KELO-COTE Silicone Gel For Scar Treatment: First Experience of Application in Russia

“Those who have deformities, scars, and pigmentations, dream of their reduction and complete removal, however, unfortunately, a burn never disappears without leaving a trace…” S. Bogdanov

1 INTRODUCTION

A scar is a mass that changes during the passage of time and whose evolution occurs “on the brink of physiology and pathology” [1]. For decades, scars were a fact of life that everyone accepted and had come to terms with. Patients were advised that little could be done and that they had to become accustomed to their scars over time. However, most patients would prefer even the slightest improvement in the general condition of their scar over its disfiguring impact, which often has a huge negative effect on a patient’s self-esteem. This is what has inspired researchers to attempt to modify the wound healing process.

2 WOUND HEALING PROCESS: MAIN FEATURES

The wound healing process involves numerous sophisticated phenomena, which can be divided into three partially overlapping phases [2]:

- inflammatory phase;
- the phase when granulation tissue is formed;
- matrix formation, or remodeling phase.

Studies have revealed that those processes are not sequential; in many aspects, they take place simultaneously.

The first wound healing phase is the inflammatory phase. The phase can be divided into early and late stages. The early stage starts from the moment when the skin is damaged, during which time there is bleeding in the wound. The blood's effect on fibrillar collagen and tissue factors leads to the activation of intrinsic and extrinsic cascades of hemostasis. Platelet damage, in turn, triggers a coagulation cascade, which also promotes hemostasis. The release of kinins stimulates the activation of complement along the 'classical' pathway. Later, it results in the release of anaphylotoxins, increased vascular permeability, and leukocyte chemotaxis.

In the early inflammation phase, neutrophils and monocytes appear in the wound, and type III collagen fibres are formed. First to appear are the neutrophils (within approximately 6 hours after the injury), while the monocytes ‘arrive’ somewhat later. The main function of neutrophils in early wound healing is to cleanse the wound of contamination with particles and bacteria. The disappearance of neutrophils from the wound after one or two days indicates that the early inflammatory phase of the healing process has finished. In contrast to the neutrophils, monocytes remain in the wound longer. Macrophage persistence is indicative of the late stage of the inflammatory phase. Macrophages continue wound scavenging by means of bacteria and cell fragment phagocytosis.

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The second phase of the wound process is the granulation phase, which is characterized by the formation of granulation tissue. During this phase, angiogenesis, reepithelialization, and collagen synthesis begin. Now, macrophages, fibroblasts, epithelial cells, and endotheliocytes are brought into the healing of the wound. The most important condition for wound healing is the extracellular matrix formation occurring at this time. The extracellular matrix primarily consists of proteoglycans, fibronectin and collagen. The synthesis of all these proteins promotes reepithelialization and neovascularization.

Maturation is the third and the last wound process phase. During this phase, the extracellular matrix is restructured and type III collagen turns into type I collagen. The wound contracts due to the combined interaction of fibroblasts, fibronectin, and collagen. As soon as the fibroblasts in the wound reach a critical mass, fibronectin and type I collagen begin to be produced. Fibroblasts line up along the “intercellular lattice,” consisting of fibronectin and collagen. Contraction of the wound occurs with the involvement of that robustly organized network of fibroblast, fibronectin, and collagen. The fibroblast pool is replenished by means of chemotaxis, which is promoted by various growth factors.

Fibronectin is later replaced by collagen, which continues to occupy more and more space and grows more robust. When type III collagen is replaced by type I collagen, tissue robustness considerably increases. The tissue in a completely formed scar is 70% more robust than undamaged skin [2].

### 3 SCARS: TYPES AND SPECIFIC FEATURES

As is known, the scar formation process depends on the depth of the injury, extent of infection, type of surgical treatment, site of the injury, individual bodily differences, time frames and types of scar treatment, and many other factors. Skin scars include the following features:

- a variety of clinical manifestations, depending on injury-specific features and the treatment received, location of the damaged skin area, the age of the scar, immune status, etc.;
- polymorphism in scar histological structure, as well as in adjacent areas.

