



Comparisons of Surgical Skin Stretching and Surgical Skin Flap Transplantation for Treatment of Stage 4 Pressure Injuries of the Hip Region: A Randomized Controlled Trial

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Abstract

Aim: To compare the effectiveness, safety, and economic benefits of surgical skin stretching with surgical skin flap transplantation for the treatment of stage 4 pressure injuries of the hip region.

Design: Prospective, randomized controlled trial.

Setting: Hospital Inpatient Department.

Methods: The participants were collected in inpatient department, who were stage 4 pressure injuries and Braden's scores were not greater than 14. Patients with uncontrolled diabetes and other severe metabolic disorders, stage 1, 2, or 3 pressure injuries, with severe heart, lung, kidney dysfunction or mental disorders, and BMI ≤ 15 were excluded. 18 and 36 patients were randomly assigned to surgical skin stretching group and surgical skin flap transplantation group respectively. The data were collected between March 2019 and February 2023.

Result: The length of hospital stays, cost, drainage volume at 24 h post-surgery, and time required for healing were less in the experimental group than in the control group. The vascular obstruction rate and re-repair of incision rate were higher in the control group than in the experimental group. The improvement of anxiety and quality of life in the experimental group were better than that in the control group. All differences were statistically significant ($P < 0.05$).

Conclusion: Surgical skin stretching were more effective than surgical skin flap transplantation in the treatment of stage 4 pressure injuries. These findings suggest that surgical skin stretching should be considered as a preferred option for stage 4 pressure injuries. However, further studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and establish the long-term efficacy and safety of these procedures.

Keywords: Stage 4 pressure injuries; Randomized controlled trial; Efficacy; Safety

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Introduction

Pressure Injuries (PIs) are defined as localized damage to the skin and/or underlying tissue, which usually occurs over a bony prominence [1]. PIs arises from pressure, friction, and shear, which leads to deformation within tissues and cells and ischemia, lymphatic flow blockage, and reperfusion damage [2-5]. PIs are classified according to severity from stage I through IV, with Stage I representing the earliest stage of PI formation, and Stage IV representing the acute grade of PIs that are characterized by substantial loss of tissue and exposed bone, tendon or muscle tissue [6].

PIs were a common problem in all health care settings. It is estimated that the incidence of PIs varies greatly; 0.4% to 38.0% for hospitals, 2.2% to 23.9% for long-term care, and 0% to 17% for home care [7]. A systematic review found that cost of pressure ulcer per patient per day varied between 2.65 € to 87.57€ for prevention and 1.71€ to 470.49€ for treatment in different settings in the United States, the United Kingdom, the Netherlands, Germany, and Spain [8]. Despite considerable resources spent on prevention and treatment, pressure injuries remain prevalent, especially for an increased trend for stage 4 PI. This is in part due to aging population [9,10]. It imposes a significant burden not only on patients and their caregivers, but also on the entire healthcare system and society. It is associated with numerous physician office and emergency room visits, nearly 3 times longer hospital stay, and at times life-threatening complications and even death [11,12].

Skin stretching and skin flap transplantation are two surgical treatments for stage 4 pressure injuries. Skin stretching involves the gradual expansion of healthy skin surrounding the wound to facilitate wound closure, while skin flap transplantation involves the transfer of healthy skin and tissue from another part of the body to the wound site [13-15]. Skin flap transplantation is a well-established and widely used technique. However, information on the application of skin stretching in the treatment of stage 4 pressure injuries is limited. Therefore, this study aims to compare the effectiveness, safety, and economic benefits of skin stretching with skin flap transplantation in the treatment of stage 4 pressure injuries, with the goal of exploring its clinical application effects and providing patients with a less traumatic, fast-recovering, and effective treatment method.

