A novel negative pressure wound therapy (NPWT) monitoring system for postoperative flap management

Tae Hyung Kim, MD, Jun Ho Park, MD*®

Abstract
Various types of flaps are widely utilized as reconstructive options for patients with soft tissue defects. However, the postoperative monitoring of the flap requires a large amount of time and effort. The aim of this study was to evaluate the efficacy and safety of this novel monitoring procedure using negative pressure wound therapy (NPWT) immediately after the flap operations.

A retrospective analysis was performed on patients who underwent free flaps and perforator flaps from March 2019 to December 2020. The flaps were managed by either novel NPWT method or conventional dressing. Among NPWT group, computed tomography angiography was performed in randomly selected 5 flaps on the third postoperative day for evaluation of pedicle compression. Statistical analysis was performed between the 2 groups.

A total of 54 flaps were included in this study. Twenty seven flaps were managed using novel NPWT method and 27 flaps were managed using conventional dressing. There was no statistically significant difference in flap survival rates between the 2 groups (P=.91). The patency of flap pedicles in the NPWT group was confirmed by comparing the computed tomography angiography findings. The estimated total flap monitoring time and cost for 5 days was significantly decreased by the application of the novel NPWT monitoring system.

Through the application of the novel postoperative monitoring system using NPWT, there is efficient evaluation of the flap. Furthermore, safe flap monitoring is possible with the reduced risk of infection by the avoidance of multiple manual dressing performed in the conventional method.

Abbreviations: CT = computed tomography, NPWT = negative pressure wound therapy.

Keywords: free flap, negative pressure wound therapy, pedicled flap

1. Introduction
The emergence of negative pressure wound therapy (NPWT) has initiated new clinical approaches for wound management, especially in wounds of the extremities. NPWT has been widely utilized for skin and soft tissue defects that resulted from various etiologies including trauma, tumor, and burn. It is known to effectively contract wounds, trigger mechanical force for wound deformation, remove interstitial fluid, and increase blood flow to the wound.[11] Furthermore, in the last decades, NPWT has been utilized in various ways, including the effective increase in skin graft take, incisional wound management, and flap salvage procedures.[2–5]

Various types of flaps are commonly used as reconstructive options for patients with soft tissue defects, and the survival rate of the flaps may reach 90% to 95% in free flap and 80.7% to 95% in pedicled or perforator flaps.[6–8] The postoperative monitoring procedure is crucial for increasing the success rate of flap surgery. However, the monitoring of the flap still requires a large amount of time and effort.[9,10] Furthermore, several previous studies have reported more convenient and precise flap monitoring procedures, such as implantable monitoring Doppler to color analyzer.[11–13]

Even though there are a few reports introducing the efficacy of immediate NPWT on free or perforator flap, the safety concerns about the monitoring flap while application of NPWT is still an unresolved problem. This safety issue is the principal cause why most surgeons are not convinced to apply NPWT on flaps immediately after operation. Additionally, the influence of vacuum-assisted closure on pedicle compression is another concern that has not been resolved.

The aim of this study was to evaluate the efficacy and safety of this novel monitoring procedure using NPWT immediately after flap operations. Specifically, this novel immediate monitoring system using NPWT for postoperative flap management serves to maximize the time and cost efficiency advantages over conventional monitoring.
2. Methods

The Institutional Review Board of our hospital (IRB No. 2020-10-150478) approved the retrospective review of the immediate monitoring system using NPWT in free flap and perforator flap management completed from March 2019 to December 2020. Proper informed consent was attained, and each patient was provided with an explanation of the procedure. In this study, we examined patients who underwent flap procedures (free flap, perforator flap) for upper and lower extremity wounds. All procedures were performed in a standard manner by the senior plastic surgeon at single institution.

