# CLINICALLY PROVEN SILICONE SCAR PREVENTION & TREATMENTS

## TO HELP IMPROVE PATIENT COMPLIANCE
















KELO-COTE®
SCAR PREVENTION & TREATMENT

# BURDEN OF SCARS



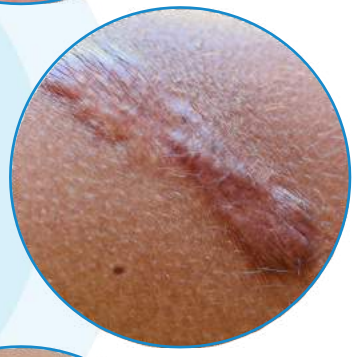




Hypertrophic scarring occurs in **40%** to **70%** of people following surgeries, and up to **90%** following burn injury.[1]

Keloids are found only in humans and occur in **5-15%** of wounds.[2]







# RISK FACTORS FOR HYPERTROPHIC AND KELOID EXCESSIVE SCARRING

Although anyone can develop excessive scarring, the risk factors are greater for:



Darker skin types, such as people from Africa, African-Caribbean and south Indian communities (especially for keloids scars).[3,4]



Younger people between the ages of 10 and 30.[3,5]



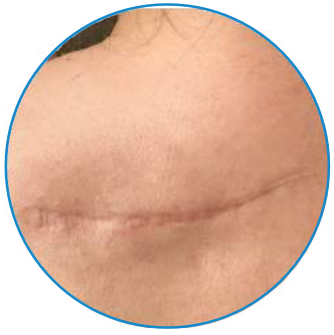
Scars that cross joints or skin creases at right angles[5] or areas of high tension after surgery and wound closure, e.g. the back of the shoulder, sternum and lower abdomen.[6]



Those with a family history of scarring,[7,8] previous scarring or who have had a greater number of surgical interventions.[9]

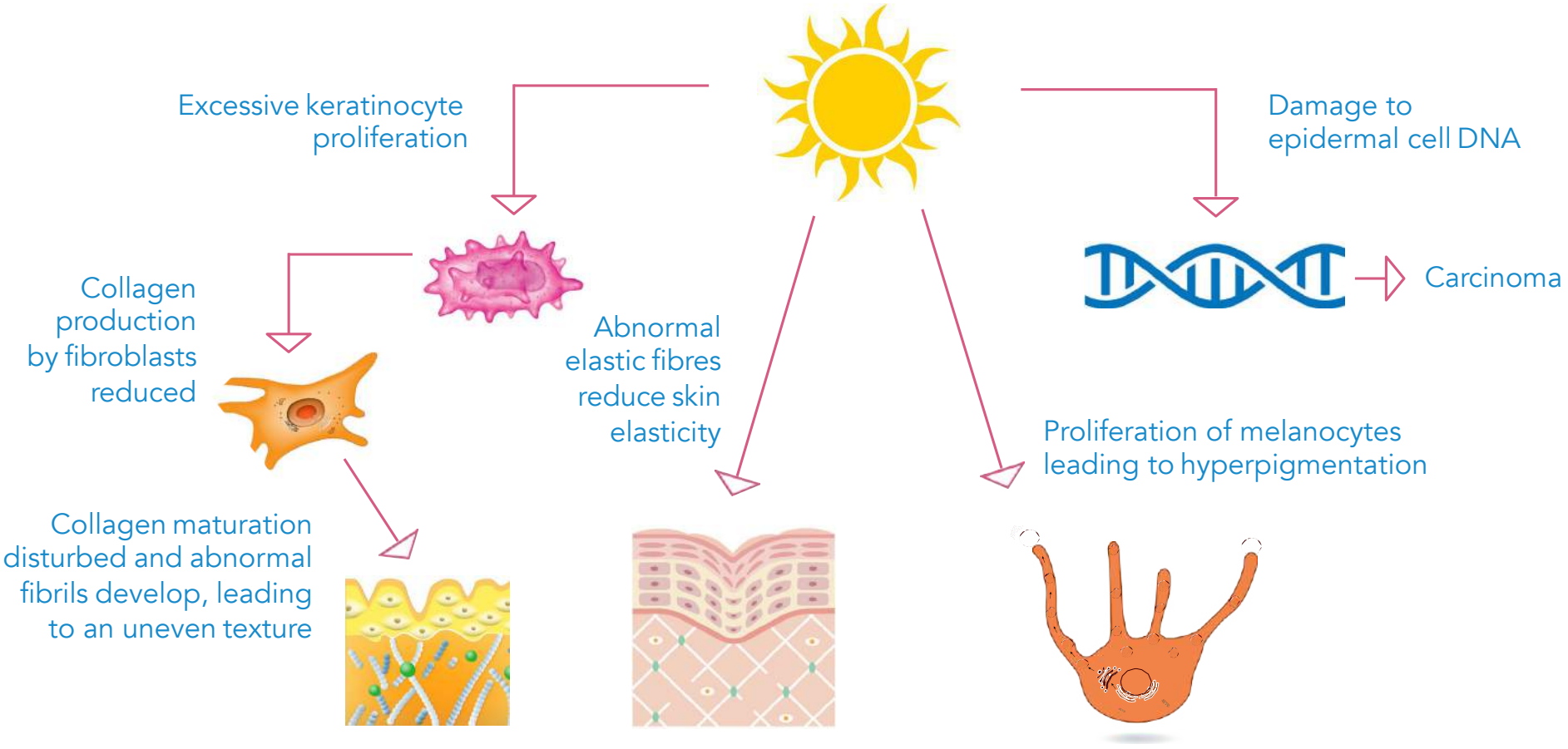


People going through hormonal changes, e.g. during pregnancy or puberty.[7,8]



Injuries affecting deeper layers of the skin.[9]

# UV RADIATION FROM THE SUN CAUSES SKIN DAMAGE IN MANY WAYS[10-16]



# IMPACT ON QUALITY OF LIFE

Scars can also influence patient psychological wellbeing, which can lead to diminished quality of life,[17] including:[18,19]

- Anxiety
- Social isolation
- Depression

Consideration should be made towards preventative measures of scarring.[20]

> A study by Reinholz et al in 2015 demonstrated that the presence of scars can significantly affect patients' quality of life[20]

The study investigated the impact of different scar types on quality of life (QoL) and showed that patients with keloids, atrophic and self-harm scars showed a pronounced effect on QoL

# HOW KELO-COTE® WORKS

- Sometimes healing wounds form excessive, unorganized collagen bundles that push upwards and form a reddened raised hard scar.
- Treating the scar with KELO-COTE® helps to create an optimal environment by regulating moisture levels and collagen production in the skin.
- KELO-COTE®'s advanced Siliclear complex is a blend of silicones that cross-link and bond to skin, drying within minutes.
- Providing 24 hours of protection and treatment.*