Four basic types of skin scars are known:
- normotrophic
- hypertrophic
- atrophic
- keloid.

However, in the view of a number of researchers, several scar tissue types are often found side by side within the same scar [1].

The most serious problems emerge in patients when pathologic hypertrophic and keloid scars are formed. A hypertrophic scar – thick, erythematous bundles of connective tissue typically raised above the skin surface – remains within the confines of the original traumatic wound. In contrast, a keloid scar consists of an overgrowth of fibrous scar tissue spreading beyond the confines of the initial injury. By some estimates, about 10% of the human population suffers from those two scar types [2].

The reasons for surplus scar growth are known. They include genetic predisposition, long-standing wounds with marginal epithelialization, and wound suppuration [3]. Usually hypertrophic and keloid scars are formed on those body sections where the wound healing process is slow (e.g., at the anterior chest wall) or in the areas subjected to frequent movements, such as a scapula, an elbow, or a knee. However, in recent years, due to the increasing popularity of various rejuvenating surgical and cosmetic procedures (e.g., laser skin exfoliation), there has been in increase in the number of cases in which hypertrophic scars develop on the face. All of this makes the problem of pathologic scar treatment and prevention a topic of urgent interest.
A scar is known to pass through several phases during its maturation [3]. They include:
- intensive growth
- plateau
- regression
- a mature scar

Distinct treatment goals must be set [4, 5] at different phases of scar maturation.

The following goals should be striven for during the intensive growth phase:
- reduction of proliferative and fibroblast biosynthetic activity
- extracellular matrix destruction
- blood supply reduction, capillary dropout
- removal of stimulatory factors (the use of drugs and procedures having an “irritating” effect, increasing the blood supply and elevating metabolism, must be avoided)

In the plateau phase, the following must be ensured:
- reduction of fibroblast biosynthetic activity
- extracellular matrix destruction;
- blood supply decrease, capillary dropout.

In the regression phase, the best tactic is to not disturb the natural process of scar remodeling. The prevention of any future atrophy of the tissues is also required at this time.

Finally, in the long-term phase, when the scar has matured, efforts should be focused on:
- removing present functional and esthetic flaws
- increasing fibroblast biosynthetic activity
- extracellular matrix recovery
- blood supply promotion

So, for successful scar treatment, the precise stage of its formation must be identified, which is not always possible in practice.

Currently, there is no uniform opinion on the mechanism by which scar tissue develops and, consequently, there is no uniform scar treatment regimen. Recently, hypertrophic and keloid scar treatments have included various pharmacological and physical therapy procedures, such as cryogenic surgery, radiotherapy, compression therapy, silicone gel sheeting, laser therapy, surgical resection, topical use of steroids and other external treatments [6, 7].

However, they often have a relatively low degree of efficacy. A recurrent course of the process is something that remains a frequent occurrence, patient satisfaction with the results is not high, and many patients are unhappy due to increased erythema. In many cases, drugs are administered irrespectively of the type and phase of scar development, and multiple drugs are used at the same time, with no consideration made for their mechanism of action or the scar maturation phase. So, despite an abundance of modalities and procedures to treat scars, we are a long way off from finding a solution to the problem.

**Healing Pathologic Scars: Kelo-Cote Silicone Gels**

A burn specialist, in contrast to doctors representing other surgical and trauma care specialties, has to deal with patients who have large areas of damaged skin with a varied depth of damage, due to which their subsequently developing scars are varied in type and nature. This requires the doctor to have know-how in the use of various scar treatments in actual practice.

Each year new drugs that promote scar growth reduction appear in the market. Today, more than 30 drug and cosmetic products are described as having “scar treatment activity” in their package inserts. Those products can be conditionally divided into several groups [3–7]. They include products promoting blood supply (which is not always justified in the scar growth phase) and a variety of enzyme products (it is necessary to know the scar’s structure at a specific phase of its development in order to use them effectively).

