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KELO-COTE®
SCAR PREVENTION
& TREATMENT

Training Manual

Module 3

The intended use of KELO-COTE is for the management of old (up to four years of age) and new hypertrophic and keloid scars resulting from general surgical procedures, trauma, wounds and burns.

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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

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How KELO-COTE Works

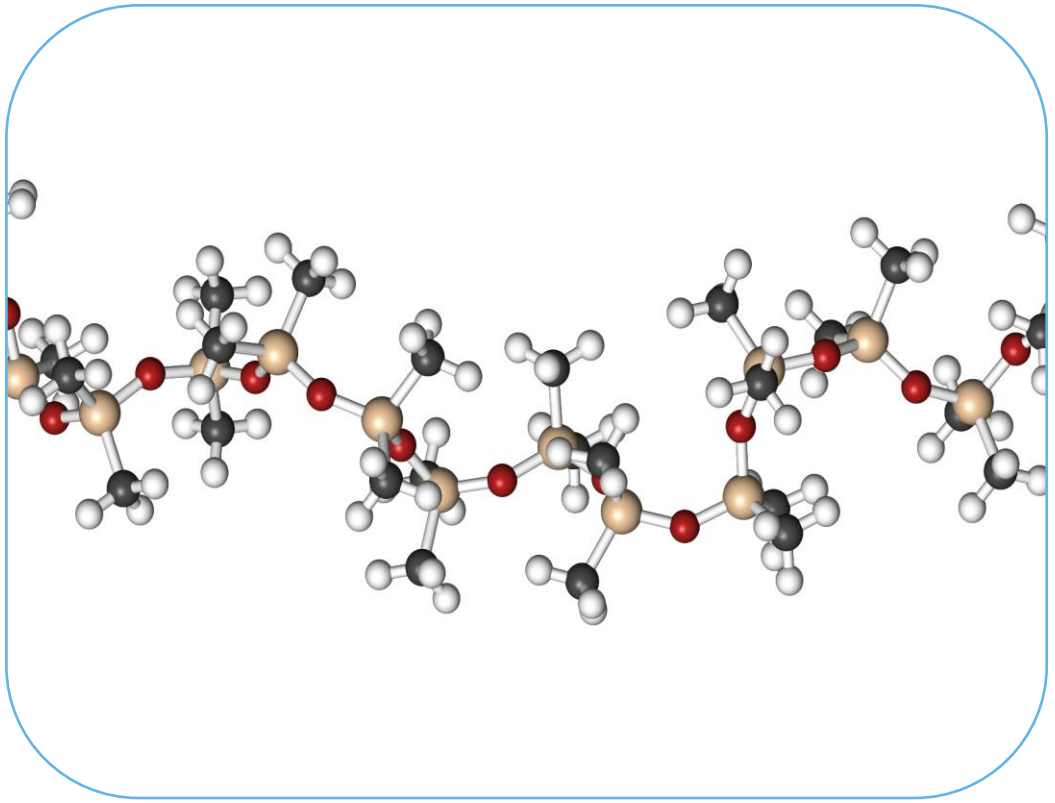
WHAT IS KELO-COTE?

KELO-COTE is a patented silicone gel that is used for the prevention and management of excessive scarring[1]

