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Training Manual

Module 3

The intended use of Kelo-Cote is for the management of old and new hypertrophic and keloid scars resulting from general surgical procedures, trauma, wounds and burns.

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Job bag no. AL/3010/11.17/0.001.

Date of preparation: March 2018



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An Overview of Kelo-Cote



OBJECTIVES

At the end of this session, you should be able to:

- Explain how Kelo-Cote works
- Summarise the key clinical data for Kelo-Cote in the prevention and treatment of excessive scarring
- Describe the Kelo-Cote product range



HOW KELO-COTE
WORKS

KEY CLINICAL DATA

PRODUCT
RANGE

SUMMARY

QUIZ

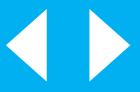
REFERENCES



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How Kelo-Cote Works



WHAT IS KELO-COTE?

Kelo-Cote is a patented silicone gel that is used for the prevention and management of excessive scarring¹



KELO-COTE
SCAR TREATMENT

HOW KELO-COTE
WORKS

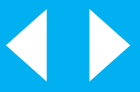
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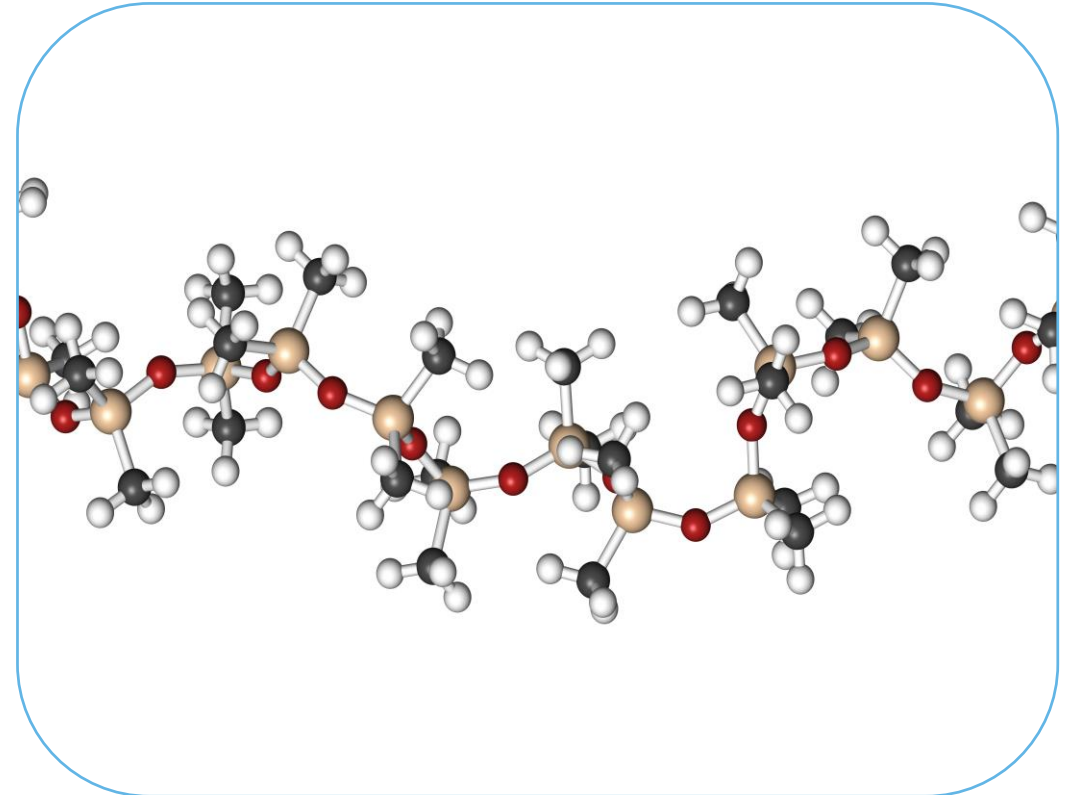
REFERENCES



CONSTITUENTS OF KELO-COTE

Proprietary mixture of:²

- Long-chain silicone polymers (polysiloxanes):
 - Provides the structure of Kelo-Cote and filler
- A volatile silicone component:
 - Evaporates across a temperature gradient when applied to the skin
 - Allows faster drying than products containing silicone oil
- Silicon dioxide:
 - Cross-links the long-chain polysiloxanes into a gel sheet
 - Associated with rapid drying





PROVIDING A BARRIER AGAINST THE ENVIRONMENT

- Upon application of a very thin layer of Kelo-Cote to the skin:^{1,3,4}
 - It dries within minutes to form a transparent, durable, flexible, gas-permeable, water impermeable silicone sheet
 - Although silicone polymers are oils that can take a long time to dry, the patented formulation of Kelo-Cote facilitates self-drying