However, the basic principles of scar treatment in all phases of its maturation are represented by the creation of a moist wound environment and compression. These are the very properties possessed by silicone products [8–10], which are now included in international standards for scar treatment. The therapeutic action of silicone products is based on the positive effect on the wound surface by the electrostatic charge retained on the surface of the coating.
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[Hirschowitz [sic], 1993, Amicucci G., 2005], and on their ability to hold moisture, which promotes epidermal hydration [11, 12]. Thus, silicone promotes both scar moisturizing and compression, which is so necessary in all phases of scar tissue development.

In Russia, the product group is rare and not yet very well known. It includes silicone dressings, silicone sheets and, effective November 2009, another silicone-based product has been introduced on the Russian drug market, the Kelo-Cote (aerosol) gel (by Advanced Bio-Technologies, USA), which we now use in patients with burn sequelae.

Kelo-Cote silicone-based gel is designed for treating hypertrophic and keloid scars. According to the manufacturers' information, it binds firmly to the epidermis, prevents chemical, physical and bacterial agents from contacting the wound surface, and ensures that a normal level of skin moisture is maintained. The microenvironment formed by the gel film positively affects collagen synthesis and does not allow the scar to grow, which improves its outward appearance.

Kelo-Cote is available as a gel and an aerosol (spray). A thin layer is applied to the wound surface once a day to form a clear film. Its application is cost-effective – one drop can be sufficient for the film to cover 100 cm² of skin area; the drying time is 4 or 5 minutes. However, the gel is washed off by water and should therefore be applied after hydrotherapeutic procedures. It is hypoallergenic. An additional advantage is that after Kelo-Cote dries, sunscreen products and even make-up can be applied to the treated skin area.

5 MATERIALS AND PROCEDURES

Our clinical studies were focused on measuring the efficacy of the Kelo-Cote product in hypertrophic and keloid scar treatment. For 10 months (from November 2009 to September 2010), we were applying Kelo-Cote in patients with post-burn, post-traumatic, post-necrotic, and post-surgery scars of various locations. The patients were aged from 6 months to 57 years. (Unfortunately it is not possible to estimate the total number of those patients who used Kelo-Cote according to our recommendations, as many patients of the state-owned health care facility do not return for follow-up examinations.)

The gel was administered during different scar growth phases – both during the first month after wound epithelialization and at one year after the injury occurred. The product's use is started after complete skin epithelialization and adaptation have taken place, i.e., after the patient has been discharged from the hospital. It is applied one or two times a day after a bath has been taken (or after the hands have been washed) if there are large areas of damage – primarily on functional areas (joints) and exposed body areas.

The duration of product use and patient observation varied from 2 to 10 months; the application surface area varied from 10 to 750 cm². During examinations of the damaged surface areas, the presence of erythema, scar elevation above the skin level, and the degree of scar softening were evaluated.

None of the examinations revealed negative reactions, such as itching, allergy, or scar tissue growth.

6 CASE STUDIES

We would like to illustrate the results of our observations with several illustrative case studies.

1. Patient N., a 45-year-old male (Fig. 1). The patient sought medical care at the clinic 10 days after a IIIa-IIIb-degree burn of the upper right extremity (total body surface area of damage – 1.5%). The examination revealed a moist eschar, especially along the wound edges. The treatment took two steps. At Step 1, the patient had wound debridement and repair with autologous tissue grafting. The patient was discharged 10 days after the surgery. The wound was epithelialized and the skin graft was successful.

A week after discharge the patient, following our recommendation, began applying Kelo-cote gel...
Fig. 1. Patient N., a 45-year-old male, skin damage on the right arm following a IIIa-IIIb-degree burn (1.5%). View of the wound area 10 days after the injury (eschar sequestration) prior to debridement and autologous tissue reconstruction (a); the treatment result 7 days after the surgery, before discharge (b); a week after discharge, in the period of increased blood supply and scar growth, the photos show minimal areas of increased blood supply (c, d). Six months after wound epithelialization (or 5.5 months after the start of Kelo-Cote use) the scars have disappeared, only the autograft area is slightly visible (e, f).

twice a day after taking a shower. No other scar treatment products were used, no compression dressings were applied, and no physical therapy procedures were performed.