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

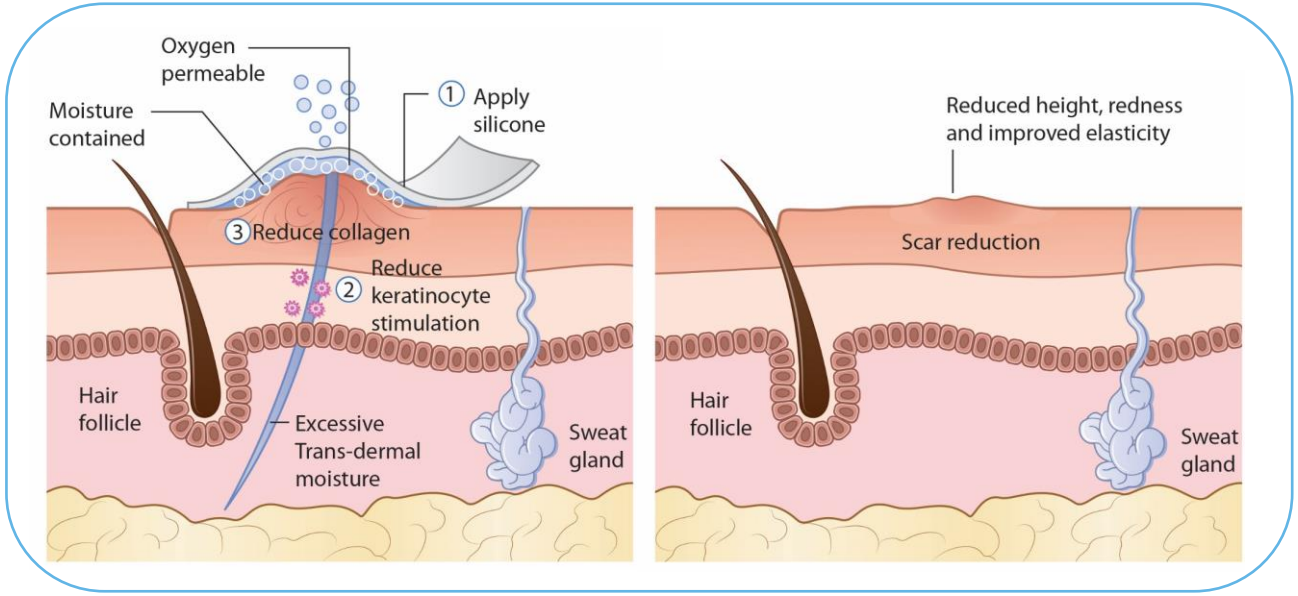


* Data on file, study of 10 subjects. When used in accordance with instructions.

Illustration taken from KELO-COTE UK website

HOW DOES KELO-COTE WORK IN SCAR MANAGEMENT?[3]

- Treatment of the scar with KELO-COTE restores the barrier function of the stratum corneum, reducing transepidermal water loss and turning off the stimulation of keratinocytes, thus preventing dermal fibroblasts from producing excess collagen[3]
- After 2-3 months of KELO-COTE treatment, collagen deposition has normalised, and scar hypertrophy is reduced[3]



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 guidelines[5]

SPF 30 protection (KELO-COTE UV)

Highly rated by patients[5]



Clinically proven formula[1]

Self-drying within 5 minutes,* increasing compliance[4]

Efficacy of sheets but more convenient to use[3]

24 hour protection with twice daily application[6,7]

Silicone gels and sheets are the "gold standard" non-invasion therapies for the prevention and treatment of abnormal scarring[8]

* Data on file, study of 10 subjects. When used in accordance with instructions.

THE HISTORY OF KELO-COTE

- KELO-COTE (ABT), Dermatix (Valeant) and Scarfade (Hanson) are all topical silicone gel treatments
- Prior to mid-2007, the formulations of Dermatix 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 Dermatix using a different formulation, the one that Hanson sells as Scarfade (only in US)
- The current Dermatix 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

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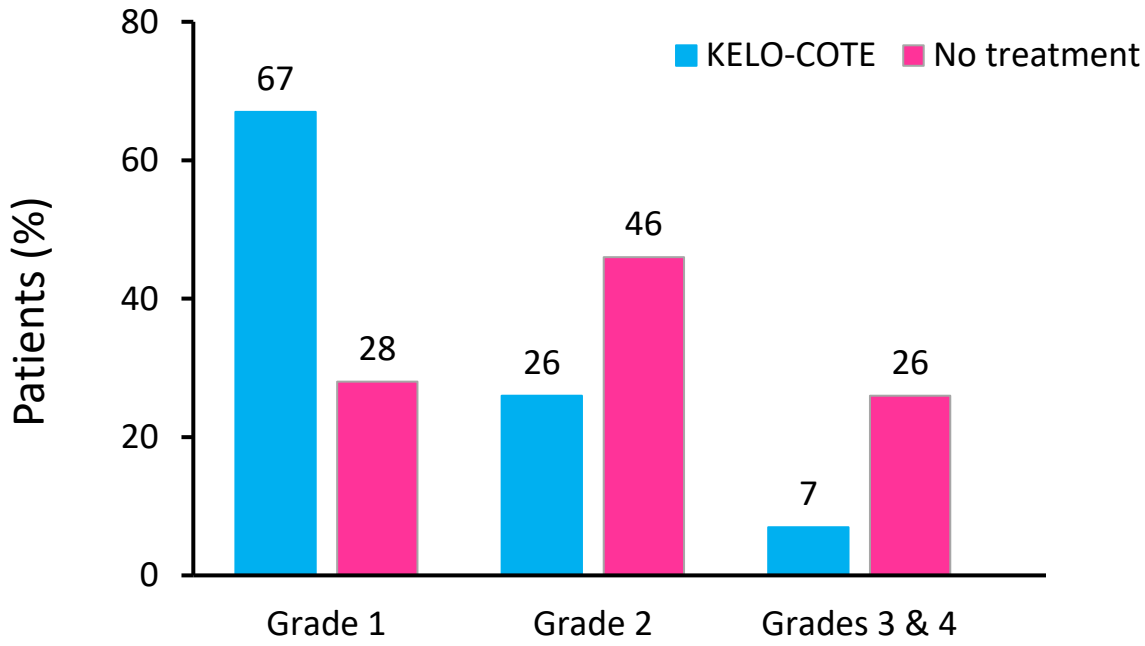
Key Clinical Data for KELO-COTE

