# RESEARCH ARTICLE

# The Effect of Postoperative Dressing Change Frequency on Wound Healing and Complications in Patients Undergoing Carpal Tunnel Release: A Randomized Clinical Trial

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Received: 9 April 2024

Accepted: 5 October 2024

#### **Abstract**

Objectives: Post-operative wound complications are relatively common. The development of an optimal protocol for the frequency of wound dressing change that results in minimal complications seems crucial. The current study aims to compare two different protocols of single and intermittent dressing change for patients undergoing carpal tunnel release (CTR) in terms of: 1) wound healing indicators and 2) complications.

Methods: In this two-arm parallel randomized clinical trial study, 60 patients who were planned to undergo CTR were enrolled. The participants were randomly assigned to two groups: group A) receiving a single dressing, and group B) receiving intermittent dressing changes every other day. After two weeks, all patients were evaluated for epithelialization, exudate amount, localized pain, localized erythema, localized edema, delayed healing, necrosis, fibrosis, final overall wound condition, final skin condition as indicators of wound healing, and signs of infection. We also employed the Visual Analogue Scale (VAS) to evaluate the pain intensity.

Results: There was no difference between the two groups in terms of basic demographic variables. The results revealed no significant difference in any of the measured wound healing indicators and complications except for the epithelialization rate which was higher in the single-dressing group (8 patients in the single group vs. 0 in the intermittent group; P-value < 0.001).

Conclusion: Overall, the findings suggest that use of the intermittent dressing change protocol for CTR surgery wounds does not improve wound healing or mitigate complications, in comparison to the single dressing protocol, which is more cost-beneficial.

Level of evidence: II

Keywords: Carpal tunnel syndrome, Early dressing removal, Mini-open carpal tunnel release, Postoperative dressing

## Introduction

ost-operative wound dressing plays a critical role in wound healing, by providing a protective barrier over the incision site that prevents direct contact, contamination, infection, and controlling potential bleeding.1 Wound environment, pathological components, and patient's condition are three major determinants of the healing process quality. The frequency of dressing change, as one of the factors affecting the wound environment, can influence the healing process.<sup>2</sup> An appropriate dressing protocol can play a crucial role in promoting a more effective wound-healing process with

There is limited literature specifically focused on the association between dressing change frequency and postsurgical wound outcomes,<sup>6</sup> particularly in the field of hand surgery. Most of these studies have compared no dressing

complications.<sup>3</sup> This is achieved by facilitating timely and efficient healing while preventing surgical site infections

and keeping the dressing for a longer period and have not focused on frequent dressing changes.<sup>7-13</sup> A protocol involving the retention of dressings for five days following spine fusion surgery in approximately 8000 cases

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Arch Bone Jt Surg. 2025;13(12):816-822 Doi: 10.22038/ABJS.2024.78146.3620 http://abjs.mums.ac.ir



significantly lowered the rate of surgical site infections (SSIs).<sup>7</sup> In hand surgery, two studies revealed no difference in Levine score and wound healing process between dressing removal after 24-72 hours and retaining it for two weeks. 14,15 Again, another study found no distinction in wound complications, such as infection, among three protocols: no dressing, having it replaced twice a week, and keeping it for two weeks. 16 Two Cochrane systematic reviews and meta-analyses presented consistent findings, indicating no significant difference in surgical site infections (SSIs) and wound dehiscence when the dressing is retained for an extended period, up to 30 days post-operation. However, it is crucial to note that these results were derived from low-quality evidence, primarily attributed to the risk of bias and imprecision. Additionally, the confidence intervals around these estimates were wide.  $^{17,18}$  In addition, the previous studies have used very limited wound healing outcomes and some of them relied on subjective data obtained from questionnaires. 14,15 Another systematic review and meta-analysis did not provide any indication that early removal of the dressing promotes wound infection. Again, the authors of this review described the methodological quality of the included studies as low and lacking adequate methodological details.<sup>6</sup> Based on these meta-analyses more randomized clinical trials are needed to achieve a robust conclusion. This general disagreement suggests that the current dressing change protocols may be a result of traditional practices rather than reliable and costeffective approaches that prioritize patients' benefits. 19 Carpal tunnel syndrome (CTS) is known as the most common entrapment neuropathy.<sup>20-23</sup> According to its frequency in our center, carpal tunnel release (CTR) is a suitable choice for addressing our research question.

