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ORIGINAL ARTICLE FACIAL SURGERY

Continuous Negative Pressure Drain is Associated with Better Outcome: A Randomized Prospective Trial in Plastic Surgery Patients

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Abstract

Background A randomized prospective trial to compare the effects on minimizing complications using continuous negative pressure drain and intermittent suction mode in plastic surgeries.

Methods There were 174 cases of stage II post-auricular flap expansion and ear reconstruction, 76 cases of skin expansion flap repair, 56 cases of breast augmentation surgery, 58 cases of abdominoplasty, and 76 cases with free skin grafts. Patients were randomized to intermittent suction mode group (control group) and continuous negative pressure external drain group (intervention group) stratified by surgery types. In the intervention group, different pressure levels were applied according to the surgery types. The drainage volume, the length of time of external drainage, incidence of seroma, flap necrosis, the first intending healing rate and drain-associated bleeding were recorded and compared.

Results Generally, fewer complications and better healing were observed in the intervention group. In patients with stage II post-auricular flap expansion and ear reconstruction, lower incidence of flap necrosis and seroma, higher first intention healing rate, greater drain volume but shorter time of drainage were observed in the intervention group ($p < 0.05$ for all). Similar results were shown in patients with skin expansion flap repair, breast augmentation, abdominoplasty, and free skin grafts. In patients who underwent free skin grafts, a higher graft success rate and lower graft infection rate were also observed ($p < 0.01$ for both). No drain-associated bleeding was observed.

Conclusions A continuous negative pressure drain was associated with better outcomes in patients underwent various plastic surgeries and is a powerful technique in the postoperative management of plastic surgery.

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Keywords Continuous negative pressure drain · Flap graft · Intermittent drain · Plastic surgery

Introduction

Various plastic surgeries have been successfully performed to overcome the challenges that require extra care and special cosmetic requirements. Seroma in the abdominoplasty area, hematoma under flaps, and flap necrosis are common complications in plastic surgery [1, 2]. Previous management of these complications has not been uniformly successful.

Poor drainage is an important cause of these complications [3]. Negative pressure therapy is an adjunct therapy used to remove fluid from acute and chronic wounds and promote healing [4]. During the past years, negative pressure therapies have been commonly used in a variety of fields, especially in challenging wounds like skin graft areas or closed surgical incision sites[5, 6]. The technique is mainly associated with removal of fluid and mechanical deformation [4, 7, 8]. The technique is extremely efficacious for stimulating healing by secondary intention [9].

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In clinical work, both continuous negative pressure drains and intermittent suction are currently used. Continuous negative pressure drains have been shown to be associated with better wound healing [10, 11]. However, the use of continuous negative pressure drains remains somewhat controversial. It has been reported to be associated with bleeding and hemoglobin loss [12, 13]. And the use of high continuous pressure may be harmful to the tissue. A study showed that tissue exposed to continuous pressure shows less granulation tissue formation than that exposed to intermittent therapy after 2 weeks of therapy [14].

In this study, to detect which mode of drainage is more effective, we conducted a randomized clinical trial to compare continuous negative pressure drains to intermittent drains in 440 patients who underwent plastic surgery procedures. The effect on reducing complications was compared.

Method

Participants

This is a randomized, unblinded, prospective study. The ethical committee of the hospital approved the study and written informed consent was obtained by all participants or their parents. From February 2010 to April 2014, a total of 440 patients who underwent plastic surgery in the department of plastic surgery were enrolled. Among them, 174 patients underwent stage II post-auricular flap expansion and ear reconstruction, 76 patients underwent skin expansion flap repair, 56 cases underwent breast augmentation surgery, 58 patients underwent abdominoplasty, and 76 patients underwent free skin grafts (Table 1). The randomization was performed by building a stratified randomization, stratified by surgery type using a random number list generated by computer. Patients who met the inclusion criteria were randomly assigned to the continuous negative pressure drain group (intervention group) and intermittent mode drain group (control group). The silicon drain tube with a diameter of 0.4 cm (Weirui Medical, Yunnan, China) was placed in the lower edge of the surgical field and connected when the operative field was closed after the main operative procedures. These surgeries were performed by the same group of surgeons according to standard practice. Patients' demographic characters are shown in Table 1.

Inclusion Criteria

Patients were included in the study if they met the following criteria: had one of the surgeries in the department of plastic surgery: stage II post-auricular flap expansion and ear reconstruction, skin expansion flap repair, breast augmentation, abdominoplasty, and free skin grafts; placement of a silicon drain tube into the wound.

Exclusion Criteria

Patients with preoperative use of anticoagulants, intraoperative injury to the flap, severe abnormalities in liver function, and abnormalities in coagulation were excluded from the study.

