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ORIGINAL ARTICLE

Effectiveness of ActiPatch in the management and prevention of pillar pain following open carpal tunnel release surgery in weight-bearing hand of elderly patients: an observational study

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ABSTRACT

Aim To confirm the effectiveness of the ActiPatch device in treating and preventing pillar pain following open carpal tunnel release surgery.

Methods Ten elderly patients with pillar pain after carpal tunnel release surgery were treated with ActiPatch for seven days. When these patients underwent surgery on the opposite hand, they were pre-emptively treated with ActiPatch to prevent pillar pain. Pain was measured using the Visual Analog Scale (VAS), functionality was assessed using the Quick Disability of the Arm, Shoulder and Hand (QuickDASH) and Michigan Hand Questionnaire (MHQ) scoring systems, and patient satisfaction was evaluated.

Results All patients showed an improvement in pain level and functional capacity after using ActiPatch for pillar pain management. Additionally, none of the patients experienced pillar pain during the subsequent preventive phase.

Conclusion The use of ActiPatch proves to be a viable and effective approach for managing and preventing pillar pain in elderly patients with weight-bearing hands who have undergone carpal tunnel release surgery.

Keywords: carpal tunnel syndrome, complications, elderly, pain management, postoperative pain

INTRODUCTION

Carpal tunnel release surgery, a prevalent intervention among hand surgeons, often yields high patient satisfaction rates, with over 90% recommending the procedure to peers (1–3). Post-surgery, notable improvements such as reduced hand numbness, diminished nocturnal tingling, and alleviated "pins and needles" hand pain are commonly reported, facilitating better sleep quality (1–4).

However, a transient yet significant issue known as "pillar pain" emerges in a subset of patient's post-carpal tunnel release. This discomfort is localized at the hand's base within the heel of the palm, specifically affecting the thenar and hypothenar eminences (1–4). Such soreness, marked by tenderness upon pressure application, hinders recovery, prolonging the expected rehabilitation period following surgery. Activities that involve palm pressure exacerbate the soreness, impeding patients' return to regular functionality (1,2).

Although pillar pain typically subsides within three months post-surgery, a small percentage of individuals might endure its effects for up to six months (1). The origins of this condition remain elusive, with theories ranging from scar tissue irritation due to bony prominences within the palm to alterations in muscle alignment and joint inflammation following the surgery (1,2).

Addressing pillar pain often involves hand therapy techniques encompassing stretching, scar massage, and desensitization, occasionally supplemented by steroid injections (3). Notably, oral medications are seldom required, and revision surgery is typically unnecessary (1–4).

Encouraging patients to maintain hand activity post-incision healing is not recommended against excessive strain, as it may cause temporary discomfort but not long-term damage. Notably, ActiPatch presents itself as a non-invasive, drug-free therapeutic option using electromagnetic pulse therapy, clinically proven for musculoskeletal pain relief, including conditions like arthritis and fibromyalgia (5–8).

ActiPatch has made its debut as an over-the-counter (OTC) 'topical' analgesic designed for localized musculoskeletal pain. Prior to its introduction, there was minimal awareness regarding this medical technology and device (5). ActiPatch is a non-invasive, low-power, user-friendly, pulsed shortwave therapy device specifically intended for addressing localized musculoskeletal pain (6). The device is devoid of heat production or sensory perception. Its utilization involves two fundamental prerequisites: activation via an on/off switch and application of the device over the targeted area of the body. The treatment is localized within the confines of the 11.5-cm diameter loop

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antenna, covering the area of 100 cm^2. The antenna is circular, pliable, and adaptable, allowing it to conform to the specific area or location being treated as needed (6).

The ActiPatch technology's potential for long-lasting pain relief offers promise in addressing common musculoskeletal complaints aligning with the unmet need for effective pain management in various conditions including osteoarthritis and rheumatoid arthritis. Backed by clinical studies and positive consumer testimonials, ActiPatch emerges as a safe and potent modality for managing chronic pain without adverse effects, marking a significant stride in pain therapy (5–8).

The incidence of pillar pain is higher in the elderly (1–4). This condition may be related to the lack of abstinence from overloading the transverse carpal ligament, which is severed in both minimally invasive and open surgery (1,4). The elderly patient's hand is a weight-bearing hand, as elderly individuals are accustomed to using their hands to assist the lower limbs, for example, when transitioning from a seated to a standing position (9).