Six months after wound epithelialization, (5.5 months after Kelo-Cote application started), that is, at the standard peak of scar tissue growth, no scars are identified and only the relief pattern of the autologous tissue graft is slightly noticeable. Full-range joint motion. Scar treatment has been discontinued.

2. Patient A., a 1.5-year-old female (Fig. 2). The patient was admitted to the clinic 4 weeks after a II-IIIa-degree boiling water burn (total body surface area of damage 7%) and 10 days after epithelialization. Scar monotherapy included Kelo-Cote aerosol (applied once daily after a bath before going to bed); no physical therapy was carried out. Only one spray container of the drug was required to complete the treatment. After 2.5 weeks, there are no scars present on the skin; pigmentation is barely visible. A positive functional and cosmetic result was achieved.

3. Patient L., a 28-year-old woman (Fig. 3). She was admitted to the clinic 4 months after discharge from an inpatient facility, where she had been receiving treatment related to IIIa–IIIb-IV-degree electrical burn injuries (total body surface area of damage 59%, area of full-thickness burns 41%). In the acute post-traumatic period, the patient was receiving general and topical intensive care, including early excisions with primary and delayed skin grafting. At the time she was admitted to our clinic, the period of active hypertrophic scar growth was seen, especially in the sternal area, where such scarring is most prone to form. Hypertrophic scars are noted both in the sternum area, and on the anterior abdominal wall. Considering the large area of the damage, the presence of damage on an exposed area of the body at the sternum, and economic factors, the patient was recommended to use Kelo-Cote gel only on the skin of the sternum – the area most prone to form scars.

The patient was applying one drop of Kelo-Cote twice daily to the chest area for three months, using only two 15-gram tubes.
No physical therapy was administered. Kelo-Cote gel was not used on the anterior abdominal wall, where skin is less prone to pathologic scarring; instead, fats of animal origin and other scar treatment products were used.

By the end of 3 months, the scar in the sternal area was visibly reduced. On the anterior abdominal wall, however, where Kelo-Cote gel had not been applied, there was no stabilization seen even 7 months after the burn injury, and the scar was continuing to grow.

4. Patient S., a 20-year-old female (Fig. 4). The patient came to the clinic 1.5 months after an injury in the brachial region and in the interior surface of the elbow joint, resulting from a motor vehicle accident.

She complained that a hypertrophic scar had developed. The brachial wound was avulsive, with celloidin flaps and subcutaneous flaps; primary sutures were overlaid. The elbow joint had been given skin autografting at 19 days after the injury occurred, after post-injury granulation tissue had formed. Since the time the patient was discharged, she had been receiving compression therapy.

We administered Kelo-Cote alone, both as a gel and a spray. No physical therapy procedures were performed. Compression therapy was also

Fig. 2. Patient A., a 1.5-year-old female, “evening tea” sequelae. Appearance 4 weeks after a boiling water II-IIIa-degree burn (7%) (10 days after epithelialization) (a, b) and 2.5 weeks after Kelo-Cote aerosol application (c, d). No scars, pigmentation is slightly visible.
5. Patient V., a 25-year-old female. She was admitted 3 days after a 2% IIIb-IV-degree flame burn. The treatment was carried out in two steps. At Step 1, early excision was performed with primary autografting (2%). The Kelo-Cote treatment course started one week after discharge. No other treatment procedures were used.

Seven months after the burn injury, or following 6.5 months of Kelo-Cote gel treatment without compression garments, no scar growth was present and movement in the joints was fully recovered.