Intervention

In the intervention group, the drain tube was connected to a disposable negative pressure drainage box (Weirui Medical, Yunnan, China) with setting specific pressure (Fig. 1). The negative pressures were set to a range from 30–40 mmHg (3.99–5.32 kPa) in the ear reconstruction group, 50–60 mmHg (6.65–7.98 kPa) in the skin expansion flap repair group, 20–30 mmHg (2.66–3.99 kPa) in the breast augmentation and abdominoplasty group, and 50–60 mmHg (6.65–7.98 kPa) in free skin graft group. In the control group, the tube was connected with a Y-type tee followed by a suction ball (Weirui Medical, Yunnan, China) and intermittent drainage was applied (Fig. 1). Specifically, the suction ball was deflated and negative pressure drainage was applied for half an hour. Then, the suction ball was clamped and the drainage stopped. The above process was repeated every 4–5 h until the tube was extubated. The drainage bottle was placed below the patient's wound to prevent the backflow of drainage.

Outcome of Measure

The drainage volume was recorded daily. All drains were removed if the fluid production was less than 5 mL on 2 consecutive days. The length of time of the drain and the volume of postoperative drainage were recorded. Wound complications recorded were seroma, flaps necrosis, and the first intending healing rate. Necrosis was defined as any visible necrosis along the edge of the wound. In the free skin graft surgeries, the graft success rate and infection rate were also recorded. Potential complications of negative pressure drainage like bleeding were also recorded.

Statistical Analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences version 13.0 (Statistical Package for the Social Sciences Inc, Chicago, IL). The incidence of seroma and flaps necrosis and the first intending healing rate were compared with a X^2 test. The

Table 1 Baseline characteristics of patients in intervention groups and control groups

Characteristics	Intervention group (n = 224)	Control group (n = 216)
Post-auricular flap expansion and ear reconstruction (n = 174)	N = 87	N = 87
Age (year)	10.5 ± 2	10 ± 1.8
Female, n (%)	32 (36.8)	34 (39.1)
Skin expansion flap repair (n = 76)	N = 38	N = 38
Age (year)	30.0 ± 14.5	31.2 ± 13.9
Female, n (%)	17 (44.7)	18 (47.4)
Breast augmentation (n = 56)	N = 28	N = 28
Age (year)	31 ± 9.8	30.2 ± 9.5
Female, n (%)	28 (100)	28 (100)
Abdominoplasty (n = 58)	N = 29	N = 29
Age (year)	47.5 ± 7.5	48.2 ± 8.1
Female, n (%)	29 (100%)	29 (100%)
Free skin grafts (n = 76)	N = 42	N = 34
Age (year)	45.5 ± 13.6	43.2 ± 12.1
Female, n (%)	11 (26.2)	5 (14.7)
Scar area		
Upper limbs	12 (28.6)	10 (29.4)
Lower limbs	27 (64.3)	23 (67.6)
Abdomen	3 (7.1)	1 (3.0)
Wound size (cm^2)	240.99 ± 161.31	227.48 ± 123.08

All are mean (standard deviation) unless otherwise indicated

average indwelling time and the volume of postoperative drainage were compared by a two-sample t test. A two-tailed P less than 0.05 was considered statistically significant.

Results

In the study, a total of 440 patients were included: 224 patients were randomized to the continuous negative pressure drain group, and 216 patients were randomized to the intermittent drain groups. No patient was excluded from the study. The distribution of baseline characteristics of patients in the continuous negative pressure drain group and intermittent drain group is shown in Table 1. There is no significant difference in age and gender in the intervention group and the control group.

Less Complications in Continuous Negative Pressure Drain Group in Stage II Post-auricular Flap Expansion and Ear Reconstruction

Continuous negative pressure drains were applied to 87 patients who underwent stage II post-auricular flap expansion and ear reconstruction. In the intervention group, there were 2 cases of flap necrosis. The incidence of flap necrosis was significantly lower than that in the intermittent group (Table 2). A significantly lower incidence of seroma and higher first intention healing rate were also observed in the experiment group. The average daily drainage amount was significantly greater in the intervention group compared to the control group (17.5 ± 5 mL and 12.1 ± 10 mL, respectively, $p < 0.05$). But the time of the drain was 6.5 ± 1.5 days in the intervention group, which was significantly shorter than that in the control group (9.5 ± 2.5 days, $p < 0.05$).

