A 9 Year Clinical Experience with Kelo-cote®
The Role of topical silicone in wound healing

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Plastic and Reconstructive Surgery

Oakland, California
Not all wounds are created equally

- Fresh surgical: sharp edges, tensionless epidermis, layered dermal repair
- Traumatized tissue: crushed irregular edges, tension
- Thermal and chemical burns: basal layer and dermis may be absent
- Post-scar (hypertrophic/keloid) excision: tendency to recur
- Scar prone locations: chin to xiphoid, intra-mucosal
- Scar prone races: related to Fitzpatrick skin types: tan easily = scar easily

Epidermis: 40 - 150 microns
Dermis: 140 - 400 microns
E & D: 180 >/= 550 microns
Choices In Topical Therapy
Dry Wounds

- **Tapes**: control tension, shear through surface protection, hydration
- **Oil based antibiotic ointments**: Polymyxin, Bacitracin, Bactroban, Neosporin
- **Skin substitutes**: Biobrane, Alloderm
- **Silicone gel**: Kelo-cote, Scarfade, Mederma
- **Silicone gel sheeting**: Cica-care, Epiform, Mepilex, Mepitel, Silgel
- **Collagens**: Clayton Chagall
- **Tissue adhesives**: cyanoacrylate-Dermabond, Epiglu, Indemil, Liquiband
- **Barrier films**: fast drying carrier solvent: Cavillon, Comfeel, Superskin
Choices In Topical Therapy
Wet Wounds

- **Silver dressings:** Acticoat, Actisorb, Avance, Flamazine
- **Foams:** absorptive for exudates-Allevyn, Flexipore
- **Alginates:** seaweed based very absorptive- Meligisorb, Algisite, Sorbsan
- **Hydrogels:** >70% water, minimally absorptive- Aquaform, Intrasite, Nu-Gel
- **Hydrocolloids:** semi-permaeable-Aquacel, Cutinova
- **Vapour permaeable films:** semi-permeable, fluid accululates-Tegaderm
- **Low-Adherance Dressings:** Telfa, Medipore, Cutilin, Xeroform
- **Multi-layer bandages:** useful for venous ulceration- Profore
## Components of Normal Wound Healing

<table>
<thead>
<tr>
<th>Process</th>
<th>Immediate to 2-5 days</th>
<th>2 days to 3 weeks</th>
<th>3 weeks to 2 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coagulation process</td>
<td>A) Immediate to 2-5 days</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>B) Hemostasis: Vasoconstriction, Platelet aggregation, Thromboplastin clot</td>
<td></td>
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<tr>
<td>Inflammatory process</td>
<td>C) Inflammation: Vasodilation, Phagocytosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Migratory/ Proliferative</td>
<td>A) 2 days to 3 weeks</td>
<td></td>
<td></td>
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<td></td>
<td>B) Granulation: Fibroblasts lay collagen, Fills &amp; new capillaries</td>
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<td></td>
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<tr>
<td></td>
<td>C) Contraction: Wound edges pull together to reduce defect</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>D) Epithelialization: Crosses moist surface up to 3 cm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remodeling process</td>
<td>A) 3 weeks to 2 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>B) New collagen forms which increases tensile strength</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>C) Scar tissue is only 80 percent as strong as original tissue</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Injury:** hours / days    weeks

- Injury: hours / days
- A) Immediate to 2-5 days
- B) Hemostasis: Vasoconstriction, Platelet aggregation, Thromboplastin clot
- C) Inflammation: Vasodilation, Phagocytosis
- A) 2 days to 3 weeks
- B) Granulation: Fibroblasts lay collagen, Fills & new capillaries
- C) Contraction: Wound edges pull together to reduce defect
- D) Epithelialization: Crosses moist surface up to 3 cm
- A) 3 weeks to 2 years
- B) New collagen forms which increases tensile strength
- C) Scar tissue is only 80 percent as strong as original tissue
Biochemical Differences

Healing wounds | Chronic wounds
---|---
↑ cell mitosis
↓ pro-inflammatory cytokines
↓ matrix metalloproteinases
↑ growth factors
↑ cells capable of responding to healing signals
Repeated trauma
Local tissue ischemia
Necrotic tissue
Heavy bacterial burden
Tissue breakdown

