Over-the-counter scar products for postsurgical patients: Disparities between online advertised benefits and evidence regarding efficacy

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Surgical patients frequently read about over-the-counter (OTC) scar products online and ask physicians for advice about product use. We summarized the characteristics of the 20 best-selling scar products on the Web site drugstore.com and reviewed the medical literature for data supporting the efficacy of OTC scar products used on fresh postsurgical wounds. Products had an average price of $16.25 (range $9.49-$59.99) and an average of 9.2 ingredients (range 1-29). Silicone, vitamin E, and onion extract were common ingredients. Although weak evidence indicates that silicone gel dressings may improve postsurgical scar appearance, published evidence does not support postoperative use of most scar products. However, many products have multiple ingredients, and few clinical trials assess the ingredient combinations of specific products. The practical information about OTC scar products and published efficacy data found in this review may help physicians to counsel patients about postsurgical product use and counter unrealistic expectations gained from online advertisements. (J Am Acad Dermatol 2009;61:e31-47.)

INTRODUCTION

Estimates based on Medicare codes over the past decade document a substantial increase in procedures to remove malignant skin lesions. Whether or not they are at high risk for pathologic scarring, patients undergoing surgery frequently seek for recommendations about using over-the-counter (OTC) scar products that they find online. Although surgery inevitably results in scarring, product advertisements that promise to “prevent” or “fade” scars by modifying scar volume, color, and texture may create unrealistic expectations about the appearance of their postsurgical scars. Patients who are enthusiastic about the products’ advertised benefits may not trust physician advice that conflicts with online information, especially if the physician lacks familiarity with the OTC products and the relevant medical literature.

Multiple reviews have summarized the evidence supporting the efficacy of various categories of scar products, but these reviews are not directly applicable to immediate postsurgical product use. To improve the physician’s ability to advise patients about the potential benefits of using OTC scar products after surgery, we identified the best-selling OTC scar products on the Web site drugstore.com and characterized their prices, advertised benefits, ingredients, vehicles, directions for use, warnings, and regulation by the U.S. Food and Drug Administration (FDA). We then reviewed the literature and solicited product manufacturers for evidence to substantiate product advertising claims. Specifically, we sought evidence supporting the efficacy of these products as defined by improvement in the overall appearance of postsurgical scars, including the prevention of pathologic scarring (hypertrophic scars and keloids). Knowledge of both the practical characteristics of OTC scar products and published evidence regarding their efficacy may improve physicians’ ability to counsel patients about the use of OTC scar treatment products after surgery of the skin.

METHODS

In May 2006, the keyword “scar” on the search function of the popular consumer Web site drugstore.com was used to identify OTC scar products.
A literature review was conducted to assess the efficacy of OTC scar products (as defined by their ability to improve scar appearance), and manufacturers of all of the products were contacted with certified letters requesting data to support the products’ advertised efficacy claims. The literature search specifically sought (1) evidence pertaining to the efficacy of ingredients listed as active on the OTC scar product labels (sunscreen, hydrocortisone, silicone, and hydroquinone) and (2) evidence of the efficacy of 3 of the most common types of OTC scar products: silicone gel dressings, topical products containing onion extract, and topical products containing vitamin E. On September 1, 2008, PubMed was searched for all English-language human studies published from January 1, 1995 to September 1, 2008 using the following key words: (1) “scar” and “silicone,” (2) “scar” and “onion,” (3) “scar” and “vitamin E,” (4) “scar” and “sunscreen,” (5) “scar” and “hydroquinone,” (6) “scar” and “hydrocortisone,” and (7) “scar” and “topical steroid.”

We examined the resulting articles and included all studies meeting our inclusion and exclusion criteria in this review. Inclusion criteria were prospective, controlled clinical trials involving application of silicone gel dressings or topical agents containing onion extract, vitamin E, sunscreen, or topical steroids to fresh postsurgical wounds closed with sutures. Studies of mature scars, evolving scars already exhibiting hypertrophic or keloid changes, burn wounds, and animals were excluded. Studies using the European product Contractubex gel (contains heparin and allantoin in addition to onion extract) were also excluded. We also examined the references provided by manufacturer responses and reviewed all prospective clinical trials that (1) involved application of a topical product to fresh postsurgical wounds closed with sutures, (2) did not meet our exclusion criteria, and (3) were not already found in our PubMed search.

RESULTS

OTC scar products from drugstore.com

The drugstore.com search yielded 20 unique OTC scar products. Table 1 lists these products from best- to worst-selling and includes information regarding the price, ingredients, vehicle, directions for use, warnings, and efficacy claims.

The average cost of the smallest available unit for each of the 20 products was $16.25 (range $9.49-$59.99). With a mean cost of $38.99, the 3 best-selling products ranked among the most expensive.

The most common marketing claims included creating smoother scars (11 products), softening scars (8 products), and minimizing discoloration (6 products). Five products claimed to be “recommended” by or the “choice” of healthcare professionals. Manufacturers recommended various frequencies and durations of application of the products to scars. Four products (Mederma, derma e Scar Gel, ScarSof Scar Softening Cream, and Mederma for Kids) recommended application at least 3 times daily for 8 weeks or more, and 3 products (Neosporin Scar Solution Silicone Scar Sheets, Curad Scar Therapy, and Dr. Blaine’s Complete Scar Care) directed patients to wear the product for about 12 hours daily for at least 4 weeks or more.