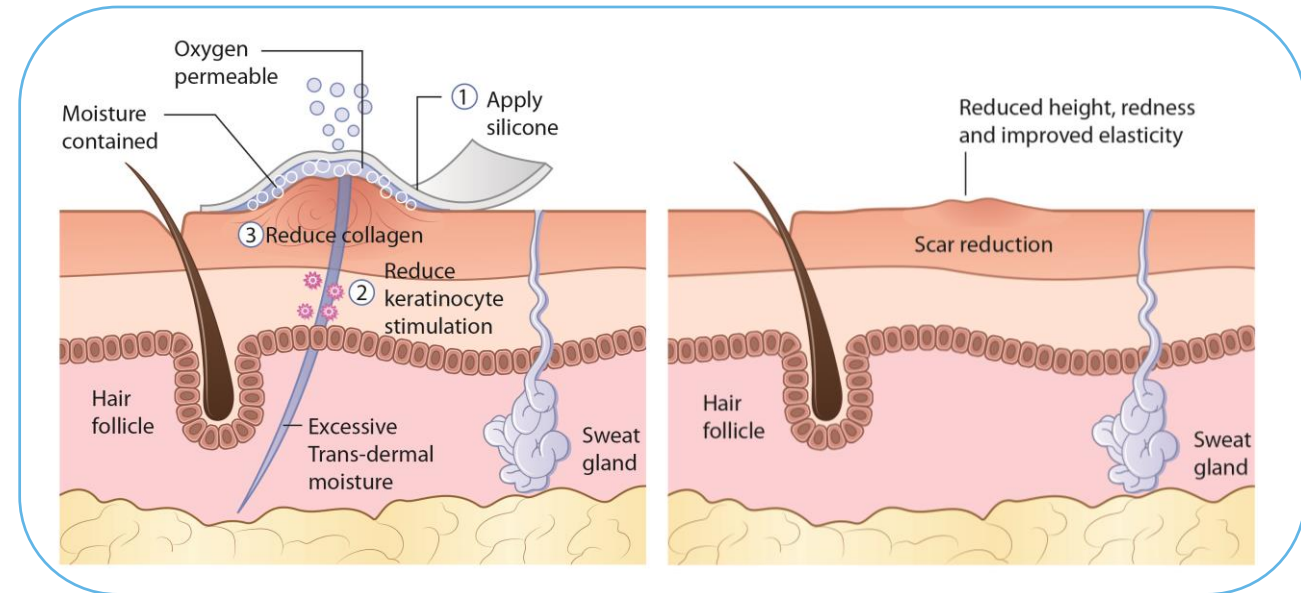


Illustration taken from Kelo-Cote UK website



HOW DOES KELO-COTE WORK IN SCAR MANAGEMENT?³

- Treatment of the wound or scar with Kelo-Cote restores the barrier function of the stratum corneum, reducing transepidermal water loss and turning off the stimulation of keratinocytes, thus inhibiting dermal fibroblasts and halting collagen production³
- After 2-3 months of Kelo-Cote treatment, collagen deposition has normalised, and scar hypertrophy is reduced³



Adapted from <http://biodermis.com.au/how-does-silicone-improve-scars/>



KEY BENEFITS OF KELO-COTE

Spray for large or sensitive areas such as burns

1st line treatment in scar guidelines⁵

SPF 30 protection

Highly rated by patients⁵



Clinically proven formula¹

Self-drying within 5 minutes, increasing compliance⁴

Efficacy of sheets but more convenient to use³

24 hour protection^{6,7}

Silicone gels and sheets are the “gold standard” non-invasion therapies for the prevention and treatment of abnormal scarring⁸



HOW KELO-COTE WORKS

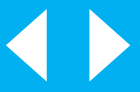
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THE HISTORY OF KELO-COTE

- Kelo-Cote (ABT), Dermatrix (Valeant) and Scarfade (Hanson) are all topical silicone gel treatments
- Prior to mid-2007, the formulations of Dermatrix and Kelo-Cote were identical (polysiloxanes, silicon dioxide) as both were manufactured by ABT
- During 2007, the agreement between ABT and Valeant ended
- Valeant then contracted with Hanson Medical, Inc., to manufacture Dermatrix using a different formulation, the one that Hanson sells as Scarfade (only in US)
- The current Dermatrix formulation is composed of polysiloxanes and dimethicone (a type of silicone oil)
- The original formulation of the Kelo-Cote brand has not changed since issue of the US patent on April 21, 1998



Valeant Pharma



ABT



Hanson



KELO-COTE
SCAR TREATMENT

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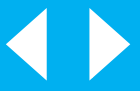
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Key Clinical Data for Kelo-Cote



KELO-COTE IN THE PREVENTION OF EXCESSIVE SCARRING¹

- 160 patients
- Prospective, randomised, parallel-group comparison study with 2 arms:
 - 80 patients with Kelo-Cote (72 completed study)
 - 80 patients had no treatment unless they showed signs of hypertrophy (76 completed study)
- Main cause of surgery: benign or malignant skin lesions needing excision
 - Also included: scar revision and cosmetic surgery (breast augmentation and reconstruction)
- Twice-daily Kelo-Cote treatment compared with no treatment, from 10 days to 3 weeks after surgery, for 4 months
- Patients were evaluated using a 4-grade scale over 6 months of treatment



HOW KELO-COTE
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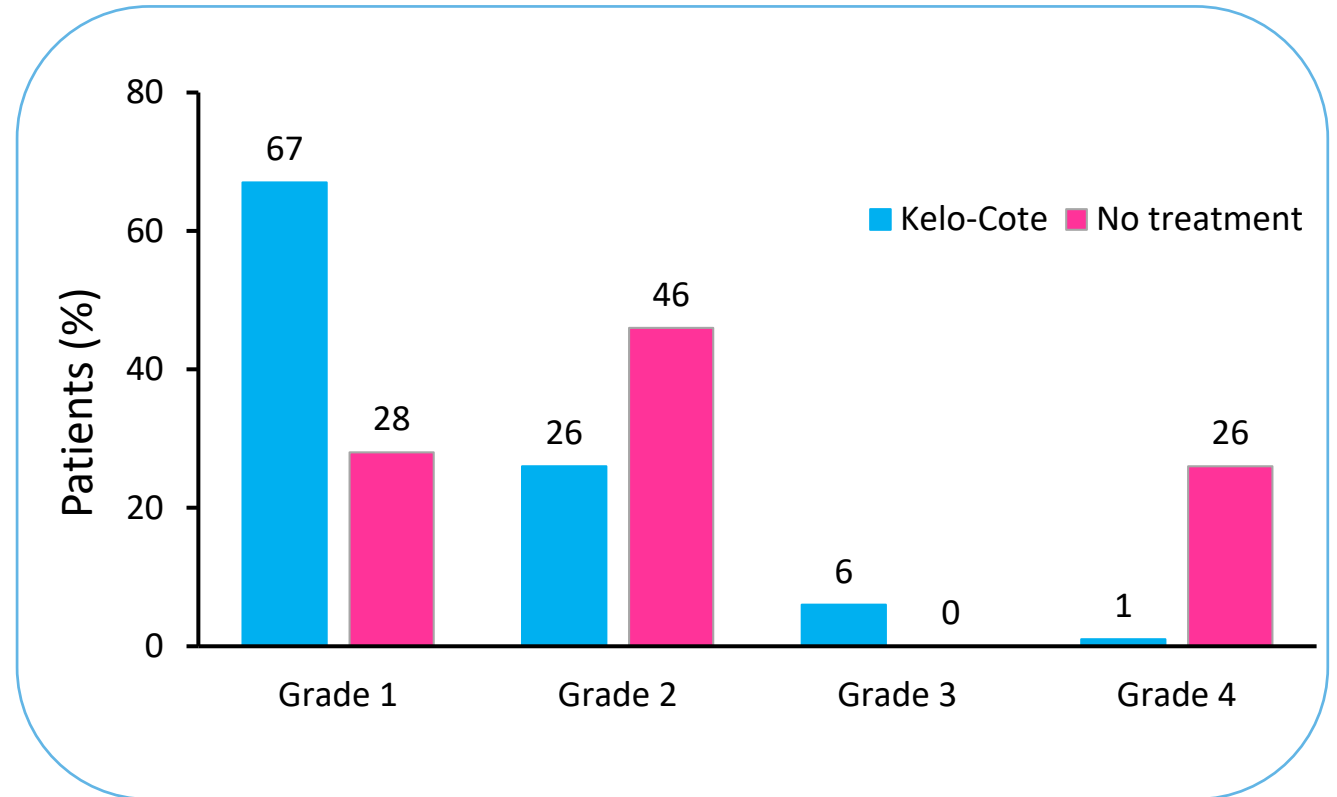
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REFERENCES