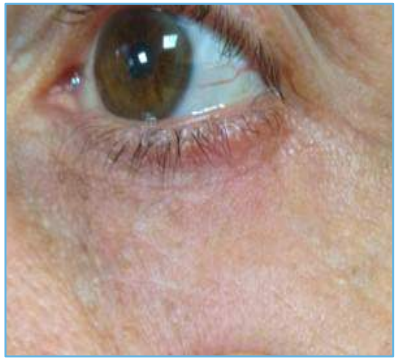
* based on two applications per day

Before using KELO-COTE®





After using KELO-COTE® for 3 months

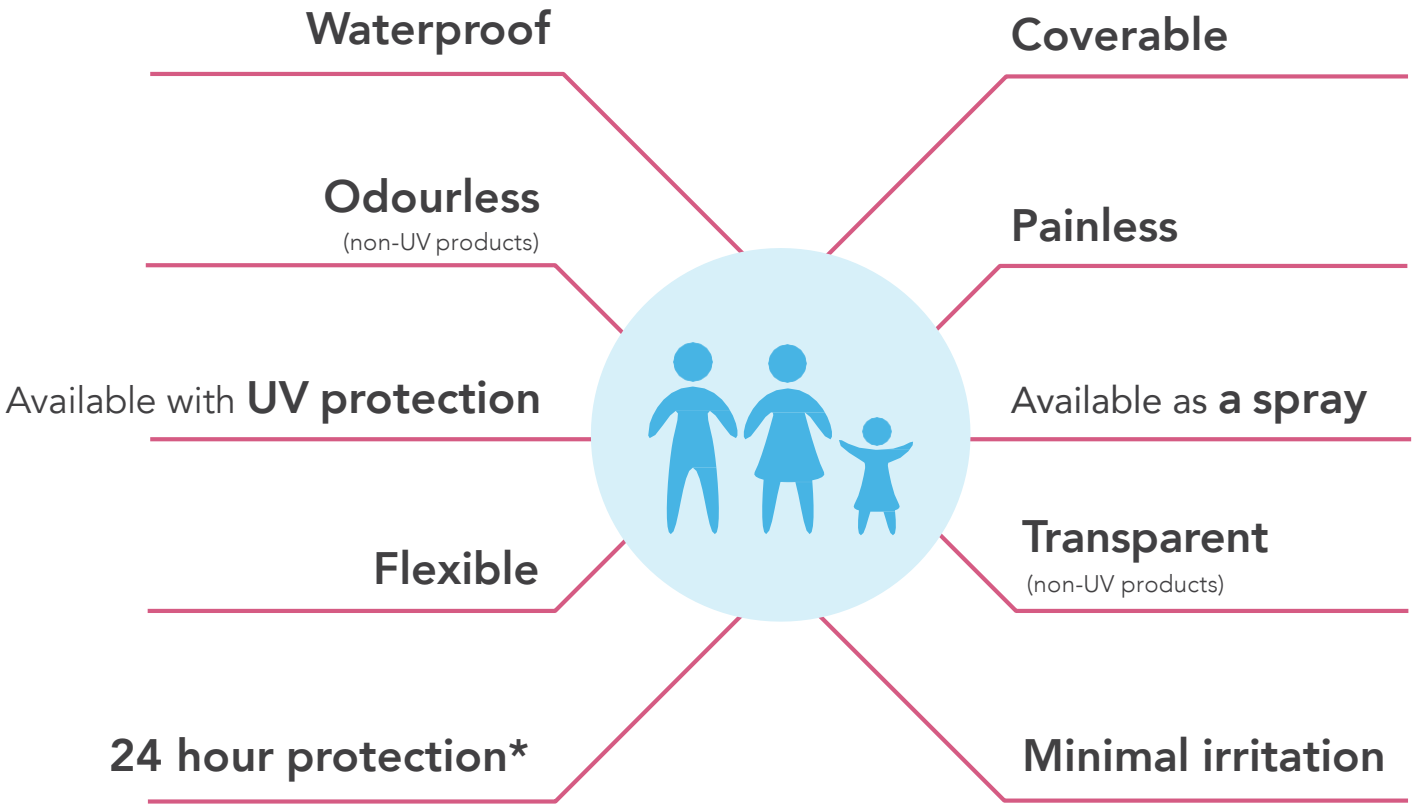




Images courtesy of Dr Federico Baietto, maxillofacial plastic reconstructive surgeon, Turin, Italy

# PATIENT COMPLIANCE

Silicone gel or sheeting are the **preferred first-line** preventative measure or treatment for hypertrophic scars and minor keloids,[21] however, **silicone gel** has **better patient acceptability**[22] and may lead to **better patient compliance**:




* based on two applications per day

1ST LINE TREATMENT*

# KELO-COTE® SCAR TREATMENTS

KELO-COTE® is an advanced formula silicone treatment which helps improve the appearance of scars and helps prevent them from forming




## KELO-COTE® SCAR GEL

- ✔ Easy to use
- ✔ Fast drying gel
- ✔ Helps soften and flatten raised scars
- ✔ Reduces redness

Available in: **6g, 15g and 60g**




## KELO-COTE® SCAR GEL UV

- ✔ With the scar treatment benefits of the standard gel
- ✔ Added SPF 30
- ✔ Protects scars from the aggravating effects of the sun

Available in: **6g and 15g**




## KELO-COTE® SCAR SPRAY

- ✔ Sensitive scars
- ✔ Burn scars
- ✔ Large scars
- Hygienic

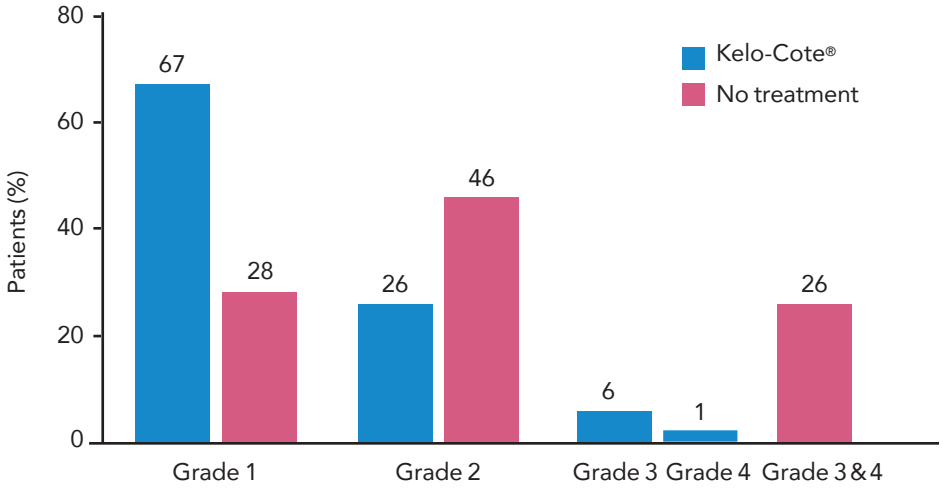
Available in: **100ml**

* Silicone gels are a first line treatment for scars by healthcare professionals including plastic surgeons