Information available online from drugstore.com and from product Web sites located with a Google search contained details about ingredients for each product sold on drugstore.com.
<table>
<thead>
<tr>
<th>Name of product</th>
<th>Best-selling rank</th>
<th>Cost of smallest quantity advertised</th>
<th>Claims of efficacy*</th>
<th>Ingredients via drugstore.com/No. of ingredients listed</th>
<th>Vehicle</th>
<th>Directions for use</th>
<th>Warnings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mederma Skin Care for Scars</td>
<td>1</td>
<td>$26.99 for 1.76 oz (50 g)</td>
<td>#1 Doctor- and pharmacist-recommended product for scars. Helps old and new scars, resulting from surgery, injury, burns, acne, and stretch marks, appear softer and smoother.</td>
<td>Water, PEG-4, onion (Allium cepa bulb extract), xanthan gum, allantoin, fragrance, methylparaben, sorbic acid/7</td>
<td>Gel</td>
<td>Apply Mederma to the scar 3 times a day for 8 weeks on new scars. Apply Mederma to scar 3 times a day for 3-6 months on existing scars.</td>
<td>Not intended for use on open wounds.</td>
</tr>
<tr>
<td>Neosporin Scar Solution silicone scar sheets</td>
<td>2</td>
<td>$29.99 for 28 sheets</td>
<td>Significantly improves the appearance of existing scars. Helps prevent the formation of scars on newly healed wounds. Technology used by burn centers and plastic surgeons.</td>
<td>Silon (silicone sheeting)/1</td>
<td>Silicone sheet</td>
<td>Neosporin Scar Solution should be used for at least 8 weeks. One package (26 sheets) provides full 12-week supply. Each sheet can be worn for 3-4 days. Each sheet should be worn for minimum of 12 hours per day. Improvement may be seen in as little as 4-8 weeks.</td>
<td>This product is not sterile and does not contain antibiotics. Do not use on open wounds or unhealed skin. If rash or other allergic reaction occurs, stop use and consult a doctor. Keep out of reach of children under age 3 and pets as sheets may present a choking hazard. For external use only. Do not use on children under 2 years of age. Do not use on mucous membranes. When using this product, avoid contact with eyes. Use in well-ventilated area. Flammable until dry. Stop use and ask a doctor if condition worsens or symptoms persist for &gt;7 days. Keep out of reach of children. If swallowed, get medical help.</td>
</tr>
<tr>
<td>Scarguard Scarcare</td>
<td>3</td>
<td>$59.99 for 1 fl oz (30 mL)</td>
<td>Clinically proven to dramatically improve appearance of both old and new scars. Simply brush on twice daily and you will see a visible difference.</td>
<td>Active ingredient: hydrocortisone 0.5%; inactive: silicone, vitamin E, collodion/4</td>
<td>Liquid</td>
<td>Clean affected area with mild soap and water, dry thoroughly. Brush on twice daily. Allow to dry for 1 min before coming into contact with clothing. Reapply if peeling. Children from 2-12 years of age: ask a doctor before using.</td>
<td>Do not use on open wound or burns. Do not use if rash or irritation develops. In case of severe reaction, consult a physician or pharmacist. Do not use on infants under 3 years of age to prevent risk of ingestion and choking.</td>
</tr>
<tr>
<td>Curad Scar Therapy</td>
<td>4</td>
<td>$15.79 for 21 pads</td>
<td>Clinically proven. Reduces raised, colored and keloid scars. Scars appear softer, smoother, and flatter. Visible results within 8 weeks. For old and new scars. Silicone-free, self-adhesive pad. Recommended by plastic surgeons and dermatologists.</td>
<td>Polyurethane, sodium acrylates, alpha-tocopherol/3</td>
<td>Clear pads</td>
<td>Wash and dry scarred area. Apply adhesive pad to scar, making sure it is completely covered. Pads can easily be cut to fit your individual scar or applied side by side. Best results if pad is worn at least 12 hours per day. Results within 8 weeks Using pads for &gt;8 weeks may further improve appearance. Change pad daily.</td>
<td>Do not use on open wound or burns. Do not use if rash or irritation develops. In case of severe reaction, consult a physician or pharmacist. Do not use on infants under 3 years of age to prevent risk of ingestion and choking.</td>
</tr>
</tbody>
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Continued
Table I. Cont’d

<table>
<thead>
<tr>
<th>Name of product</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Vita-K Solution for Scars and Bruises</td>
<td>5</td>
<td>$10.31 for 2 oz (56 g)</td>
<td>Dramatic results in just weeks! You don’t have to live with embarrassing, ugly stretch marks or other unsightly skin conditions any longer. Thanks to Vita-K Solution. Clinical tests have shown that Vita-K Solution for Scars and Bruises is an effective remedy that helps fade away the appearance of stretch marks, ridge lines and other skin discolorations in just weeks. Apply Vita-K Solution to the desired area and watch the transformation begin. Vita-K Solution’s rich, cream formula penetrates deep and results have been reported with the first application. Surgeons and dermatologists have long known the remarkable benefits of vitamin K and have used it to help speed the return to normal skin tones after surgery and to minimize scarring and bruising. Start using Vita-K Solution for Scars and Bruises today and start showing off your beautiful, flawless skin. Guaranteed!</td>
<td>Water, safflower oil, mineral oil, propylene glycol, caprylic/capric triglyceride, glyceryl stearate, PEG-100 stearate, dimethicone, stearic acid, phytanodione (Super Vitamin K), magnesium ascorbyl phosphate, hydroxyethylcellulose, ethoxydiglycol, silica, titanium dioxide, iron oxide, carborner, triethanolamine, methylparaben, diazolidinyl urea, shavegrass extract (Equisetum arvense)/21</td>
<td>Cream</td>
<td>For best results apply a sufficient amount on desired area twice a day, preferably after shower or bath. When desired results are achieved, continue to use once a day to help keep scars and bruises from reappearing. Results may vary depending on your skin type and condition.</td>
<td>For external use only. Avoid contact with eyes. If irritation develops, discontinue use. Keep away from children.</td>
</tr>
<tr>
<td>derma e Scar Gel</td>
<td>6</td>
<td>$18.49 for 2 oz (56 g)</td>
<td>A unique blend of botanical extracts in this greaseless, pleasant-smelling gel softens, smoothes, and helps to diminish the appearance of scars. Also excellent for stretch marks, callouses, scar tissue, and other skin hardening.</td>
<td>Purified water, onion extract (allicin), glycerin, allantoin, dl-panthenol, Carbomer 940, methylparaben, triethanolamine, urea, fragrant oils/10</td>
<td>Gel</td>
<td>For new scars, apply 3-5 times daily for 8 weeks and for old scars 3 to 6 months for maximum benefit. Start at the center of the scar and gently spread gel outward.</td>
<td>None indicated.</td>
</tr>
<tr>
<td>Scarguard Liquid Lightener</td>
<td>7</td>
<td>$59.99 for 1 fl oz (30 mL)</td>
<td>To lighten dark skin discolorations, anywhere. First choice of thousands of dermatologists and plastic surgeons nationwide. Clinically proven to dramatically improve the appearance of darkened (brown) skin discolorations. Effective in lightening essentially any dark discolorations, including brown/age spots, under-eye circles and freckles. Simply brush on twice daily and see a visible difference.</td>
<td>Active ingredients: hydroquinone 2% Inactive ingredients: retinoic acid, melatonin, methylsulfonylmethane, butyldihydroxytoluene, sodium metabisulfite, arbutin, cystamine licorice root, dandelion root, hydroxyanisole, ascorbic acid, hydroxypropylcellulose, kojic acid, azelaic acid, acetone, propylene glycol, ethyl alcohol, distilled water/18</td>
<td>Liquid</td>
<td>Brush a small amount twice daily. Limit sun exposure and use a sunscreen, a sun-blocking agent or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from recurring. Discontinue if symptoms persist for &gt;6 months.</td>
<td>For external use only. Do not use on children &lt;12 years of age. Do not use on mucous membranes. When using this product, mild irritation may occur. Avoid contact with eyes. If contact occurs, rinse with warm water. Stop use and ask a doctor if irritation becomes severe or condition worsens.</td>
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<tr>
<td>Product Name</td>
<td>Size</td>
<td>Price</td>
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<tr>
<td>2nd Skin Scar Gel</td>
<td>15 g</td>
<td>$9.69</td>
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<td></td>
</tr>
<tr>
<td>Sudden Change Scar Zone</td>
<td>1 oz (28 g)</td>
<td>$9.99</td>
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<td></td>
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<tr>
<td>Scar FX Scar Esthetique Ointment for Scars</td>
<td>1.7 oz (51 mL)</td>
<td>$21.99</td>
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</tbody>
</table>