The present study aimed to compare the post-surgical wound healing indicators including epithelialization, exudate amount, localized pain, erythema, and edema, as well as complications including delayed healing, necrosis, fibrosis, final overall condition, final skin condition, and final pain VAS score between two groups of patients undergoing CTR: A) Those who underwent single dressing change and B) those who underwent intermittent dressing change.

#### **Materials and Methods**

## Study setting and ethics

The present two-arm parallel randomized clinical trial study was conducted in 2020-2021 in (removed due to blinding reasons). The study protocol was approved by the ethics committee of our institute (removed due to blinding reasons) and adhered to the principles outlined in the Helsinki Declaration.<sup>24</sup> The allocation ratio was 1:1.

#### **Participants**

We enrolled the patients diagnosed with CTS who were referred to our centers. The inclusion criteria were 1) diagnosed and confirmed with CTS (according to clinical features and electrodiagnostic studies), 2) aged between 18 and 85 years, 3) no history of surgery, organ transplant, use of immunosuppressive agents, or other conditions causing immunosuppression, or having autoimmune diseases, 4) indicated and scheduled for elective CTR. Our exclusion criteria were 1) refusal to participate in the study, 2) trauma to the surgical site during the follow-up period, 3) failure to

follow the prescribed dressing method more than once, 4) changing the dressing in an unsterile manner, 5) use of antibiotics other than the department's guidelines, 6) occurrence of any medical emergency, and 7) undergoing another surgery.

A simple non-probability sampling method was employed. The recruitment period was from April 2018 and January 2019 during which eligible participants were enrolled. The follow-up period commenced immediately after the intervention and lasted for two weeks during which participants were monitored for outcomes. The process of sampling was carried out using a predesigned form and during a face-to-face interview with the individuals, in the study centers. Patients who met the inclusion criteria were eligible to participate after receiving information about the research process. Written informed consent was obtained using a standard form. Randomized codes were written on separate sheets and placed in envelopes. Group assignment was determined by each patient selecting one envelope. The code was then shown to a study investigator to instruct the intervention. A total of 60 included participants were randomly allocated into two groups, A) single dressing, and B) intermittent dressing change. There was no follow-up attrition during the study.

#### Sample size

The study's required sample size was determined through a comparison of means between two independent groups. G-Power software (version 3.1) was utilized for this estimation, with parameters set at a 95% confidence interval, a significance level of 0.05, and a power of 80%. The effect size (d=0.75) representing the average difference in daily activity and performance post-surgery between groups (not changing dressing for two weeks vs. changing dressing twice a week) was considered. Initially estimating 29 participants per group, a rounded-up figure of 30 individuals per group was chosen for enhanced precision, resulting in a total sample size of 60 for the entire study.

## Intervention

All of the CTR operations were carried out by a senior board-certified hand surgeon (EV or AM). First, we had the patient in a supine position on a hand-operating table. Surgery was performed under local anesthesia (lidocaine 2% + adrenaline 1:100,000). An about 4-cm long incision was made within the carpal tunnel region, along the radial border of the wrist crease, or within the thenar eminence. After observing the wrist to ensure adequate release, the incision was closed using nylon surgical sutures (3-0, Supabon<sup>TM</sup>, Karaj, Iran), and the standard dressing was applied to protect the incision site. All of the patients underwent the same bulky dressing protocol, comprised of five 8-layer sterile gauzes and a 5-cm compression tape. The patients received a single prophylaxis dose of intravenous cefazolin (30 mg/kg).

The participants in group A were asked to return in case of any sign of infection and excessive pain. Also, the dressing was kept in place until the first post-operation visit (two weeks later). While in group B, it was changed every other day for two weeks in the hospital by the research investigator. After dressing removal, the operator cleansed the incision site using normal saline

and povidone-iodine solution as a disinfectant before applying a sterile non-bulky dressing comprised of two sterile gauzes. No antibiotic was administered after the operation. The surgeon was blinded to the designated dressing protocol and an orthopedic researcher, not involved in the research assessed the outcomes.