PREVENTION OF EXCESSIVE SCARRING WITH KELO-COTE

- Two-thirds of patients who used Kelo-Cote did not develop excessive scarring after 4 months of treatment¹
- A further 26% developed only mildly hypertrophic scars¹
- 26% of patients who received no treatment developed keloids¹



Data adapted from Signorini M, et al. Aesth Plast Surg 2007;31:183–187.

Grade 1: normal; Grade 2: mildly hypertrophic; Grade 3: hypertrophic; Grade 4: keloid



HOW KELO-COTE
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KELO-COTE SPRAY AND COMPRESSION⁸

- 43 patients with two comparable areas of split-thickness grafted burn wounds
 - 38 patients completed 18 months of follow-up
- Single-centre, randomised controlled trial, intraindividual comparison
- Two treatment groups:
 - Compression garments + Kelo-Cote spray vs. compression alone
 - Compression garments + silicone gel sheeting vs. compression alone
- Treatment lasted for 12 months
- Outcome measures: Vancouver Scar Scale, scar redness and height
- Long-term follow-up for 18 months



HOW KELO-COTE
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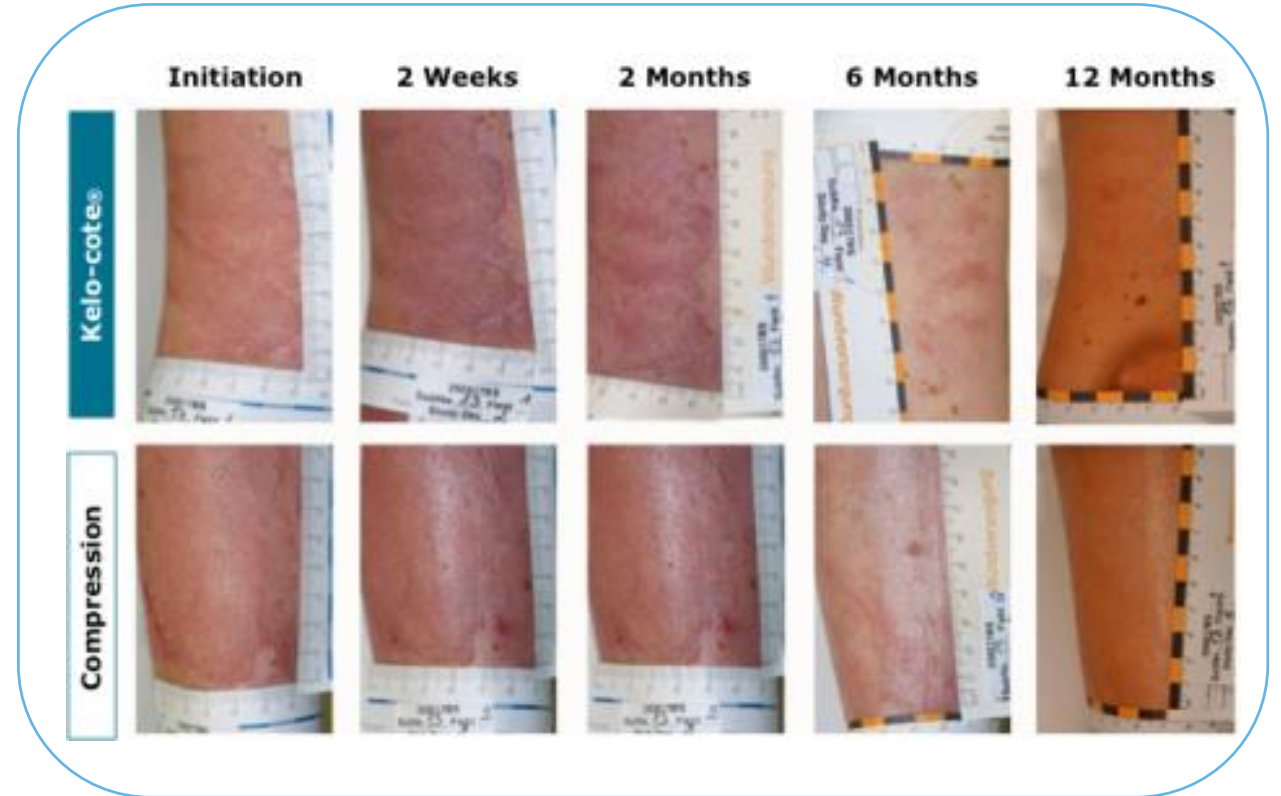
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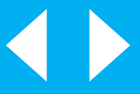
REFERENCES



