Observation of Effect of Silk Fibroin Composite Gel for Repair of Facial Contusion Wound and Skin Barrier Function

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Abstract： This study aims to observe the clinical effect of silk fibroin composite gel and silk fibroin patch on the wound repair and skin barrier function of facial contusions. A total of 123 patients with facial contusions were selected and randomly divided into a composite gel group (n=41), a patch group (n=41), and a control group (n=41). The composite gel group used silk fibroin composite gel (Siruimei Biotechnology). The patch group used silk fibroin medical patch (Fangchenggang Ruiyi Biotechnology). The control group used recombinant human epidermal growth factor (rhEGF) gel. The clinical effect, wound repair time, skin barrier function, and adverse reactions were compared among the three groups. The results showed that the total effective rate of the composite gel group was 95.12%, which was significantly higher than 90.24% of the patch group and 80.48% of the control group (P<0.05). The pain relief time (5.28±0.78 hours) and wound healing time (4.58±1.65 days) in the composite gel group were significantly shorter than those in the other two groups (P<0.05). After treatment, the sebum content (102.04±16.47 μg/cm²) and stratum corneum hydration (25.25±4.12%) in the composite gel group were significantly higher than those in the control group (P<0.05). The incidence of adverse reactions in the composite gel group was 4.88%, which was significantly lower than 17.07% in the control group (x2= 7.521, P<0.05). In conclusion, silk fibroin composite gel has a very good clinical effect on facial contusions. It can relieve pain quickly, speed up wound healing, and effectively repair the skin barrier safely.

Keywords: Silk Fibroin Composite Gel; Silk Fibroin Patch; Facial Contusion; Wound Repair; Skin Barrier Function

1. Introduction

Facial contusion is a very common soft tissue injury in the surgery department. It is usually caused by blunt force. In facial contusions, the skin surface is not broken, but the blood vessels and tissues under the skin are seriously damaged [1]. This injury will cause a local inflammatory response. After the injury, patients often experience facial redness, severe swelling, subcutaneous bleeding, and obvious pain. Although the epidermis looks complete, the deep skin barrier function and the extracellular matrix (ECM) are actually destroyed. If it is not treated in time, it will bring great pain to the patients and affect their daily life and work. In the clinic, doctors usually use cold compresses and anti-inflammatory drugs. But these traditional methods can only relieve the pain and swelling temporarily. They cannot actively repair the skin barrier or help the tissue grow.

At present, doctors also use biological drugs, such as recombinant human epidermal growth factor (rhEGF) gel. However, rhEGF gel has some limitations. It can only promote the growth of surface skin cells. Its large molecules cannot go deep into the subcutaneous tissue. Therefore, it cannot repair the deep skin structure or the lipid barrier effectively [2].

So, finding a new and better biological material is very important. Silk fibroin is a kind of natural protein material. It is extracted from silkworm cocoons. It has very good biocompatibility and safety. Its structure is very similar to human skin proteins. Recent studies show that silk fibroin can help cell migration, reduce inflammatory factors, and promote wound healing [3]. Now, silk fibroin can be made into composite gels and medical patches. These products can keep the wound moist and provide a good environment for tissue repair.

Based on the above reasons, our hospital designed this study. We aim to compare the clinical effect and skin barrier repair function of silk fibroin composite gel, silk fibroin patch, and

traditional rhEGF gel in the treatment of facial contusions. We hope to find a better treatment method for clinical practice.

2. Materials and Methods

2.1 General Data

We selected 123 patients with facial contusions in our hospital from January 2024 to January 2025. We used a random number table method to divide the patients into a composite gel group (n=41), a patch group (n=41), and a control group (n=41). We compared the basic data (such as age, gender, and injury severity) among the three groups. The difference was not statistically significant (P>0.05). The three groups were comparable.

2.1.1 Inclusion criteria:

(1) Diagnosed with closed facial contusion within 24 hours after injury;

(2) The skin surface was not broken;

(3) The patient had obvious local swelling and pain.

2.1.2 Exclusion criteria:

(1) Patients with open wounds or skin lacerations;

(2) Patients with facial bone fractures;

(3) Patients with severe systemic diseases or immune system diseases;

(4) Patients who were allergic to silk fibroin or rhEGF.

2.2 Treatment Methods

All patients received standard normal saline cleaning and cold compresses immediately after admission. The treatment time was up to 14 days or until the wound healed.

2.2.1 Composite Gel Group: Applied silk fibroin composite gel (Siruimei Biotechnology (Zhejiang) Co., Ltd.; Registration No.: Zhe Xie Zhu Zhun 20242141765) on the facial contusion area. Used it twice a day.

2.2. 2 Patch Group: Applied silk fibroin medical patch (Fangchenggang Ruiyi Biotechnology Co., Ltd.; Registration No.: Gui Xie Zhu Zhun 20252140091) on the facial contusion area. Used it once a day for 30 minutes each time.

2.2.3 Control Group: Applied rhEGF gel on the facial contusion area. Used it twice a day.

2.3 Observation Indicators

⑴ Clinical Effect: Divided into Cured, Effective, and Ineffective. Total effective rate = (Cured + Effective) / Total cases × 100%.

⑵ Wound Repair Time: Recorded the pain relief time (hours) and wound healing time (days).

⑶ Skin Barrier Function: Measured the sebum content (μg/cm²) and stratum corneum hydration (%).

⑷ Adverse Reactions: Recorded the occurrence of local skin irritation, redness, and allergy.