Surgical treatments for intractable pillar pain described in the literature focus on modification of surgical technique or incision (10–12) or on excision of the hook of hamate (13).

Pillar pain treatment usually includes rest, bracing and physiotherapy (1–4).

Non-surgical treatment is different and related to the hypothetical aetiology. In elderly patients the presence and treatment of base thumb arthritis (9,14) or scaphoid disease (15–19) should be considered when pillar pain is radial.

Given the effectiveness of ActiPatch on managing chronic and acute pain (5–8), we conducted an observational study on an elderly population who developed pillar pain after open carpal tunnel release managing the pain with ActiPatch and preventing the occurrence of pillar pain with this device in controlateral open carpal tunnel release.

This study aims to confirm the effectiveness of the ActiPatch device in treating and preventing pillar pain following open carpal tunnel release surgery.

PATIENTS AND METHODS

Patients and study design

During the period spanning November 2022 to December 2023, 250 patients diagnosed with carpal tunnel syndrome in the Hand Surgery Unit of Fondazione Policlinico “A. Gemelli” in Rome underwent carpal tunnel open release procedures administered by a sole surgeon. Within this cohort, 10 elderly patients (age ranging from 76 to 90 years old) experienced postoperative pillar pain following the procedure and were subsequently treated with ActiPatch samples for treatment and prevention of pillar pain.

All study participants, or their legal guardian, provided an informed written consent prior to the study enrolment.

Methods

The patients, after developing pillar pain, were treated with ActiPatch samples, which were applied continuously for 7 days with beneficial outcomes observed (Figure 1). During the contralateral carpal tunnel open release, ActiPatch samples were integrated into the dressing at the 7-day mark to evaluate their efficacy in averting pillar pain onset (Figure 2).

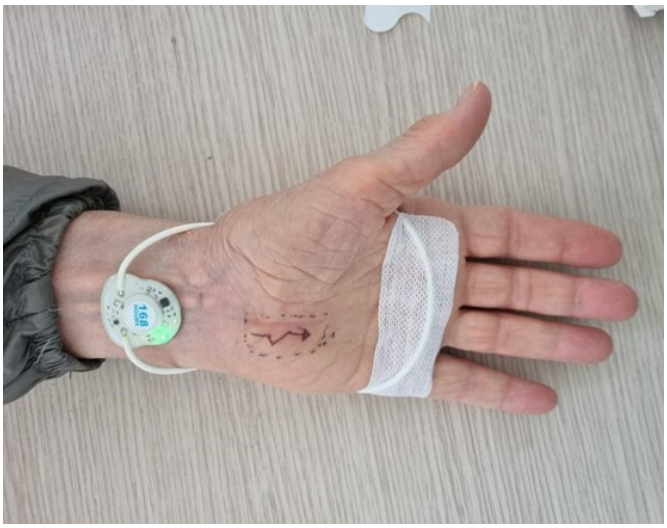

Figure 1. Application of Actipatch in pillar pain treatment (De Vitis R. 2023)

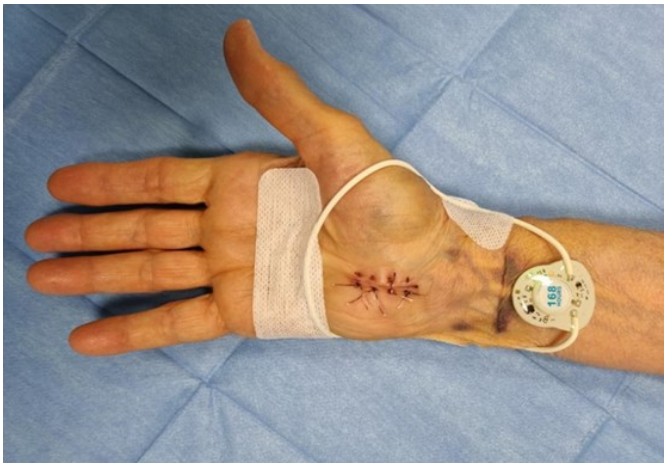

Figure 2. Application of Actipatch in pillar pain prevention (De Vitis R. 2023)

The ActiPatch functions as a low-power pulsed shortwave therapy apparatus at the frequency of 27.12 MHz. It emits pulses at a rate of 1000 per second, each lasting for 100 microseconds. Its peak power reaches 73 microWatts per square centimetre, accompanied by an electromagnetic flux density of 30 microTeslas. While the precise mechanism of action is still being unveiled, unpublished data suggest a non-invasive neuromodulation effect. This effect potentially involves the stimulation of afferent nerves through inductive coupling and stochastic resonance. The device is designed for the use of up to 24 hours a day and can be applied to the localized pain area either using medical tape or a specifically engineered wrap.