Materials and Methods

Participants

The study setting was the Affiliated Hospital of Zunyi Medical University in Guizhou province, China. Patients were collected between March 2019 and February 2023 in inpatient department. Inclusion criteria were as follows: (1) adults aged 18 years or older, (2) Patients with stage 4 pressure injuries; and (3) a Braden Scale score of 14 or less (this cut-off point was selected because it indicates at least moderate PI risk and the need for more aggressive PI treatment interventions than those used for any inpatient). Exclusion criteria were as follows: (1) Patients with uncontrolled diabetes and other severe metabolic disorders; (2) Patients with stage 1, 2, or 3 or other type pressure injuries; (3) patients with severe heart, lung, kidney dysfunction or mental disorders; (4) Extremely thin patients with a BMI ≤ 15 . The process of selection was presented in flowchart (Figure 1). In total, 54 patients with stage 4 pressure injuries were recruited. Sociodemographic, lifestyle, history of disease, pressure injury's characteristics and information about surgery and recovery were collected.

Study procedures were reviewed and approved by the institutional review board of the Second Affiliated Hospital of Zunyi Medical University, and all participants or their legal proxy provided informed consent before study participation.

Design

Our study was a pragmatic, prospective, randomized controlled trial of hospital-based therapy for patients with stage 4 pressure injuries of the hip region, which adopted a 2:1 randomization schedule. Of the 54 subjects, 18 were randomized to the experimental group and 36 to the control group. The experimental group underwent debridement and skin traction, while the control group experienced debridement and skin flap transfer. The treatment in the control group was regarded as usual care for people with stage 4 PIs, because this method was relatively mature in our hospital, and allocating more patients to this group increased the power of the study.

Randomization

Patients were enrolled in this trial by doctors who evaluated the study participants. A statistician generated random numbers using a computer program and kept them in sealed, opaque envelopes. The allocation sequence was concealed from the researchers until the time of surgery, but not for patients and surgeons because they were aware of the treatment assignment. Outcome assessors were blinded to treatment allocation to minimize bias. Analysis was performed by blinded personnel.

Surgery

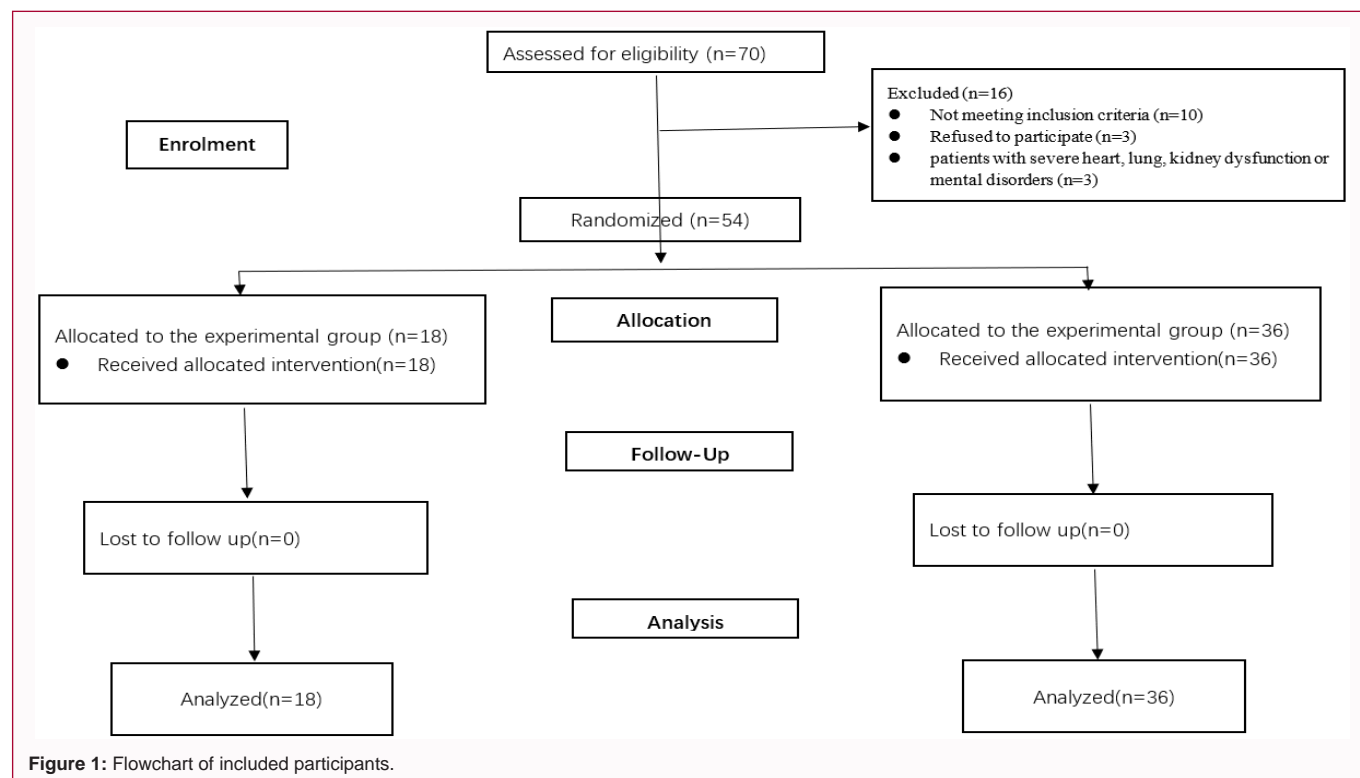
Surgical skin stretching: The patient was placed in the prone position under general anesthesia or without anesthesia (those paralyzed or without any sensation). After disinfection of the surgical area with iodine povidone solution containing an effective iodine concentration of 4.5 g/L to 5.5 g/L three times, the area was draped and exposed. The endogenous secretions in the wound cavity were rinsed repeatedly with 3% hydrogen peroxide disinfectant followed by 0.9% sterile saline and then disinfected again with iodine povidone solution containing an effective iodine concentration of 4.5 g/L to 5.5 g/L. Necrotic and inactive tissue and inflammatory granulation were excised using a high-frequency electric knife while preserving healthy tissue, then rinsing the wound cavity with the liquid mentioned above. The bleeding points were treated with electric coagulation, and hemostasis was achieved by filling the wound with a medical collagen sponge. Skin stretchers were placed at a distance of 2 cm to 3 cm from the wound edge on both sides, and the tension was adjusted based on the size of the skin tension at the wound edge to avoid blood supply obstruction, to produce continuous traction force, and to bring together the skin on both sides of the wound edge. The wound was then wrapped with sterile dressings. The skin stretching force was adjusted based on the size of the skin tension at the wound edge to avoid blood supply obstruction.