#### Outcomes

Two outcome measures were employed, 1) the wound assessment tool that was designed by the authors, using items extracted from the Bates-Jensen Wound Assessment Tool (BWAT) that were applicable to acute surgical wound,<sup>25</sup> and 2) the VAS score for pain intensity.<sup>26</sup> The outcome measurement was carried out at the first post-operation visit and two weeks after the surgery. During follow-up, photos of the wounds were taken to monitor changes in the wounds.

## Bates-Jensen Wound Assessment Tool (BWAT):

Although initially designed for chronic conditions, BWAT can also be applied to post-surgical wounds.<sup>27</sup> This tool consists of 13 parameters (each having 5 scores), including two wound measurements (area and depth) and 11 observable conditions related to the wound (wound edges, wound undermining, necrotic tissue type, necrotic tissue amount, granulation tissue, epithelialization, exudate type, exudate amount, surrounding skin color, peripheral tissue edema, and peripheral tissue induration). The following items of BWAT which were applicable to acute wounds were implemented in our study: Epithelialization, exudate amount, skin color surrounding the wound, peripheral tissue edema, necrotic tissue amount, and wound edge skin condition.

Epithelialization was evaluated by an orthopedics resident student and by observation, considering that epithelialization appears as pink or red skin. The presence of exudate was assessed by checking the dressing. Also, tissues within 4 cm of wound edge were checked for erythema and edema. Non-pitting edema appears as skin that is shiny and taut is differentiable from pitting edema by firmly pressing a finger down into the tissues. Delayed healing was defined as observing no signs of tissue repair as well as the formation of new blood vessels and tissues. Assessment for necrosis comprised of looking for the predominant part of the necrotic

tissue that may appear as different types according to color, consistency, and adherence (1) white/gray non-viable tissue, 2) non-adherent yellow slough (thin, mucinous substance; scattered throughout wound bed; easily separated from wound tissue), 3) loosely adherent, yellow slough (thick, stringy, clumps of debris; attached to wound tissue), 4) adherent, soft, black eschar (soggy tissue; strongly attached to tissue in center or base of the wound), 5) firmly adherent, hard/black eschar (firm, crusty tissue; strongly attached to wound base and edges (like a hard scab)). The wound edges were evaluated for signs of hyperkeratosis by checking for callous-like tissue formation. Also, we checked for signs of fibrosis and maceration, by looking for hard and rigid touch, and breakdown of skin due to prolonged exposure to moisture, respectively.<sup>28</sup>

#### VAS Score:

The VAS is a unidimensional measure utilized to record pain intensity and track its progression or compare severity among patients with similar conditions.  $^{29,30,31,32}$ 

#### Statistical analysis

The data were analyzed using the Statistical Package for Social Sciences (SPSS) version 23. The normality of quantitative variables was determined using the Kolmogorov-Smirnov test and histogram chart. Descriptive statistics were used to describe the demographic characteristics of the participants, including frequency distribution tables, mean, and standard deviation. The results were analyzed using Chi-square and Fisher's exact test for qualitative variables along with independent t-test or Mann-Whitney test for quantitative variables. A P-value of <0.05 was considered significant.

## Results

#### Descriptive data

Figure 1 illustrates the study flow diagram. There was no follow-up attrition and all of the 60 participants received the intended intervention and were analyzed for the primary outcome, after a two-week follow-up [Figure 1]. There were no significant differences between the groups in terms of basic demographic characteristics [Table 1].

Table 1. Participants' baseline demographic data and clinical characteristics (N=60)								
Variable		Group A Single (n=30)	Group B Intermittent (n=30)	P-value				
Age (year) mean ± SD		47.46 ± 9.32	50.76 ± 11.82	0.23*				
Weight mean ± SD		75.00 ± 7.74	77.30 ± 9.11	0.29*				
History of smoking N (%)		3 (10)	5 (16.7)	0.70**				
Pain at baseline N (%)	Yes	30 (100)	28 (93.3)	0.49**				
	No	0 (0)	2 (6.7)					
Background disease N (%)	Diabetes	12 (40)	10 (33.3)	0.59***				
	Other diseases****	11 (36.7)	14 (56)	0.43***				
Length of incision (mm) mean ± SD		46.83 ± 5.90	45.33 ± 6.14	0.34*				