6. Patient I., a 2-year-old male. He was admitted 3 months after a plastic surgery repair with perforation (mesh expansion ratio 1:2) had been performed on the chest, following a boiling water burn. As of the time of admission, a hypertrophic scar was actively forming in the middle of the transplanted skin graft; glenohumeral joint abduction was difficult. Other scar treatment products and animal fats had been used after the plastic surgery.

The patient was administered a course of Kelo-Cote applications. The gel was applied for 3 months. By the end of that period, positive changes were observed in the injury area. The scars had become softer, paler, with less elevation above the healthy skin surface. The right glenohumeral joint is fully abductable. The treatment is being continued.
Fig. 4. Patient S., a 20-year-old female, motor vehicle accident sequelae.
Appearance at 1.5 months after the injury – there is hypertrophic scar formation (a, b), and at 5 months after the treatment was started with Kelo-Cote gel and aerosol (c, d). A flat scar has formed on the upper arm; mobility in the elbow joint is completely recovered.

Fig. 5. Patient V., a 25-year-old female, a flame burn, 2% IIIb-IV-degree. Appearance 7 days after early excision with primary plastic surgery (2%) (10 days after the burn injury) before discharge (a), one month after discharge, or 3 weeks after Kelo-Cote treatment was started (b, c), and at 6.5 months after Kelo-Cote gel use without a compression garment (d, e). Scar growth is absent, movement in the joints is completely recovered.
Fig. 6. Patient I., a 2-year-old male, boiling water burn sequelae. Appearance 3 months after plastic surgery repair of the chest, with a mesh ratio of 1 to 2: a hypertrophic scar is present in the center of the transplanted skin graft, there is difficulty with glenohumeral joint abduction (a–c). Appearance 3 months after Kelo-Cote gel application: softer, paler scars are seen, their elevation above the healthy skin surface is reduced, and the right glenohumeral joint is fully abductable.

Fig. 7. Patient K., a 4-year-old male, IIIa-IIIb-IV-degree flame burn 59% (47%). Appearance one month after discharge from an inpatient facility. Various types of scars, contractures in major joints (a, b). View of dermal surface at 3 months (c, d), 6 months (e) and 9 months (f) after Kelo-Cote gel treatment. At the end of this treatment stage, the scar tissue is soft, the knee joint contracture has not progressed and, instead, has been regressing, and the full range of motion has been restored at the dorsum of the hand.
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7. Patient K., a 4-year-old male. The patient came to our clinic one month after discharge from an inpatient facility. Flame burn sequelae 59% (47%), a IIIa-IIIb-IV-degree burn. During the accident, the patient also received heat inhalation injuries; as a result, he was given artificial lung ventilation (ALV) for a period of one month. Due to his age, donor graft shortages, psychoemotional state, scar treatment posed difficulties (wearing compression garments, removable splints, massage, etc.). Various types of scars and contractures of the major joints were forming.

Kelo-Cote was administered to the hand and the right knee joint. After 9 months (h–l) of gel treatment, the scar tissue was soft. As the patient grew, the knee joint contracture did not progress, rather, it was in regression; full range of motion was restored on the dorsum of the hand. The treatment is being continued.

7 FINDINGS

1. Kelo-Cote silicone gel (aerosol) use in patients with post-burn, post-traumatic, post-necrotic and post-surgical dermal injuries and scars results in the rapid reduction of erythema and scar height, improves the moisture content and elasticity of skin in damaged areas, significantly prevents hypertrophic and keloid scar development, and makes it possible to restore the flexibility of flexor surfaces.

2. Kelo-Cote is a user-friendly product, does not cause allergic reactions, and is effective in all phases of scar growth.

3. The product is cost-efficient – one 15-gram tube is sufficient for a 2-month treatment of post-surgical or post-traumatic scars up to 10 cm long.

4. In burn patients with large surface areas of damage, a specialized approach is required. If complete treatment of all damaged dermal areas with Kelo-Cote is cost challenging, then it should be applied only in the areas of the major joints and on exposed areas of the body.

5. Kelo-Cote silicone gel (aerosol) can be recommended for wide-scale use in outpatient treatment settings.

References