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Observation on the Clinical Efficacy of Silk Fibroin Medical Dressing in the Treatment of Facial Burn

Huang Jiahui, Yuan Yijun, Zeng Zhenyu, Xu Yuting*

First People's Hospital of Xinmi, Zhengzhou, Henan, 452370, China

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Abstract: To observe the clinical curative effect of putting the silk fibroin medical dressing on face burns, a prospective and randomized controlled research was launched. One hundred patients with facial burns who entered our hospital for treatment from January 2024 to December 2024 were picked as the study subjects. Relying on the method of random number table, these cases got randomly assigned into two groups: the trial group (50 cases) and the control group (50 cases). Following the foundation debridement work, patients in the control group accepted the collagen patch dressing, while the trial group utilized the medical dressing of silk fibroin. As a result, we conducted comparisons and analyses concerning the time needed for wound healing, the level of pain at varying time points, and the happening rate of adverse reactions. The mean time consumed for wound healing among the trial group was recorded as 11.52±2.34 days, which showed a notable shortness compared to the control group (14.86±3.15 days), and such difference possessed statistical meaning ($P<0.05$). When checked on the 3rd day and 7th day post-treatment, the trial group's VAS scores presented obviously lower than the control group's ($P<0.05$). Regarding the adverse reaction incidence rate, no statistical difference was found between the two groups ($P>0.05$). The application of silk fibroin medical dressing for treating facial burns can successfully cut down the healing time of wounds, ease the pain feeling of patients, and it shows great safety, thus owning clinical value for wide popularization.

1. Introduction

Because the skin plays the role as the most outside defense line for the human body, it is extremely easy to suffer from the hurting of burns. The burn happening on the face is belonging to one of the most frequently seen acute traumas. It brings not only intense pain and exudation, but also gives heavy negative influence to the mental health of patients because of the potential scar leaving [1]. Therefore, hunting for an effective kind of medical dressing to boost the wound healing speed is quite critical in clinical work. During the past few years, biomaterials from nature have drawn growing attention. As a type of natural macromolecular protein obtained from silk, silk fibroin has displayed wonderful biocompatibility and wound repairing abilities in plenty of pre-clinical as well as clinical researches [2]. The present study plans to prospectively observe the clinical functioning of a brand-new silk fibroin medical dressing (Fangchenggang Ruiyi Biotechnology Co., Ltd.) making a comparison with the traditional collagen patch dressing in treating facial burns, so as to supply

reference basis for the selection of clinical materials.

2. Data and Methods

2.1 General Information

One hundred patients suffering from burns on the face, who took medical care inside the burn department of this hospital, were picked out as the research targets.

2.1.1 Standards for inclusion

(1) The clinical diagnosis confirmed that the facial wounds belong to superficial II degree up to deep II degree burns; (2) The proportion of the burned area accounts for less than 5% regarding the total body surface area (TBSA); (3) Every participating patient showed complete willingness to take part in the current study, and they had already signed the informed consent documents by themselves.

2.1.2 Standards for exclusion

(1) Cases combining with severe functional impairments of vital organs including the heart, liver, and kidney; (2) Those who merge with heavy whole-body infections or possess immune system illnesses.

All the included cases were separated into a trial group and a control group in a random way, containing 50 cases per group. Inside the trial group, male cases were 28 and female cases were 22; their ages distributed from 22 to 60 years, with a mean age reaching (38.5±6.2) years. Inside the control group, there were 27 males and 23 females; the age distribution was 23 to 59 years, and the average was (39.1±5.8) years. By comparing the baseline data including sex and age between the two groups, no statistical significance could be seen ($P>0.05$), which proved they had comparability.

2.2 Treatment Methods

After entering the hospital, the routine therapy was given to sufferers in both two groups. The therapy contents included fighting against infection, fluid replacement, and strictly carrying out wound debridement for the face. We used physiological saline water to flush the wound surfaces until they were clean.

2.2.1 Control group

The control group took the application of collagen patch dressing. We pasted this dressing on the face wound, and paid attention to make it tightly fit with the skin. The action of changing dressing was executed once per day.

2.2.2 Trial group

For the trial group, we applied the silk fibroin medical dressing (Production company: Fangchenggang Ruiyi Biotechnology Co., Ltd.; Guangxi Medical Device Registration No. 20252140091). During the operating steps, operators tore open the outer package, took the silk fibroin dressing out, and made it directly cover on the facial burn wound that had been cleaned. It was strictly required that the dressing must overpass the wound edges completely. According to the fluid exudation situation of the wound, we changed the dressing one time every day. The treatment course for the two groups did not stop until their wound surfaces achieved 100% healing.

2.3 Observation Indexes

2.3.1 Wound healing time

We made a record of the specific days costing from the first time of applying dressing to the complete epithelialization appearing on the facial wound of the two groups.