**2nd Skin Scar Gel** is medically proven to help flatten and fade scars. Ideal for many areas where a pad would not work. When used as directed, the 2nd Skin Scar Gel helps in the softening, smoothing, and flattening of hypertrophic or keloid scars.

**Active ingredients:**
- Silicone/1 Gel
- Gel

When used as directed, the 2nd Skin Scar Gel helps in the softening, smoothing, and flattening of hypertrophic or keloid scars.

**Silicone/1 Gel**

- Clean and dry hands and the scar site.
- Apply a thin coat on the affected area, allowing to air dry.
- Upon reapplication, wash the scar site in mild soapy warm water and dry. Follow this procedure daily. Reapplication recommended after bathing, exercising or as needed.

**Sudden Change Scar Zone** Topical Scar Diminishing Cream

**Active ingredients:**
- Octinoxate 7.5% (sunscreen)
- Zinc oxide 3.93% (sunscreen)
- Dimethicone (silicone)

**Inactive ingredients:**
- Water, hydrogenated polydecene, PEG-30 dipolyhydroxystearate, PEG-22/ dodecyl glycol copolymer, caprylic/capric triglyceride, PEG-8, hydrogenated castor oil, cyclopentasiloxane (silicon fluid), sodium chloride, silica, octyldodecanol Camellia sinensis leaf extract (green tea), butylenes glycol, Allium cepa (onion) bulb extract, DMDM hydantoin, tocopherol acetate (vitamin E), lauryl glucoside, phytonadione (vitamin K)2

Massaging Scar Zone into the scar begins the process of reducing its appearance by helping it fade, diminish and become less noticeable. When massaged into the scar twice daily, Scar Zone even helps raised and discolored scars become flatter, softer, smoother and closer to the skin’s own natural tone. Green Tea’s combination of antioxidants and ECGG helps restore damaged skin cells. Scar Zone works on new wounds that have healed or on older scars that are still visible. So no matter how long you’ve had the scar, Scar Zone should help.

**Active ingredients:**
- Cetyl alcohol, caprylic/capric triglyceride, cetyl palmitate, glycerin, dimethicone, glucosamine, Coenzyme (Q10), retinyl palmitate (vitamin A), copper peptide, Pycnogenol, arnica, cholecalciferol (vitamin D), beta carotene, tocopherol acetate (vitamin E), seaweed extract, squalane, Calendula extract, algae extract, comfrey, lecithin, ascorbyl palmitate, ascorbic acid (vitamin C), ceteareth 20, citric acid, sodium hyaluronate, steareth-2, methylparaben, propylparaben

**Infusion of arnica and calendula, cetyl alcohol, caprylic/capric triglyceride, cetyl palmitate, glycerin, dimethicone, glucosamine, Coenzyme (Q10), retinyl palmitate (vitamin A), copper peptide, Pycnogenol, arnica, cholecalciferol (vitamin D), beta carotene, tocopherol acetate (vitamin E), seaweed extract, squalane, Calendula extract, algae extract, comfrey, lecithin, ascorbyl palmitate, ascorbic acid (vitamin C), ceteareth 20, citric acid, sodium hyaluronate, steareth-2, methylparaben, propylparaben**

**Scar FX Scar Esthetique Ointment**

**Active ingredients:**
- Cetyl alcohol, caprylic/capric triglyceride, cetyl palmitate, glycerin, dimethicone, glucosamine, Coenzyme (Q10), retinyl palmitate (vitamin A), copper peptide, Pycnogenol, arnica, cholecalciferol (vitamin D), beta carotene, tocopherol acetate (vitamin E), seaweed extract, squalane, Calendula extract, algae extract, comfrey, lecithin, ascorbyl palmitate, ascorbic acid (vitamin C), ceteareth 20, citric acid, sodium hyaluronate, steareth-2, methylparaben, propylparaben

New! Effective relief for scars.

**Infusion of arnica and calendula, cetyl alcohol, caprylic/capric triglyceride, cetyl palmitate, glycerin, dimethicone, glucosamine, Coenzyme (Q10), retinyl palmitate (vitamin A), copper peptide, Pycnogenol, arnica, cholecalciferol (vitamin D), beta carotene, tocopherol acetate (vitamin E), seaweed extract, squalane, Calendula extract, algae extract, comfrey, lecithin, ascorbyl palmitate, ascorbic acid (vitamin C), ceteareth 20, citric acid, sodium hyaluronate, steareth-2, methylparaben, propylparaben**

**Scar FX Scar Esthetique Ointment**

Apply Scar Esthetique Ointment 3-4 times daily over your scar. Results can take as little as 72 hours up to 3 months.