KELO-COTE IN THE PREVENTION OF EXCESSIVE SCARRING[1]

- 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

PREVENTION OF EXCESSIVE SCARRING WITH KELO-COTE

- Two-thirds of patients who used KELO-COTE did not develop excessive scarring after 4 months of treatment[1]
- A further 26% developed only mildly hypertrophic scars[1]
- 26% of patients who received no treatment developed hypertrophic and keloid scars[1]



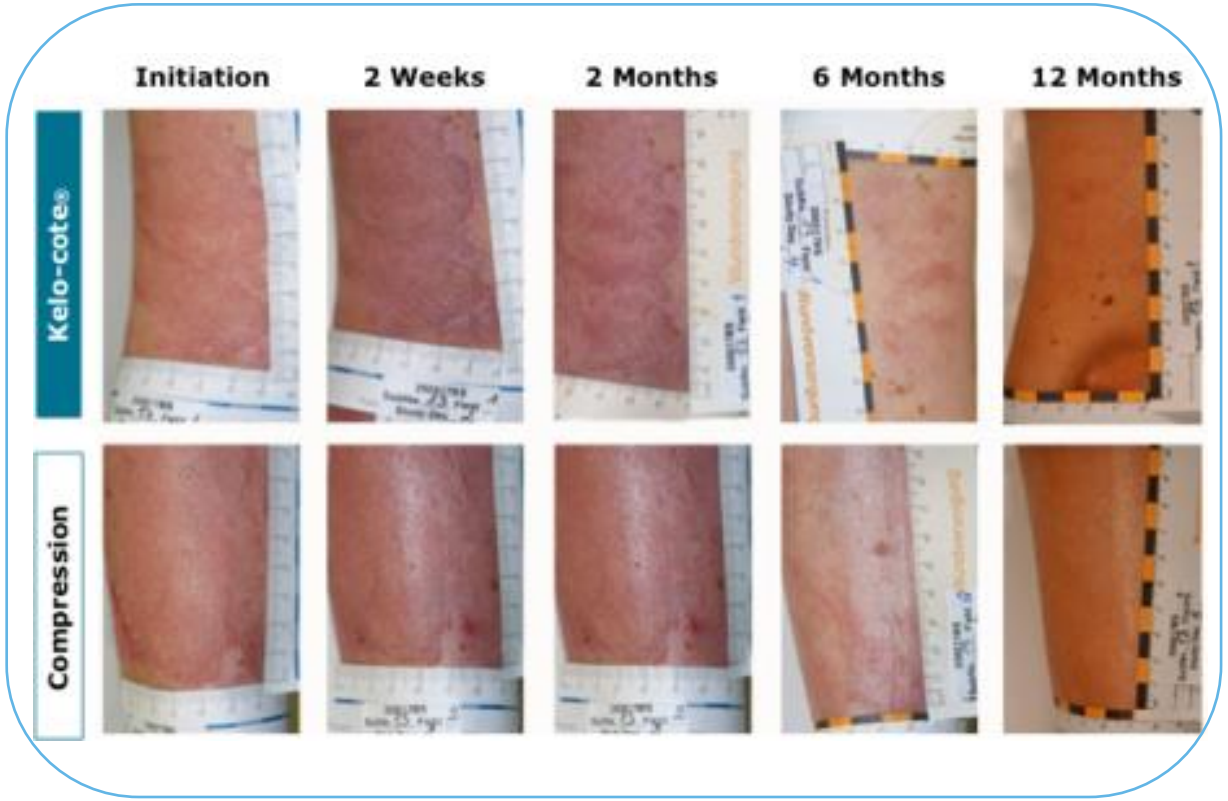
Data adapted from Signorini M, et al. Aesth Plast Surg 2007;31:183–187.
Grade 1: normal; Grade 2: mildly hypertrophic; Grade 3: hypertrophic; Grade 4: keloid