After insertion of the flap to the recipient site with simple interrupted sutures, the suture site was fully protected with antibiotic ointment-coated Physiotulle (hydrocolloid based non-adherent wound contact layer, Coloplast, Ltd. Peterborough, UK). The vacuum-assisted closure (VAC) sponge was then placed over the portion covered with Physiotulle and it was set in a continuous mode at ~125 mm Hg. A large window was routinely made comprising almost the entire flap to allow for serial flap monitoring because the margin of the sponge did not pass into the flap skin paddle more than 1 cm from the incision site (Fig. 1). All patients underwent flap monitoring with serial flap examinations through the transparent window created by the novel NPWT application. NPWT was removed 5 days after operation.

In contrast, conventional monitoring with manual dressing was performed in a standard way for the conventional dressing group. Manual monitoring was performed with the examiner using aseptic surgical gloves and cleansing the discharge on the suture site with a saline-soaked gauze. After antibiotic-coated Physiotulle was applied over the flap and the suture site, the sterile burn gauze was covered without compression.

During the day of operation, all the flaps were monitored for flap color, temperature, capillary refill, and external Doppler sound every 2 hours, and every 4 hours during the next 24 hours. A 6-hour monitoring extension was performed until the third postoperative day and an 8-hour monitoring extension was performed for the succeeding 48 hours. Postoperatively, the patients were kept in the hospital until the senior surgeon (JHP) determined that the patient was medically and surgically fit for discharge. Surgical outcomes were evaluated according to survival rate and complication rate, which includes the occurrence of the infection, hematoma, seroma, complete flap loss, and partial flap loss.

Before discontinuing NPWT on the third postoperative day, computed tomography (CT) angiography was performed on 5 randomly selected flaps to identify if pedicle compression or fluid collection existed in the sub-flap plane (Fig. 2). The diameter of pedicles investigated before and after NPWT was measured using a picture archiving and communication system. Surgical outcomes were analyzed at the outpatient clinic 1 month after the flap surgery. Furthermore, the total monitoring time per patient throughout the 5 days after the flap surgery was recorded. For statistical analysis of monitoring time and expenditure, a comparison between NPWT and the conventional method was conducted using the Mann–Whitney U test.

SPSS v26.0 (IBM Corp., Armonk, NY) was used to analyze the results and perform all statistical tests, with the significance set at \( P < .05 \).

3. Results

A total of 54 flaps were included in this study. The patients belong to the age group of 29 to 90 years with a mean age of 57.5 ± 16.6 years. The mean duration of follow-up was 3.1 months. All other characteristics are outlined in Table 1. The indications to perform flap management surgery included trauma (N = 23), malignancy (N = 5), diabetic gangrene (N = 9), and burn reconstruction (N = 5), and the areas were all confined to the upper and lower extremities. In this study, a total of 27 flaps (9 free flaps and 18 perforator flaps) were included for the NPWT group, and a total of 27 flaps (6 free flaps and 21 perforator flaps) were included for the conventional dressing group. The average flap size was 126.3 ± 42.1 cm² with a mean operative time of 440.4 ± 50.9 minutes. All the free flaps were anterolateral thigh flaps, except one radial forearm flap conducted in the NPWT group. The mean operative time was 439 ± 65.4 minutes in the conventional group and 428.7 ± 27 minutes in the NPWT group; however, this was not statistically significant.

Table 2 shows there was no statistically significant difference in flap survival rates between the 2 groups (89% in the NPWT group vs 89% in the conventional group, \( P = .91 \)). The patency of the flap pedicles in the NPWT group was confirmed by comparing CT angiography before the flap operation and 3 days after flap operation with NPWT (Fig. 2). By analyzing the diameter of perforators or anastomosed vessels before and after NPWT, there was no statistically significant difference 2 groups as summarized in Table 3 (\( P = .978 \)).