# KELO-COTE® HELPS PREVENTS UNSIGHTLY SCARS AND DIMINISHES THE APPEARANCE OF EXISTING SCARS

- Prevents raised abnormal scarring in 67% of surgery patients after 4 months of twice-daily treatment; a further 26% developed only mildly hypertrophic scarring.[17]
- Improves symptoms of existing hypertrophic scars or keloids in up to 84% of patients.[23]
- Is associated with a significant reduction of itching, irritation or skin maceration when compared with no treatment.[22]
- Is easier to use and better tolerated than silicone gel sheeting.[22,24]
- Is not associated with the development of allergy.[25]

## Prevention of scarring with Kelo-Cote®[17]

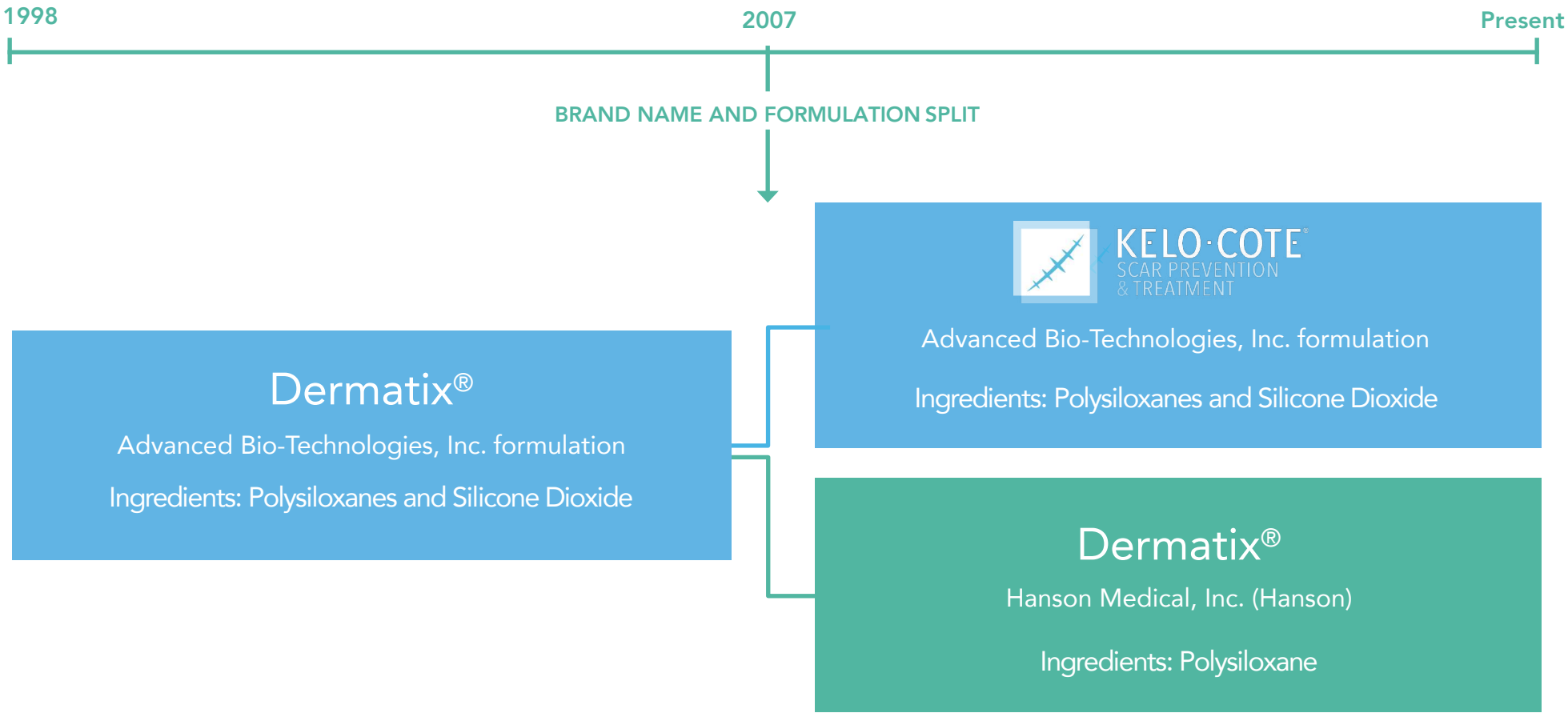



Grade 1: normal
Grade 2: mildly hypertrophic
Grade 3: hypertrophic
Grade 4: keloid

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

# KELO-COTE® HISTORY

The original formulation of the KELO-COTE® brand has not changed since issue of US patent on April 21, 1998.



# KELO-COTE®: TREATING SCARS FOR OVER 20 YEARS

Spray for large or sensitive areas such as burn

1st line treatment in scar guidelines[26]

SPF 30 protection

Highly rated by patients[27]




Clinically proven formula

Self-drying technology within 5 minutes *

Efficacy of sheets but more convenient to use

24 hour protection**

> Silicone gels and sheets are the '**gold standard**' non-invasive therapies for prevention and treatment of hypertrophic scars and minor keloid scars[21]

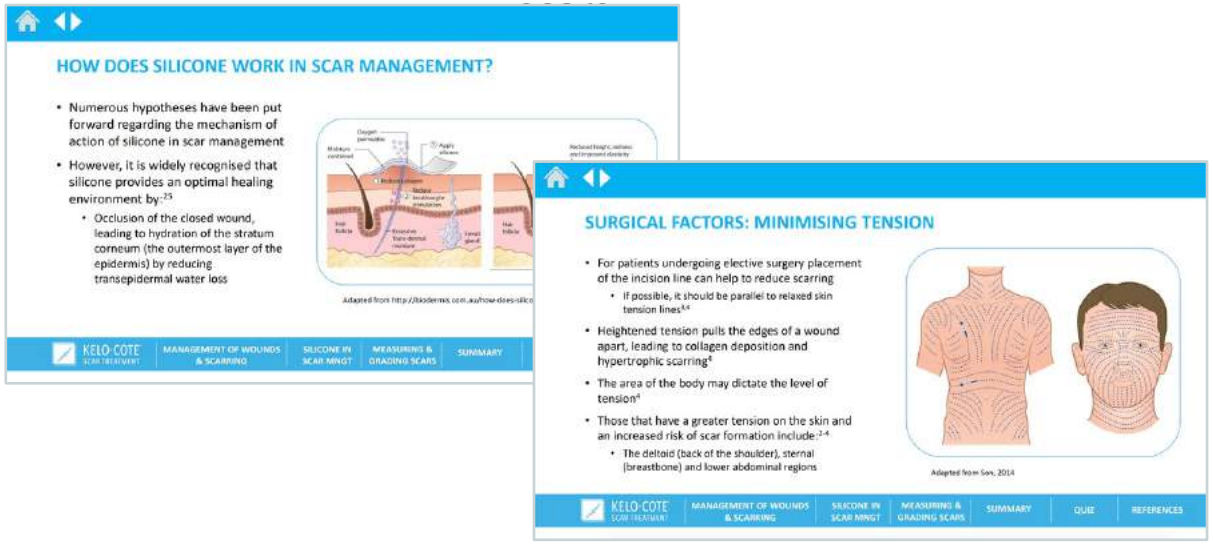
*Data on file, study of 10 subjects. When used in accordance with instructions.
**based on two applications per day