KELO-COTE ADDED TO COMPRESSION⁸

- The addition of Kelo-Cote spray to compression in burns patients achieved a smooth outcome
- However, there was no additional benefit of using Kelo-Cote spray in combination with compression compared with compression alone
- Kelo-Cote achieved comparable results to the gel sheeting
- However, there were fewer side effects in patients using Kelo-Cote spray compared with silicone sheeting





TREATMENT OF EXCESSIVE SCARRING: AN OBSERVATIONAL STUDY⁹

- Evaluation carried out in Germany, Austria and Switzerland between May 2003 to January 2005
- 1522 patients with hypertrophic scars or keloids (92% were scars aged <3 months)
- Study period 2-6 months (maximum 10 months)
- Evaluations made by dermatologists and patients
- Key evaluation parameters:
 - Scar colour compared to surrounding skin
 - Height and pliability of scars
 - Pain, tenderness and itchiness of scars
 - Each parameter was rated none, mild, moderate or severe
- Initial physician evaluation was conducted after the first 3 months of treatment



HOW KELO-COTE
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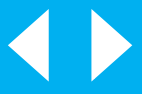
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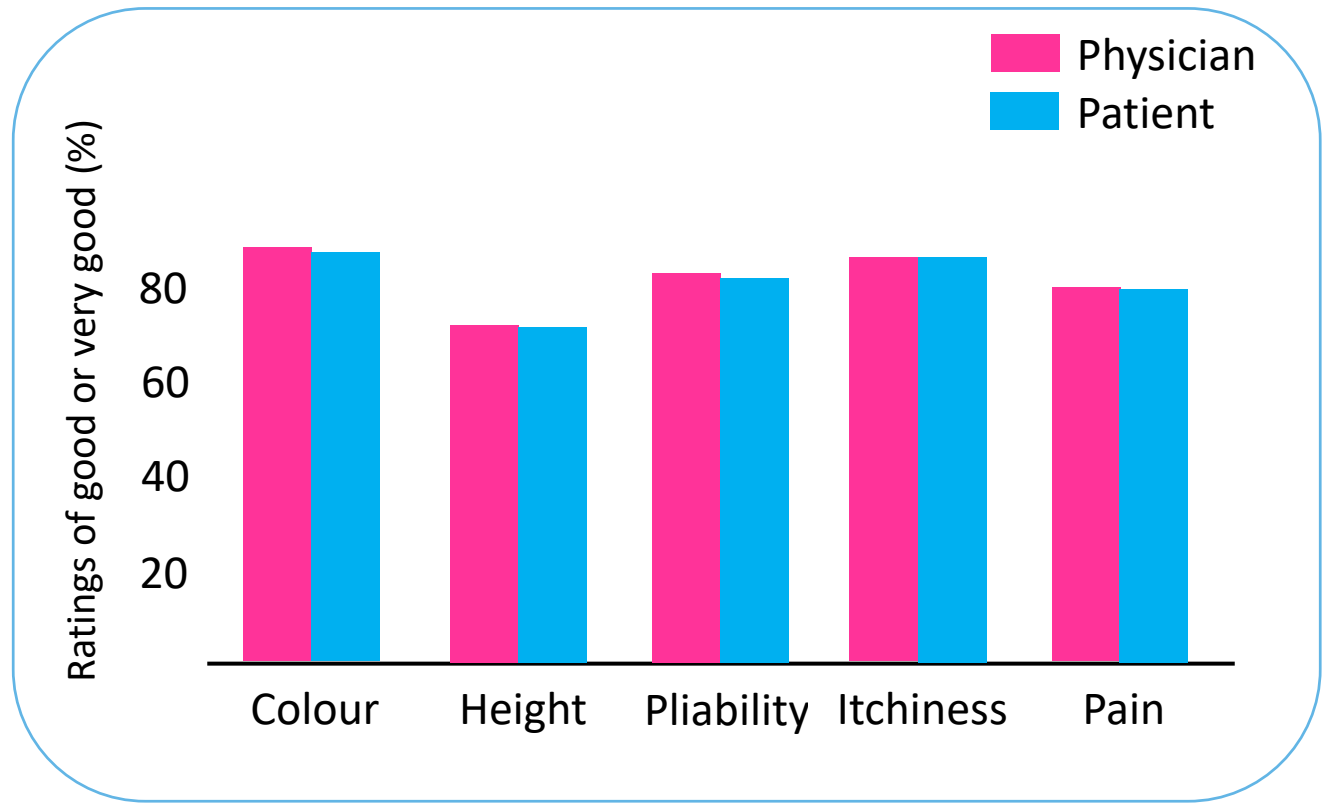
QUIZ

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TREATMENT OF EXCESSIVE SCARRING⁹

- Improvement of each scar symptom was rated good/very good by 70-84% of physicians and by 70-85% of patients
- Good or very good overall effectiveness was the outcome according to 83% of physicians and 81% of patients
- 99% of physicians and 98% of patients felt that the tolerability of Kelo-Cote was good or very good



Adapted from Sepehrmanesh M. Komp Dermatologie 2006;1:30-32.