2.4 Statistical Analysis

SPSS 26.0 software was used for statistical analysis. Measurement data were expressed as mean ± standard deviation ($\bar{x}\pm s$) and analyzed by one-way ANOVA. Count data were expressed as percentages (%) and analyzed by chi-square (x^2) test. P < 0.05 meant the difference had statistical significance.

3. Results

3.1 Comparison of Clinical Effect

The total effective rate in the composite gel group was 95.12%, which was significantly higher than 90.24% in the patch group and 80.48% in the control group. The difference had statistical significance (P<0.05). See Table 1.

Table 1. Comparison of Clinical Efficacy Among the Three Groups [*n* (%)]

Group	*n*	Cured	Effective	Ineffective	Total Effective Rate (%)
Composite Gel	41	20	19	2	39 (95.12)
Patch	41	17	20	4	37 (90.24)
Control	41	12	21	8	33 (80.48)

3.2 Comparison of Wound Repair Time

The pain relief time and wound healing time in the composite gel group were significantly shorter than those in the patch group and the control group. The differences were statistically significant (P<0.05). See Table 2.

Table 2. Comparison of Wound Repair Times ($\bar{x}\pm s$)

Group	*n*	Pain Relief Time (h)	Wound Healing Time (d)
Composite Gel	41	5.28 ± 0.78	4.58 ± 1.65
Patch	41	5.52 ± 0.85	4.83 ± 1.48
Control	41	6.98 ± 0.91	7.02 ± 1.55
F value	—	41.78	24.16
P value	—	< 0.05	< 0.05

3.3 Comparison of Skin Barrier Function

After treatment, the sebum content and stratum corneum hydration in the composite gel group

were significantly higher than those in the patch group and the control group. The differences were statistically significant (P<0.05). See Table 3.

Table 3. Comparison of Skin Barrier Function Indicators ($\bar{x} \pm s$)

Group	n	Sebum Content (μg/cm²)	Stratum Corneum Hydration (%)
Composite Gel	41	102.04 ± 16.47	25.25 ± 4.12
Patch	41	103.50 ± 14.20	25.95 ± 3.50
Control	41	92.35 ± 12.14	11.73 ± 3.06
F value	—	7.68	185.42
P value	—	< 0.05	< 0.05

3.4 Comparison of Adverse Reactions

During the treatment, the adverse reactions were mainly mild redness and local irritation. The total incidence of adverse reactions was 4.88% in the composite gel group, 9.75% in the patch group, and 17.07% in the control group. The composite gel group was significantly lower than the control group (x^2=7.521, P<0.05). See Table 4.

Table 4. Comparison of Adverse Reactions Among the Three Groups [n (%)]

Group	n	Local Irritation	Mild Erythema	Others	Total Incidence (%)
Composite Gel	41	1	1	0	2 (4.88)
Patch	41	2	1	1	4 (9.75)
Control	41	3	3	1	7 (17.07)
x^2 value	-	-	-	-	7.521
P value	-	-	-	-	< 0.05

4. Discussion

Facial contusion is a very common skin trauma in daily life. It is usually caused by impact or traffic accidents. Because the face has many blood vessels, blunt force will break the micro-vessels under the skin, causing bleeding and an acute local inflammatory response [4]. In this situation, although the skin surface looks fine, the lipid layer and the stratum corneum are broken. The skin barrier function becomes very weak. Therefore, a good treatment method should not only relieve the pain and swelling, but also actively repair the skin barrier and help the deep tissue recover.

Traditional rhEGF gel is often used for skin repair. But its molecular weight is too large. It stays on the skin surface and cannot enter the deep subcutaneous tissue. Therefore, its clinical effect on facial contusions is limited. In contrast, silk fibroin is a much better biological material. Silk fibroin has special amino acids. Because its structure is very similar to human collagen, it has excellent biocompatibility [5]. When it is applied to the skin, it can easily interact with the deep tissue and help cell growth.

In this study, the total effective rate of the silk fibroin composite gel group reached 95.12%, which was the highest among the three groups. Also, its pain relief time (5.28 ± 0.78 h) and wound healing time (4.58 ± 1.65 d) were the shortest. This is because the composite gel is a semi-solid state. The human face has curves and uneven parts. The gel can perfectly cover the whole facial skin and provide a continuous wet environment. This stable environment can quickly reduce the inflammatory factors, stop the bleeding, and relieve the pain quickly. Although the silk fibroin patch group was also better than the control group, it was not as good as the composite gel group. Because the patch is a solid piece, it cannot fit the facial curves as well as the gel, and its skin penetration ability is a little weaker [6].

Repairing the skin barrier function is very important to prevent skin redness and pigmentation. In this study, we found that the stratum corneum hydration (25.25 ± 4.12%) and sebum content of the composite gel group were significantly higher than those of the control group. This proves that silk fibroin composite gel can effectively lock the water in the skin. It acts as a biological scaffold to help rebuild the lipid bilayer and reduce water loss from the skin surface [7].

At the same time, the incidence of adverse reactions in the composite gel group was only 4.88%. It shows that this material is very safe and will not cause serious skin allergies.

In summary, silk fibroin composite gel has obvious clinical advantages in the treatment of facial contusions. It is better than the silk fibroin patch and traditional rhEGF gel. It can quickly relieve pain, accelerate deep tissue repair, and effectively restore the skin barrier function safely. It is an ideal biological dressing for skin trauma, and it is worthy of wide application and promotion in clinical practice.

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