# RESOURCES

## HEALTHCARE PROFESSIONALS

Healthcare professional Resources and Training modules now available on the KELO-COTE® website.

Includes information on wound healing,  scar formation and treatment regimes for excessive




https://kelo-cote.co.uk/information-healthcare-professionals/

# SCAR DIFFERENTIATION



## IMMATURE SCAR

- Red, sometimes itchy or painful and can be slightly elevated[26]
- May become flat over time, with pigmentation which can be paler or darker than the surrounding skin[26]



## KELOID

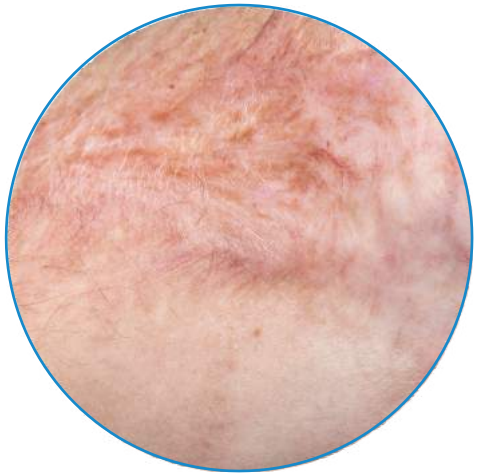
- Focally raised, itchy scar extending over normal tissue[26]
- May develop up to 1 year after the injury without regression[26]
- Most likely to form on the anterior chest, shoulders, earlobes, upper arms and cheeks[1]

# SCAR DIFFERENTIATION



## LINEAR HYPERTROPHIC

- Red, raised and sometimes itchy scar; confined to the border of the original wound[26]
- Appear within 4 to 8 weeks following wounding[1] and may increase rapidly in size for 3-6 months[14]
- Generally mature to an elevated, slightly rope-like appearance with variable width[26]
- Most likely to form on the shoulders, neck, presternum, knees and ankles[1]

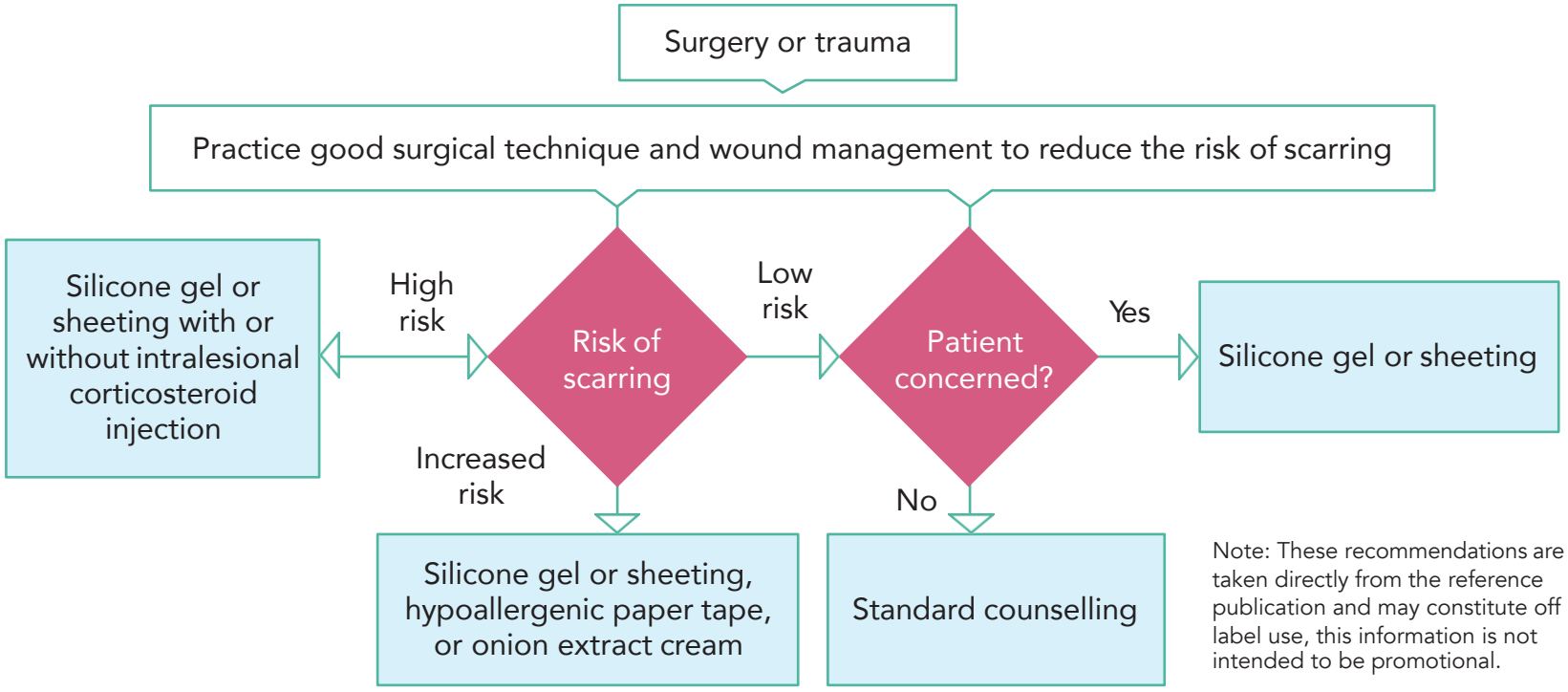


## WIDESPREAD HYPERTROPHIC

- Widespread, red, raised scar, which is sometimes itchy[26]
- Remains within the borders of the injury[26]
- Common after burns, mechanical trauma or necrotising infections[21]

# CURRENT GUIDELINES

## Algorithm for preventing hypertrophic or keloid scars after surgery or trauma[26]




Note: These recommendations are taken directly from the reference publication and may constitute off label use, this information is not intended to be promotional.

