

1 **Evaluation of Therapeutic Outcomes of Reconstruction of Pressure Ulcer Injuries by**
2 **Flap Coatings in Patients Admitted to Taleghani Hospital in Kermanshah during**
3 **2015-2016**
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6 **Objective:** *Pressure ulcers, following cancer and heart disease, are considered as the third most*
7 *costly health problem. In addition to high cost of treatments, considerable time is spent on care*
8 *for patients. This study tends to evaluate the therapeutic outcomes of reconstruction of pressure*
9 *ulcer injuries by flap coatings.*

10 **Methods:** *This study is prospective; 85 patients with pressure ulcer who referred to Taleghani*
11 *Hospital in Kermanshah during 2015-2016 for treatment by muscular coating flaps were*
12 *followed up 1 week and 3 months after discharge. Reconstruction was done again if the*
13 *treatment was unsuccessful. Data was analyzed by SPSS software version 22.*

14 **Results:** *The success rate of pressure ulcer reconstruction by coating flaps significantly*
15 *increased after 1 week and 3 months ($P < 0.05$, 50.6% and 90.5%, respectively). The success rate*
16 *of pressure ulcer reconstruction by coating flaps significantly increased after 1 week and 3*
17 *months in terms of age, gender, and BMI ($P < 0.05$).*

18 **Conclusion:** *The success of pressure ulcer reconstruction increased by coating flaps after 3*
19 *months.*

20 **Keywords:** pressure ulcer, coating flap, reconstruction.

21 **Introduction**

22 Pressure ulcer is caused by local damage due to pressure and ischemic injuries in the soft tissue,
23 muscle, cartilage and bone (1). Pressure ulcer is often found on bone eminences as red areas
24 without skin changes or as areas with loss of epidermis and derma and may extend to
25 subcutaneous tissues and muscles and bone (2). Pressure ulcer is a major health problem which
26 usually occurs in patients who require long-term care. American scientists (2003, 2013) estimate
27 that 1.3-3 million adults are affected by pressure ulcers (3). The risk factors of pressure ulcers
28 include inactivity, low BMI, some medicines and medical equipment, age, moisture,
29 malnutrition, peripheral circulation disorder, fever, and obesity (4). Pressure ulcer is associated
30 with complications such as pain, infection, increased hospitalization time, increased hospital
31 costs, increased mortality and reduced quality of life (5). Currently, billions of dollars are spent
32 in care centers worldwide for prevention and treatment of pressure ulcers, particularly for
33 patients with long-term hospital stay (6). Pressure ulcer have been identified as one of the most
34 costly health disorders in the 21st century (7). In various studies, the prevalence of pressure
35 ulcers has been reported at 3.5-69% (8). If pressure ulcers are not treated, they lead to lethal and

36 dangerous complications, including osteomyelitis and death (9). Although pressure ulcers are
 37 said to be preventable, this does not seem to be easy in practice, and these ulcers are seen in the
 38 best centers in the United States (10). Patients, families, healthcare providers, and the community
 39 are significantly affected by physical, financial and social consequences of pressure ulcers and
 40 patients with pressure ulcers inevitably experience pain, malformation, disability and dependence
 41 on others (11). Large defects caused by pressure ulcers are usually repaired by plastic surgeons.
 42 Among ulcer reconstruction methods, skin graft such as flap is considered as the most suitable
 43 method aesthetically and functionally (12). Surgery for treatment of pressure ulcer is based on
 44 three principles: 1) radical debridement of all necrotic tissue; 2) osteotomy of the affected bones
 45 under the ulcer; 3) application of different flaps to cover the ulcer area (13). Little is known
 46 about application of flap coatings to repair pressure ulcer. Due to failure to reconstruct the
 47 postoperative pressure ulcer, this study tends to investigate the therapeutic outcomes of pressure
 48 ulcer reconstruction by flap coatings in Kermanshah during 2015-2016 and determine its role in
 49 preserving the organs as well as incidence of complications related to these treatments.

50 **Materials and Methods**

51 The present study is a descriptive-analytical (prospective) study approval by the ethics
 52 committee of Kermanshah University of Medical Sciences. The studied population included
 53 patients with pressure ulcers; after describing the project, the participants completed the
 54 informed consent form. The patients who had a history of human immunodeficiency and diabetes
 55 were excluded. The sample size was calculated at 85 based on Yang's study and treatment
 56 success rate. Therefore, total number of samples was 85 (14). The sample size formula is as
 57 follows:

$$n = \frac{Z_{1-\alpha/2}^2 (p(1-p))}{d^2} = \frac{(1.96)^2 ((0.76)(0.24))}{(0.09)^2} \approx 85$$

58 Considering the 95% confidence level and the 9% accuracy, treatment success rate was 76%,
 59 with a minimum sample size of 85 in each group. The sample size formula is as follows.