For external use only. Keep out of your eyes. Do not use on open wounds. If a rash occurs, discontinue for 24 hours.

For external use only. Avoid contact with eyes. Not intended for open wounds. If still under treatment for wound or other skin conditions, consult your physician before using. Discontinue use if irritation occurs. For children under 6 months of age, consult a doctor. Keep out of reach of children.
<table>
<thead>
<tr>
<th>Name of product</th>
<th>Best-selling rank</th>
<th>Cost of smallest quantity advertised</th>
<th>Claims of efficacy*</th>
<th>Ingredients via No. of ingredients listed</th>
<th>Vehicle</th>
<th>Directions for use</th>
<th>Warnings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scar FX silicone sheet</td>
<td>11</td>
<td>$18.99 for one 1.5- x 3-inch sheet</td>
<td>Proven effective against surgical scars, burns, and keloids. The choice of plastic surgeons and dermatologists for non-surgical scar care. Why live with scars... begin your scar care today. Just one Scar FX is necessary to improve the texture and color for each scar. Scar FX is a medically proven product to help reduce your scars. Scar FX is effective on the most severe scars, hypertrophic [scars], and keloids as well as burns. Scar FX is a nonsurgical, low-cost approach to soften and smooth your scar. Scar FX neutralizes the scar's color and works to flatten raised scars. It is easy to use and has no reported side effects. The most inexpensive way to manage your scar is Scar FX.</td>
<td>Silicone/1</td>
<td>Silicone sheet</td>
<td>It is applied daily over your scar.</td>
<td>None indicated.</td>
</tr>
<tr>
<td>ScarSof Scar Softening Cream</td>
<td>12</td>
<td>$15.09 for 2 oz (57 g)</td>
<td>ScarSof is the original scar softening cream with retinol. It has been tested with excellent results by surgeons and other professionals to help a variety of skin conditions. Users of ScarSof have found that it provides significant improvement in the appearance and suppleness of damaged skin when used daily as directed. Don't let the name fool you, it is not just for scars. ScarSof is for any damaged skin including wrinkles, stretch marks, acne scars, burns, and even age spots.</td>
<td>Aloe vera, glycerin, cocoa butter, lanolin, tocopheryl acetate (vitamin E), retinyl palmitate (vitamin A) ergocalciferol, DMDMH, triethanolamine-carbopol 940/9</td>
<td>Cream</td>
<td>Gently massage into healed skin several times daily until soft and supple. In general, scars continue to soften for at least 2 years.</td>
<td>None indicated.</td>
</tr>
<tr>
<td>Complex Cu3 Intensive Hydrating Gel</td>
<td>13</td>
<td>$31.99 for 2.5 oz (70 g)</td>
<td>Patented copper peptide complex enhances tissue repair environment.</td>
<td>Purified water, glycerin, carborner, benzyl alcohol, preztadite copper acetate, sodium chloride/6</td>
<td>Gel</td>
<td>Must be applied immediately postprocedure. Use liberally every 2-3 hours for the first day and then every 4-6 hours for the next 7 to 10 days. Do not allow the treated area to dry out. Skin may be gently cleansed with Complex Cu3 Cleanser or saline between applications or as advised by your physician.</td>
<td>None indicated.</td>
</tr>
</tbody>
</table>
Palmer’s Cocoa Butter Formula Scar Serum, Vitamin E

Cost: $11.49 for 1 fl oz (30 mL)

Ingredients: Tocopheryl acetate (vitamin E), theobroma cacao seed butter (cocoa), shark liver oil (squalene), dimethicone, Allium cepa bulb extract (onion)/5

DermaFresh Scar & Stretch Mark Renewal Patches

Cost: $9.49 One kit = 2 large and 2 medium patches

Ingredients: Fenugreek, hop, chamomile, jojoba oil, wheat germ oil, marigold extract, avocado oil, vitamin A, vitamin B, vitamin C, vitamin E, kaolin, silicone dioxide/10

Dr. Varon’s Scar Treatment

Cost: $17.99 2 oz (30 mL)

Ingredients: Active ingredients: hydrocortisone 0.5%, silicone 4.0% Inactive ingredients: water, kojic acid, arbutin, sorbitol, carbomer, triethanolamine, EDTA, methylparaben, propylparaben, phenoxyethanol, fragrance/13

Dr. Blaine’s Complete Scar Care Treatment

Cost: $19.99 for one 2-3.5-inch pad and 0.5 fl oz solution

Ingredients: Silicone, vitamin E (alpha-tocopherol)/2

For external use only. Not intended for use on open wounds. For external use only. Discontinue use if irritation or redness develops. Keep out of reach of children.
<table>
<thead>
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<th>Name of product</th>
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<tbody>
<tr>
<td>Mederma for Kids Skin Care for Scars</td>
<td>18</td>
<td>$15.99 for 0.7 oz (20 g)</td>
<td>Goes on purple, dries clear Kid-friendly scent! Helps old and new scars resulting from cuts and scrapes, stitches, burns, bug bites, and surgery, appear softer and smoother.</td>
<td>Water (purified), PEG-4, Allium cepa bulb extract (onion), xanthan gum, allantoin, fragrance, methylparaben, sorbic acid, D&amp;C violet 2, FD&amp;C Red 4/10</td>
<td>Gel</td>
<td>Apply a thin coat of Mederma for Kids to the scar 3 times a day for 8 weeks on new scars. Apply a Mederma for Kids to the scar 3 times a day for 3 to 6 months on existing scars.</td>
<td>For external use only. Not intended for use on open wounds. This product should be used under adult supervision.</td>
</tr>
<tr>
<td>Nexcare Incision Care Kit</td>
<td>19</td>
<td>$15.79 for 3 antiseptic wipes, 3 liquid skin protectant swabs, 3 long-wear sterile dressings</td>
<td>Everything you typically need to care for your incision until it heals. #1 Hospital brand. Ideal for arthroscopy, carpal tunnel surgery, laparoscopy, biopsy, abrasions and cuts and more. Continue with your after-surgery care by using Nexcare Scar Care Kit to help improve cosmetic results.</td>
<td>No additional information</td>
<td>Wipes, swabs, and dressings</td>
<td>Continue with your after-surgery care by using Nexcare Incision Care Kit to help improve cosmetic results.</td>
<td>This kit is not intended for use on infected wounds.</td>
</tr>
<tr>
<td>Nexcare Scar Care Kit</td>
<td>20</td>
<td>$10.99 for 24 Steri-Strip Skin Closures, 4 liquid skin-protectant swabs, 4 long-wear sterile covers</td>
<td>#1 Hospital brand. Ideal for: incision support after surgery, after removal of stitches and staples, treatment of small cuts and wounds. Nexcare Scar Care Kit conveniently provides everything you typically need to support your surgical incision as it heals.</td>
<td>Tegaderm/1</td>
<td>Swabs and dressings</td>
<td>Continue with your after-surgery care by using Nexcare Scar Care Kit to help improve cosmetic results.</td>
<td>This kit is not intended for use on infected wounds.</td>
</tr>
<tr>
<td>Average</td>
<td></td>
<td>$16.15</td>
<td>9.2 ingredients listed</td>
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PEG. Polyethylene glycol.