Degrades ECM
• impaired cell migration
• impaired connective tissue deposition
Degrades growth factors

↑ Production MMPs and ↓ TIMPs

Chronic wound delayed healing

Prolonged inflammation
Stimulation of macrophage and neutrophils to wound bed

Release of pro-inflammatory cytokines

TNFα and IL-1β
**TIME Principles of Wound Bed Preparation**

Wound bed preparation accelerates healing

<table>
<thead>
<tr>
<th>Tissue non viable or deficient</th>
<th>Infection or inflammation</th>
<th>Moisture imbalance</th>
<th>Edge of wound non advancing or undermined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defective matrix and cell debris</td>
<td>High bacterial counts or prolonged inflammation</td>
<td>Desiccation or excess fluid</td>
<td>Non-migrating keratinocytes Non-responsive wound cells</td>
</tr>
</tbody>
</table>

- **Debridement**
  - Low bacterial counts and controlled inflammation
  - Restore cell migration, maceration avoided
  - Stimulate keratinocyte migration

- **Antimicrobials**
  - Low bacterial counts and controlled inflammation
  - Restore cell migration, maceration avoided
  - Stimulate keratinocyte migration

- **Dressings compression**
  - Low bacterial counts and controlled inflammation
  - Restore cell migration, maceration avoided
  - Stimulate keratinocyte migration

- **Biological agents**
  - Low bacterial counts and controlled inflammation
  - Restore cell migration, maceration avoided
  - Stimulate keratinocyte migration

- **Adjunct Therapies Debridement**
  - Low bacterial counts and controlled inflammation
  - Restore cell migration, maceration avoided
  - Stimulate keratinocyte migration
Debridement Methods

• Surgical: excise
• Mechanical: adherence, sheer, irrigate
• Autolytic: topical
• Enzymatic: topical
• Biological: topical
Autolytic Debridement

- The process by which the wound bed utilizes phagocytic cells and proteolytic enzymes to remove debris
- This process can be promoted and enhanced by maintaining a moist wound environment
Autolytic Debridement Considerations

- Less aggressive
- Slower
- Easy to perform
- Little or no discomfort
- Performed in any setting
- Contraindication: infection
Enzymatic Debridement

- The use of topically applied chemical agents to stimulate the breakdown of necrotic tissue

- Common Topical Agents
  - Papain-Urea
  - Papain-Urea-Chlorophyllin
  - Collagenase
Enzymatic Debridement

**Collagenase**

- Derived from *Clostridium Hystoliticum*
- Highly specific for peptide sequence found in collagen
- Less aggressive debridement
- Site of action – collagen fibers anchoring necrotic tissue to the wound bed

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Enzymatic Debridement

**Papain-Urea**

- Proteolytic enzyme derived papaya$^6$
- Urea is added as a denaturant$^6$
- Site of action – cysteine residues on protein$^8$

$^6$Falabella (1998) $^8$Sherry and Fletcher (1962)
Enzymatic Debridement Considerations

- Should be painless
- Less traumatic than surgical or mechanical debridement
- Easy dressing change
- Observe caution with infected wounds

- Consider for individuals who:
  - Cannot tolerate surgery
  - Long-term-care facility
  - Home care*

*Agency for Healthcare Research and Quality (1994)
The right method is a **clinical decision** that requires judgment.
Bacterial Balance

- Intact skin is a physical barrier
- Skin secretes fatty acids and antibacterial polypeptides
- Normal flora prevent pathogenic flora from establishing
Bacterial Burden

- Tissue bacterial levels > $10^5$/gram have consistently resulted in impaired healing causing:
  - Metabolic load
  - Produces endotoxins and proteases

13Robson (1997)  14Dow (2001)
Efficacy of traditional topical antibiotics

- Leyden & Kligman, 1979: Neomycin contact sensitivity < 1% skin testing.
- Booth, et al., 1994: Minimum Inhibitory Concentration mg/L

