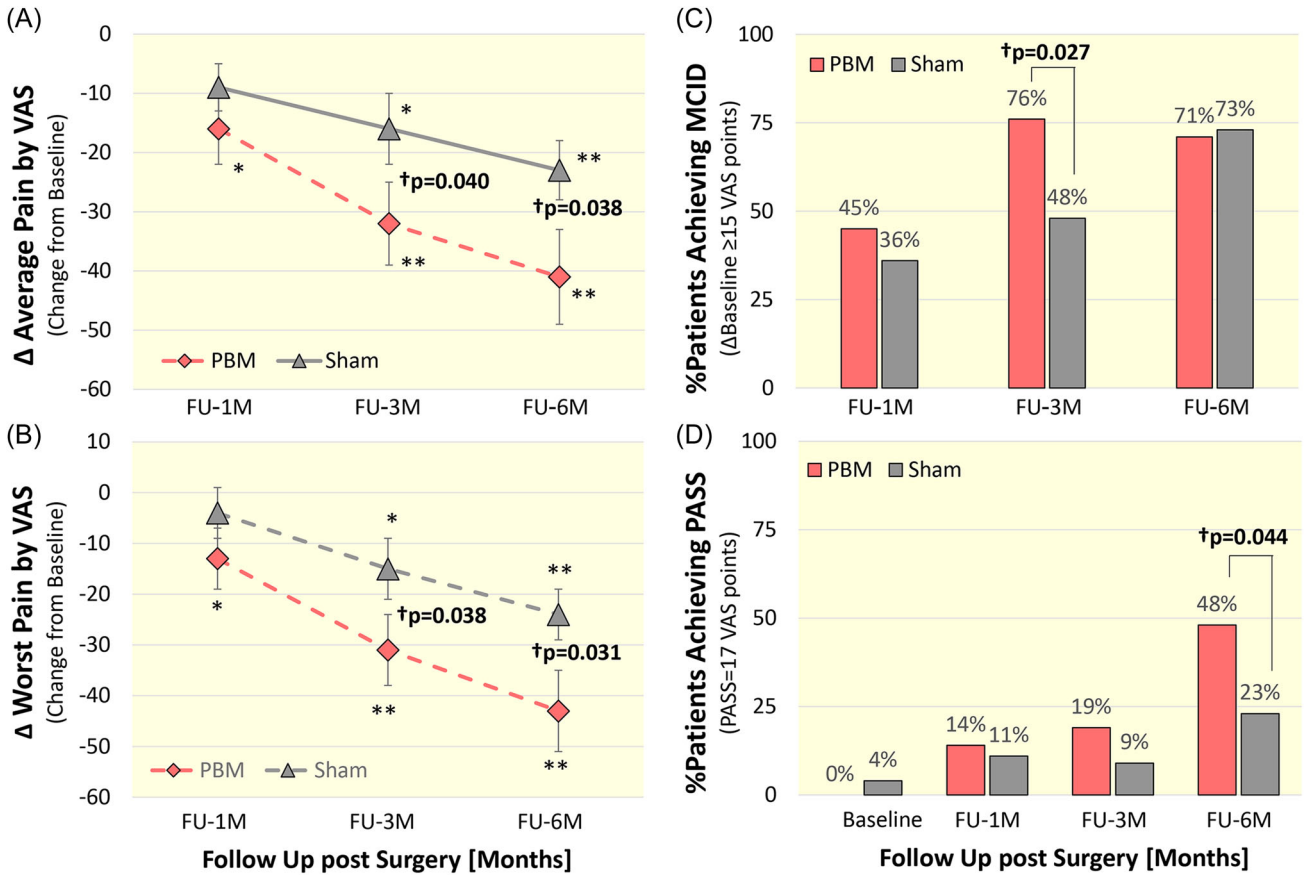

FIGURE 4 Effect of photobiomodulation on pain. The average reduction in pain level by visual analogue scale (VAS) from baseline (mean ± SEM) in (A) average pain and (B) worst pain is depicted similar to Figure 3. $*p < 0.05$, $**p < 0.001$ by superiority paired t test with Bonferroni's correction for three comparisons. †PBM versus Sham by superiority 2-sample t test. Note that PBM was superior to Sham in pain reduction score at 3 and 6 months. The proportion of patients achieving minimal clinical important difference (MCID)(30) and patient acceptable symptom state (PASS)(30) is depicted in the bar graphs (C) and (D). Note that more patients in the PBM group compared to the sham group achieved MCID at 3 months and PASS at 6 months. †PBM versus Sham by superiority χ^2.