60 A questionnaire based on main objectives of the project including demographic information,
 61 treatment complications, treatment outcome, reconstruction, number of flaps to assess the
 62 success of flap coating in patients was completed for each patient. Patients were first examined
 63 by a collaborator assistant to examine exclusion criteria. Subsequently, the coating flaps were

64 examined in terms of efficiency and preserving the related member function and complications
 65 and failure of the treatment. The results were presented after final examination. Then, the
 66 patient's condition was followed up to 1 week and 3 months later; they underwent reconstruction
 67 in the event of a failure (the reconstruction site did not get close to normal state). Data was
 68 transferred to SSPS software version 22. For data analysis, descriptive statistics (mean, tables,
 69 one-dimensional and two-dimensional graphs, standard deviation and variance) were used.
 70 Quantitative data analysis was based on KS test. Then, independent t-test or Mann-Whitney test
 71 were used. For qualitative data, Chi-square test or Fisher's exact test were used ($p < 0.05$).

72 Results

73 In this study, 85 eligible patients with pressure ulcer who referred to Taleghani Hospital in
 74 Kermanshah during 2015-2016 were examined. Patients aged 28-43 years (33.61 ± 3.96); 63% of
 75 the participants were male; 57% of participants had BMI < 25; 61.2% had Ischial ulcer, 23.5%
 76 had Sacral ulcer, 11.8% had Trochanter ulcer, 3.5% had heel ulcer, 61.2% had upper glothea
 77 pedicle flap and 5.9% had complications. Table 1 presents the results.

78 **Table 1: frequency and percentage frequency of demographic variables**

Demographic variables	N (%)
Age	
30	26 (14.8)
30-35	35 (14.8)
35-40	20 (22.2)
>40	4 (4.7)
Gender	
Female	31 (36.5)
Male	54 (63.5)
Flap type	
Upper glothea pedicle	52 (61.2)
V-Y	2 (23.5)
Lateral thigh	10 (11.8)
Advanced	3 (3.5)
BMI	
<25	36 (42.5)
>25	49 (57.5)
Type of pressure ulcer	
Ischial	52 (61.2)
Sacral	2 (23.5)
Trochanter	10 (11.8)
Heel	3 (3.5)
Type of Complications	
Partial necrosis	4 (4.7)
Complete necrosis	2 (2.4)
Seroma	2 (2.4)

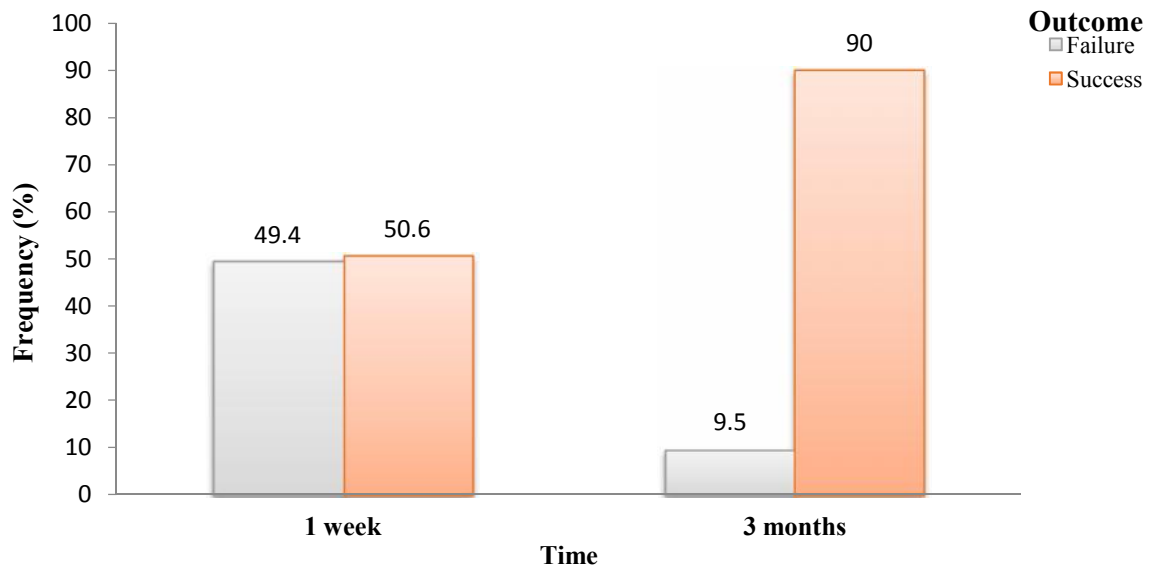
No Complications	77 (90.5)
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79 Wilcoxon test was used to compare the success rate of pressure ulcer reconstruction by coating
 80 flaps after 3 months in terms of demographic variables. According to Table 2, there was a
 81 significant difference in success rate of pressure ulcer reconstruction by coating flaps between
 82 patients younger than 33 years and older than 33 years, between male and female patients,
 83 between patients with BMI<25 and BMI>25 after one week and 3 months (P<0.05) Thus,
 84 success rate of pressure ulcer reconstruction increased by coating flaps in patients after 3 months.