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>A: Neomycin</th>
<th>B: Bacitracin</th>
<th>C: Polymyxin B</th>
<th>(TAO): A+B+C</th>
<th>Synergy</th>
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</thead>
<tbody>
<tr>
<td>Staph Aureus</td>
<td>1</td>
<td>54</td>
<td>61</td>
<td></td>
<td>synergy</td>
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<tr>
<td>Pseudomonas aerug.</td>
<td>32</td>
<td>&gt;6917</td>
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<td></td>
<td>synergy</td>
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<tr>
<td>Enteric bacillus</td>
<td>8</td>
<td>&gt;6917</td>
<td>1</td>
<td></td>
<td>synergy</td>
</tr>
</tbody>
</table>

- Dire, et al., 1995: Uncomplicated sutured soft tissue trauma wounds

<table>
<thead>
<tr>
<th>Topical Agent</th>
<th>Infection Rate</th>
</tr>
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<tbody>
<tr>
<td>Bacitracin Zinc</td>
<td>5.5%</td>
</tr>
<tr>
<td>TAO</td>
<td>4.5%</td>
</tr>
<tr>
<td>Petroleum</td>
<td>17.6%</td>
</tr>
</tbody>
</table>
3 “Rules” for Topical Antimicrobial Agents?

• Do not use antibiotics that are used systemically – ability to breed resistant organisms (topical gentamicin, tobramycin)

• Do not use agents that are common allergens (neomycin, gentamicin, amikacin, tobramycin, bacitracin, lanolin)

• Do not use agents that have high cellular toxicity in healable wounds (povidone iodine, chlorhexidine, hydrogen peroxide)

Sibbald 2003
Topical Antimicrobials: Silver

- Centuries of use
- Cytotoxicity associated with carriers not silver - ex. Silver nitrate, Silver sulfadiazine
- Traditional delivery required repeated applications due to binding with chlorine and proteins
- New silver dressings allow for continued silver release into the dressing - up to 7 days

Demling and DeSanti (2001)
Why Silver for Wound Bed Preparation?

- Broad spectrum antimicrobial: yeasts, molds & bacteria, including MRSA

- Kills microbes on contact: inhibition cellular respiration, denatures nucleic acids, alters cell membrane permeability

- Does not induce resistance: if used at adequate levels

- Low mammalian cell toxicity
Nanocrystalline Silver

- Decreased size of silver particles leads to increased proportion of surface atoms

- The nanocrystalline structure is responsible for the rapid and long lasting action\(^\text{15}\)

\(^{17}\text{Demling and DeSanti (2001)}\)
Evaluating Silver Products

- Minimum bactericidal concentration (MBC) - amount of antimicrobial agent required to kill a given microbe

  MBC is represented by a log reduction of 3

  Stratton et al (1991)
  
  – The silver required varies from 5ppm - 50+ ppm for clinically relevant microbes

  
  – MBC of silver for MRSA = 60.5 ppm

  Calculated from Maple et al (1992)
Moist Wound Environment

Additional benefits

• Faster healing
• Capacity for autolysis
• Decreased rates of infection
• Reduced wound trauma
• Decreased pain
• Fewer dressing changes
• Cost effective
Exudate from a Chronic Wound

- Different from acute wound
- Imbalance of growth factors and pro-inflammatory cytokines
- Excessively high levels of proteases
- Degrades ECM and selectively inhibits proliferating cells

*Enoch and Harding, 2003*
Managing Moisture Imbalance

- Exudate amount

<table>
<thead>
<tr>
<th>Films</th>
<th>Hydrogel</th>
<th>Hydrocolloid</th>
<th>Alginate</th>
<th>Foams</th>
<th>Specialty Absorbent</th>
<th>Suction Vac</th>
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<tbody>
<tr>
<td>None</td>
<td>Small</td>
<td>Moderate</td>
<td>Large</td>
<td>None</td>
<td>Small</td>
<td>Moderate</td>
</tr>
</tbody>
</table>
Suction Vac Therapy

