The Kelo-cote® Difference

Clarification of Formulations, Ingredients and Clinical Studies

Kelo-cote® (Advanced Bio-Technologies, Inc.), Dermatix® (Valeant Pharmaceuticals) and Scarfade® (Hanson Medical, Inc.) are three brand names of topical silicone gel intended for the management of abnormal scars. It is important to understand the history of each brand and the development pathway to clearly differentiate between the current formulations of each and to accurately interpret all clinical studies conducted to date under the brand name Dermatix®.

- Prior to mid-2007, the brand known as Dermatix® was manufactured for Valeant Pharmaceuticals (Valeant) by Advanced Bio-Technologies, Inc. (ABT), using the identical patented formulation that ABT sells under the **Kelo-cote®** name. The only difference between these products during that time was the artwork on the tube and carton. During 2007, the agreement between ABT and Valeant ended, and the last shipment of Dermatix® using the **Kelo-cote®** formulation was on September 19, 2007.

- Valeant then contracted with Hanson Medical, Inc. (Hanson) to manufacture Dermatix® for them using a different formulation, the same that Hanson sells under the brand name Scarfade®. Valeant also developed two brand extensions, Dermatix® Ultra and Dermatix®C, which are combination products of silicones and other ingredients including Vitamin C, none of which are related to the patented **Kelo-cote®** formulation.

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

Key points of differentiation between Kelo-cote® and the current formulation of Dermatix®(Hanson formula):

	Kelo-cote®	Dermatix® (Hanson Formula)
Ingredients	Long chain polymers + silicon dioxide	Long chain polymers + silicone oil (dimethicone)
Patented formulation	Yes	No
Self-drying claim	Only self-drying silicone gel. Patented proprietary blend of silicones allows only **Kelo-cote®** to make this claim. Silicone dioxide cross-links with polymers to form a silicone sheet on the skin.[1]	Silicone oil prevents product from drying; recommendation on package is to wipe away excess gel. No cross linking activity, which compromises ability to remain on the skin for very long.[2]
Proof of drying[3]	After 8 hours at 80˚C, **Kelo-cote®** lost 84.2% of its weight, signifying evaporation and drying.	After 8 hours at 80˚C, the current Dermatix® formulation lost only 1.7% of its weight, indicating the oil remains on the skin and does not evaporate and dry.

Excerpt from Kelo-cote® patent document:

"After the blend is in place on the wound, evaporation of the volatile diluents restores the consistency of the silicone fluid silica to its undiluted state, thereby allowing the advantages of increased wound adhesion and "smear proofing" to be achieved without producing further damage to the wound or undue pain and discomfort during application." (US Patent Number 5,741,509)[4]

Clinical Studies: Classified by Formulation

Unlike pharmaceutical studies, which are written using generic names of study drugs, silicone gel and spray studies have been written using the brand name of the product studied. With the change in Dermatix® formulation, it now becomes necessary to identify which formulation of Dermatix® was used in the study, as results can only be attributed to the specific formulation studied and cannot apply to Dermatix® in all its formulations.

In general, clinical studies written as Dermatix® prior to July 2007 were completed using the Kelo-cote® formulation:

Lead Author	Study Name	Publication	Number of Patients	Formulation Used in Study
Sebastian G	Efficacy and tolerability of a novel silicon gel for scar treatment (Therapy surveillance with Dermatix®)	Poster presented at: 7 Darmstadt live symposium for surgical dermatology, aesthetic and plastic surgery in conjunction with the 27th Annual Meeting of the German Association for Operative and Oncological Dermatology. ABT data on file	111	**Kelo-cote®**
Murison M	Preliminary evaluation of the efficacy of Dermatix silicone gel in the reduction of scar elevation and pigmentation	J Plast Reconstr Aesthet Surg 2006; 59:437–439	6	**Kelo-cote®**
Sepehrmanesh M	Observational study of 1522 patients using Dermatix® silicone gel	Kompendium Dermatologie 2006; 1:30–32	1522	**Kelo-cote®**
Chernoff WG	The efficacy of topical silicone gel elastomers in the treatment of hypertrophic scars, keloid scars, and post-laser exfoliation erythema	Aesth. Plast. Surg 2007; 31:495-500	30	**Kelo-cote®**
Signorini M	Clinical evaluation of a new self-drying silicone gel in the prevention of hypertrophy in new scars: a preliminary report	Aesth Plast Surg 2007;31:183–187	160	**Kelo-cote®**
Fonseca-Capdevila E	Prevention of scar sequels after excision of benign cutaneous lesions	Piel 2007; 22(9):421-6	131	**Kelo-cote®**

Note that **Kelo-cote®** is the only silicone gel in a spray formulation, so all studies completed using Dermatix® Spray were done using the **Kelo-cote® Spray** formulation. Dermatix® currently offers no spray presentation.

Kelo-cote®: A Tradition of Efficacy, Tolerability, and Consistency

- 80% of physicians rate the efficacy of the **Kelo-cote®** formulation as good or very good using objective measures (Vancouver scar scale)[5]
- Only 1.5% incidence of mild side effects[5]
- Data shows the **Kelo-cote®** formulation works on all types of scars, as well as old and new scars.[5,6]
- Proven to help prevent abnormal scars in post-operative patients. Only 33% of **Kelo-cote®** formulation patients (n=80) developed hypertrophy while 72% of untreated patients (n=80) developed hypertrophy.[6]
- Recently completed studies are awaiting publication and confirm positive results seen in earlier studies done with **Kelo-cote®** formulation.

References
1. Kelo-cote® package insert, ABT **2.** Dermatix® package insert, Valeant **3.** Data on file, ABT **4.** US Patent Office, Patent Number 5,741,509 **5.** Sepehrmanesh M. Observational study of 1522 patients using Dermatix® silicone gel. Kompendium Dermatologie 2006;1:30–32. **6.** Signorini M, Clementoni MT. Cllinical evaluation of a new self-drying silicone gel in the prevention of hypertrophy in new scars: a preliminary report. Aesth Plast Surg 2007;31:183–187