<sup>\*</sup> Independent samples t-test; \*\* Fischer's exact test; \*\*\* Chi-square test; \*\*\*\* Anemia, hypothyroidism, cardiovascular diseases

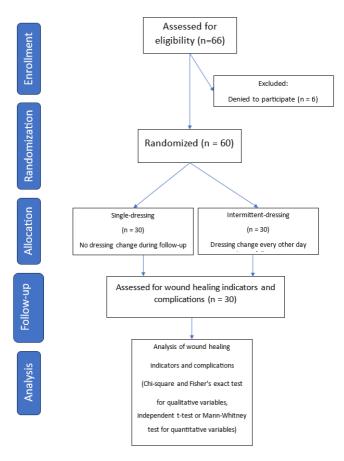


Figure 1. The study design flowchart

## Wound healing indicators

The epithelialization rate was significantly higher in group A (26.7% vs. 0%, P<0.01). No significant difference was found across the groups in terms of other wound healing process outcomes and complications variables [Table 2].

## **Complications**

The groups were not significantly different regarding wound complications rate [Table 2].

Table 2. Healing process outcomes and complications of the groups								
Va	riable	A Single (n=30)	B Intermittent (n=30)	P-value				
Epithelialization N (%)		8 (26.7)	0 (0)	< 0.001				
Exudate amount N (%)	Dry	30 (100)	27 (90)	0.23*				
	Slight	0 (0)	3 (10)					
Localized pain N (%)		8 (26.7)	13 (43.3)	0.17**				
Localized erythema N (%)		6 (20)	9 (30)	0.37**				
Localized edema N (%)		3 (10)	3 (10)	>0.99*				
Delayed healing N (%)		2 (6.7)	2 (6.7)	>0.99*				
Necrosis N (%)		3 (10)	1 (3.3)	0.61*				
Fibrosis N (%)		8 (26.7)	11 (36.7)	0.40**				

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Table 2. Continued				
	Healed	29 (96.7)	29 (96.7)	>0.99*
Final overall condition N (%)	Not changed	1 (3.3)	1 (3.3)	>0.99*
	Normal	27 (90)	28 (93.30)	>0.99*
Final skin condition N (%)	Maceration	1 (3.3)	1 (3.3)	>0.99*
That skin condition is (70)	Hyperkeratotic	2 (6.7)	0 (0)	>0.99*
	Callus	0 (0)	1 (3.3)	>0.99*
VAS*** score mean ± SD		4.00 ± 1.59	3.56 ± 1.81	0.29****

<sup>\*</sup> Fischer's exact test; \*\* Chi-square test; \*\*\* Visual analogue scale; \*\*\*\* Mann-Whitney U-test

## **Discussion**

The optimal frequency of dressing change and whether to replace the dressing post-operation remains uncertain and is often based on the surgeon's clinical judgment as well as the patient's condition.<sup>33,34</sup> We compared two dressing protocols, single and intermittent post-surgical dressing, in patients undergoing CTR, evaluating the wound healing process and complications. The findings of our study suggest that intermittent changing of the post-op dressing may not affect wound outcomes, compared to single dressing protocol. Based on our findings, except for the epithelialization level, there was no statistically significant difference across the groups.

#### Limitations

This study had some limitations. The generalizability of our results may be limited by the relatively small sample size and short follow-up period, though we aimed at comparison of early results post-operation. Further, the specific sampled population, clean elective surgeries without the use of foreign materials, may cause less generalizability. More definitive evidence would be provided by larger randomized controlled trials evaluating longer-term outcomes of different dressing protocols in a more diverse group of surgeries. Also, the effect of different regimens of dressing in other populations such as patients with the immune system, metabolic, and vascular diseases could be evaluated. As a randomized clinical trial with a high level of evidence, this research contributes to the enhanced reliability of the findings. Furthermore, the absence of any loss to follow-up ensures complete data, thereby minimizing potential bias. Note that all patients underwent the same type and method of surgery, enhancing the dependability of our results in comparison to some previous studies.