(1-4) Notes: Ingredients are only specified as active where noted.

*All statements are direct quotes from product marketing.
product except the 3M Nexcare Incision Kit. Of the 19 products with ingredients listed, the average contained 9.2 ingredients (range 1-29). In order of frequency, the 10 most common ingredients of the 20 products evaluated were as follows: silicone (including derivatives such as dimethicone or silicon dioxide), vitamin E (or derivatives), water, methylparaben, glycerin, onion extract, carbomer, polyethylene glycol, vitamin A (or derivatives), and vitamin C (or derivatives). Manufacturers specified active versus inactive ingredients on product labeling in only 4 of the 20 products (Scarguard ScarCare, Scarguard Scar Lightener, Sudden Change Scar Zone Topical Diminishing Cream, and Dr. Varon’s Scar Treatment). The only ingredients specifically identified as active in these products were hydrocortisone, sunscreens, hydroquinone, and silicone (or silicone derivatives). Many products had specific warnings. Ten of the 20 products warned against use on open wounds. Six of the products stated that they should not be used on children. Many products also recommended against application near the eyes, mucous membranes, or infected wounds.

**FDA regulation**

There is no comprehensive database to allow consumers to determine whether an OTC product is classified by the FDA as a drug, device, or cosmetic. FDA classification of individual products is a complex process beyond the scope of this article. In general, products that alter appearance are considered cosmetics, products that treat or prevent disease are defined as drugs, and instruments that treat or prevent disease are labeled as devices\(^5\) (see Table II for full definitions). A particular product may fit into multiple categories. Because OTC scar products aim to improve scar appearance, most manufacturers market scar products as cosmetics. FDA regulation varies depending on whether a device is considered a drug, a cosmetic, a high-risk device, or a low-risk device. Whereas drugs and high-risk devices require premarketing proof of safety and effectiveness, low-risk devices generally do not require premarket approval, and cosmetics do not require registration with the FDA at all.\(^5^-^8\)

Table III summarizes FDA regulations of drugs, devices, and cosmetics.

**Literature review**

Nine papers out of the 344 articles generated from our search (321 from PubMed and 23 from manufacturers) met our inclusion criteria. Of the articles reporting clinical trials of topical scar products, the majority were excluded for the following reasons: patients applied products to mature scars or evolving scars already exhibiting hypertrophic changes; patients’ scars were not specified as postsurgical; the study involved burn patients; or there was no control group. Among the 9 articles that met our inclusion criteria, 5 trials including 403 patients (830 wounds) evaluated the effects of silicone on scars. Two trials studied silicone gel sheeting,\(^9,^10\) two studied silicone gel,\(^11,^12\) and one studied both.\(^13\) Table IV provides a detailed summary of the silicone gel dressing trials. Two trials assessing the effects of onion extract on the scars of 38 patients (62 wounds) fulfilled our criteria for review.\(^14,^15\) Table V summarizes the onion extract trials. One trial evaluating the effects of vitamin E on scars met our review criteria\(^16\) (summarized in Table V). The final article that met our review criteria was obtained from the manufacturer of the Nexcare Scar Care Kit and evaluated the effects of paper tape on scars\(^17\) (see Table V). No trials fulfilled our review criteria for topical hydrocortisone, sunscreen, or hydroquinone.

**Manufacturer data**

We received postal confirmation of receipt of our certified letter requesting data to support product effectiveness claims from all but one of the manufacturers. Six manufacturers replied to our letters, five in print and one by telephone. In the single telephone reply, a representative from the product manufacturer presented anecdotal patient reports of product efficacy but could not provide any objective data. Among the 5 companies that sent written responses, one company stated they could not share any data because of confidentiality and privacy concerns. The other 4 written replies did not provide any laboratory or clinical data that had not been published in the medical literature. Two manufacturers qualified their marketing claims, explaining that “cosmetic results may vary by individual” or that the advertising claims “do not qualify as drug claims.” Only one reference, which was provided by the manufacturers of Nexcare Scar Care Kit, a product containing Steri-Strip adhesive skin closures, met our inclusion criteria\(^17\) (see Table V).

**DISCUSSION**

When researching OTC scar products online, consumers encounter many products that claim to be “recommended” by doctors, pharmacists, dermatologists, and surgeons for their “clinically proven” benefits to scars. The findings of this study may help physicians who counsel patients in the perioperative period to create realistic expectations about the effects of these products on postoperative scars.

Current labeling guidelines for products classified as cosmetics can introduce considerable confusion...
for consumers and physicians. OTC scar products that are marketed as cosmetics are not required to designate active versus inactive ingredients. Only 4 of the 20 products from drugstore.com differentiated between active and inactive ingredients. Many consumers may interpret the “active” ingredient to be the product component most likely to benefit the appearance of the scar, but this assumption may not be correct.