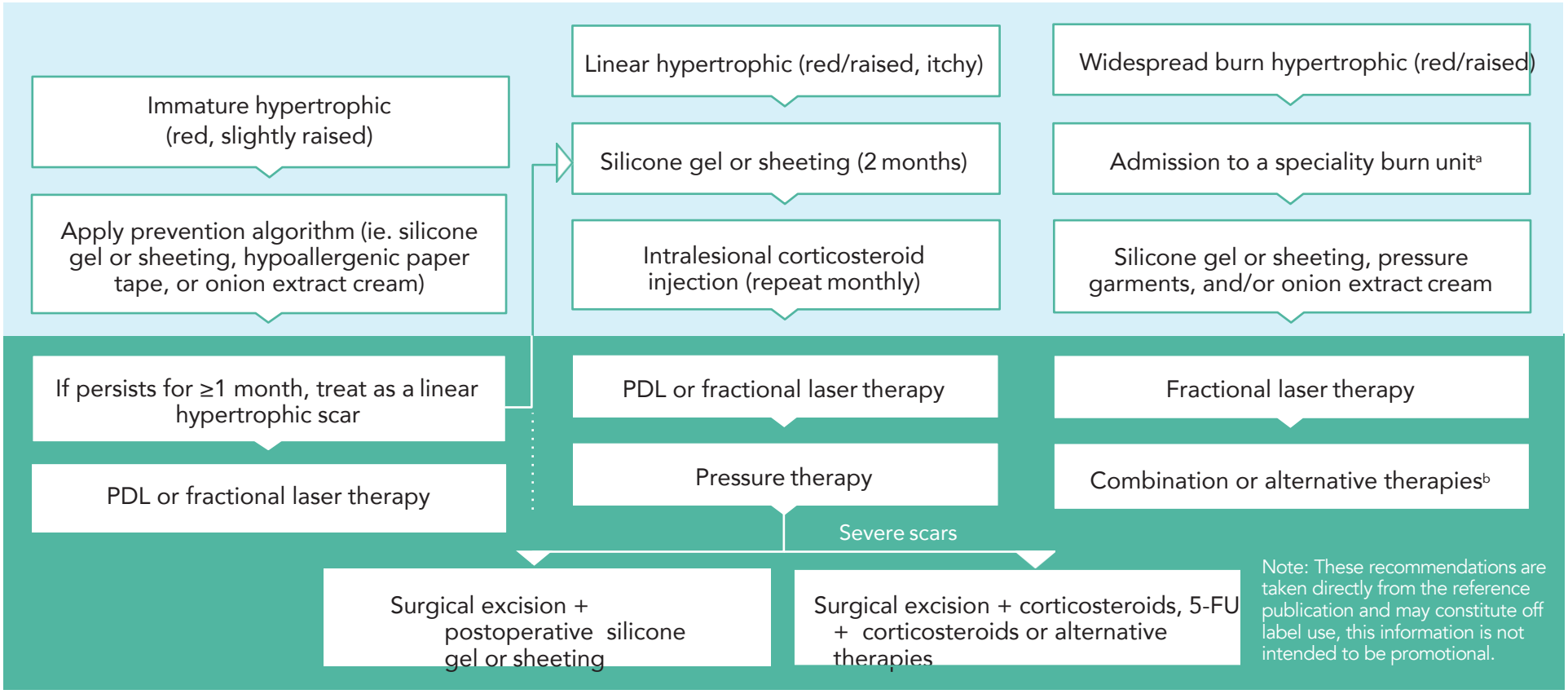
Adapted from Gold 2014[26]

> Silicone gels and sheets are the only non-invasive measure with "enough supporting data to make evidence-based recommendations"[21]

# HYPERTROPHIC GUIDELINES

## Management algorithm for hypertrophic scars[26]

Light blue indicates initial management strategies; green indicates secondary management options.



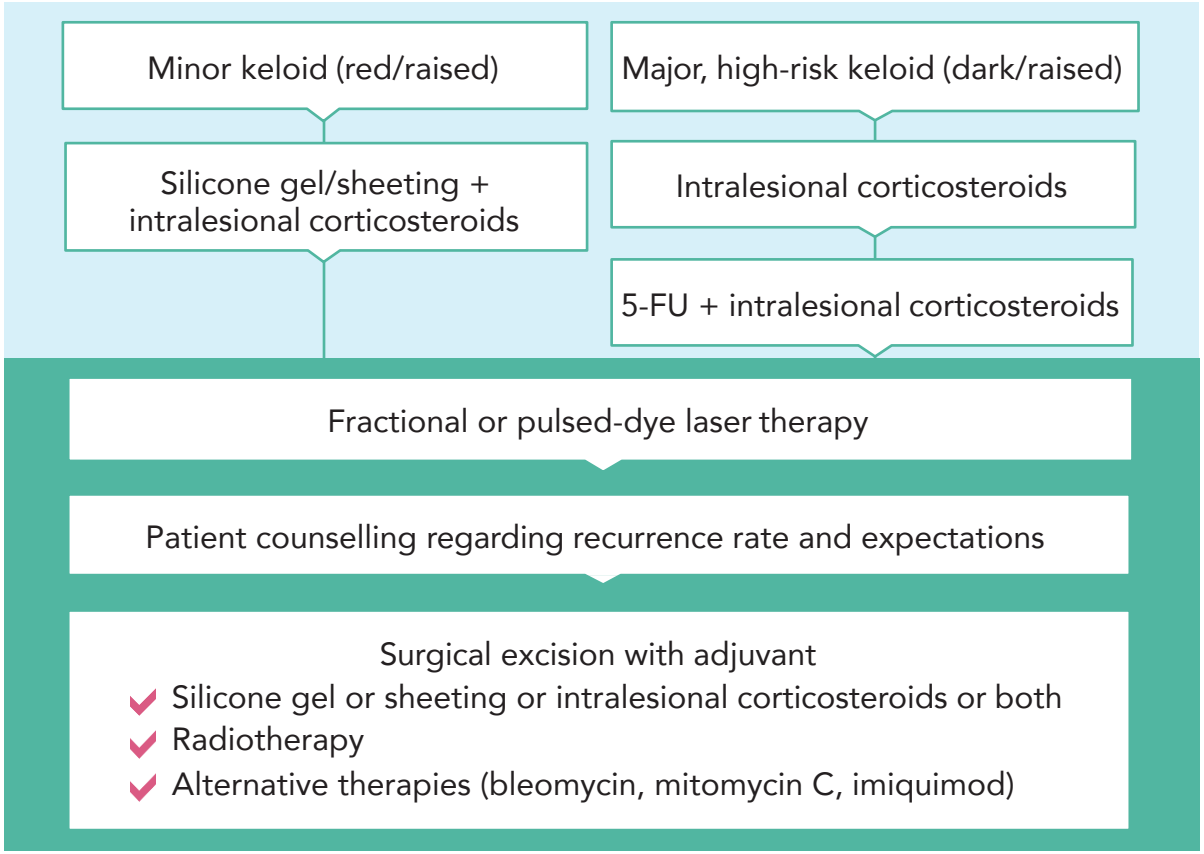

PDL, pulsed-dye laser. [a]scar prevention and treatment should not begin before epithelium and wound stabilization. [b]Combination and alternative therapies include massage, physical therapy, corticosteroids, tension-relieving surgical intervention, excision, grafting or flap coverage, hydrocolloid dressings, antihistamines, and laser therapy.