The evaluation of patients encompassed the utilization of the Visual Analog Scale (VAS) score (explain scoring system Done) (20), Quick Disability of the Arm, Shoulder and Hand (QuickDASH) (explain scoring system) (21) and abbreviation in full Michigan Hand Questionnaire (MHQ) (explain scoring system)(22) assessment tools and abbreviation in full Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines were followed in writing the manuscript.

The VAS score (Visual Analog Scale) is a tool used to measure a person's subjective experience of pain, discomfort, or other symptoms. It typically consists of a horizontal line, usually 10 cm long, with one end labelled as "no pain" (or "no dis-

comfort") and the other end labelled as "worst possible pain" (or "worst imaginable discomfort").

The patient marks a point on the line that represents the intensity of their experience. The score is then measured by the distance from the "no pain" end to the point marked by the patient, providing a numerical value, usually between 0 and 10. It is commonly used in clinical settings to assess pain levels and track changes over time.

The QuickDASH score is a shortened version of the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire, designed to measure a patient's physical function and symptoms in upper limb disorders. It helps assess the impact of musculoskeletal conditions on daily activities. The QuickDASH consists of 11 questions that focus on the patient's ability to perform specific physical activities (e.g., opening a jar, carrying heavy objects), as well as the level of pain, tingling, or weakness they experience. Each question is scored on a 5-point scale, where higher scores indicate greater disability.

The Michigan Hand Questionnaire (MHQ) is a patient-reported outcome measure designed to assess the impact of hand conditions on a person's daily life. It evaluates hand function, symptoms, and the patient's perception of their hand's health, particularly in people with hand injuries or disorders such as arthritis or carpal tunnel syndrome. The questionnaire covers six domains: Overall Hand Function (how well the hand functions in daily activities), Activities of Daily Living (ADLs) (ability to perform tasks like eating, dressing, etc.), Work Performance (impact of the hand condition on work activities), Pain (level and frequency of hand pain), Aesthetics (patient's perception of the hand's appearance), and Patient Satisfaction (satisfaction with the hand's health and function).

Statistical analysis

The Kolmogorov-Smirnov test was used to determine the normal distribution of data. A paired t test was performed to evaluate the difference between the preoperative and postoperative values. A p-value of <0.05 was considered statistically significant.

RESULTS

The population of this study consisted of 10 elderly patients, four males and six females with age ranging from 76 to 90 years. No patient was lost at follow-up. All patients were treated with open carpal tunnel release after clinical and electromyographical diagnosis. No intraoperative complications occurred. All patients exhibited improvement in both pain levels and functional capacity following the application of ActiPatch for the management of pillar pain. Furthermore, none of the patients experienced pillar pain during the subsequent preventive phase.

All patients were evaluated for VAS, QDASH and MHQ before and after the treatment with ActiPatch. The improvement of all the three measurements for both treatment (Table 1) and prevention (Table 2) of pillar pain was statistically significant ($p< 0.05$). As for the QDASH it showed an average improvement of 52 points while being used for pillar pain treatment and almost 37 points in pillar pain prevention, going from a mean score of 67.5 ± 3.7 (range 72.73 - 61.36) to a mean score of 15.5 ± 5.3 (range 22.73 - 6.82) for pillar pain treatment (Table 1) and from a mean score of 47.1 ± 8.7 (range 57.5-25) to a mean score of 10.5 ± 3.9 (range 18.18-6.82) for pillar pain prevention respectively (Table 2).

Similar results are available for VAS where the improvement of 8.2 and 4.4 points respectively was registered for pillar pain treatment (Table 1) and prevention (Table 2). In the occasion of the treatment the VAS improved from a mean value of 8.8 ± 1.0 (range 10-7) to a mean value of 0.6 ± 0.7 (range 2 - 0), while in the prevention the VAS decreased from a mean value of 4.8 ± 0.9 (range 6 - 3) to a mean value of 0.4 ± 0.5 (range 1 - 0).