Management of open wounds

- increases granulation rate > 5x’s
- success depends on pore size, -125mmHg
- reduces wound volume
- requires changing every 2 days
- vascular ingrowth and healing appear to be due cell deformation
- early epithelial cells lack rete pegs and are easily strained to 5-20%, postulated mechanism

Modern Scar Concepts (1)

- New keratinocytes lack rete pegs, are fragile, deformable and produce many fibrotic growth factors
- Fibroblasts within the injury zone are more sensitive to these and other growth factors
- Sulphated side chains develop from chondroitin produced from these fibroblasts
- The side chains cause water binding and subsequent scar rigidity
Collagenesis - Deposition - Resorption

Collagenesis

• Scar volume is dependent on the volume of collagen
• Collagen formation: mRNA mediated
• Fibroblast interferon β (IFN-β): inhibitor of collagenesis
• Transforming Growth Factor TGF β 1 (adult): stimulates collagenesis
• TGF β 3 (infant): inhibits collagenesis
• Renovo/Retinae: inhibitors of TGF-β1 activation: reduced collagenesis improving scars
• Gamma interferons and other cytokines down regulate collagen and matrix synthesis and increase monocyte retention within the wound
Collagen Deposition & Resorption

- Fibroblast and monocyte collagenase: reduce collagen deposition
- Metalloproteinases inhibit collagenases: promoting collagen deposition
- Expression of fetal metalloproteinase: loss of scarless healing
- Intralesional steroids inhibit fibroblast growth
  inhibit collagen deposition:
  - increase monocyte collagenase secretion
  - no influence on metalloproteinase
  - no influence on collagen production
Modern Scar Concepts (4)

+ The Role of Tissue Hypoxemia

- impedes epithelialisation
- increases infection: neutrophil dependent
+ reduces collagenesis in an epithelialised wound
+ compression and radiation lead to local fibroblastic hypoxemia

: Compression and radiation should be used after epithelialisation is complete
Summary of Treatments for Hypertrophic Scar and Keloids

- Surgery
- Laser Excision
- Pulse Dye Laser Reduction
- Cryotherapy
- Pressure Therapy
- Radiotherapy
- Steroid, Interferon, 5-FU Injections, Colchicine
- Topical Aldara 5%
- Prolonged taping*
- Silicone gel/sheeting*  
  patient controlled  
  inexpensive  
  non-prescription  
  few if any complications  
  well tolerated
Prolonged Paper Tape To Scar

Atkinson, et al, PRS Nov 2005; 116 (6), 1648-

- 70 pts acute scars: s/p caesarian section, Brisbane, Australia
- Micropore tape to randomized 1/2 pts after staple removal 4-7 days post-op
- Tape applied continuously for 12 weeks
- The control group received no treatment
- Scar volume was assessed by ultrasound
- Scar volume was reduced in the treatment group (p<0.05)
- High correlation between subjective scar rating & intradermal scarring (p<0.001)
- Authors postulate that tension is the cause of significant scarring
Management of Common Keloids

- Earlobe - If primary excision:
  - 3 x daily peroxide and triple antibiotic
  - remove nylon 5.0 sutures at 10-14 days, then:
    - Dermajet inject Kenalog (trimacrinolone 40mg/ml)
    - start Kelo-cote after sutures out for at least 3 months
    - start compressive clamp “ear-ring” : no Nickel
    - return every 6 weeks for further injections

  - excision alone: 45-100% recurrence
  - excision and Kenalog injection: < 50% recurrence
  - excision and irradiation: < 10% recurrence
  - excision and button compression: no recurrences
MadaJet Needle-Free Injector

Pressure Earrings
For Post Op Ear Lobe Keloid Treatment

Glori-Sil® Pressure Earrings

Glori-Sil Compression earrings are attractively designed plus hypo-allergenic and nickel-free. Fitted with DuraSil™-K silicone sheeting. Clear finish is heat-cured for durability.