Complications such as infection, seroma, and hematoma were not observed in this study. However, 3 complications were noted in each group. There was partial necrosis in 3 perforator flaps of the NPWT group which were treated with 1 month of serial debridement and split thickness skin grafts. On the conventional dressing group complete flap necrosis was noted in 3 perforator flaps after signs of venous congestion which were managed with an alternative gastrocnemius muscle flap and split thickness skin grafts.
The total monitoring time per flap recorded until day 5 was significantly decreased by the application of the novel NPWT monitoring system, as summarized in Table 4 (93 ± 3.9 minutes in the NPWT group vs 448.9 ± 26.7 minutes in the conventional group on postoperative day 5, $P < .05$). The total cost per flap recorded until day 5 also significantly decreased by NPWT, as summarized in Table 4 (110.7 dollars in the NPWT group vs 146.8 dollars in the conventional group on postoperative day 5, $P < .05$).

### Table 1

| Criteria                        | Conventional group | NPWT group      | $P$-value |
|---------------------------------|--------------------|-----------------|-----------|
| Patient numbers                 | 21                 | 21              | .980      |
| Age, y (range)                  | 56.8 (29–92)       | 58.3 (44–90)    | .762      |
| Body mass index, kg/m$^2$ (range)| 24.9 (17–42)       | 24.7 (20.8–28.9)| .349      |
| Diabetes                        |                    |                 |           |
| Yes                             | 6                  | 6               |           |
| No                              | 15                 | 15              |           |
| Hypertension                    |                    |                 | .494      |
| Yes                             | 5                  | 6               |           |
| No                              | 16                 | 15              |           |
| Smoking                         |                    |                 | .573      |
| Yes                             | 9                  | 8               |           |
| No                              | 12                 | 13              |           |
| Cardiovascular disease          |                    |                 | .339      |
| Yes                             | 4                  | 2               |           |
| No                              | 17                 | 19              |           |
| Diagnosis                       |                    |                 | .414      |
| Trauma                          | 14                 | 9               |           |
| Malignancy                      | 3                  | 2               |           |
| DM foot                         | 3                  | 6               |           |
| Burn                            | 1                  | 4               |           |
| Defects                         |                    |                 | .592      |
| Lower extremity                 | 14                 | 17              |           |
| Upper extremity                 | 7                  | 4               |           |

NPWT = negative pressure wound therapy.

### 3.1. Case no. 1

A 47-year-old man with diabetes mellitus presented with painful bullae formation in his left foot. It was noted that his high-sensitivity C-reactive protein was elevated and the HbA1c level was at 14.5%. Infection control was facilitated with proper antibiotics (Tazoperan) against Pseudomonas infection and necrotic tissue debridement, and copious saline irrigation was performed prior to surgery. The specialists from the department of endocrinology strictly monitored the patient’s glycemic
Table 2
Surgical outcomes of conventional monitoring and NPWT monitoring groups.

|                          | Conventional group | NPWT group | P-value |
|--------------------------|--------------------|------------|---------|
| Total number of flaps    | 27                 | 27         |         |
| Free flap                | 6                  | 9          |         |
| Perforator flap          | 21                 | 18         |         |
| Average flap size        | 117.8 ± 43.1       | 137.1 ± 41.8 | .4     |
| Mean operation time      | 459 ± 65.4         | 428.7 ± 27.0 | .33    |
| Flap survival            | 24                 | 24         | .91     |
| Flap complication        | 3                  | 3          |         |
| Infection                | –                  | –          |         |
| Hematoma                 | –                  | –          |         |
| Seroma                   | –                  | –          |         |
| Partial necrosis         | 2                  | 3          |         |
| Complete necrosis        | 1                  | 1          |         |

NPWT = negative pressure wound therapy.