HOW KELO-COTE WORKS

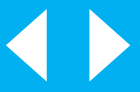
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KELO-COTE VS. SILICONE GEL SHEETING¹⁰

- Randomised study in 140 patients with bilateral early hypertrophic scars or keloids
- For each patient, one scar was treated and the other left untreated
- Each patient was assigned to one of three groups:
 - Kelo-Cote applied morning and evening
 - Silicone gel sheeting applied every day and left in place during the morning and night
 - Kelo-Cote applied in the morning and silicone gel sheeting applied at night
- Evaluations included redness, height and softening of the scars



HOW KELO-COTE
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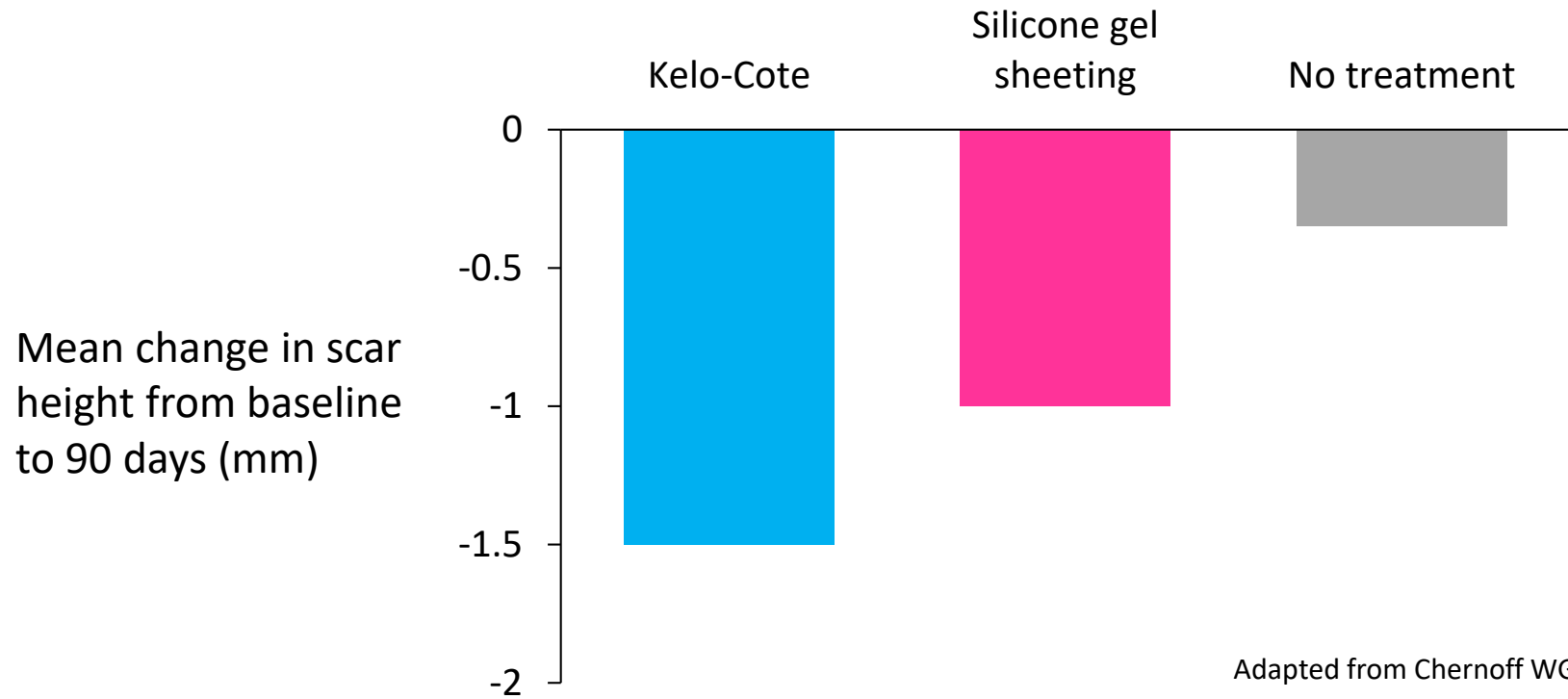
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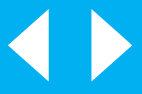
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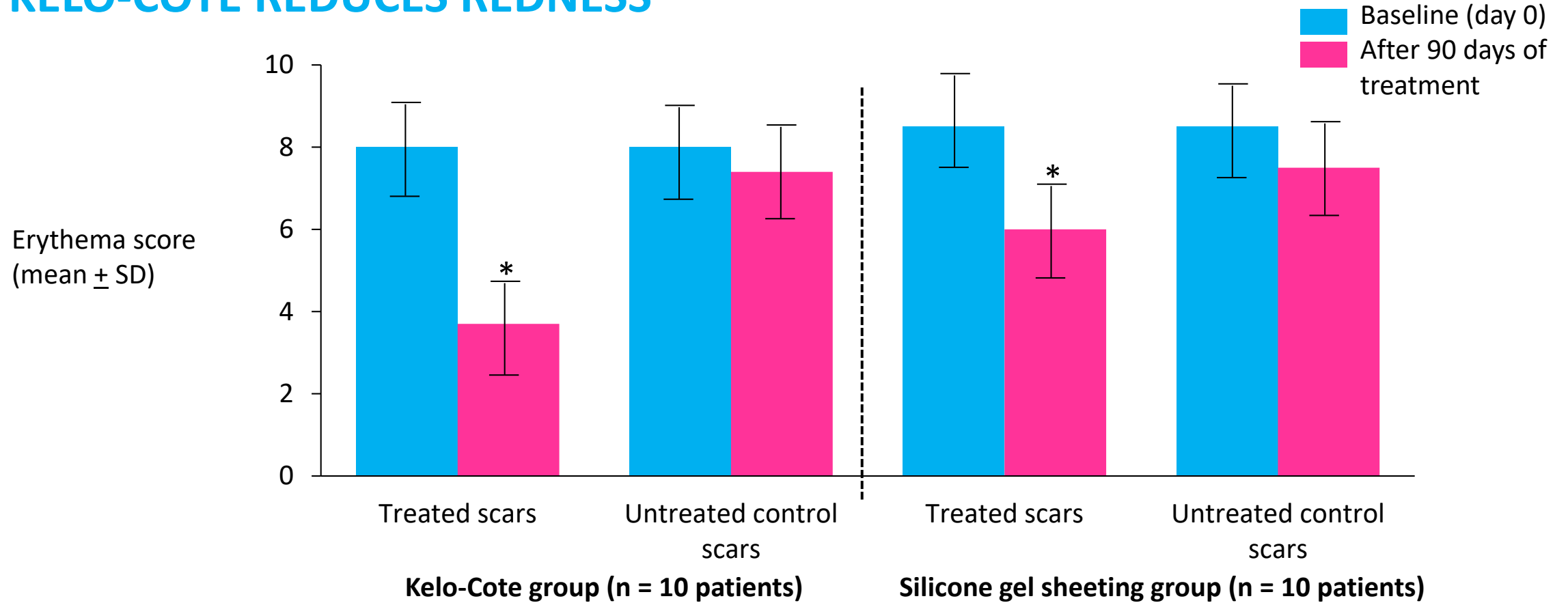
KELO-COTE REDUCES SCAR HEIGHT