The MHQ improved for both treatment (Table 1) and prevention (Table 2), with the mean values that increased of 28.8 and 23.4 points, respectively. In particular, the mean treatment MHQ score improved from 42.7 ± 1.1 (range 43.8 - 41.7) to 71.5 ± 3.0 (range 74.6 - 66.3), while the mean prevention MHQ score improved from 49.5 ± 4.1 (range 45.8 - 60.4) to 72.9 ± 2.6 (range 70.4-76.7).

When a paired comparison of outcomes was performed, at final follow up the values of all three parameters (VAS, QDASH and MHQ) were very similar with the use of ActiPatch for both treatment (Table 1) and prevention (Table 2).

DISCUSSION

In our observational study important data that arise from the two series, when a paired comparison of outcomes is performed, indicate that at final follow-up the values of all three parameters (VAS, QDASH and MHQ) are very similar with the use of ActiPatch for both treatment and prevention. This confirms the goodness of this approach for both scenarios: the development of pillar pain secondarily to a procedure or in case of a preventive treatment when high suspicion of pillar pain development is present.

Another interesting observation could be that in case of prevention the net improvement of the scores is inferior when compared to the one registered in case of the treatment. A possible explanation of such results lies in the fact that the starting point of ActiPatch application differs in the two cases, since, when used for prevention at seven days after surgery, the patients did not develop the complete symptoms and limitations of a fully manifested pillar pain as it happened when ActiPatch was applied for the treatment.

Pillar pain or pillar tenderness is a frequently cited occurrence in the medical literature subsequent to both open and closed surgical methodologies, yet a precise and uniform definition of this phenomenon remains elusive. A comprehensive analysis of existing literature unveils varied depictions: discomfort localized in the thenar or hypothenar eminences, radial and ulnar tenderness, thenar-specific tenderness, and pain specifically situated in the hypothenar area (1). Hunt and Osterman refer to "pain spanning the thenar and hypothenar regions along the surgical incision"(2), while Nathan et al. delineate discomfort within the vicinity of the surgical incision (3). Wilson defines a "critical pillar rectangle" or the pillar region wherein pain sensations may manifest (23). Most authors differentiate pillar pain from scar tenderness, another frequently cited complication. Vranceanu asserted that preoperative pain sensitization is associated with postoperative pillar pain after open carpal tunnel release (24).

Table 1. Data of patients treated with Actipatch after pillar pain developement: pre-treatment and after 7 days

Patient	VAS		QDash		MHQ	
	Pre	Post	Pre	Post	Pre	Post
1	9	1	68.18	18.18	43.8	70.4
2	10	0	68.18	9.09	41.7	68.3
3	8	1	61.36	22.73	43.8	74.6
4	9	0	72.73	13.64	41.7	70.4
5	10	0	63.64	15.91	41.7	74.6
6	8	0	63.64	15.91	43.8	70.4
7	9	0	68.18	6.82	43.8	70.4
8	10	1	72.73	18.18	41.7	74.6
9	8	2	68.18	22.73	41.7	66.3
10	7	1	68.18	11.36	43.8	74.6
Mean ±SD	8.8 ± 1.0	0.6 ± 0.7	67.5 ± 3.7	15.5 ± 5.3	42.7 ± 1.1	71.5 ± 3.0

VAS, Visual Analog Scale; Qdash, Quick Disability of the Arm, Shoulder and Hand; MHQ, Michigan Hand Questionnaire; Pre, pre-operative; Post, post-operative; SD, standard deviation

Table 2. Data of patients treated with Actipatch to prevent pillar pain developement: pre-treatment and after 7 days

Patient	VAS		QDash		MHQ	
	Pre	Post	Pre	Post	Pre	Post
1	5	0	50	9.09	47.7	72.5
2	6	0	57.5	6.82	45.8	74.6
3	5	1	50	11.36	47.7	70.4
4	5	0	50	6.82	47.7	76.7
5	5	1	47.43	11.36	50	70.4
6	4	1	43.18	18.18	50	70.4
7	6	0	52.27	6.82	50	76.7
8	5	1	50	15.91	47.7	70.4
9	4	0	45.45	9.09	47.9	74.6
10	3	0	25	9.09	60.4	72.5
Mean Value ±SD	4.8 ± 0.9	0.4 ± 0.5	47.1 ± 8.7	10.5 ± 3.9	49.5 ± 4.1	72.9 ± 2.6