Table 3
Vessel diameter measured on 5 randomly selected flaps during NPWT monitoring in CT angiography.

|                   | Before NPWT | During NPWT | P-value |
|-------------------|-------------|-------------|---------|
| Diameter (mean±SD, mm) | 2.3±0.7     | 2.3±0.8     | .978    |
| 1                 | 2.1         | 2           |         |
| 2                 | 2.31        | 2.20        |         |
| 3                 | 2.35        | 2.42        |         |
| 4                 | 3.17        | 3.11        |         |
| 5                 | 1.66        | 1.58        |         |

Values area presented as number (mm).
NPWT = negative pressure wound therapy.

control. Under general anesthesia, the free ALT flap transfer was performed to resurface the wound. The defect size was 7 cm × 5 cm, and the flap was 8 cm × 18 cm. Flap inset and vessel anastomosis were performed with the dorsalis pedis artery and veins and the donor site was closed by direct closure method. The operation duration was 460 minutes. The flap suture margin was covered with a sponge for the NPWT monitoring system with a contact barrier (Physiotulle) underneath it (Fig. 3). On the third postoperative day, CT angiography was performed to ensure that the pedicle was intact and the NPWT monitoring system was monitored in the same way as the other NPWT system. The flap survived without complication.

3.2. Case no. 2
A 90-year-old woman was admitted for evaluation of a mass in her right trochanteric area. On physical examination, the mass was ulcer-like with a size of 3 cm × 2 cm, which occurred spontaneously. Given the primary differential of basal cell carcinoma, the mass was resected with a safety margin of 5 mm and partial muscle layer involvement was noted. The perforator flap using the ascending branch of the lateral circumflex femoral artery was developed. The skin defect size was 3.5 cm × 3 cm, and the flap size was 9.5 cm × 7.5 cm (Fig. 4). The donor site was primarily closed with a simple interrupted suture. The monitoring was performed using the novel NPWT monitoring system and the flap survived and healed accordingly.

3.3. Case no. 3
A 51-year-old man was transferred with contact burn of the right upper extremity. He presented with a full skin necrosis and an exposed flexor carpi ulnaris on his right forearm. The sensory and motor functions were intact. At the level of the hand, the median nerve, ulnar nerve, and radial nerve functions were normal. A radial artery perforator flap reconstruction was planned. The raw surface size was 6 cm × 3 cm, and the flap size was 7 cm × 4 cm (Fig. 5). The donor site was covered with split skin graft combined with acellular dermal matrix. The flap was monitored in the same way as the other NPWT system. The flap survived completely without complications.

3.4. Case no. 4
A 51-year-old man without other medical history was transferred with large size of raw surface with full-depth skin loss on his right upper extremity. He was initially presented with abscess on his forearm. There was no history of trauma, infection, or any surgical procedure. It was noted that his high-sensitivity C-reactive protein was elevated, and cefazolin-resistance enterobacter was identified in the culture study. After serial debridement and NPWT application, infection was controlled and healthy granulation tissue was prepared for free flap reconstruction. The raw surface size was 7 cm × 12 cm, and the flap size was 8 cm × 15 cm (Fig. 6). The donor site was primarily closed. The flap was monitored in the same way as the other NPWT system. The flap survived completely without complications.

4. Discussion
NPWT has been widely used in addressing acute and chronic wounds since the first introduction by Argenta and Morykwas.\(^{14-17}\) The mechanisms of action of NPWT include stabilization of the wound environment by decreasing wound edema, removal of the wound exudate, increase blood flow to the

Table 4
Comparison of estimated costs and consumed monitoring time between 2 groups until fifth postoperative day.

|                          | Conventional group | NPWT group | P-value |
|--------------------------|--------------------|------------|---------|
| Total number             | 27                 | 27         |         |
| Number of dressing changes (range) | 27.5 times (25–29)/flap | 2 times/flap |         |
| Ointment*                | $2.07              | –          |         |
| NPWT canister            | –                  | $32.7      |         |
| NPWT sponge              | –                  | $39        |         |
| Total costs (range)      | $146.8 (133.3–161.2) | $110.7 (92.7–118.7) | \(<.05\) |
| Monitoring time, min     | 448.9 ± 26.7       | 93 ± 3.9   | \(<.05\) |