KELO-COTE SPRAY AND COMPRESSION[9]

- 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 gaments + 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

KELO-COTE ADDED TO COMPRESSION[9]

- 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 for the other treatment outcomes, compared with compression alone
- KELO-COTE achieved comparable results to the gel sheeting. In addition, silicone spray therapy and pressure garment therapy were better at improving scar pigmentation than silicone gel sheet and pressure garment therapy
- However, there were fewer side effects in patients using KELO-COTE spray compared with silicone sheeting

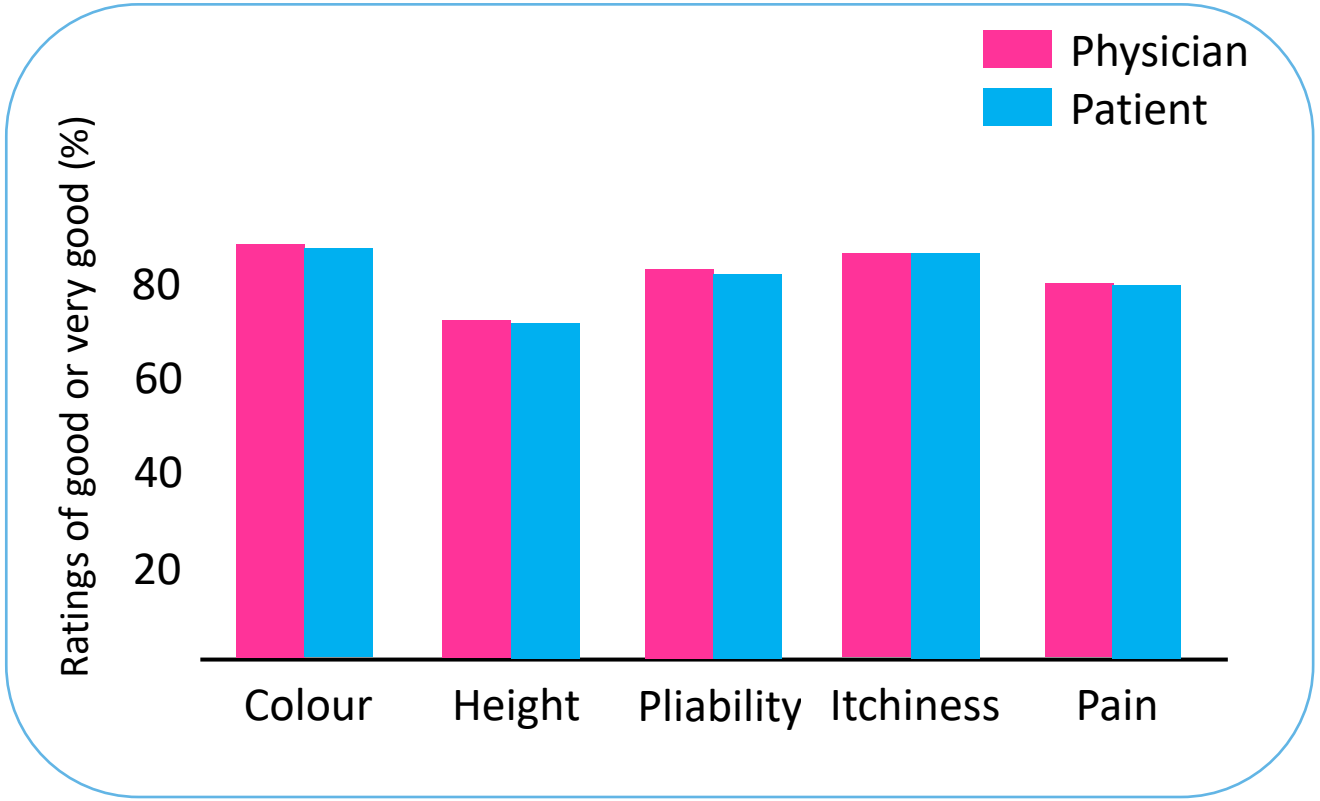


TREATMENT OF EXCESSIVE SCARRING: AN OBSERVATIONAL STUDY[10]