Average Lobe
PS-14 Oval
Management of Common Keloids

- Earlobe - if secondary excision:
  excise and within 14 days: post-op irradiation
  either one dose of 10 Gy or up to 15 Gy in 2-4 fractions
  sutures out 14 days post-op
  Kenalog injection, compressive ear-ring and 6 week follow-up

- Dose irradiation most important factor: give $>900$ Gy
- Irradiation completed within 1-3 weeks equally effective
- ear lobe 98% successful at $>1$ yr follow-up
- small subsequent recurrences can be re-irradiated: 15 Gy

- 14 healthy subjects with hypertrophic and or erythematous scars as a result of trauma
- Scars were at least 2 years old
- Candela flashlamp-pumped dye laser: 6.5-6.75 J/cm² 1-2 treatments
- 57% improved: lightening and flatter after one treatment
- 83% improved after 2 treatments
- Continued improvement over 6 months
- Improvement was not location specific, depth of scar not assessed
Irradiation mostly contraindicated
Re-resection definitely harmful
Laser excision usually harmful
Pulse Dye lasers not helpful
Aldara 5% not helpful
Silicone sheeting not helpful
Steroid injections very helpful
Kelo-cote helpful if < 5mm raised
Kelo-cote® unique formulation

- Kelo-cote® composition:
  - Long chain polymers of silicone (Polysiloxanes)
  - Minimal Silicone dixoide cross links polymers
  - A volatile solvent allows silicone to dry on the stratum corneum in an ultra-thin sheet
Silicone Composition

Silanes: monomers

- R
- Methyl
- Higher Alkyl
- Phenyl
- CF3CH2CH2

Characteristics
- Hydrophobicity & Low surface tension
- Organic-compatibility and Paintability
- Thermo-stabile, Organo-compatible, Hydrophobic
- Solvent resistant

Siloxanes: polymers

more crosslinked: more solid
recurring silicone / oxygen backbone
end / side chains determine functionality

R: ie.: amine, carboxy, hydroxyl, epoxyl
Favorable properties related to scar reduction

- Intermediate forms: elastomers: gel, rubber
- Solid-liquid binding requires catalyst ‘curing’: ie. platinum, stannous octoate
- Delivery in an evaporative solvent may provide the ability to change the properties of the silicone upon delivery

- Properties influencing scar reduction include:
  - Thickness: < 0.254mm
  - Moisture vapor transmission rate: < 15mg/cm2/day
  - Oxygen permeability: > 600cc/100 in.sup.2/day
  - High stretch: 1.5lbs/in stretches > 110% length
  - Tensile strength: > 100g
  - Penetrability: 4-7mm
  - Peel strength: 2-6 g
Silicone Mode of Action

- **Potential Theories**
  - Hydration: increases
  - Oxygenation: decreases
  - Protection: increases
  - Cellular Strain: increases ?
  - Modulation of growth factors
Silicone Mode of Action

Hydration

- Kelo-cote is semi-occlusive aerating and hydrating
- Silicone absorption is limited to the epidermis
- Stratum corneum regulates fibroblast/collagenesis
- Hydration normalises the collagen synthesis
Silicone Mode of Action

Hydration

- **But not all breathable dressings will reduce scars**
- In a study comparing silicone and hydrogel dressings, silicone normalised collagen synthesis, other breathable non-silicone dressings did not
- Silicone has a scar reducing characteristic not seen with polyurethanes
- Further research ongoing
Silicone Mode of Action

Protection

• Microbial, chemical or physical irritation promote excessive collagen production in early scars:
• Keratinocyte dependent: exposed cell release growth factors
• Fibroblast dependent: Staph epidermidis Immortalization Theory
• Intact dermis is necessary for normal wound healing
Silicone Mode of Action

Modulation Theory

- Silicones oils and sheeting appear to have an influence on Fibroblast growth factors and transforming growth factors

- Silicone reduces FGF growth factors in vivo, yet (opposite in vitro)
  - Fibroblast are reduced
  - Collagenase is increased

- “Collagen production is normalised”
History of Silicone in Scar Reduction

Good review: Mustoe, et al, PRS 2002:110(2) 560-

- Perkins et al, 1983: reported silicone a new treatment for hypertrophic scars
- Ahn, et al, 1989: silicone gel improved texture, color, thickness and itching from small hypertrophic scars
- Sawada & Sone, 1990: 20% silicone gel 82% improved hypertrophic scars and keloids a.c.t. glycerin 22% improved
- Sawada & Sone, 1992: silicone gel an elastomer sheeting vs. petroleum, 6 months f/u silicone group much softer, less red
- Pamieri, et al, 1995: Found Vit E enhanced hypertrophic scar and keloids
- Phillips, et al. 1996: hydrocolloid dressings no evidence to support reduce scarring after hypertrophic scar or keloid established