*Mean 2 ointments were needed for the first 24 hours at every dressing.
NPWT = negative pressure wound therapy.
Figure 3. The first case of NPWT monitoring system. (A) Photographic findings of 47-year-old male patient who was diagnosed with diabetic gangrene on left foot. (B) Anterolateral thigh free flap was used to cover the defect with multiple tendon exposure. (C) NPWT was applied immediately after operation (D) Postoperative photographic finding; 1 month. NPWT = negative pressure wound therapy.
wound, and infection prevention.\cite{1,18,19} Additionally, it is frequently used for soft tissue defect cases because of its characteristic of mechanical stimulation for tissue expansion.\cite{20}

NPWT has been utilized in a broad spectrum of clinical work including application to incision sites for wound healing promotion and wound complication reduction.\cite{21,22} The negative pressure produced by a vacuum device removed the fluid and infectious substances from the wound and enhanced tissue perfusion, especially in unstable, high-tension wounds. Along with incisional NPWT utilization, NPWT has shown great success when employed in skin grafting procedures.\cite{23} Compared with conventional bolster dressing, it improved adherence of the skin graft to the wound bed, leading to a significantly increased rate of graft take.\cite{24} It also helped accelerate microvessel maturation of the wound surfaces.\cite{1}

The flap procedure is one of the most important surgical options in the reconstructive field for managing large skin and soft tissue defects, including wounds containing bony exposure. Successful use of NPWT in these previously introduced reconstructive procedures has led to a progressive development in the usage of the flap procedure. For the last decade, the flap salvage tools that were mostly considered were heparin injection and leech therapy.\cite{2,3} However, NPWT has emerged as a safer alternative to these methods with increased salvage rates.\cite{4,5}

Uygur et al.\cite{4} concluded that NPWT is effective in the removal of excess interstitial fluid under the flap and venous congestion resolution. Goldstein et al.\cite{5} demonstrated that NPWT may contribute to the viability of random local flaps by venous congestion resolution. Vaienti et al.\cite{25} reported that NPWT can be useful in flap management in lower extremity reconstruction with pedicled or free flaps that were compromised by venous congestion. There are numerous previous studies that introduced the efficacy of NPWT on pedicled flaps and free muscle flaps in lessening complication rates and improving salvage rates compared with traditional flap management.\cite{5,12,26,27} However, only a few studies have introduced the application of NPWT immediately on free flap containing skin.

Lin et al.\cite{28} applied NPWT immediately after free flaps in head and neck reconstruction and compared it with conventional wound care wherein it was observed that the complication and infection rates were much lower than conventional (9.7% vs 37% in complication rate and 0.0% vs 14.8% in infection rate, respectively). However, neither visual nor Doppler monitoring was possible because of the full coverage of the flap by vacuum sponge. In a previous study, Bi et al.\cite{13} introduced the modification of NPWT to a skin-containing free flap wherein the VAC sponge was placed in a standard fashion with a negative pressure of 125 mmHg. This method made serial flap examination possible by the creation of a small window on the distal portion of the flap. However, visual monitoring of the entire flap was not possible; thus, it was not able to address the criticism on the safety of NPWT on free flaps. In this present study, a novel NPWT technique was developed to monitor the entire flap and address the safety concerns of the procedure. Utilization of a transparent film on most of the flap area permits the examination of flap color change, capillary refilling status, and warmth of the flap without missing portions of the flap. Through this technique, the interstitial fluid could be removed through the sponge without affecting flap perfusion. Additionally, CT angiography findings eliminate the occurrence of added pressure to the free flap pedicle by the vacuum sponge, which is a concept that has not been introduced before.