Surgical skin flap transplantation: The first few steps of skin flap transplantation were the same as surgical skin stretching. After hemostasis by electrocoagulation and stopping bleeding by collagen sponge, based on the size and depth of the wound, a perforator flap or any other type of flap was designed. The flap was designed by marking the desired flap shape on the donor site, and then the skin and subcutaneous tissue were incised along the marked lines to expose the flap perforating vessels. The flap was elevated at the deep fascial layer, carried with its perforating pedicle, and transferred to cover the wound completely. The subcutaneous tissue was sutured with absorbable sutures, while the skin was sutured intermittently with silk sutures, and a drain was placed under the flap. The donor site was directly closed by suturing, and the skin was disinfected again with a povidone-iodine solution containing an effective iodine concentration of 4.5 g/L to 5.5 g/L. After drying, the surgical area was covered with sterile dressings.

Nursing

Pre-operative nursing: The bed lying position and the change of body position were designed according to the patient's extremity muscle strength and pressure injury. All patients were given decompression at the pressure injury before operation, and the skin was kept clean and dry. A culture of traumatic secretions was performed, and antibiotics was used for anti-infection treatment. Nutritional support treatment was provided according to the patient's nutritional status to ensure adequate nutritional intake. Routine dressing change was performed in patients with more wound secretions, and continuous wound cavity flushing was performed in patients with sinus formation. Preoperative posture training is provided to facilitate quicker adaptation to postoperative posture requirements and to ensure maximum patient comfort for postoperative rehabilitation.

Postoperative nursing: Basic nursing contents of postoperative were the same as preoperative. Special nursing steps were conducted as follows.