- 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

TREATMENT OF EXCESSIVE SCARRING[10]

- 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



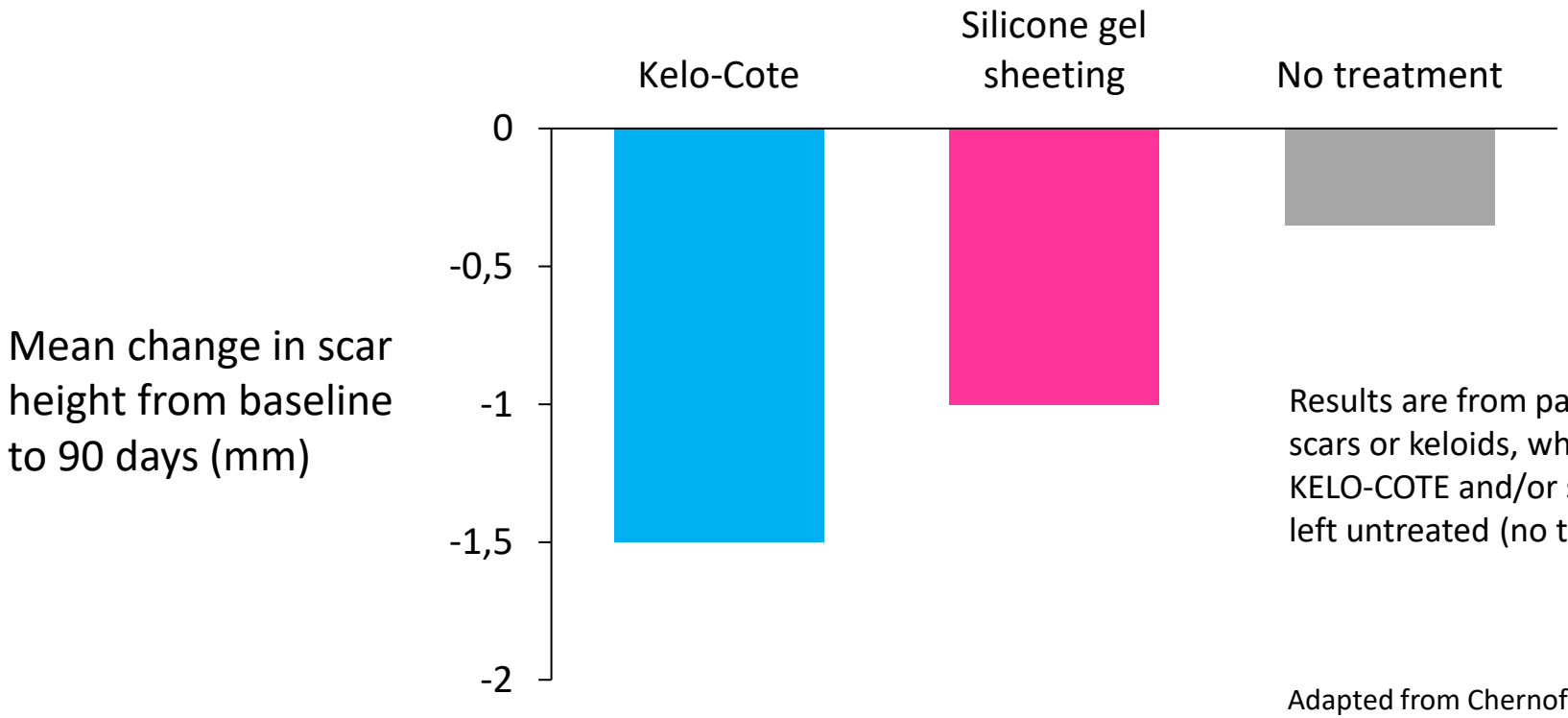
Adapted from Sepehrmanesh M. Komp Dermatologie 2006;1:30–32.