One of the major considerations in managing patients who have undergone flap surgery is status monitoring of the flap. As most reconstructive surgeons agree, postoperative management of the flap is a vital procedure in minimizing major complications. Early detection of flap problems can improve overall flap salvage.\cite{29} Although many types of flap monitoring methods

![Figure 4. The second case of NPWT monitoring system.](Image)
have been introduced before including implantable Doppler, near-infrared spectroscopy, and laser Doppler flowmetry, none have been recognized as a gold-standard diagnostic tool. Through observation, the first 24 hours after free flap is crucial for monitoring the flap and establishing complications. According to Abouyared et al.,[30] frequent monitoring with hourly flap checks in the first 24 hours is ideal and this frequency can decrease every 4 hours for the subsequent 2 to 3 days. However, shorter intervals are accepted to be ideal, such as 30-minute intervals for the first 24 hours.[29] These short intervals and time-consuming postoperative conventional monitoring of the free flap is considered a burden to surgeons, residents, or nurses who are responsible for the patients. Additionally, flaps are exposed to the risks of infection and mechanical injury to the vascular system, which can lead to hematoma and seroma by manual examination and dressings. However, application of this novel monitoring technique significantly decreased the total time consumption for postoperative flap from 448.9 to 93 minutes on the first

Figure 5. The third case of NPWT monitoring system. (A) Photographic findings of 51-year-old male patient with exposure of flexor carpi ulnaris tendon after burn injury. (B) Radial artery perforator flap was designed to cover the defect. (C) After elevation of perforator flap. (D) Immediate postoperative photographic finding with sign of venous congestion at the distal portion of the flap. (E) Schematic diagram of NPWT system on the patient, Doppler monitoring site (red arrow). (F) Postoperative photographic finding; 1 month. Congestion of the flap was relieved, and the mesh graft was well taken. NPWT = negative pressure wound therapy.
Figure 6. The fourth case of NPWT monitoring system. (A) Photographic findings of 51-year-old male patient after resection of abscess formation on right forearm. (B) After elevation of anterolateral thigh free flap. (C) Immediate postoperative finding with application of the novel NPWT system. (D) After removal of NPWT system on 5th postoperative day. (E) Postoperative photographic finding; 1 month. NPWT = negative pressure wound therapy.
The study has a few limitations. First, an accurate pressure map produced by applying NPWT has not been measured. However, there was no significant difference between the NPWT and conventional monitoring groups in complication rate and absence of pedicle compression identified by CT angiography. The pressure produced by NPWT was regarded as minimal. Second, it was a retrospective study with a relatively short-term follow-up period. There was no evaluation of operative characteristics (e.g., wound initial state, flap types) or the flap monitoring protocol characteristics (e.g., use of a heating lamp, intensive care unit care, patient mobility status). Furthermore, the patients were not homogeneous with respect to the medical history and type of flaps; thus, this could have influenced the surgical outcomes, including survival and complication rates. Additionally, there were no specific indications for choosing monitoring options between the conventional method and the NPWT system. However, as we accomplished acceptable surgical outcomes compared with those reported in previous studies, our novel NPWT monitoring system in an incisional manner had confirmed its safety in a limited way. A larger sample size with a prospective and controlled study is recommended to determine the advantageous mechanism of NPWT. Finally, the cost of vacuum sponges, tapes, and dressing materials can vary among nations and hospitals. The comparison of the results would be different from the results of this present study. However, the simplicity and safety of this novel NPWT monitoring system compared with those of the conventional manual monitoring method have been elaborately proven by the results. Further investigation is needed to prospectively evaluate the efficiency of NPWT with a larger number of cases.

5. Conclusions
Postoperative flap monitoring is a crucial and essential procedure for increasing the flap success rate. Although most surgeons have been directed to adhere to the practice of conventional monitoring, the application of this novel monitoring system using NPWT allows for serial flap monitoring that is similar to the conventional method. Furthermore, flap monitoring with less effort can be possible with the reduced risk of infection by avoiding multiple manual dressing (conventional method). This novel flap monitoring method using NPWT proved to be safe and efficient; therefore, it could be recognized as a gold-standard flap monitoring system in the future.

Author contributions
Conceptualization: Jun Ho Park.
Data curation: Tae Hyung Kim.
Project administration: Jun Ho Park.
Supervision: Jun Ho Park.
Writing – original draft: Tae Hyung Kim.
Writing – review & editing: Jun Ho Park.

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