Adapted from Gold 2014[26]

# KELOID GUIDELINES

## Management algorithm for keloids[26]

Light blue indicates initial management strategies; green indicates secondary management options.




Adapted from Gold 2014[26]

> Silicone gels and sheets are the only non-invasive measure with enough supporting data to make evidence-based recommendations[26]

Note: These recommendations are taken directly from the reference publication and may constitute off label use, this information is not intended to be promotional.

# KELO-COTE® AVAILABILITY

KELO-COTE® Scar Treatment 15g, 60g and 100ml are available on **prescription**




| Product | Size | Drug tariff |
|---|---|---|
| Kelo-Cote® silicone scar gel | 15g | £17.88 |
| Kelo-Cote® UV silicone scar gel SPF30 | 15g | £17.88 |
| Kelo-Cote® silicone scar gel | 60g | £51.00 |
| Kelo-Cote® silicone scar spray | 100ml | £51.00 |

## Scar size guidelines:

**6g** for scars up to 7.5cm long | **15g** for scars between 7.5cm and 10cm long | **60g** for scars larger than 10cm long

# KELO-COTE® AVAILABILITY

Available from pharmacy or online at

Boots Let's feel good

amazon.co.uk

Superdrug and in store



**KELO-COTE® SCAR GEL**

**RRP 6g: £19.49**

**RRP 15g: £32.18**

**RRP 60g: £91.80**



**KELO-COTE® SCAR GEL UV**

**RRP 6g: £19.99**

**RRP 15g: £31.50**



**KELO-COTE® SCAR SPRAY**

**RRP 100ml: £91.80**

## Scar size guidelines:

6g for scars up to 7.5cm long | 15g for scars between 7.5cm and 10cm long | 60g for scars larger than 10cm long

# HOW TO USE KELO-COTE®



- Patients should begin treatment as soon as the wound is closed, scabs have gone or stitches have been removed. The wound should be clean and dry.




- Treatment requires application of a very thin layer of KELO-COTE® onto the scar twice a day. Once applied, patients should not rub the gel in.




- KELO-COTE® self-dries within 5 minutes* forming a flexible, waterproof layer that offers 24 hour protection.




- The recommended minimum treatment time is 60-90 days. If improvement still occurs after 90 days, patients are recommended to continue treatment.



- KELO-COTE® is suitable for adults and children from 3 months.

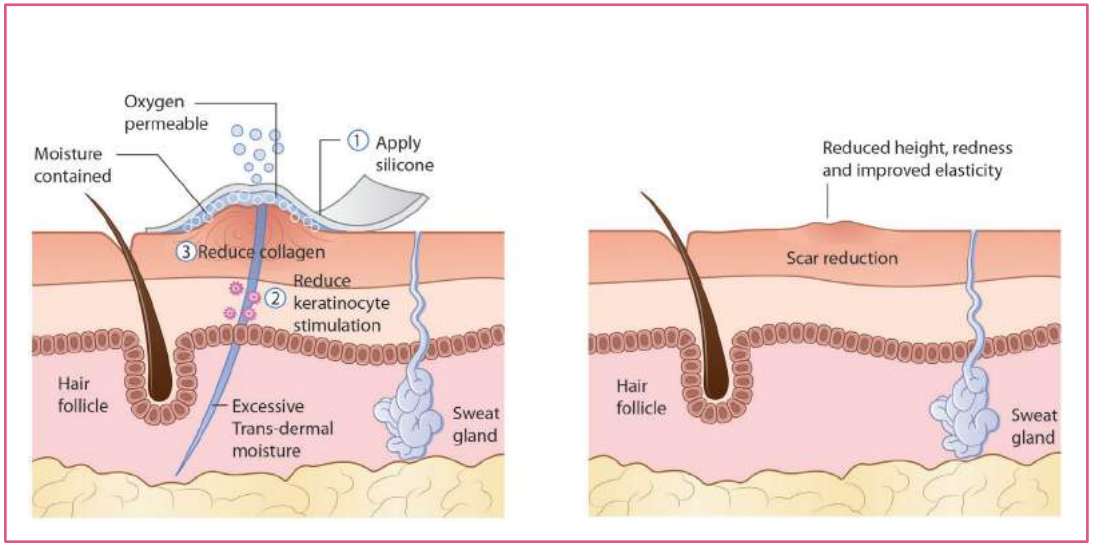
KELO-COTE®: effective for both old** and new scars to help prevent excessive and abnormal scar formation[28,29]

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

** Clinical data supports efficacy for scars up to 4 years but KELO-COTE® is most effective on new scars.[27]

# TECHNICAL MODE OF ACTION FOR KELO-COTE®

- Treatment of the scar with KELO-COTE® helps restore the barrier function of the stratum corneum, reducing transepidermal water loss and decreasing the stimulation of keratinocytes, thus reducing/slowing dermal fibroblasts and reducing collagen production.[28]
- After 2-3 months of KELO-COTE® treatment, collagen deposition and scar hypertrophy is reduced.[28]
- In a clinical study only 1.5% of patients were observed to have adverse reactions to KELO-COTE®.[23]




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

# CLINICAL STUDIES AT A GLANCE

## PREVENTION

| Author/year | Subjects | Purpose | Main results/outcome |
|---|---|---|---|
| **Signorini, M et al, 2007** | Patients who had undergone surgery (n=148) | RCT to verify the efficacy of a topical silicone treatment. | Scar maturation/appearance was significantly improved in the silicone gel group vs. the no treatment group. |
| **Steinstraesser, L et al, 2011** | Patients with split-thickness graft burns (n=38) | Open, single-centre, RCT comparing pressure garment therapy vs. silicone gel sheet/spray for the prevention of hypertrophic scarring. | Silicone spray was comparable to silicone gel sheet efficacy with no significant differences. Use of pressure garment therapy alone produced results equivalent to those of combined silicone and pressure garment therapy in the prevention of hypertrophic scars. |
| **De Giorgi V, et al, 2009** | Patients who had undergone outpatient surgery (n=110) | RCT to evaluate UV silicone gel in treating surgical wounds vs. control group prescribed zinc oxide cream. | UV silicone gel reduces the risk of scar formation vs. control. |