Kelo-Cote reduced scar height by a greater amount than silicone gel sheeting or no treatment¹⁰





KELO-COTE REDUCES REDNESS¹⁰



*p ≤ 0.001 vs. no treatment
 Symptoms rated on a visual analogue from 0 (none) to 10 (worst)

Adapted from Chernoff WG, et al. Aesth Plast Surg 2007;31:395–500.



HOW KELO-COTE WORKS

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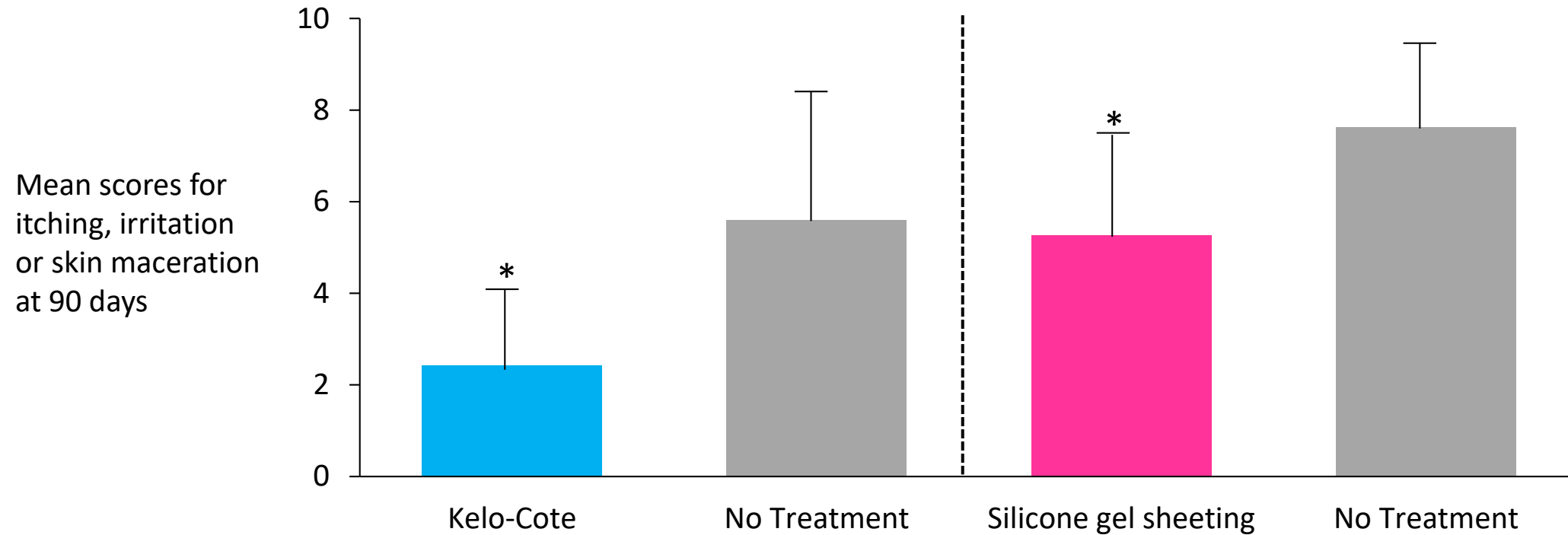
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KELO-COTE REDUCES SYMPTOMS¹⁰



* $p \leq 0.001$ vs. no treatment

Symptoms rated on a visual analogue from 0 (none) to 10 (worst)

Adapted from Chernoff WG, et al. Aesth Plast Surg 2007;31:395–500.



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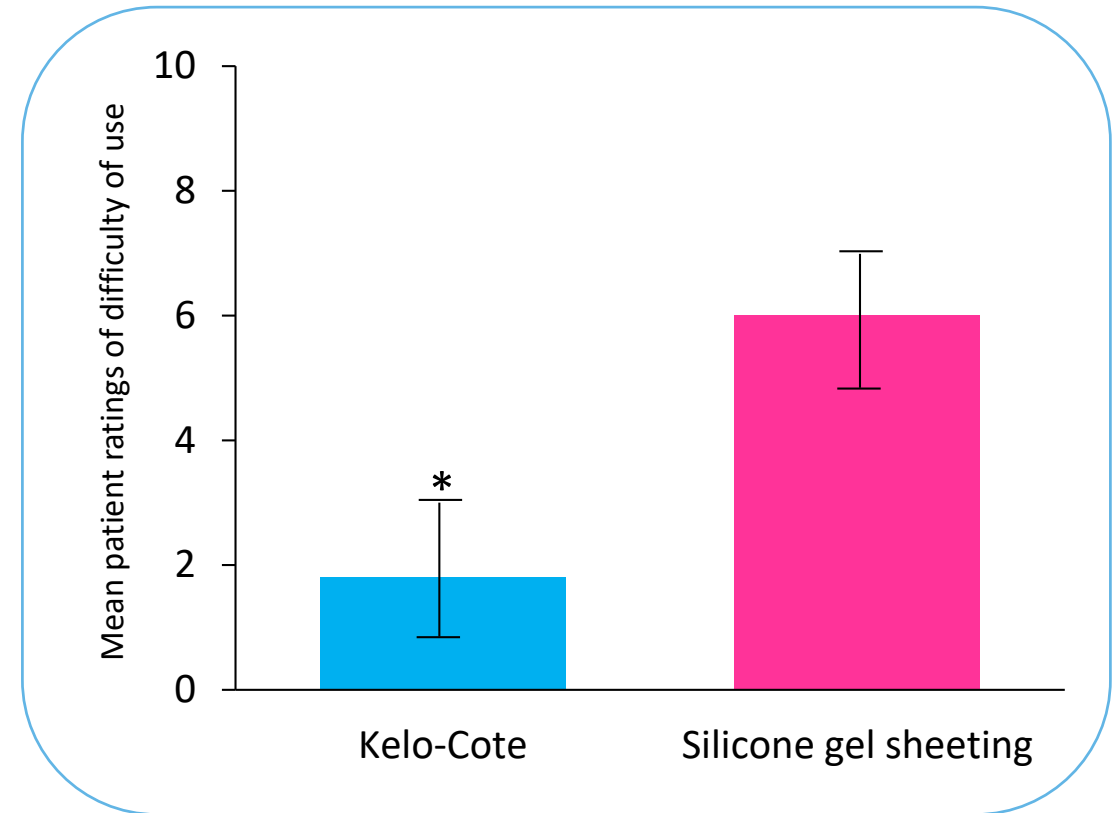
QUIZ