VAS, Visual Analog Scale; Qdash, Quick Disability of the Arm, Shoulder and Hand; MHQ, Michigan Hand Questionnaire; Pre, pre-operative; Post, post-operative; SD, standard deviation

Considering a neurogenic aetiology in the literature the benefit from a supplement treatment is minimal (25–27). Reportedly, excellent functional outcomes and satisfaction using simple infiltration of local anaesthetic for pillar pain after carpal tunnel decompression have been achieved (28).

Extracorporeal shock wave therapy (ESWT) was tested in the treatment of pillar pain (29–31). After ESWT, hand function and pain score in patients with pillar pain improved faster compared to control patients. Hence, ESWT can be used as a safe and effective non-invasive technique in patients with pillar pain after carpal tunnel release. A significant number of patients still complain of painful symptoms two or even three years after surgery and ESWT resulted effective also for treating this condition (31).

Carpal tunnel release is indicated also in elderly patients because it is effective in bringing about remission of pain and nocturnal awakenings (32). Elderly patients often use their hand by forcing on the intertenar region in position changes or in using canes or walkers. For this reason, the elderly patient's hand can be defined as weight bearing.

In our experience ActiPatch produced an improvement in pillar pain both in pain alleviation evaluated with VAS and enhanced quality of life evaluated with QuickDash and MHQ.

The results of our observational study, although with the limitations of the limited number of patients, showed that ActiPatch is an effective non-invasive, non-drug therapeutic alternative in both the treatment of pillar pain and its prevention.

In our experience those non-drug treatment results are appropriate in elderly patients who often take many medications for conditions of internal medicine concern.

This research engaged participants who voluntarily opted to be part of the sample, potentially limiting its representation of the entire population experiencing pillar pain. This approach mirrors the methodology of numerous clinical trials, where patients volunteer for participation. Furthermore, our findings stem exclusively from individuals who actively responded to our survey. While tests for non-response bias did not indicate signs of responder bias, the presence of bias remains a plausible factor.

The study's open design might suggest that the reported benefit stems from a robust placebo effect. However, a strong correlation between reported pain relief and actual changes in consumer behaviour was observed. Pain alleviation corresponded with enhanced quality of life and reduced systemic medication use, suggesting that the observed trial device's benefits were not solely due to a placebo effect. Moreover, some published randomized controlled trials employing placebo controls indicated minimal placebo effects with this medical device (33–35). Consequently, while it is improbable that a placebo effect played a significant role in the ActiPatch device's reported effectiveness, it cannot be entirely discounted as a contributing factor. What remains evident is that subjects using the device reported decreased pain levels and subsequently opted to purchase the commercially

available device to sustain the therapeutic benefits leading to reported enhancements in their quality of life.

In conclusion, the utilization of ActiPatch emerges as a viable and effective approach for both the management and prevention of pillar pain in elderly patients with weight-bearing hands who have undergone open carpal tunnel release surgery.

There remains a necessity for additional randomized controlled studies focusing on this device concerning pillar pain. Additionally, elucidating a distinct mechanism of action, presumed to involve non-invasive neuromodulation, is crucial. This concerted effort aims to foster acceptance of the technology among patients and within the medical community. Further research and fine-tuning of the technology have the potential to amplify its clinical efficacy, presenting a secure alternative therapy for chronic musculoskeletal pain in the near future benefitting numerous individuals.

AUTHOR CONTRIBUTIONS

Writing – original draft, G.M.S. and A.C.; Data curation, A.C., L.C., A.M., M.M. and R.D.V.; Formal Analysis, A.C., L.C., A.M., M.M. and R.D.V.; Software, A.C.; Writing – review & editing, G.T., M.P. and R.D.V.; Conceptualization, R.D.V.; Investigation, R.D.V.; Methodology, R.D.V.; Supervision, R.D.V. All authors have read and agreed to the published version of the manuscript.

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TRANSPARENCY DECLARATION

Conflict of interests: None to declare.

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