KELO-COTE VS. SILICONE GEL SHEETING[11]

- Randomised study in 30 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

KELO-COTE REDUCES SCAR HEIGHT[11]

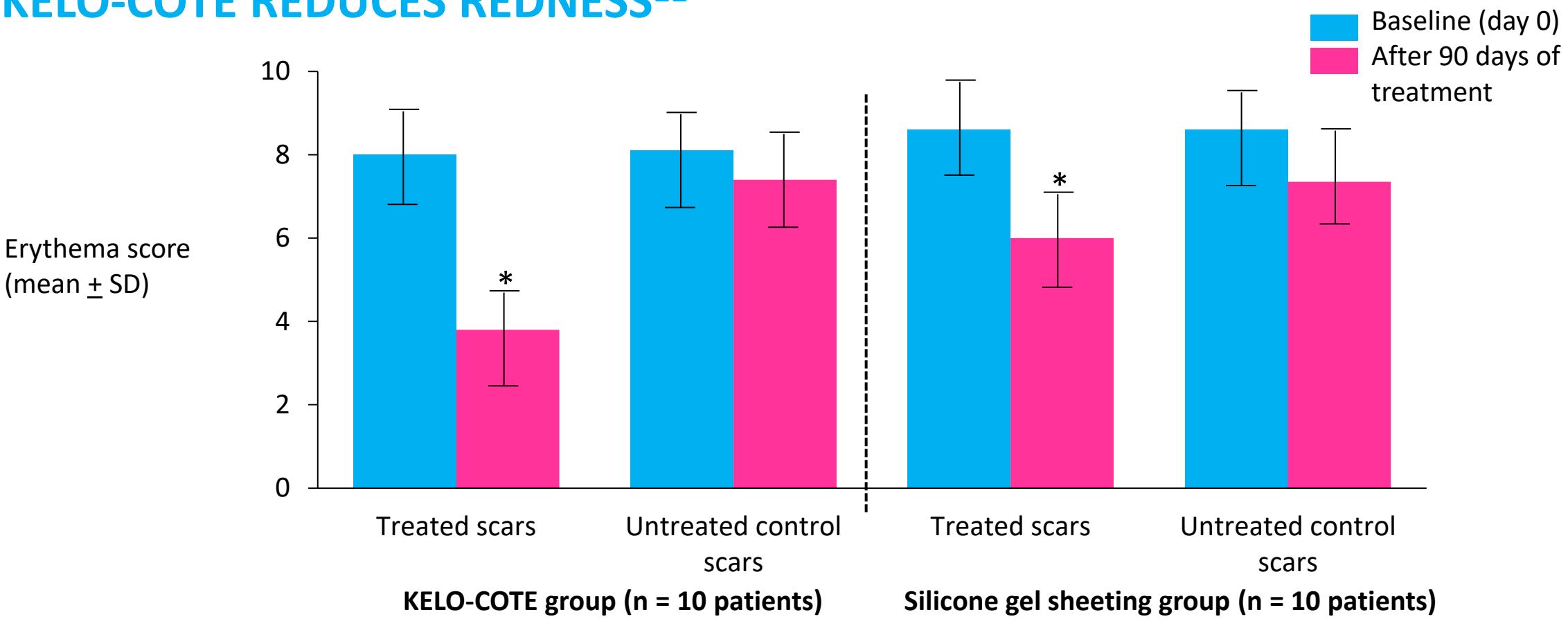
KELO-COTE reduced scar height by a greater amount than silicone gel sheeting or no treatment



Results are from patients with bilateral early hypertrophic scars or keloids, where one scar was treated (with either KELO-COTE and/or silicone gel sheeting) and the other was left untreated (no treatment)

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

KELO-COTE REDUCES REDNESS[11]