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KELO-COTE IS EASIER TO USE THAN SILICONE GEL SHEETING¹⁰

- Patients stated that Kelo-Cote was far easier to use than silicone gel sheeting
- Kelo-Cote made adhering to their treatment regimen easier than silicone gel sheeting



* $p < 0.001$ vs. silicone gel sheeting
Ease of use rated on a visual analogue from 0 (easy) to 10 (difficult)

Adapted from Chernoff WG, et al. Aesth Plast Surg 2007;31:395–500.



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KELO-COTE IS WELL-TOLERATED¹¹

- Kelo-Cote scar gel was applied to a patch of skin on the backs of 54 healthy volunteers, and covered with an occlusive dressing
- Volunteers were aged 24-68 years and known to have sensitive skin
- Applications were repeated nine times over a 3-week period in order to induce any potential allergy
- After at least 2 weeks without Kelo-Cote, volunteers underwent further application on the previously treated skin site and another that had not been exposed to Kelo-Cote
- The control was an application of distilled water
- The skin at the test areas was examined by study investigators before the first application of Kelo-Cote or control and again after the challenge
- Any patient discomfort was also reported
- **Redness was not apparent in any of the volunteers after application of Kelo-Cote**
- **No volunteers developed an allergy to Kelo-Cote**



HOW KELO-COTE
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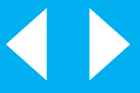
REFERENCES



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The Kelo-Cote Product Range



KELO-COTE SCAR GEL

- Different sizes to match the size of the wound
 - 6 g tube for scars <7.5 cm long
 - 15 g tube for scars between 7.5-10 cm long
 - 60 g tube for scars ≥ 10 cm long



HOW KELO-COTE
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KELO-COTE UV GEL

- Guidelines recommend avoiding exposure of wounds to the sun⁵
- Kelo-Cote UV Gel protects scars from the aggravating effects of the sun
- Kelo-Cote UV Gel contains an SPF30 sunscreen, which is particularly useful for protection of areas of skin exposed to the sun, e.g. face and hands
 - 6 g tube for scars <7.5 cm long
 - 15 g tube for scars 7.5-10 cm long
- SPF30 can absorb up to 97% of UVB radiation¹²



HOW KELO-COTE
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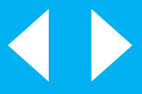
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KELO-COTE SPRAY

- Kelo-Cote Spray is useful for hard-to-reach areas, joints, hairy areas, skin creases and larger wounds such as those caused by burns and trauma
- No need to touch the wound area – more hygienic
- 100 ml spray for wounds up to 100 cm²



HOW KELO-COTE
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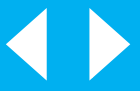
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HOW KELO-COTE IS USED



Kelo-Cote should be used on clean and dry skin as soon the wound is closed, or the stitches have been removed and any scabs have fallen off. Kelo-Cote should not be used on open wounds.



A very small drop of Kelo-Cote is put on the finger and then applied to the wound/scar area, twice a day. Kelo-Cote should not be rubbed into the skin.



Kelo-Cote should be allowed to dry naturally, which usually takes 4-5 minutes. Any excess product that has not dried after 5 minutes should be removed. Once dry, cosmetics and sunscreen can be applied over the treated area.



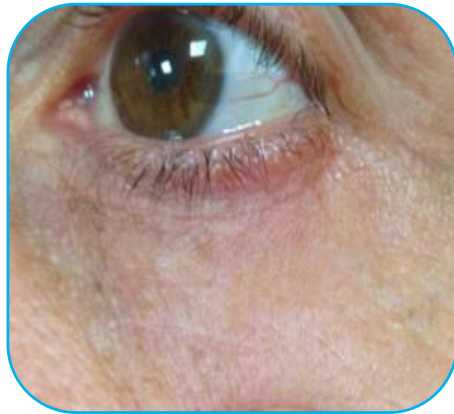
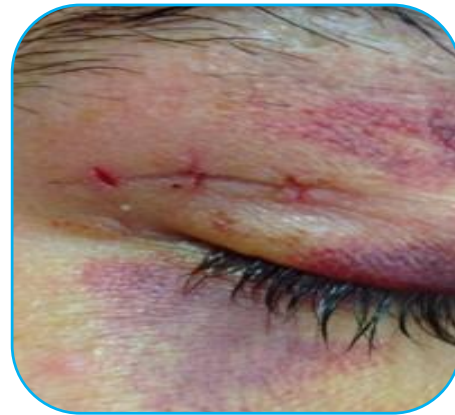
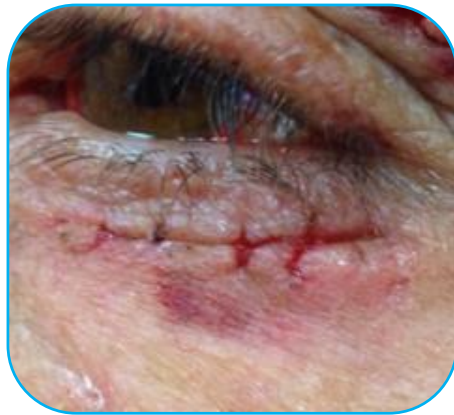
The recommended minimum treatment period with Kelo-Cote is 60-90 days. If improvement still occurs after 90 days of treatment, Kelo-Cote should be continued.