Literature lacks double blind placebo controlled studies
Placebo Controlled Pilot Study Evaluating Kelo-cote in the Reduction of Scarring Following Cleft Lip Repair

- 33 patients, Santiago, Chile, 1996
- Methods: mm vertical scar shortening (A-B) mm depth lip notch *average width scar mm
  scar softness 0-3 grade
  scar erythema 0-3 grade
- 6 week follow-up results
Markedly reduced erythema (p< 0.005)
Reduced horizontal scar width (p<0.05)
Chan, et al, 2005: PRS Sept 15

- Placebo controlled study prospective clinical trial of silicone gel (Scarfade®) in the prevention of hypertrophic median sternotomy scars
  - 100 wounds/50 pts Malaysia
  - Reduction of: pigmentation (p=0.02)
  - vascularity (p=0.001)
  - pliability (p=0.001)
  - height (p=0.001)
  - pain (p=0.001)
  - itchiness (p=0.001)
Sebastian et al, 2005

- Non-placebo controlled study Kelo-cote on scars: all-comers, up to 48 month follow-up
  - Data 111 patients Germany, Switzerland & Austria
  - Study: legal requirement for ‘new’ products
  - Independent study
  - Data is on all types of scars
  - Different ages of scars
  - Measurement tool is Vancouver scar scale, which is standard measurement for scars
Sebastian et al, 2005

- Patients & physicians assessment of tolerability and efficacy using 4 point scale
- Vancouver scar scale

<table>
<thead>
<tr>
<th>Score</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tbody>
<tr>
<td>Pigmentation</td>
<td>Normal</td>
<td>Hypopigmentation</td>
<td>Hyperpigmentation</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Vascularity</td>
<td>Normal</td>
<td>Pink</td>
<td>Red</td>
<td>Purple</td>
<td></td>
<td></td>
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<tr>
<td>Pliability</td>
<td>Normal</td>
<td>Supple</td>
<td>Yielding</td>
<td>Firm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>Flat</td>
<td>1 to 2 mm</td>
<td>2 to 5 mm</td>
<td>&gt;5 mm</td>
<td>Banding (rope-like)</td>
<td>Contracture</td>
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<tr>
<td>Pain</td>
<td>None</td>
<td>Occasional</td>
<td>Requires medication</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Itchiness</td>
<td>None</td>
<td>Occasional</td>
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</tbody>
</table>
Patient and Physician assessment of efficacy

% of respondents

Very Good
Good
Moderate
Unsatisfactory

Doctor
Patient
Sebastian et al, 2005

Results of patient and physician assessment - Tolerability

Patient and Physician assessment of Tolerability

% of respondents

Very Good  Good  Moderate  Unsatisfactory

Doctor  Patient

0  20  40  60  80  100
Sebastian et al, 2005

Decrease in Vancouver Scar Scale - Redness

% of patients (n=111)

- Normal skin
- No redness but dark appearance
- Redness disappears with pressure
- Severe redness

- Baseline
- After 1 month
- After 2 months
- After 3 months
Sebastian et al, 2005

Decrease in Vancouver Scar Scale - Elevation

% of patients (n=111)

Baseline

After 1 month

After 2 months

After 3 months

Flat Scar

1-4mm above skin

4-8 mm above skin

>8mm above skin
Sebastian et al, 2005

Decrease in Vancouver Scar Scale - Hardness

% of patients (n=111)

- 0%
- 10%
- 20%
- 30%
- 40%
- 50%
- 60%
- 70%
- 80%
- 90%
- 100%

- Soft like normal skin
- Partially soft
- Rubberly Hard
- Very Hard

Baseline
After 1 month
After 2 months
After 3 months
Sebastian et al, 2005

Decrease in Vancouver Scar Scale - Pain

% of patients (n=111)