Less Complications in Continuous Negative Pressure Drain Group in Skin Expansion Flap Repair

Continuous negative pressure drains were applied to 38 patients with skin expansion flap repairs. In the intervention group, a significantly lower incidence of flap necrosis (2.6% and 15.7%, respectively) was observed (Table 3). A marginally lower incidence of seroma (7.9% and 26.3%, respectively) was also observed. A significantly higher first intending healing rate was observed in the intervention group (86.8% vs 63.2%, $p = 0.02$). There were no significant differences in time of drainage (2.2 ± 1.0 days and 2.5 ± 1.0 days, respectively). The volume of postoperative

Fig. 1 Drainage device used in the study. **a** The disposable negative pressure drainage box (front); **b** the disposable negative pressure drainage box (back); **c** the suction ball used in the control group

Table 2 Comparison of outcome measurements in stage II post-auricular flap expansion and ear reconstruction

Outcome	Intervention group (n = 87)	Control group (n = 87)	P value
Flap necrosis, n (%)	2 (2.3)	12 (13.8)	< 0.01
Seroma, n (%)	8 (9.2)	23 (26.4)	< 0.01
The first intending healing, n (%)	77 (88.5)	52 (59.8)	< 0.01
Indwelling time of the drain (days)	6.5 ± 1.5	9.5 ± 2.5	< 0.01
Volume of postoperative drainage (mL/24 h)	17.5 ± 5.2	12.1 ± 10.1	< 0.01

drainage was significantly higher in the intervention group (9.6 ± 3.2 mL and 5.3 ± 5.6 mL, respectively, $p < 0.01$)

Less Complications in Continuous Negative Pressure Drain Group in Breast Augmentation

Continuous negative pressure drains were applied to 28 breast augmentation patients. No flap necrosis happened in either group (Table 4). One patient developed seroma in the intervention group, while 6 patients developed seroma in the control group ($p = 0.04$). The volume of postoperative drainage was significantly greater in the intervention group (16.75 ± 5.9 mL and 9.7 ± 4.1 mL, respectively, $p = 0.04$), but the time of drainage was significantly lower than that in the control group (2.1 ± 1.1 days and 2.7 ± 1.2 days, respectively, $p < 0.01$).

Table 3 Comparison of outcome measurements in skin expansion flap repair group

Outcome	Intervention group (n = 38)	Control group (n = 38)	P value
Flap necrosis, n (%)	1 (2.6)	6 (15.8)	0.03
Seroma, n (%)	3 (7.9)	10 (26.3)	0.07
The first intending healing, n (%)	33 (86.8)	24 (63.2)	0.02
Indwelling time of the drain (days)	2.2 ± 1.0	2.5 ± 1.0	0.1
Volume of postoperative drainage (mL/24 h)	9.6 ± 3.2	5.3 ± 5.6	< 0.01

Table 4 Comparison of outcome measurements in breast augmentation group

Outcome	Intervention group (n = 28)	Control group (n = 28)	P value
Flap necrosis, n (%)	0	0	–
Seroma, n (%)	1 (1.6)	6 (4.2)	0.04
The first intending healing, n (%)	27 (96.4)	25 (89.3)	0.3
Indwelling time of the drain (days)	2.1 ± 1.1	2.7 ± 1.2	0.04
Volume of postoperative drainage (mL/24 h)	16.8 ± 5.9	9.7 ± 4.1	< 0.01

Less Complications in Continuous Negative Pressure Drain Group in Abdominoplasty

Continuous negative pressure drains were applied to 29 patients with abdominoplasty. No flap necrosis happened in the intervention group, while 4 cases of flap necrosis (13.7%) happened in the control group (Table 5). The incidence of seroma in the intervention group was significantly lower than that in the control group (3.4% and 20.6%, respectively, $p = 0.04$). The average daily volume of postoperative drainage was significantly greater in the intervention group (13.6 ± 4.5 mL and 8.0 ± 4.0 mL, respectively, $p < 0.01$). No difference in time of drainage was detected in the two groups.

Less Complications in Continuous Negative Pressure Drain Group in Free Skin Graft

Continuous negative pressure drains were applied to 42 patients who underwent free skin grafts. In the intervention group, there was 1 case (2.4%) of flap necrosis, the incidence of flap necrosis was significantly lower than in the control group (17.6%, $p = 0.02$, Table 6). A significantly lower incidence of seroma (9.5% and 29.4%) and a higher first intention healing rate (88.1% and 64.7%) were observed in the intervention group. Larger volumes of postoperative drainage (10.4 ± 2.4 mL vs 6.7 ± 2.2 mL) but shorter drainage times (4.3 ± 1.2 days vs 6.9 ± 2.5 days) were observed in the intervention group. The graft success rate in the intervention group was significantly higher (95.2% vs 76.5%), while the graft infection rate was significantly lower (7.1% and 67.6%) than in the control group ($p < 0.01$ for both).

During the drainage period, no drainage associated bleeding was observed in either group.