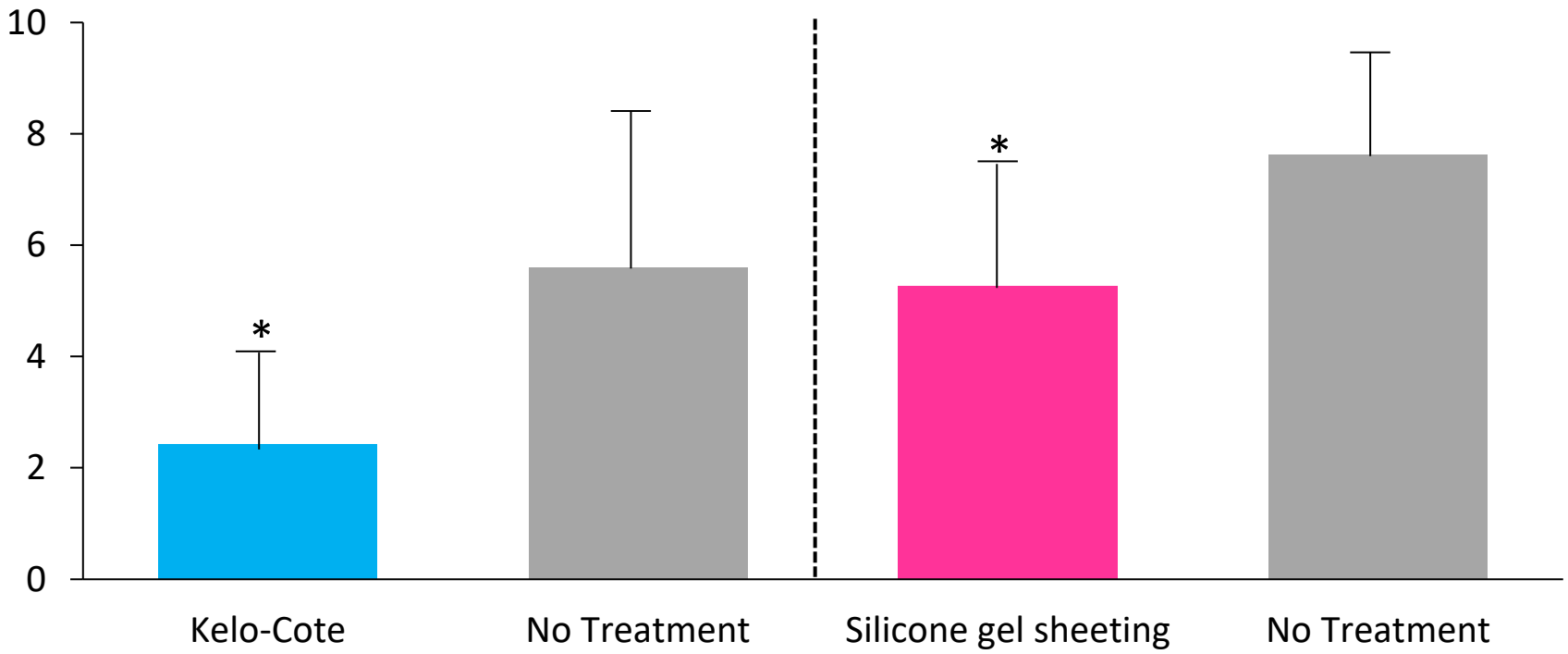


*p≤0.001 vs. no treatment
Symptoms rated on a visual analogue from 0 (none) to 10 (worst)

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

KELO-COTE REDUCES SYMPTOMS[11]