Maintaining a moist environment and absorbing excess exudate are key aspects of this process, helping to prevent skin maceration and other wound complications. <sup>35,36</sup> Dressings also contribute to maintaining the ideal temperature for wound healing. Lower temperatures may inhibit the activity of enzymes and cells involved in the healing process. If the ideal temperature is reinstated, it may take several hours to regain full mitotic activity. <sup>37</sup> The levels of wound epithelialization were higher in the single-dressing group. This may be attributed to the fact that moisture promotes re-epithelialization, <sup>38-40</sup> and maintaining the

primary dressing in place for a longer period can prevent the wound area from drying out. In line with our results, in a study by Veiga et al., proper wound closure facilitated the process of epithelialization.<sup>9</sup>

Three studies involving breast surgery patients showed no significant difference in surgical site infections (SSIs) between dressing and no-dressing groups, though the level of colonization (a risk factor for SSIs) was higher in the no-dressing group.<sup>8-10</sup> Similarly, in other studies on pediatric and urologic/abdominal surgery patients, no significant difference was observed between early dressing removal and retention in terms of the wound healing process and infection.<sup>11-13</sup> Likewise, there was no variance in the rate of post-operative wound infection between the two protocols: no dressing after 48 hours post-operation and changing the dressing every other day in patients who had undergone intra-abdominal surgeries.<sup>41</sup>

Two previous systematic reviews and meta-analyses found no difference between keeping the wound dressed and removing the dressing early in the post-operation period. Unlike the present study, a limited number of variables such as SSI and wound dehiscence were evaluated in the included studies.<sup>6,17</sup> In a study on spine surgery patients, the protocol of keeping the post-operation dressing for several days resulted in fewer SSIs compared to having it removed earlier.<sup>7</sup> However, the results of most other studies were in line with ours. For instance, a randomized clinical trial on hand surgery patients (carpal tunnel or trigger finger release) found no short-term difference between keeping the dressing until the first follow-up or replacing it twice a week, in terms of wound dehiscence, superficial infection, pain, functionality, and scar condition.<sup>16</sup>

Overall, considering the expenses and time consumed by the frequent commute required for intermittent dressing changes, 11,17 this protocol may not be a suitable option for some patients. However, some patients may find reassurance in frequent supervision by a healthcare professional. Additionally, having their wound consistently covered can boost patients' confidence in the safety of their wound. It also helps mitigate unwanted hygienic issues and discomfort, 11 as the dressing is changed every other day, allowing patients to adjust the bulkiness of their dressing during each visit based on their wound condition. This approach enables them to regain their daily function, normal range of motion, and

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appearance, as important factors of quality of life, as soon as possible. 16,42 Consequently, it is suggested that the optimal dressing change protocol should be determined according to the patient's preference for how soon they wish to return to daily function and how cautious they want to and can be with their wound and dressing.

#### Conclusion

Based on the findings of the current study, employing either single or intermittent dressing change protocols may not affect wound outcomes and its final condition. These results suggest that the decision regarding the wound dressing protocol could be made by the surgeon, depending on each patient's status.

#### **Acknowledgement**

We appreciate Dr. Mehraneh Movahedi for her assistance in the outcome assessment and Shahryar Hashemi for his assistance with the submission.

Contribution: AH: Conceptualization, Authors Investigation, Validation, Visualization, Writing - Original Draft/ MD: Conceptualization, Investigation, Validation, Visualization. Writing -Review & Editing/ Conceptualization, **Funding** Acquisition, Project AM: Conceptualization, Administration, Supervision/ Resources, Methodology, **Project** Administration, Supervision, Writing - Review & Editing/ All authors read and approved the final manuscript.

**Declaration of Conflict of Interest:** The authors do NOT

have any potential conflicts of interest for this manuscript. *Declaration of Funding:* This work was supported as a research project financed by the Research Council of Mashhad University of Medical Sciences (research project number 940037).

**Declaration of Ethical Approval for Study:** The study was approved by the Research Ethics Committee of Mashhad University of Medical Sciences (approval number: IR.MUMS.fm.REC.1396.498) and was conducted in accordance with the ethical standards in the 1964 Declaration of Helsinki.

**Declaration of Informed Consent:** All participants were informed on the experiment and were asked to fill a voluntary consent form. Also, they were informed that not participating in the study would not affect their treatment process.

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