- No pain
- Painful sometimes
- Moderate Pain
- Severe Pain

Baseline
After 1 month
After 2 months
After 3 months
Sebastian et al, 2005

Results by type of scar

Type of scar (%)

- Linear Hypertrophic scar: 40%
- Widespread Hypertrophic scar: 6%
- Mature Scar: 10%
- Major Keloid: 10%
- Immature scar: 17%
- Minor Keloid: 17%

% of patients (n=111)

- Good
- Very good
Sebastian et al, 2005

Results by age of scar

Age of scar (%)

- <3 months: 27%
- 3-6 months: 23%
- 6-12 months: 18%
- 12-24 months: 11%
- >24 months: 11%

Graph showing the percentage of patients in different age groups and their scar quality.
Summary of study

- Kelo-cote® rated: good/very good > 80% patients & physicians
- Physicians rated tolerability: good/very good 100% of patients
- Kelo-cote® decreased: redness, elevation, hardness, itchiness and pain of scars over a two month period
- Kelo-cote® can be used on old and new scars
- Kelo-cote® can be used to treat all types of scars
Indications for use

- Kelo-cote® is indicated for the management of:
  - Acute healing scars
  - Hypertrophic scars
  - Keloids

- Kelo-cote®™ has also been used for scars resulting from:
  - Trauma
  - Burns
  - Surgery
  - Acne
  - Post laser erythema
Length of treatment

- Minimum treatment should be 2 months
- Treat larger and older scars >3 months
- Active persons apply usually in am
- May treat with other topicals in pm
Instructions for use 0.5 oz Kelo-cote

- Ensure the area is clean and dry.
- Apply a very thin layer and allow to dry
- Apply once daily, or twice daily
- Maximum effect, 24 hours of continuous contact
- Once dry, OK to cover with pressure garments, sun block or cosmetics
- If not dried within 4–5 minutes: too much
- Gently remove the excess and allow the drying
- Larger and older scars > 90 days
- 0.5 oz contains enough Kelo-cote®, for: 7.5–10cm 2x/day for 90 days
- Reduce drying time hotter climates, keep in the refrigerator
- In colder weather, use low setting on hair dryer to reduce drying time
Warnings and Precautions

- Avoid direct contact with eyes, mucous membranes, & open wounds
- Kelo-cote® may stain clothing if not completely dry
- Store below 77°F (25°C)
- Do not use after the expiration date
Mederma: $25, 50g, EtOH, water, PEG-4, xanthum gum, sorbic acid

Scarguard: $72, 100g, with hydrocortisone, Vit E

Cimeosil: $56, 14 gram, polysiloxanes

Skin Esthetique: $24, 170g, dimethicone, arnica, copper, seaweed

Scarfade: $25, 50g, silicone dioxide, micro quartz crystals +/- vit E, K, co-enzyme Q-10

Pro-Sil: $17.50, glide-on, silicone “creams and oils”
• Kelo-cote® is a unique patent protected silicone gel

• 80% patients rate Kelo-cote® as good or very good in scar reduction

• 100% physicians rate Kelo-cote® good or very good in pt tolerability

• Kelo-cote® softens, flattens & reduces the redness of old & new scars

• Kelo-cote® is a comparatively cost effective treatment
Clinical Care: ‘Olsen’s Rule’

• “Most wounds heal proportionate to the time and attention they are given”
• Steristrip minimum of 4 - 7 days & then another 5 days after changing strips
• Early application of Kelo-cote, avoid any contact with clothing for 6 weeks minimum: diapers OK
• All open wounds treated with 1/2 peroxide, bacitracin, minimum of twice daily
Hand
Breast Reduction
Mastopexy Augmentation
Verbal testimonial: Mastopexy Augmentation
Breast Cancer Reconstruction

- Bilateral Transverse Rectus Abdominus Myocutaneous Flap
Abdominoplasty

< Olsen’s Rule
Facelift
Head and Neck Excisional Surgery
Cleft Lip Surgery
Looking into the Future

Bioglass and nano crystal Silver Spray