Skin stretching:

(1) **Skin care.** Since the skin retractor needed to be placed locally for continuous traction after surgery, and the fixed stent was metal, it was necessary to avoid stent pressure on the skin. Small pillows can be placed on the stent's left and right or upper and lower sides to reduce the local pressure and prevent the pressure injury wound from forming again.

(2) **Local warmth.** Paid attention to the traction site's warmth, adjusted the temperature in the hospital room between 22°C and 25°C, or used a 60W frame baking lamp to give local light baking at 30 cm to 40 cm from the traction site to keep warm.

(3) **Avoid external force.** Be gentle when assisting patients in turning over, and avoid dragging and tugging. Keep the integrity of the traction skin and prevent ischemia of the skin edge caused by external force and excessive traction.

(4) **Blood circulation observation.** The tightness of the skin edge, peripheral blood supply, and skin color should be closely observed. A certain traction force should be maintained, whose strength should make the skin around the wound fully tense without affecting the local blood supply and keep the skin in the maximum stretch state. If the skin was too tight or loose or the pain was obvious, the traction force should be adjusted in time to maintain adequate traction.

Skin flap transplantation:

(1) **Local warmth.** Cold stimulation of blood vessels may cause vasoconstriction and subsequently affected blood circulation. After flap surgery, thermal care should be carried out, generally keeping the temperature in the room between 22°C and 25°C, and keeping warm with a 60-watt light bulb at a distance of 30 cm to 40 cm from the light baking. During this period, patient rounds needed to be strengthened, and flap temperature, color, and tension needed to be

closely observed to prevent the occurrence of arteriovenous crisis.

(2) **Postural management.** To prevent pressure on the flap, the patients should be placed in the healthy side after surgery to fully suspend the skinned area. Patients were required to change the position on time by assisting with family members. The actions should be gentle, which avoided external force causing the suture of the flap edge to break open.

(3) **Negative pressure suction management.** Negative pressure suction was beneficial for removing deep secretions and necrotic tissue, continuously draining exudate, and promoting the growth of granulation tissue and wound repair. The negative pressure drainage tube was prevented from being compressed or folded, and the disposable sterile drainage tube was changed regularly. The amount, color and properties of the drainage fluid was observed and recorded.

Measures

The primary outcomes of this study were the effectiveness and safety of surgical skin stretching. A series of measures were used to assess between two groups, which included length of stay, cost, drainage volume at 24 h post-surgery, time required for healing, bacterial infection, incision dehiscence, distal necrosis, vascular obstruction, re-repair of incision, and hypertrophic scar. The following measurements were used to evaluate the other outcomes in this study: (1) FPS-R pain scale was used to measure pain levels preoperatively, 1 day postoperatively, and 5 days postoperatively [16]; (2) Hamilton Anxiety Scale was used to assess anxiety levels preoperatively, 1 day post-operatively, and 5 days post-operatively [17]; (3) SF-36 Quality of Life Scale was used to measure quality of life pre-operatively, 1 day post-operatively, and 5 days post-operatively [18,19].

Data analysis

Epidata 3.02 software was used to establish the database. Data were analyzed using the SPSS software program, version 22.0

(Statistical Package for the Social Sciences, Chicago, Illinois). Continuous variables were presented as mean ± standard deviation, and categorical variables were presented as number (percentage). To compare characteristics between two groups, T-test was conducted for continuous data and Chi-square test (or Yates Continuity Correction) was used for categorical data. The difference was considered statistically significant at P value <0.05.

Results

There were no statistically significant differences in age, sex, height, weight, body mass index, smoking, alcohol consumption, education level, average annual household income, history of hypertension, history of diabetes, and history of hyperlipidemia between two groups (P>0.05), as shown in Table 1.

There were no statistically significant differences between the experimental and control groups in terms of pressure injury area, presence of sinus tract or tunnel, presence of local anesthesia loss, ability to turn over independently, presence of urinary and fecal incontinence, and bacterial culture (P>0.05). The length of surgery and the amount of bleeding during surgery in the experimental group were greatly lower than those in the control group, and the differences

Table 1: Characteristics of included patients for stage 4 pressure injuries.