# CLINICAL STUDIES AT A GLANCE

## TREATMENT

| Author/year | Subjects | Purpose | Main results/outcome |
|---|---|---|---|
| **Chernoff WG et al, 2007** | Patients with bilateral active scars (n=30) | Prospective study to evaluate the efficacy of KELO-COTE® vs. silicone gel sheeting, plus a combination of these treatments in improving scars. | Both Dermatix/KELO-COTE® and silicone gel sheeting reduced symptoms of itching, irritation, and skin maceration. |
| **Sepehrmanesh M, 2006** | Patients with hypertrophic or keloid scars (n=1,522). | Observational study to evaluate the efficacy of KELO-COTE®'s silicone gel. | Scar improvement and treatment satisfaction is high with KELO-COTE®.<br><br>70-84% physicians reported scar improvements. 98% physicians and patients rated tolerability as very good/good. |

# CLINICAL STUDIES AT A GLANCE

## OTHER

| Author/year | Subjects | Purpose | Main results/outcome |
|---|---|---|---|
| **Reinholz, M et al, 2015** | Outpatients (n=130) | Qualitative patient study to assess quality of life (QoL) on patients with different scars. | Keloids, atrophic and self-harm scars showed a pronounced effect on QoL. |
| **Mustoe TA et al, 2002** | Qualitative overview >300 references | To provide evidence-based recommendations on prevention and treatment of abnormal scarring. | Silicone gel sheeting and intralesional corticosteroids are the only treatments with sufficient efficacy evidence on preventing and treating scars. |
| **Monstrey S, M et al, 2014** | n/a | Practical evidence-based guidelines for the management of hypertrophic scars and keloids. | Silicone sheeting or gel is first line, gold-standard treatment option for hypertrophic scars and keloids. |
| **Due E, et al. 2007** | 14 healthy male volunteers | To examine the effect of ultraviolet irridation on human cutaneous cicatrices. | Postoperative sun exposure aggravates the appearance of new scars and should not be exposed to sunlight during wound healing. |

# CLINICAL STUDY – SILICONE SCAR GEL

**Study details**

Signorini M, et al. Clinical evaluation of a new self-drying silicone gel in the treatment of scars: a preliminary report. Aesthetic Plastic Surgery 2007;31(2):183-7.

**Type of study**

RCT.

**Purpose**

To verify the efficacy of a topical silicone treatment.

**No. of patients**

Patients who had undergone surgery (n=148).

**Arms**

Treatment group: Dermatix; (KELO-COTE® formulation) 2 x daily for 4 months. Control group.

**Follow up length**

Baseline, 1, 2, 3, 4, and 6 months.

**Results**

Scar grade. Treatment vs. control scars at 6 months

| | 1 (mild) | 2 (mildly hypertrophic) | 3 (hypertrophic) | 4 (keloid) |
|---|---|---|---|---|
| Treatment | 67% | 26% | 6% | 1% |
| Control | 28% | 46% | 26% | 26%* |

* significantly different ($p<0.001$)

**Conclusion**

The tested self-drying silicone gel was appealing due to its effectiveness and ease of use. The authors concluded that this treatment option would be their first choice for preventing hypertrophy of recent scars especially in visible areas.

# CLINICAL STUDY – SILICONE SCAR SPRAY

| | |
|---|---|
| Study details | Steinstraesser L, et al. Pressure garment therapy alone and in combination with silicone for the prevention of hypertrophic scarring: randomized controlled trial with intraindividual comparison. Plastic and Reconstructive Surgery 2011; 128(4): 306-313. |
| Type of study | Open, single-centre, RCT. |
| Purpose | To assess the efficacy of pressure garment therapy alone and in combination with silicone gel sheet or spray therapy for the prevention of hypertrophic scarring. |
| No. of patients | 38 patients with two comparable areas of split-thickness graft burn wounds. |
| Arms | Randomly assigned to two treatment groups: 1) silicone gel sheet (Mepiform) or 2) self-drying silicone spray (Dermatix; KELO-COTE® formulation). All participants had pressure garment therapy (Jobskin). |
| Follow up length | Scar assessment was carried out baseline, 2 weeks, 2 months, 6 months, 12 months, 18 months. |
| Results | • Silicone spray was comparable to silicone gel sheet efficacy with no significant differences ($p = 0.608$) in Vancouver Scar Scale score.<br>• Silicone spray combined with pressure garment therapy significantly improved scar VSS rating, improved scar smoothing ($p = 0.047$), improved pigmentation ($p = 0.050$), reduced itching ($p<0.001$) and improved pain ($p=0.027$) after 18 months.<br>• No patient treated with silicone spray and pressure garment therapy reported any side effects.<br>• Use of pressure garment therapy alone produced results equivalent to those of combined silicone and pressure garment therapy in the prevention of hypertrophic scars and reduced redness ($p=0.001$). The only therapy that smoothed scars was silicone spray in combination with pressure garment therapy. |
| Conclusion | Silicone with pressure garment therapy is associated with significant improvements in scar appearance along with itching and pain. |

# CLINICAL STUDY – UV SILICONE GEL ON SURGICAL WOUNDS

| | |
|---|---|
| Study details | De Giorgi V, et al. The use of silicone gel in the treatment of fresh surgical scars: a randomized study. Clinical and Experimental Dermatology 2009;34:688-93. |
| Type of study | RCT. |
| Purpose | To evaluate UV silicone gel in treating surgical wounds vs. control group prescribed zinc oxide cream. |
| No. of patients | 110 patients (55 men, 55 women) who had undergone outpatient surgery. |
| Arms | Treatment group: UV silicone gel 2 x daily (n=65). Control: zinc oxide cream (n=45). |
| Follow up length | Every month for 3 months, then every 2 months for a total of 8 months follow up. |
| Results | • In the treatment group, only 18 patients (27%) had formation of a non-physiological scar: diastasic scar in 10 patients (15%), hypertrophic scar in 6 (9%) and atrophic scar in 2 (3%). No keloid scars were recorded.<br>• In the control group, 25 (55%) had an altered scar: keloid scars in 5 patients (11%), hypertrophic scar in 10 (22%), diastasic scar in 8 (18%) and atrophic scar in 2 (4%). |
| Conclusion | UV silicone gel reduced the formation of keloid and hypertrophic scars. |