85 **Table 2: frequency and comparison of success rate of pressure ulcer reconstruction by coating flaps in terms of variables**

Variable	Section (month)	Outcome		Test statistic	P-value
		Failure	Success		
<33	3	11 (9.28)	27 (1.71)	2.52	0.012
>33	3	6 (8.12)	41 (87.2)	3.3	0.001
Female	3	3 (9.7)	28 (90.3)	3.05	0.002
Male	3	14 (25.9)	40 (74.1)	2.85	0.004
BMI<25	3	3 (7.7)	36 (92.3)	3.87	>0.001
BMI 25	3	14 (30.4)	32 (69.6)	2.13	0.033

86 Based on the results, there was a significant difference in success rate of pressure ulcer
 87 reconstruction by coating flaps after one week and three months (P<0.05). Thus, success rate of
 88 pressure ulcer reconstruction increased by coating flaps after 3 months (Figure 1).



89
 90

Figure 1: frequency of success rate of pressure ulcer reconstruction by coating ulcers after three months

91 **Discussion and Conclusion**

92 There are interventions for management of pressure ulcers. These interventions include a wide
93 range of palliative measures to treatments involving reconstructive surgical procedures. Surgery
94 typically involves ulcer debridement, along with replacement of damaged tissue with a new
95 tissue at the site of the ulcer. While reconstructive surgery is an acceptable method in ulcer
96 management (15). In this study, success rate of pressure ulcer reconstruction was increased by
97 coating flaps after 3 months. Moreover, pressure ulcer reconstruction by coating flap was
98 successful after 3 months in terms of age, gender, and BMI. Therefore, these variables did not
99 have a negative effect on this success.

100 According to the results, the highest incidence of pressure ulcer was in men in the Ischial area,
101 which is consistent with Alizadeh et al. (16). Perhaps the reason for this is the differences in
102 muscle and skeletal structure of men and higher fat accumulation in women's buttocks.

103 The most common incidence of ulcer was in the age range of 30 to 35 years old. The results of
104 this study were consistent with Dr. Baqae et al. who found that the incidence of ulcer increased
105 with age (17).

106 Consistent with the current study, Marchi et al. reported the prevalence of Ischial ulcer (62.3%),
107 Sacral (41.7%), and trochanteric (18.4%). The most commonly used flaps were gluteus flap
108 (62%) followed by V-Y flap (29%). Lin et al. (2014) concluded that no cases of death or
109 recurrence of pressure ulcer due to flap surgery have been reported. The benefits of flap surgery
110 include a shorter duration of surgery, less bleeding and less trauma, making the flaps an ideal
111 choice for covering sacral ulcers (19).

112 A strength of this study was that it was semi-experimental. In addition, all patients were
113 surgically operated by an experienced surgeon and the same procedure. However, this study had
114 limitations: First, due to the limited number of similar studies, the current study cannot be
115 compared with other studies. Therefore, it is suggested that further studies be developed in the
116 future. Second, this study did not have control group. Therefore, it is recommended to consider
117 this in future studies.

118 Based on objective observations, coating flaps lead to successful reconstruction of pressure
119 ulcers after three months of treatment. Moreover, age, gender, and BMI of patients cannot affect
120 the improvement process. Based on the results, success rate of pressure ulcer reconstruction
121 increased by coating flaps after three months.

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