The PubMed search failed to generate any data to support the postsurgical use of 3 out of the 4 ingredients designated as active (hydrocortisone, sunscreens, and hydroquinone). Among all of the products, silicone was the only ingredient listed as “active” which also had evidence from the PubMed search substantiating its use. However, confusion may arise when consumers find that not all products with silicone list it as an “active” ingredient. Among the products listed on drugstore.com 10 products contained silicone or silicone derivatives, but only two products (Sudden Change Scar Zone Topical Scar Diminishing Cream and Dr. Varon’s Scar Treatment) listed silicone as an active ingredient. One product (Scarguard ScarCare) clearly designated silicone as an inactive ingredient. Consumers may wonder whether silicone is as effective as an active versus an inactive ingredient.

Current regulations mandate that cosmetics list ingredients by chemical name in descending order of predominance but do not require disclosure of ingredient amounts or concentrations. Vita-K Solution for Scars & Bruises, the fifth best-selling product on drugstore.com illustrates the confusion consumers might encounter when reading product ingredients. Phytonadione (vitamin K) is not designated an active ingredient and is listed as the tenth of 21 ingredients. However, the prominence of “Vita-K” in the product’s marketing name implies that vitamin K is an important ingredient that is beneficial to the appearance of scars. Consumers may purchase this product expecting vitamin K to yield great benefits; however, this ingredient may in reality be a minor component of the product with no significant influence on scar appearance.

To help consumers sort through confusing interpretations of product labels and aid in the decision of whether to purchase a particular product, physicians may turn to published medical data. Mederma advertises itself as the “#1 Doctor and pharmacist recommended product for scars” and was the best-selling product on drugstore.com. The product lists onion extract second among its ingredients (no ingredients are designated active). In vitro studies suggest that onion extracts containing quercetin, cepaene, and thiosulfinates could improve wound
<table>
<thead>
<tr>
<th>FDA regulation of drugs, devices, and cosmetics</th>
<th>Drugs (prescription and OTC)</th>
<th>Class III devices (highest risk)</th>
<th>Class II devices (intermediate risk)</th>
<th>Class I devices (lowest risk)</th>
<th>Cosmetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>Lidocaine, atenolol, acetaminophen</td>
<td>Heart valves, breast implants, injectable dermal fillers</td>
<td>Sutures, powered wheelchairs, lasers</td>
<td>Bandages, examination gloves</td>
<td>Lipstick, hair gel, moisturizing lotion</td>
</tr>
<tr>
<td>FDA regulation department</td>
<td>Center for Drug Evaluation and Research</td>
<td>Center for Devices and Radiological Health</td>
<td>Center for Devices and Radiological Health</td>
<td>Center for Devices and Radiological Health</td>
<td>Center for Food Safety and Applied Nutrition</td>
</tr>
<tr>
<td>Premarket review</td>
<td>NDA; the NDA includes extensive laboratory and clinical data. The clinical data must demonstrate safety and effectiveness (favorable benefit-to-risk ratio).</td>
<td>PMA is usually required. The PMA application includes extensive laboratory and clinical data. The clinical data must demonstrate safety and effectiveness (favorable benefit-to-risk ratio).</td>
<td>Premarket notification is usually required. This is done by a 510(k) submission. The 510(k) does not require clinical data.</td>
<td>Most do not require premarket review.</td>
<td>Do not require premarket review (color additives are an exception). Registration with the FDA is voluntary.</td>
</tr>
<tr>
<td>Summary of FDA regulation</td>
<td>NDA and specific labeling and manufacturing regulations</td>
<td>PMA and general controls*</td>
<td>Special controls† and general controls*</td>
<td>General controls*</td>
<td>Labeling and packaging regulations; inspection of manufacturing facilities</td>
</tr>
</tbody>
</table>

*General controls include establishment registration, device listing with the FDA, and labeling regulations. Good manufacturing practices regulation is also a general control, but many Class I devices are exempt from this regulation.

†Special controls include special labeling requirements, mandatory performance standards, and postmarket surveillance.

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*FDA, Food and Drug Administration; NDA, new drug application; OTC, over-the-counter; PMA, premarket approval.


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**Table IV. Review of silicone gel dressings**