We are not aware of specific studies evaluating PBM use post-RCAS. However, a few studies assessed the acute and long-term effects of PBMs following other orthopedic surgical procedures. Saebo et al.[36] found that nine sessions of PBM (super-pulsed 904 nm laser, 2 min) after distal radius fracture repair (during the immobilization period) ($n = 53$) resulted in significantly superior ROM and grip strength, and a reduction in night pain. In a separate study, Saebo et al.[22] found that PBM in addition to home-based exercise after cast removal ($n = 50$) resulted in significantly improved function and significantly less analgesic medication consumption. Langella et al.[37] reported that a single session of PBM (multiwave, 25 min) administered 8–12 h post-total hip arthroplasty ($n = 18$) resulted in significantly reduced acute pain and significantly decreased TNFa and IL-8 cytokine levels. Similarly, Nesioonpour et al.[38] reported that a single session of PBM (650/808 nm) immediately after tibial fracture repair ($n = 54$) resulted in significantly reduced pain and opioid consumption. Two small pilot studies evaluated the feasibility of PBM for patients undergoing total knee arthroplasty. In the first study, de Rezende et al.[39] reported administering PBM to 9 patients immediately following the surgery and 24 h later at the hospital. In the second study, Vassão and Laakso[40] reported a case series ($n = 4$) of patients who applied light patches at home daily the week before surgery and every other day on the week after the surgery. These studies show that PBM may be useful for patients undergoing orthopedic surgical procedures and can easily be included as part of a multimodal treatment for rehabilitation.

The specific device used in this study is a self-applied, home-use device that is sold over-the-counter without a prescription, making it much more convenient for patients and time-efficient for the clinical team. Indeed, the participants of this study found the device easy to use and reported that they were likely to recommend the device even after a period of 3 months of constant use. To date, the safety and efficacy of this device have been reported for treatment of temporomandibular joint pain,[41,42] diabetic foot ulcers,[25,43,44] postoperative

TABLE 3 Patient reported outcomes.

Patient-reported outcomes	Timepoint	PBM	Sham	PBM vs. Sham (*p* Value)
Pain (average)	Baseline	75 [67,82]	64 [55,72]	0.050
	FU-1M	59 [47,71]*	54 [45,63]	0.192
	FU-3M	42 [30,54]**	48 [39,58]*	**0.040**
	FU-6M	34 [20,48]**	40 [29,51]**	**0.038**
Pain (worst)	Baseline	87 [82,92]	79 [71,87]	0.082
	FU-1M	74 [62,85]*	74 [65,84]	0.117
	FU-3M	56 [43,69]**	62 [51,73]*	**0.038**
	FU-6M	44 [28,61]**	52 [40,64]**	**0.031**
QuickDASH	Baseline	74 [66,83]	67 [59,75]	0.228
	FU-1M	71 [62,80]	68 [61,75]	0.269
	FU-3M	55 [44,66]*	59 [51,68]	0.068
	FU-6M	44 [31,58]**	49 [39,59]**	**0.029**
SF-12–PCS	Baseline	34.4 [31.1,37.7]	36.5 [34.1,38.9]	0.300
	FU-1M	35.6 [32.9,38.4]	36.5 [33.8,39.2]	0.217
	FU-3M	37 [33.8,40.3]	36.6 [33.9,39.2]	0.18
	FU-6M	41.5 [37.4,45.6]*	38.1 [34.5,41.6]	**0.031**
SF-12–MCS	Baseline	39.5 [34.8,44.2]	39.4 [34.9,44]	0.985
	FU-1M	37.4 [32.2,42.7]	40.9 [34.9,47]	0.749
	FU-3M	43.3 [36.5,50.1]	43.4 [37.8,49.1]*	0.373
	FU-6M	44.7 [39.6,49.8]**	41.2 [34.3,48.1]	**0.032**

Note: Mean[95% CI]; comparisons within group between time points by superiority paired *t* test with Bonferroni's correction for three comparisons.
Abbreviation: PBM, photobiomodulation.
*$p < 0.05$ and ** $p < 0.001$ comparison between groups by 2-sample *t* test (2-tailed for baseline, superiority for change from baseline at follow-ups).

wounds,[45] and oral mucositis.[27,46] In this study, similar to previous studies conducted with this device, no device-related adverse events were reported.

Limitations

(1) The follow-up time of the study was limited to 6 months postsurgery. Although complete recovery may take additional time, social security compensations in the form of paid recovery leave from work and house assistance are limited to 3 and 6 months, respectively and therefore, our focus was acceleration within this time frame. (2) The patient population included both partial and full thickness tears on a background of trauma or degeneration which may be considered non-homogeneous. However, the distribution between the groups was not significantly different. Further studies should be carried out to explore whether these co-variates modify the effect of PBM. (3) The number of self-administered treatments was not tracked. In future studies, we plan to add a tracker as part of the device to collect information.

Conclusion

Self-applied photobiomodulation at home following RCAS significantly accelerates improvement in patient-reported outcomes including pain, disability and quality of life, and does not modify improvements in ROM or shoulder function. This noninvasive, nonpharmacological add-on therapeutic modality is easy to use, encourages active patient involvement, and is cost-effective because it does not require additional visits to the clinic or clinical staff time. These findings, together with the existing literature, may indicate the usefulness of photobiomodulation in accelerating recovery and rehabilitation following other orthopedic surgeries.