	Skin stretching (n=18)	Skin flap transplantation (n=36)	P-value
Age (years)	55.2 ± 11.6	50.7 ± 12.9	0.22
Sex			0.687
Male	11 (61.1%)	24 (66.7%)	
Female	7 (38.9%)	12 (33.3%)	
Height (cm)	162.1 ± 8.5	161.4 ± 6.9	0.762
Weight (kg)	57.6 ± 10.0	55.8 ± 8.3	0.493
Body mass index (kg/m²)	21.8 ± 2.5	21.4 ± 2.7	0.578
Ever smoked			1
Yes	6 (33.3%)	12 (33.3%)	
No	12 (66.7%)	24 (66.7%)	
Ever drank			1.000 ^a
Yes	4 (22.2%)	9 (25.0%)	
No	14 (77.8%)	27 (75.0%)	
Education level			0.42
Secondary school, vocational school and below	13 (72.2%)	22 (61.1%)	
College, university and above	5 (27.8%)	14 (38.9%)	
Average household income (RMB, yuan)	41209 ± 4601	43780 ± 6384	0.135
History of hypertension			--
Yes	1	6	
No	17	30	
History of diabetes			--
Yes	2	4	
No	16	32	
History of hyperlipidemia			--
Yes	2	0	
No	16	36	

T-test was conducted for continuous data and Chi-square test for categorical data

^a: Yates Continuity Correction for Pearson's chi-squared test

Table 2: Comparison of Pressure Ulcer and Surgical Characteristics between two groups.

	Skin stretching (n=18)	Skin flap transplantation (n=36)	P-value
Pressure injury area			0.54
<100 cm ²	11 (61.1%)	25 (69.4%)	
>=100 cm ²	7 (38.9%)	11 (30.6%)	
Presence of Sinus Tract or Tunnel			1.000 ^a
Yes	13 (72.2%)	27 (75.0%)	
No	5 (27.8%)	9 (25.0%)	
Presence of Purulent Secretions			--
Yes	17 (94.4%)	34 (94.4%)	
No	1 (5.6%)	2 (5.6%)	
Presence of Odor			--
Yes	15 (83.3%)	35 (97.2%)	
No	3 (16.7%)	1 (2.8%)	
Presence of Local Anesthesia Loss			0.892 ^a
Yes	16 (88.9%)	30 (83.3%)	
No	2 (11.1%)	6 (16.7%)	
Ability to Turn Over Independently			1.000 ^a
Yes	3 (16.7%)	6 (16.7%)	
No	15 (83.3%)	30 (83.3%)	
Presence of Urinary and Fecal Incontinence			0.679
Yes	13 (72.2%)	24 (66.7%)	
No	5 (27.8%)	12 (33.3%)	
Bacterial Culture			0.564
Positive	10 (55.6%)	17 (47.2%)	
Negative	8 (44.4%)	19 (52.8%)	
Length of surgery (minutes)	62 ± 23	220 ± 40	<0.001
Amount of bleeding during surgery (mL)	25.6 ± 7.8	76.8 ± 6.8	<0.001

T-test was conducted for continuous data and Chi-square test for categorical data

^a: Yates Continuity Correction for Pearson's chi-squared test

were statistically significant (P<0.05), as shown in Table 2.

The length of hospital stays, cost, drainage volume at 24 h post-surgery, and time required for healing were all less in the experimental group than in the control group, and the differences were statistically significant (P<0.05). The vascular obstruction rate and re-repair of incision rate were higher in the control group than in the experimental group, and the differences were statistically significant (P<0.05), as shown in Table 3.

The difference between the FPS-R pain scores of the two groups before surgery was not statistically significant (P>0.05); the FPS-R pain scores of the two groups slightly decreased after surgery, but the differences were not statistically significant (P>0.05); there were also no statistical differences in these two groups both for before and after surgery (P>0.05). The difference in HAMA Hamilton anxiety scores between the two groups before surgery was not statistically significant (P>0.05); after surgery, the anxiety scores of both groups decreased, and the difference was statistically significant (P<0.05); the differences in these two groups were also statistically significant both for before

Table 3: Comparisons of recovery characteristics between two treatments for stage 4 pressure injuries.