# CLINICAL STUDY – EFFICACY OF TOPICAL SILICONE GEL

| | |
|---|---|
| Study details | Chernoff WG, et al. The efficacy of topical silicone gel elastomers in the treatment of hypertrophic scars, keloid scars, and post-laser exfoliation erythema. Aesthetic Plastic Surgery 2007;31(5):495-500. |
| Type of study | Prospective study. |
| Purpose | To evaluate the efficacy of KELO-COTE® silicone gel (SG), silicone gel sheeting (SGS), and a combination of these treatments in improving scars. |
| No. of patients | 30 |
| Arms | Group 1 (n=10) - SG (Dermatix; KELO-COTE® formulation) 2 x daily<br>Group 2 (n = 10) - SGS (morning and night)<br>Group 3 (n=10) - SG (morning) and SGS (night). Bilateral scar - no treatment control |
| Follow up length | 90 days |
| Results | • Group 1, 2, and 3 were significantly less elevated (P<0.001) and groups 1 and 2 were significantly less red (P<0.001), less symptomatic (p<0.001) vs. untreated control scar.<br>• SG was easier to use than SGS (p <0.001).<br>• Group 3 participants rated improvement most favourably. |
| Conclusion | The authors concluded that KELO-COTE® was a useful treatment for managing abnormal scars. |

# CLINICAL STUDY – KELO-COTE® OBSERVATIONAL STUDY

| | |
|---|---|
| Study details | Sepehrmanesh M. Scar Management: Observational study of 1522 patients using KELO-COTE® silicone gel. Kompendium Dermatologie 2006;1:30–32. |
| Type of study | Prospective, multi-centre, open label, non-controlled, large-scale observational study. |
| Purpose | To evaluate the efficacy of KELO-COTE®'s patented silicone gel technology in treating redness, itchiness, pain and elevation. |
| No. of patients | 1,522 (1065F, 457M). |
| Arms | Dermatix; (KELO-COTE® formulation) 2 x daily. |
| Follow up length | Observational period of 2-6 months (maximum of 10 months). |
| Results | • 70-84.2% physicians reported improvement in scar symptoms.<br>• 69.8-85.1% patients reported improvement in scar symptoms.<br>• 98.7% physicians and 98.2% patients rated tolerability as very good/good.<br>• Satisfaction was rated equally by physicians and patients.<br>• 26 AEs observed in 23 patients (1.5%; burning, redness or itching). |
| Conclusion | KELO-COTE® showed good effectiveness, clear regression of scar symptoms and was well tolerated. |

# CLINICAL STUDY – IMPACT OF SCARRING ON QOL

| | |
|---|---|
| Study details | Reinholz, M et al. The dermatology life quality index as a means to assess life quality in patients with different scar types. J Eur Acad Dermatol Venereol. 2015;29(11):2112-9. |
| Type of study | Qualitative patient study. |
| Purpose | To assess quality of life (QoL) on patients with different scars using the Dermatology Life Quality Index (DLQI). |
| No. of patients | 130 patients in an outpatient clinic. |
| Results | • Patients in the physiological scar group scored a mean DLQI score of 2.07 ± 3.56. Patients in the keloid-, hypertrophic scar-, atrophic scar- and self-harm scar group scored 6.06 ± 4.00, 2.53 ± 2.48, 7.26 ± 6.72 and 12.00 ± 3.85 respectively.<br>• Compared to baseline the difference in the overall score for keloids was +3.99 ($p<0.001$), hypertrophic scars scored +0.45 (ns), atrophic scars +5.19 ($p<0.01$) and self-harm scars +9.93 ($p<0.001$). |
| Conclusion | Different scar types can affect patients differently, with some scars appearing to be more distressing for patients than others. Patients with keloids, atrophic and self-harm scars showed a pronounced effect on QoL. |

# CLINICAL STUDY – SCAR MANAGEMENT GUIDELINES

| | |
|---|---|
| **Study details** | Mustoe TA, et al. International clinical recommendations on scar management. [Review]. Plastic & Reconstructive Surgery 2002;110(2):560-71. |
| **Type of study** | Qualitative overview. |
| **Purpose** | To provide evidence-based recommendations on prevention and treatment of abnormal scarring. |
| **No. of patients** | N/A - review of over 300 studies. |
| **Results** | • Recommendations support a move to a more evidence-based approach in scar management.<br>• Primary role for silicone gel sheeting and intralesional corticosteroids in the management of a wide variety of abnormal scars.<br>(Please note: following this recommendation would result in off-label use of intralesional corticosteroids) |
| **Conclusion** | Silicone gel sheeting and intralesional corticosteroids are the only treatments with sufficient evidence to make evidence based recommendations. |

# CLINICAL STUDY – EVIDENCE-BASED GUIDELINES

| | |
|---|---|
| Study details | Monstrey S, et al. Updated Scar Management Practical Guidelines: Non-invasive and invasive measures. Journal of Plastic, Reconstructive & Aesthetic Surgery 2014;67:1017-25. |
| Type of study | Practical evidence-based guidelines. |
| Purpose | To provide an updated set of practical evidence-based guidelines for the management of hypertrophic scars and keloids. |
| Results | • The guidelines were developed by an international group of 24 experts from a wide range of specialities.<br>• An initial set of strategies to minimize the risk of scar formation is applicable to all types of scars and is indicated before, during and immediately after surgery. |
| Conclusion | Silicone sheeting or gel should be considered as the first-line prophylactic and treatment option for hypertrophic scars and keloids. Other (more specialized) scar treatment options are available for high-risk patients and/or scars. |

# CLINICAL STUDY – SOLAR RADIATION ON SCARS

| | |
|---|---|
| Study details | Due E, et al. Effect of UV Irradiation on Cutaneous Cicatrices: A Randomized, Controlled Trial with Clinical, Skin Reflectance, Histological, Immunohistochemical and Biochemical Evaluations. Acta Derm Venereol 2007; 87: 27-32. |
| Type of study | Randomised, controlled clinical study. |
| Purpose | To examine the effect of ultraviolet irridation on human cutaneous cicatrices. |
| No. of patients | 14 healthy male volunteers. |
| Arms | UV radiation vs. no UV exposure. |
| Follow up length | 5 and 12 weeks. |
| Results | • At 12 weeks: blinded investigators considered that second intention wounds exposed to UV radiation had healed with a more disfiguring scar than those of the control subjects.<br>• At 5 and 12 weeks: A greater increase in pigmentation was observed in both primary closure and second intention wounds in the UV group relative to the control group. |
| Conclusion | Postoperative sun exposure aggravates the appearance of young cicatrices. Wounds and cicatrices should not be exposed to sunlight during the postoperative wound healing period. |

# BURDEN OF SCARS

Annually, **100 million** patients develop scars in the developed world alone as a result of **55 million** elective operations and **25 million** operations after trauma.[1]



Scarring can affect anyone, annually in the UK there are:

**4.7m** surgical procedures[30]

**28,000** cosmetic surgery procedures[31]

**177,700** C-sections[32]

**130,000** burns admissions to A&E[33]

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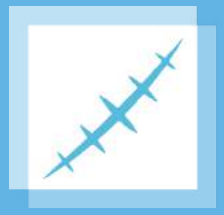

KELO-COTE®
SCAR PREVENTION
& TREATMENT

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