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Silicone gel (Dermatix, self-drying and transparent gel)</td>
<td>Silicone gel (Scarfade)</td>
<td>Silicone gel sheets (Cica Care)</td>
<td>Silicone gel sheets (Sil-K or silicone gel (Epiderm); silicone held in place by Micropore tape)</td>
<td>Silicone gel sheets held in place by Steri-Strips</td>
</tr>
<tr>
<td>Surgery type</td>
<td>Lesion excision, cosmetic surgery, and scar revisions¹</td>
<td>Sternotomy</td>
<td>Dermatologic surgery†</td>
<td>Breast reduction</td>
<td>Bilateral McKissock reduction mammoplasties</td>
</tr>
<tr>
<td>Study design</td>
<td>Patients randomized to treatment or control; unblinded study</td>
<td>Upper and lower halves of each wound were randomized to treatment or control; double-blind study.</td>
<td>Patients in high- and low-risk groups were randomized to treatment or control; unblinded study.</td>
<td>Patients randomized to treatment on the left lateral and right medial sides or the left medial and right lateral of their scars and control on the other side; unblinded study.</td>
<td>Each patient had one treatment and one control breast. Half were assigned treatment of breast on dominant hand side (randomization not specified); unblinded study.</td>
</tr>
<tr>
<td>Patient population</td>
<td>Patients recruited in Italy; ethnicity not specified</td>
<td>Patients recruited in Malaysia; ethnicity: 56% Malaysian, 36% Chinese, 8% Indian</td>
<td>Patients recruited in Nashville, TN; ethnicity not specified</td>
<td>Patients recruited in the Netherlands; ethnicity not specified</td>
<td>Patients recruited in Puerto Rico; ethnicity not specified</td>
</tr>
<tr>
<td>No. of wounds</td>
<td>148</td>
<td>100 (each incision divided in half)</td>
<td>66</td>
<td>476 (incision on each breast, each incision divided in half)</td>
<td>40 (incision on each breast)</td>
</tr>
<tr>
<td>No. of patients completing study</td>
<td>148</td>
<td>50</td>
<td>66</td>
<td>119§</td>
<td>20</td>
</tr>
<tr>
<td>High-risk patients</td>
<td>Scar revision patients were included, but these patients were a minority (total number not specified)</td>
<td>No</td>
<td>Patients stratified into high- and low-risk groups</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Treatment regimen</td>
<td>Apply twice a day for 4 months with additional applications after bathing or intensive sports Start: 10 days to 3 weeks post-op</td>
<td>Apply morning and night for 3 months Start: 2 weeks post-op</td>
<td>Apply 12-24 hours per day for 6 months Start: 2 days post-op</td>
<td>Apply 24 hours per day for 3 months Start: 3 days post-op</td>
<td>Apply 12 hours per day for 2 months Start: time of suture removal</td>
</tr>
<tr>
<td>Control treatment</td>
<td>No initial treatment(^{1})</td>
<td>Control gel made of water, glycerin, propylene glycol, and hydroxyethyl cellulose</td>
<td>No treatment</td>
<td>Micropore non-occlusive tape</td>
<td>No treatment</td>
</tr>
<tr>
<td>-------------------</td>
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<td>-------------</td>
<td>-----------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>6 months</td>
<td>3 months</td>
<td>6 months</td>
<td>12 months</td>
<td>6 months</td>
</tr>
<tr>
<td>Primary end point</td>
<td>Scars graded on a scale of 1 to 4 based on color, texture, size, and elevation Classes: 1. Normal. 2. Mildly hypertrophic. 3. Hypertrophic. 4. Keloid</td>
<td>Pigmentation, vascularity, pliability, height, pain, itchiness</td>
<td>6 months</td>
<td>Abnormal scar (hypertrophic or keloid) assessed by physician observation, patient opinion, and photographic analysis</td>
<td>12 months</td>
</tr>
<tr>
<td>Result</td>
<td>Statistically significant improvement in scar quality (more Grade 1 and 2 scars, fewer Grade 3 and 4 scars) of group treated with self-drying silicone gel compared to group receiving no initial treatment</td>
<td>Improvement in all criteria assessed in silicone group as compared to control gel group</td>
<td>Statistically significant disease in abnormal scar formation in silicone-treated patients vs no treatment control in high-risk group only</td>
<td>No improvement in scar hypertrophy in either of the silicone groups compared to the Micropore control group. If silicone groups are considered together, there was a statistically significant increase in scar hypertrophy of silicone-treated vs Micropore controls.</td>
<td>Statistically significant decrease in hypertrophy in silicone-treated group as compared to control</td>
</tr>
</tbody>
</table>

\(^{\text{1}}\)Preliminary report.

\(^{2}\)Location: face (24%), dorsum (19%), abdomen (17%), leg (16%), chest (13%), arm (11%).

\(^{3}\)Location: back (27%), arms (14%), breast/chest (12%), face (11%), legs (6%), thorax (5%), hands (3%), foot (2%), head (2%), ear (2%).

\(^{4}\)At 6 months, there were 129, but 10 were lost to follow-up.

\(^{5}\)History of keloids and/or hypertrophic scars.

\(^{6}\)Conventional treatment (pressure garments, intralesional steroids, or traditional silicone gel sheeting) offered at follow-up visits if subjects had clear evidence of a developing hypertrophic scar.
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Surgery type</td>
<td>Onion extract gel</td>
<td>Onion extract gel</td>
<td>Aquaphor plus vitamin E\textsuperscript{a}</td>
<td>Micropore paper tape</td>
</tr>
<tr>
<td></td>
<td>Mohs surgery or excisional</td>
<td>Mohs surgery (locations not</td>
<td>Mohs surgery (locations not</td>
<td>Cesarean section</td>
</tr>
<tr>
<td></td>
<td>dermatologic surgery\textsuperscript{1}</td>
<td>specified)</td>
<td>specified)</td>
<td></td>
</tr>
<tr>
<td>Study design</td>
<td>Scar halves randomized to</td>
<td>Patients assigned to treatment</td>
<td>Scar halves randomized to</td>
<td>Patients</td>
</tr>
<tr>
<td></td>
<td>treatment or control; double-blind study</td>
<td>or control group (randomization</td>
<td>treatment or control; double-blind study</td>
<td></td>
</tr>
<tr>
<td>Patient population</td>
<td>Patients recruited in Boston, MA; ethnicity: 100% Caucasian</td>
<td>Patients recruited in Houston, TX; ethnicity not specified</td>
<td>Patients recruited in Miami, FL; ethnicity not specified</td>
<td>Patients recruited in Australia; ethnicity not specified</td>
</tr>
<tr>
<td>No. of wounds</td>
<td>48</td>
<td>14</td>
<td>20</td>
<td>39</td>
</tr>
<tr>
<td>No. of patients completing study</td>
<td>24</td>
<td>14\textsuperscript{4}</td>
<td>10\textsuperscript{6}</td>
<td>39</td>
</tr>
<tr>
<td>High-risk\textsuperscript{jj} patients</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Treatment regimen</td>
<td>Apply 3 times per day for 8 weeks Start: time of suture removal</td>
<td>Apply 3 times per day for 1 month Start: time of suture removal</td>
<td>Apply 2 times per day for 4 weeks Start: after surgery</td>
<td>Wear tape every day for 12 weeks; application details not specified. Start: 4-6 days after surgery (time of suture/staple removal)</td>
</tr>
<tr>
<td>Control treatment</td>
<td>Petrolatum ointment</td>
<td>Aquaphor (petrolatum-based</td>
<td>Aquaphor (petrolatum-based</td>
<td>No treatment</td>
</tr>
<tr>
<td>Duration of follow-up</td>
<td>12 weeks\textsuperscript{1}</td>
<td>ointment)</td>
<td>ointment)</td>
<td></td>
</tr>
<tr>
<td>Primary end point</td>
<td>Redness, thickness, and overall cosmetic appearance rated by blinded investigators</td>
<td>Erythema and pruritus</td>
<td>Overall appearance of each scar half, rated by physicians and patients</td>
<td>Scar hypertrophy</td>
</tr>
<tr>
<td>Result</td>
<td>No statistically significant difference between onion extract gel group and control petrolatum ointment group for all criteria assessed</td>
<td>No statistically significant difference between pre- and posttreatment scar erythema and pruritus in onion extract gel group; statistically significant posttreatment reduction in scar erythema in petrolatum group</td>
<td>In 90% of cases, topical vitamin E had no effect on (or worsened) appearance of scars.</td>
<td>Odds of developing a hypertrophic scar were significantly greater in the control group than the treatment group.</td>
</tr>
</tbody>
</table>

\textsuperscript{a}Contents of two d-alpha tocopheryl oral vitamin supplement capsules added at a concentration of 320 IU/g.