	Skin stretching (n=18)	Skin flap transplantation (n=36)	P-value
Length of stay (day)	24.8 ± 8.2	40.8 ± 9.4	<0.001
Cost (RMB, yuan)	18200.3 ± 10235.6	28828.1 ± 13431.6	0.005
Drainage volume at 24 h post-surgery			0.012
<=10 mL	14 (77.8%)	15 (41.7%)	
>10 mL	4 (22.2%)	21 (58.3%)	
Time required for healing (hour)	575.4 ± 195.2	785.0 ± 234.5	0.002
Bacterial infection			0.399
Yes	4 (22.2%)	12 (33.3%)	
No	14 (77.8%)	24 (66.7%)	
Incision dehiscence			--
Yes	2 (11.1%)	5 (13.9%)	
No	16 (88.9%)	31 (86.1%)	
Distal necrosis			--
Yes	0 (0.0%)	5 (13.9%)	
No	18 (100.0%)	31 (86.1%)	
Vascular obstruction			0.037^a
Yes	1 (5.6%)	13 (36.1%)	
No	17 (94.4%)	23 (63.9%)	
Re-repair of incision			0.035
Yes	2 (11.1%)	14 (38.9%)	
No	16 (88.9%)	22 (61.1%)	
Hypertrophic scar			0.892 ^a
Yes	2 (22.2%)	6 (16.7%)	
No	16 (77.8%)	30 (83.3%)	

a: Yates Continuity Correction for Pearson's chi-squared test

and after surgery ($P < 0.05$). The differences in all dimensions of SF-36 quality of life before surgery between the two groups were not statistically significant ($P > 0.05$); after surgery, the SF-36 quality of life scores increased in both groups, and the values in Physical Function (PF), role limitations due to physical Health Problems (RP), General Health perceptions (GH), and Vitality (VT) dimensions were much higher in experimental group than that in control group ($P < 0.05$). The values in all dimensions in the experimental group were higher after surgery than before ($P < 0.05$). The values in all dimensions in the control group increased after surgery, except for role limitations due to physical Health Problems (RP), General Health perceptions (GH), as shown in Table 4.

Discussion

Pressure injuries continue to plague patients and the healthcare community [20]. Despite advances in medicine, the incidence of pressure injuries has remained stable and even slightly increased over more recent years [21,22]. Traditionally, the main treatment for chronic, difficult-to-heal pressure injuries was skin flap transplantation [13,14]. However, this approach has been found to potentially increase patient pain and trauma, and is also prone to infection and necrosis due to the poor abrasion resistance of the flap, resulting in repeated grafting in some patients, which may lead to severe scarring even if the wound heals. In this study, skin retraction was performed on patients with stage 4 pressure injuries of the hip

region. Compared with traditional treatment, the length of hospital stays, cost, drainage volume at 24-h post-surgery, time required for healing, number of vascular obstruction and re-repair of incision were significantly decreased. The patient's anxiety level significantly reduced, while the quality of life greatly improved.

Skin retraction is a method of rapid wound closure by applying a linear load cycle to the skin using a skin retraction device, which is composed of three main structures: The skin attachment system, the retraction power system, and the tension maintenance system. Whereas the viscoelasticity of the skin itself is the histological basis of skin retraction, a complex network of collagen and elastic fibers confers the mechanical extensibility of the skin [23]. It has been clinically proven to be effective and safe. During the treatment process, through the skin's own growth and repair properties, the soft tissues of the skin are continuously repaired, grown and reconstructed to promote wound closure through its own growth-repair properties with minor damage to the soft tissues of the skin during the retraction process. X Chen, et al. conducted a study of application of skin traction for surgical treatment of grade IV pressure sore and found that this method was cost effective because it had a high success rate with a short stay in hospital and lower rate of the recurrence [15]. In this study, we showed that the use of skin retraction is simpler than flap transfer, reduces the skin retrieval and implantation steps, effectively reduces the surgical wound and intraoperative bleeding, and shortens the operation time. In addition, drainage volume at 24-h post-surgery, time required for healing, number of vascular obstruction and re-repair of incision were less than those in the control group. This may be explained by the fact that skin flap transfer requires a continuous arterial blood supply and good venous return. The timely detection and accurate diagnosis of vascular crises during the nursing process is critical in preventing skin graft necrosis. However, in clinical practice, this is usually achieved by observation, which is simple and convenient, but the accuracy of observations is often affected by factors such as the experience of nursing staff and environmental conditions. To address these issues, skin traction surgery may be a viable option to reduce the influence of uncontrollable factors during this process. Skin traction surgery has been shown to be effective in reducing healing time and improving cure rates, likely due to the improved blood flow and increased durability of skin.