Kelo-Cote is suitable for children and adults, including people with sensitive skin (excluding the UV product).



BEFORE AND AFTER USING KELO-COTE



**Twice-daily
application for
3 months**

Images courtesy of Dr Federico Baietto, maxillofacial plastic reconstructive surgeon, Turin, Italy



HOW KELO-COTE
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Summary



SUMMARY

- Kelo-Cote works to prevent and treat excessive scarring by providing an optimal environment for wound healing, including occlusion, hydration and inhibition of collagen production
- A key clinical study in 160 patients has shown that Kelo-Cote prevents excessive scar formation in two-thirds of patients following surgery
- Although the efficacy of Kelo-Cote in the treatment of scars is comparable to silicone gel sheeting, Kelo-Cote has better tolerability and compliance is better
- Additionally, patients find Kelo-Cote easier to use than silicone gel sheeting
- Kelo-Cote has a portfolio of products to choose from and is supported by published clinical trial data



HOW KELO-COTE
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Quiz Questions



QUESTION 1

In the Signorini study how many patients did not develop excessive scarring with Kelo-Cote application?

- A. 26%
- B. 46%
- C. 67%
- D. 76%



HOW KELO-COTE
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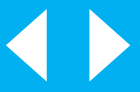
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QUESTION 2

True or false: the 15 g tube of Kelo-Cote is appropriate for the treatment of scars >10 cm in length.

- A. True
- B. False



HOW KELO-COTE
WORKS

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QUESTION 3

How many patients participated in the observational study of Kelo-Cote for the management of excessive scarring?

- A. 1522
- B. 1255
- C. 2521
- D. 1512



HOW KELO-COTE
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QUESTION 4

What is the recommended minimum treatment period for Kelo-Cote?

- A. 10-30 days
- B. 30-60 days
- C. 60-90 days
- D. 90-120 days



HOW KELO-COTE
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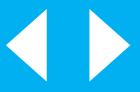
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QUESTION 5

Which of the following is not correct about Kelo-Cote?

- A. It is water impermeable
- B. It is water permeable
- C. It is gas permeable
- D. It is transparent



HOW KELO-COTE
WORKS

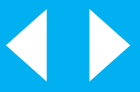
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QUESTION 6

Production of collagen is switched off in what type of cells by Kelo-Cote?

- A. Epidermal fibroblasts
- B. Dermal keratinocytes
- C. Epidermal keratinocytes
- D. Dermal fibroblasts



HOW KELO-COTE
WORKS

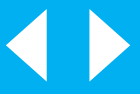
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QUESTION 7

Which component of Kelo-Cote provides its structure?

- A. Silicon dioxide
- B. Polysiloxanes
- C. Silicone oil
- D. Polycarbonate



QUESTION 8

When did the formulation of Dermatix change?

- A. 1998
- B. 2000
- C. 2007
- D. 2015



HOW KELO-COTE
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QUESTION 9

In the patch testing study, how many times was Kelo-Cote or control applied over the 3-week period?

- A. 3
- B. 6
- C. 9
- D. 12



HOW KELO-COTE
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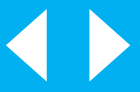
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QUESTION 10

True or false. SPF30 can absorb up to 99% of UVB radiation.

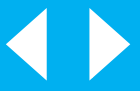
- A. True
- B. False



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Quiz Answers



QUESTION 1

In the Signorini study how many patients did not develop excessive scarring with Kelo-Cote application?

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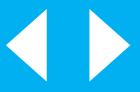
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QUESTION 2

True or false: the 15 g tube of Kelo-Cote is appropriate for the treatment of scars >10 cm in length.

A. True

B. False. It is for scars 7.5-10cm in length.



HOW KELO-COTE
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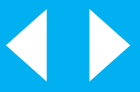
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- B. 1255
- C. 2521
- D. 1512



HOW KELO-COTE
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QUESTION 4

What is the recommended minimum treatment period for Kelo-Cote?

- A. 10-30 days
- B. 30-60 days
- C. 60-90 days**
- D. 90-120 days



HOW KELO-COTE
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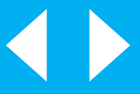
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QUESTION 5

Which of the following is not correct about Kelo-Cote?

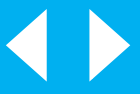
- A. It is water impermeable
- B. It is water permeable**
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QUESTION 6

Production of collagen is switched off in what type of cells by Kelo-Cote?

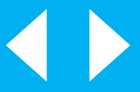
- A. Epidermal fibroblasts
- B. Dermal keratinocytes
- C. Epidermal keratinocytes
- D. Dermal fibroblasts**



QUESTION 7

Which component of Kelo-Cote provides its structure?

- A. Silicon dioxide
- B. Polysiloxanes**
- C. Silicone oil
- D. Polycarbonate



QUESTION 8

When did the formulation of Dermatix change?

- A. 1998
- B. 2000
- C. 2007**
- D. 2015



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QUESTION 9

In the patch testing study, how many times was Kelo-Cote or control applied over the 3-week period?

- A. 3
- B. 6
- C. 9**
- D. 12



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QUESTION 10

True or false. SPF30 can absorb up to 99% of UVB radiation.

A. True

B. False. It can absorb up to 97% of UVB radiation.



KELO-COTE
SCAR TREATMENT

HOW KELO-COTE
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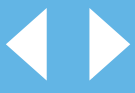
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