\textsuperscript{1}Location: head (50%), trunk (29%), extremities (21%).

\textsuperscript{4}Seventeen patients began the study, but 3 dropped out of the onion extract gel group because of skin irritation and did not complete the study.

\textsuperscript{6}Fifteen patients began the study, but 5 patients developed irritation on the vitamin E–treated half of their scars and did not complete the study.

\textsuperscript{jj}History of keloids and/or hypertrophic scars.

\textsuperscript{1}Telephone interview also performed at 11 months.
healing by stabilizing mast cells, decreasing inflammation, inhibiting fibroblast activity, and preventing infection.19-24 In addition, a study using a rabbit ear model demonstrated an improvement in collagen organization in Mederma-treated scars.25

However, despite these laboratory data, clinical data do not support the benefits of onion extract for improvement of postoperative scar appearance. One randomized double-blind trial reported no statistically significant difference in the 12-week postoperative appearance of scars treated with onion extract gel versus petrolatum ointment.14 Another trial showed that scars treated with onion extract gel had increased erythema compared to scars treated with petrolatum ointment at the 4-week follow-up visit.15

Vitamin E and its derivatives were the second most common ingredient in the OTC scar products. Numerous cosmetic products use topical vitamin E as an antioxidant, a humectant, and an emollient,26-30 properties which may be beneficial in improving scar appearance. As a humectant and emollient, vitamin E promotes skin hydration. The antioxidant properties theoretically may prevent abnormal scarring by reducing cell damage from free radicals released by neutrophils in the inflammatory phase of wound healing.27

Our literature search yielded a single trial evaluating the effects of vitamin E on postoperative scars. This randomized double-blind trial showed no benefit to the appearance of postsurgical scars from application of a petrolatum-based ointment containing vitamin E compared to application of a control ointment without vitamin E.16 Thirty-three percent of patients developed contact dermatitis to the vitamin E-containing ointment (compared to 0% with the control ointment), but the generalizability of this adverse effect is limited. Products containing cosmetic grade vitamin E derivatives such as tocopherol acetate may be less likely to cause irritation than the metic grade vitamin E derivatives such as tocopherol in modulating fibroblast activity and improving scar appearance.13,51,37,38

Current literature provides some data to support the use of silicone gel dressings to improve the appearance of postoperative scars. Out of the 10 products containing silicone or silicone derivatives, 3 products (Neosporin Scar Solution Silicone Scar Sheets, Scar FX Silicone Sheet, and Dr. Blaine’s Complete Scar Care Treatment) contained silicone gel sheets, and one product (2nd Skin Scar Gel) contained silicone gel. Three trials (two evaluating silicone gel11,12 and one studying silicone sheeting10) found improvement in the silicone treatment group as compared to controls. However, two of these studies10,11 were done on chest wounds (sternotomy or breast surgery) and may not be applicable to surgeries in other locations. It is difficult to assess whether the silicone dressings are more effective than other simple hydrating dressings such as petrolatum ointment. Only one trial showed superior appearance of scars treated with a silicone gel dressing compared to a control gel.11 A recent Cochrane Collaboration meta-analysis of the use of silicone gel sheeting for the prevention or treatment of hypertrophic or keloid scars provides limited additional support for the use of silicone dressings.39

Although the review’s authors caution that the trials in their review are of poor quality, they conclude that silicone gel sheeting appears to prevent abnormal scarring in high-risk individuals.

The studies provided by the manufacturers did not supply any convincing data for use of their individual products. The one reference (from the manufacturers of Nexcare Scar Care Kit) that met our inclusion criteria demonstrated that Micropore paper tape applied daily for 3 months to cesarean section wounds led to decreased scar hypertrophy compared to wounds left untreated.17 While this study indicates that prolonged support of certain wounds with tape may improve scar appearance, the study does not provide any evidence that the Nexcare Scar Care Kit (which contains Steri-Strip skin closures, liquid skin protectant swabs, and sterile covers) improves scar appearance. On the contrary, consumers may forgo purchase of Nexcare Scar Care Kit for a cheaper roll of paper tape to support their scars.

Of note, two products (Complex Cu3 Intensive Hydrating Gel and Scar FX Scar Esthetique Ointment) contain copper peptide complexes. In vitro studies of copper peptide complexes suggest that these compounds may increase the rate of wound healing by increasing collagen and glycosaminoglycan synthesis.40-42 and increased extracellular matrix accumulation has been observed with injection of copper peptides in rat models.15
Products containing copper peptide complexes may have clinical utility, but randomized clinical trials are needed to assess the efficacy of the topical application of these products to postsurgical scars.

This review has several limitations. First, only 9 clinical trials met our inclusion criteria. Most of the trials evaluated a single ingredient, whereas many OTC scar products contain numerous ingredients. Randomized clinical trials evaluating the specific combinations of ingredients in the currently marketed products are needed to make better recommendations about individual products. Second, this review only assessed the top 20 best-selling products on drugstore.com. It is possible that other OTC products, including products not available in the United States, may improve the appearance of scars. Third, interpreting the medical literature to discern the benefits of OTC scar products poses multiple challenges. Several complexities hinder the comparison of multiple scar studies: the locations and types of scars evaluated within and among studies are variable; studies have a range of follow-up and scar treatment periods; and many studies use different controls (eg, control gels, no treatment). Finally, it is difficult to objectively evaluate and compare the efficacy of scar products because of the absence of a standardized method in the literature to judge the appearance of scars.

Despite these limitations, this study provides valuable insight into the consumer perspective of OTC scar products and demonstrates the disparity between the online advertised benefits of many products and existing data to support their efficacy. Patients who learn about these products online may present to physicians with unrealistic expectations about the benefits of particular products. Practical knowledge about existing products and the current medical literature will allow physicians to help patients make informed decisions regarding the use of OTC products after surgery of the skin.

REFERENCES