Mean scores for itching, irritation or skin maceration at 90 days

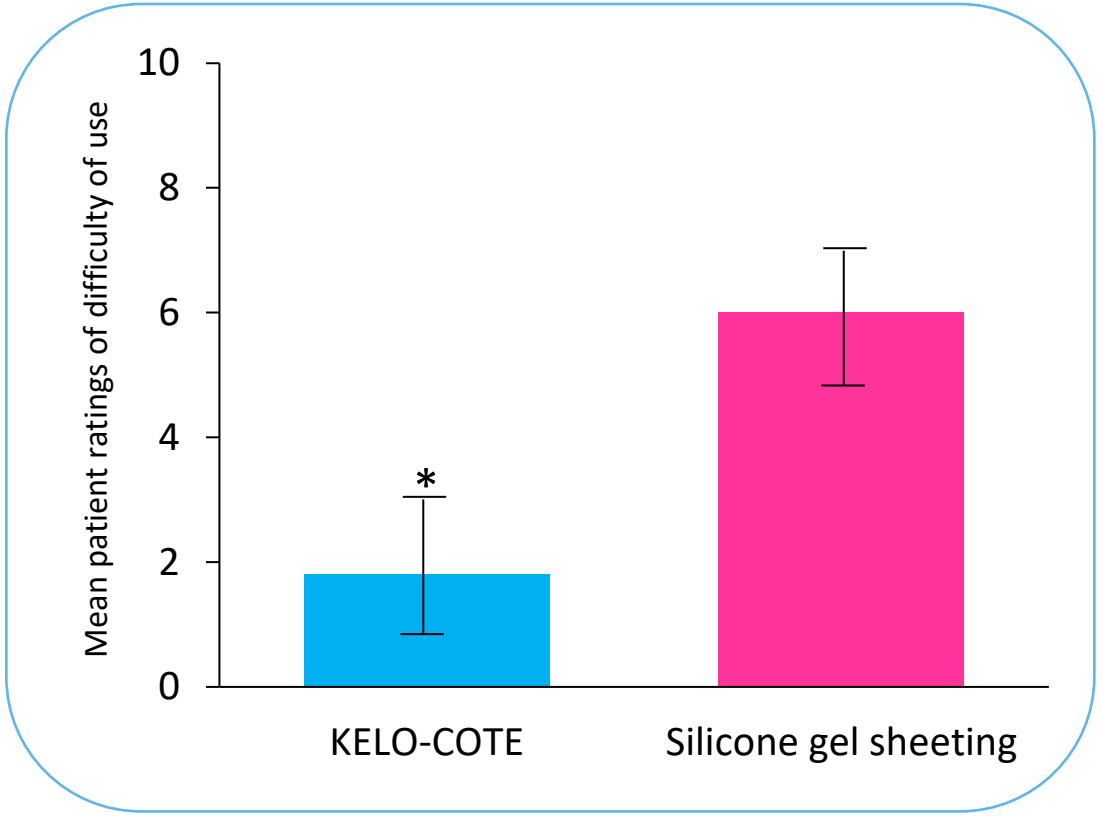


*p≤0.001 vs. no treatment
Symptoms rated on a visual analogue from 0 (none) to 10 (worst)

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

KELO-COTE IS EASIER TO USE THAN SILICONE GEL SHEETING[11]

- 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.

KELO-COTE IS WELL-TOLERATED[12]

- KELO-COTE scar gel was applied to a patch of skin on the backs of 51 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 covered with an occlusive dressing
- 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**

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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



KELO-COTE UV GEL

- Guidelines recommend avoiding exposure of wounds to the sun[5]
- 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 radiation[13]



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 cm^2



HOW KELO-COTE IS USED



KELO-COTE should be used on clean and dry skin as soon as the wound has healed, stitches have been remove 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.

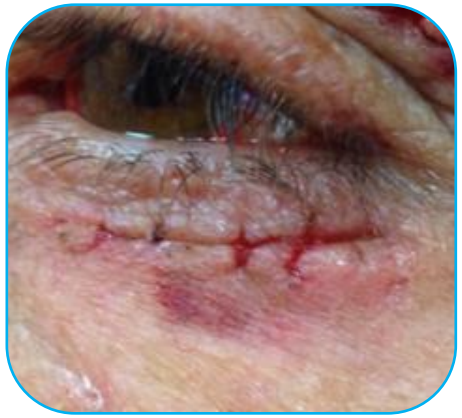
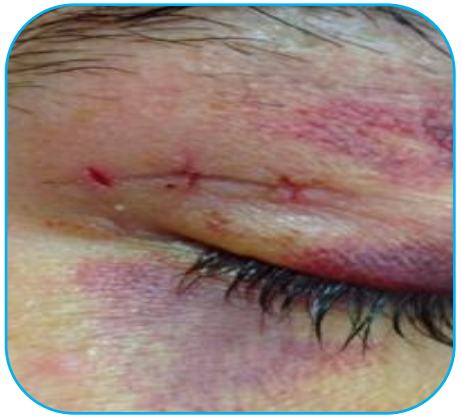


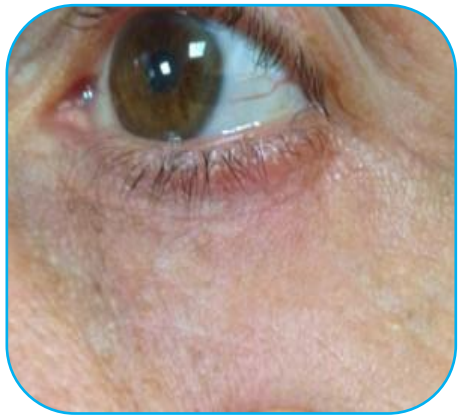
The recommended minimum treatment period with KELO-COTE is 60-90 days. If improvement still occurs after 90 days of treatment, KELO-COTE should be continued.



KELO-COTE is suitable for children (from 3 months) 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

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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 excessive 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 been shown to have better tolerability and compliance
- 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

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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%

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

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

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

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

QUESTION 6

Production of excess 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

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

QUESTION 10

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

A. True

B. False

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Quiz Answers

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

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REFERENCES

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