2.3.2 Pain score

The Visual Analogue Scale (VAS) was selected to evaluate the pain level of the sufferers at the time before treating, the 3rd day after treating, and the 7th day after treating. The highest mark is 10 points. 0 point represents having zero pain feeling, and 10 points represents the severe pain that the patient is unable to bear.

2.3.3 Bad reactions

In the entire treating process, we gave close observation and recorded if the sufferers appeared conditions like local allergy, redness with swelling, and the second-time infection.

2.4 Statistical

The SPSS 26.0 statistical software was used to do the data processing work. For those measurement data such as the time for healing and VAS scores, we used the format of mean value ± standard deviation ($\bar{x} \pm s$), to express them. Also, the t-test of independent samples was used to conduct the between-group comparison.

3. Results

3.1 Comparison of wound healing time between the two groups

Based on clinical observations, the trial group's wound healing time was (11.52±2.34) d, and the control group's time was (14.86±3.15) d. The time consumed for wound healing in the trial group was evidently shorter than that in the control group, and such difference showed statistical significance (t=5.986, P<0.05).

3.2 The comparison of VAS score values between two groups at different time nodes

In the time before giving therapy, we made a comparison regarding the VAS scores of the two groups, and the difference had no statistical meaning (P>0.05). On the 3rd day and 7th day after treating, the VAS points of both two groups all produced a decreasing change when comparing with the situation before therapy. However, the going-down trend inside the trial group manifested much more obviously. The trial group got lower VAS points than the control group, with differences indicating statistical significance (P<0.05). See Table 1.

Table 1. Comparison of VAS scores between the two groups (mean ± SD, points)

Group	n	Before treatment	Day 3	Day 7
Trial group	50	7.35 ± 1.12	4.12 ± 0.85*	2.05 ± 0.64*
Control group	50	7.40 ± 1.08	5.36 ± 1.02	3.48 ± 0.77

Note: Compared with the control group at the same time point, P<0.05.

3.3 Comparison of adverse reactions between the two groups

In the course of treatment, 1 case showing slight redness and swelling appeared in the trial group, making the incidence rate 2.0% (1/50); 2 cases with mild allergy and 1 case with increased exudate appeared in the control group, leading to an incidence rate of 6.0% (3/50). When comparing the adverse reaction incidence between the two groups, the difference did not reach statistical significance (x^2=1.042, P=0.307>0.05).

4. Discussion

Due to the reason that the face belongs to the exposing part of human body, the burn on the face becomes one of the acute traumas that doctors see most frequently in the burn surgery department. The skin on the face is relatively thin, carrying abundant blood supply and nerve endings. Because of this, after getting burned, patients mostly endure intense pain, severe swelling, and massive tissue exudation. If the wound surface fails to get proper and timely management, wound infection can happen very easily. This will result in a prolonged healing period and even leave obvious scarring behind, bringing heavy negative impacts to the appearance and mental health of the patients. Thus, picking a perfect medical dressing for wound covering holds extremely vital clinical significance to encourage wound repair.

The reference literature concerning the treatment effect of collagen patch dressing pointed out that, applying collagen patch dressing has a definite curative effect in healing face burns, because it has the ability to block the bacteria to a certain degree [3]. Even so, along with the progress of biological materials in recent times, people have raised higher standards for the moisture retention, air breathing ability, and biological activity of the dressings. In our current research, a prospective randomized controlled trial was applied to test a novel material. The trial group adopted the medical dressing of silk fibroin produced by Fangchenggang Ruiyi Biotechnology Co., Ltd. (Guangxi Medical Device Registration No. 20252140091). Silk fibroin belongs to natural macromolecular proteins extracted from natural silk. It enjoys superior biocompatibility and moisture permeability, and is capable of promoting fibroblast proliferation as well as extracellular matrix synthesis [4].

The outcomes of our study proved that the trial group's wound healing time was notably shorter than the control group's (P<0.05). This points out that the medical dressing made of silk fibroin can offer a more ideal micro-environment for the wound to heal, speeding up the re-epithelialization of the burn surfaces, which matches the conclusions of recent studies on biomaterials [5]. Meanwhile, at 3 days and 7 days post-treatment, the VAS pain scores in the trial group presented lower than those in the control group (P<0.05). The reason is that the silk fibroin dressing is able to build a soft protective membrane on the wound, preventing the exposed nerve endings from being stimulated by the outside environment, therefore obtaining a nice pain-relieving effect. Regarding safety performance, the adverse reactions between the two groups displayed no significant difference, verifying its great safety in clinic.

To sum up, for patients suffering from facial burns, the application of silk fibroin medical dressing (Guangxi Medical Device Registration No. 20252140091) can effectively speed up wound healing, lower the pain level of patients, and it possesses trustworthy safety. Hence, it deserves further popularization and usage in clinical practice.

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