The results of this study showed that FPS-R pain scores were not statistically different between the experimental and control groups, nor were they statistically different preoperatively or postoperatively. This may be partly explained by the fact that all patients included in this study were stage 4 pressure injury patients. At the stage 4 pressure injury stage, tissue damage has penetrated to the level of bones and even joints, when pain sensation usually decreases or disappears. When the tissue damage is severe, the nerve endings may have been compressed, destroyed, or completely damaged, resulting in nerve signals that cannot be transmitted or are blocked and thus cannot be transmitted from the nerve endings to the central nervous system and produce pain sensations in the brain. In addition, stage 4 pressure injuries are usually the result of long-term development, and patients may have gradually adapted to the pain sensation. The experimental group showed significantly lower anxiety and improved quality of life compared with the control group, suggesting that skin retraction may reduce postoperative reactions and improve patients' psychological status and quality of life. This may be related to the short operative time of skin retraction, low intraoperative bleeding, low vascular obstruction and re-repair of incision rates, low trauma,

Table 4: Scales for pain, anxiety and health-related quality of life between two groups.

	Range	Before surgery			After surgery			P _{before-after} Value	
		Skin stretching (n=18)	Skin flap transplantation (n=36)	P value	Skin stretching (n=18)	Skin flap transplantation (n=36)	P value	Skin stretching	Skin flap transplantation
FPS-R pain Scale	0-10	2.5 ± 1.3	2.4 ± 1.0	0.756	1.7 ± 1.1	1.9 ± 1.3	0.578	0.054	0.067
Hamilton Anxiety Rating Scale	0-56	27.6 ± 8.6	29.2 ± 8.8	0.529	10.5 ± 5.6	17.5 ± 6.4	<0.001	<0.001	<0.001
SF-36 quality of life scale									
Physical functioning	0-100	58.7 ± 16.5	61.4 ± 15.1	0.551	84.3 ± 10.5	73.5 ± 12.6	0.003	<0.001	<0.001
Role limitations due to physical health problems	0-100	64.1 ± 18.6	61.5 ± 17.4	0.615	83.6 ± 8.6	67.5 ± 14.4	<0.001	<0.001	0.116
Body pain	0-100	57.6 ± 14.2	56.4 ± 16.2	0.791	77.6 ± 8.1	74.3 ± 8.8	0.188	<0.001	<0.001
General health perceptions	0-100	67.6 ± 12.1	69.1 ± 13.5	0.673	85.6 ± 9.7	70.8 ± 8.1	<0.001	<0.001	0.519
Vitality	0-100	51.5 ± 12.9	50.8 ± 14.4	0.863	76.6 ± 10.4	70.1 ± 11.3	0.046	<0.001	<0.001
Social functioning	0-100	57.6 ± 14.7	53.6 ± 17.8	0.415	67.6 ± 6.9	67.7 ± 7.6	0.954	0.013	<0.001
Role limitations due to emotional problems	0-100	62.6 ± 10.9	60.6 ± 14.8	0.614	77.6 ± 11.3	72.0 ± 12.0	0.106	<0.001	<0.001
Mental health	0-100	61.6 ± 15.5	68.7 ± 11.2	0.060	75.2 ± 13.9	73.7 ± 9.6	0.644	0.009	0.046

and fast recovery.

In conclusion, skin retraction is more effective, less traumatic, and has fewer complications than flap transfer for stage 4 pressure injuries. Not only can it effectively reduce the pain and anxiety level, but also significantly improve their quality of life, which is worthy of clinical promotion.

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