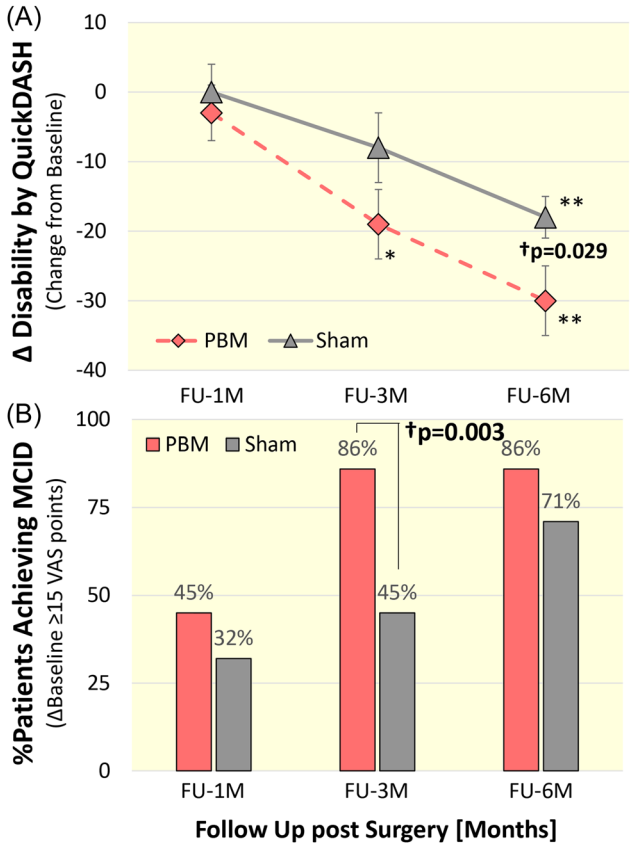

FIGURE 5 Effect of photobiomodulation on disability (QuickDASH). The average reduction from baseline (mean ± SEM) in disability as reported in the QuickDASH questionnaire is depicted similar to Figure 4 with the same statistical tests. (A) QuickDASH average score. (B) MCID(32). Note that PBM was superior to Sham in the reduction on average disability score at 3 and 6 months and that more patients in the PBM group achieved MCID at 3 months. MCID, minimal clinical important difference; PBM, photobiomodulation.

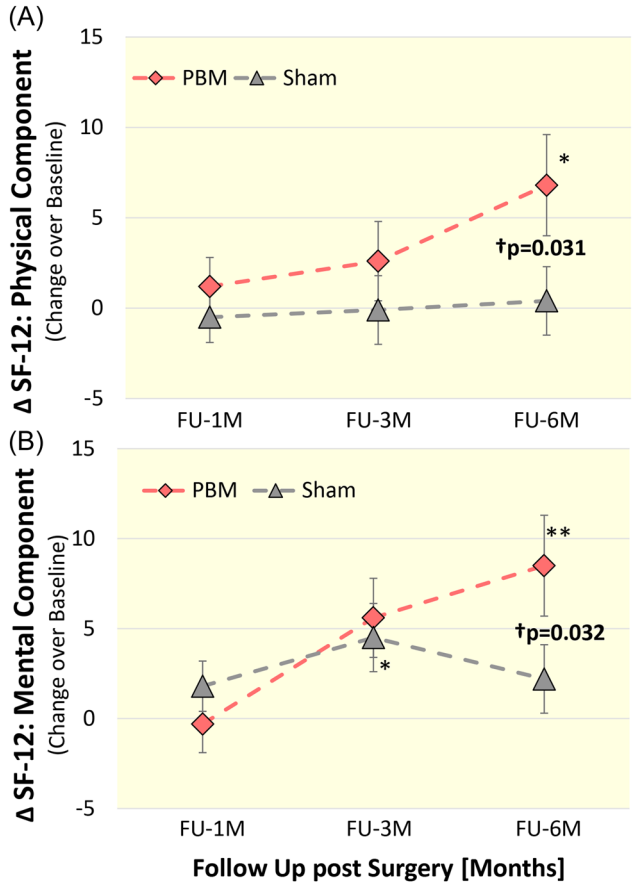

FIGURE 6 Effect of photobiomodulation on quality of life (SF-12). The average improvement from baseline (mean ± SEM) in the (A) physical and (B) mental components of quality of life questionnaire SF-12 is depicted similar to Figure 4 with the same statistical tests. Note that PBM was superior to Sham in quality of life at 6 months. PBM, photobiomodulation.

AUTHOR CONTRIBUTIONS

Rabie Abufoul recruited patients, performed clinical evaluations, collected patient questionnaires, and interpreted the data. Lilach Gavish designed the study, conducted the literature search, prepared the clinical report forms, validated the data, performed analysis, supervised data collection, interpreted the data, and wrote the initial draft. Marwan Haddad was the principal investigator, designed the study, supervised clinical evaluations, and interpreted the data. All authors critically reviewed the manuscript for important intellectual content, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

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CONFLICT OF INTEREST STATEMENT

L. G. is paid as a consultant by the manufacturer of the device to give recommendations for treatment protocols. The manufacturer of the device provided active/sham devices, administrative, and technical assistance. The manufacturer was not involved in the evaluations or analysis of the data. The remaining authors declare no conflict of interest.

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