Discussion

In this randomized study, comparing to the intermittent suction mode, significantly fewer wound complications were observed using continuous negative pressure external drains in patients who underwent various plastic surgeries. Specifically, in patients who underwent stage II post-

Table 5 Comparison of outcome measurements in abdominoplasty group

Outcome	Intervention group (n = 29)	Control group (n = 29)	P value
Flap necrosis, n (%)	0	4 (13.7)	0.04
Seroma, n (%)	1 (3.4)	6 (20.6)	0.04
The first intending healing, n (%)	27 (93.1)	19 (62.5)	< 0.01
Indwelling time of the drain (days)	2.7 ± 1.0	2.8 ± 1.2	0.3
Volume of postoperative drainage (mL/24 h)	13.6 ± 4.5	8.0 ± 4.0	< 0.01

Table 6 Comparison of outcome measurements in free skin graft

Outcome	Intervention group (n = 42)	Control group (n = 34)	P value
Flap necrosis, n (%)	1 (2.4)	6 (17.6)	0.02
Seroma, n (%)	4 (9.5)	10 (29.4)	0.03
The first intending healing, n (%)	37 (88.1)	22 (64.7)	< 0.01
Indwelling time of the drain (days)	4.3 ± 1.2	6.9 ± 2.5	< 0.01
Volume of postoperative drainage (mL/24 h)	10.4 ± 2.4	6.7 ± 2.2	< 0.01
The skin graft success rate, n (%)	40 (95.2)	26 (76.5)	< 0.01
The skin graft infection, n (%)	3 (7.1)	23 (67.6)	< 0.01

auricular flap expansion and ear reconstruction, or skin expansion flap repair, or breast augmentation surgery, or abdominoplasty, or free skin grafts, the continuous negative pressure drains were associated with lower incidences of flap necrosis and seroma, greater volumes of drainage but shorter times of drainage, and a higher first intending healing rate. No drainage associated bleeding was observed.

Negative pressure therapies have been applied in wound healing since the 1990s and have subsequently been adopted in the treatment of complex surgical and traumatic wounds [4]. During the past years, negative pressure therapies have been commonly used in a variety of fields, mostly challenging wounds such as skin graft area, or closed surgical incision sites[5, 6, 15]. Negative pressure therapy is mainly associated with removal of fluid and mechanical deformation [4, 7, 8]. Fluid removal could both decrease the edema and thus decrease the interstitial pressure and shorten distances of diffusion, and remove soluble factors that may affect the healing process [4, 16]. On the other hand, mechanical deformation could increase the growth of tissue, which is important in plastic surgeries [17]. Other effects of negative pressure therapy include increased blood flow, modulated inhibitory contents in wound fluid [18, 19]. In our study, negative pressure therapy without polyurethane foam was applied to promote wound healing. Fewer wound complications were observed in continuous negative pressure group, which is consistent with these proposed hypotheses.

The observed effect of continuous negative pressure drains is consistent with the few previous reports. Berman et al. [20] found that in orthopedic wounds, continuous negative pressure drains had clear advantages over intermittent drains with respect to hematoma evacuation, wound drainage, wound healing, and other possible complications. Fujiwara et al. [21] observed that the proliferation potency of *E. coli* was lower under continuous negative pressure drainage compared to intermittent drainage, which might explain the lower flap infection rate in the intervention group in our study.

Clinically, the level of negative pressure is generally inconsistently determined based on individual experience. The optimal pressure level is still inconclusive [22, 23]. Borgquist et al. [24] reported that wound edge microvascular blood flow changed with different negative pressures, which suggested the levels of pressure for negative pressure wound therapy should be tailored depending on the wound type and tissue composition. High negative pressure was associated with complications like bleeding [12]. In our study, we tailored different negative pressures in respective plastic procedures and no bleeding was observed, which suggested the pressures applied in the study were safe and effective. And in our study, continuous negative pressure did not show a higher risk of drain-associated complications.

To increase the validity of our results, we randomized the participants in the continuous negative pressure drain group and the intermittent drain group. Randomization is one of the strengths of our study. Age, gender, and other baseline characteristics were balanced in the two groups. The randomization also minimized the possibility that the results resulted from other unmeasured confounders. Practically, the negative pressure drainage box used in the study is small in size, can be carried around and did not restrict the patients' activities, which makes early exercise possible. Complications caused by long-term postoperation bed rest can be avoided and might be associated with better long-term outcomes.

In conclusion, our study suggested that compared to intermittent drains, continuous negative pressure external drains are associated with fewer wound complications in patients who underwent various plastic surgeries. We also suggested the appropriate negative pressure ranges for specific plastic procedures. Hence, continuous negative pressure drain is a powerful, convenient, and safe technique in the postoperative management of plastic surgery patients.

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Compliance with Ethical Standards

Conflict of interest The authors report no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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