



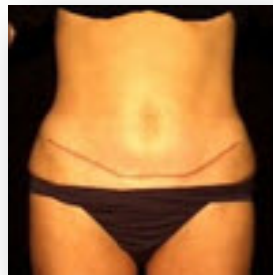
**embrace[®] Advanced Scar Therapy:
Introducing a Scar-Minimizing Product that
Works!**

Michael Longaker, MD, MBA, FACS

Scar Prevention: a growing, unmet need



- 80 million major surgical procedures performed in the US each year¹
- 230 million performed worldwide¹
- 91% of patients believe even a small reduction in their scar would be valuable²
- 75% of patients would go to any length to minimize their scarring²



¹ www.cdc.gov/nchs 2006 data 46M in patient, 35M outpatient

² Young, VL, et al., Insight into Patient and Clinical Concerns about Scar Appearance: Semi quantitative Structured Surveys. Journal of Plastic and Reconstructive Surgery, July 2009, 256-265.



embrace[®] Advanced Scar Therapy



- Novel technology that delivers the best clinical outcome in the \$15+ billion scar market worldwide
- Clinical efficacy validated through multiple clinical trials
- Intellectual property protected by 7 US issued patents, 18 pending US patents, 3 foreign issued patents, 31 pending foreign patents, and 1 Patent Cooperation Treaty (PCT) application
- FDA cleared
- Commercial Launch in 2013



Competitive landscape: imperfect solutions



Existing treatments do not effectively stress shield healing wounds to reduce scar formation and have little to no clinical evidence



Steri-strips™



Inconsistent strain



Silicone Sheeting



No tension off-loading



Gels and lotions



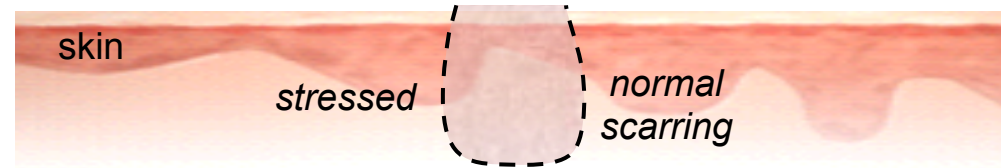
Unproven mechanism of action



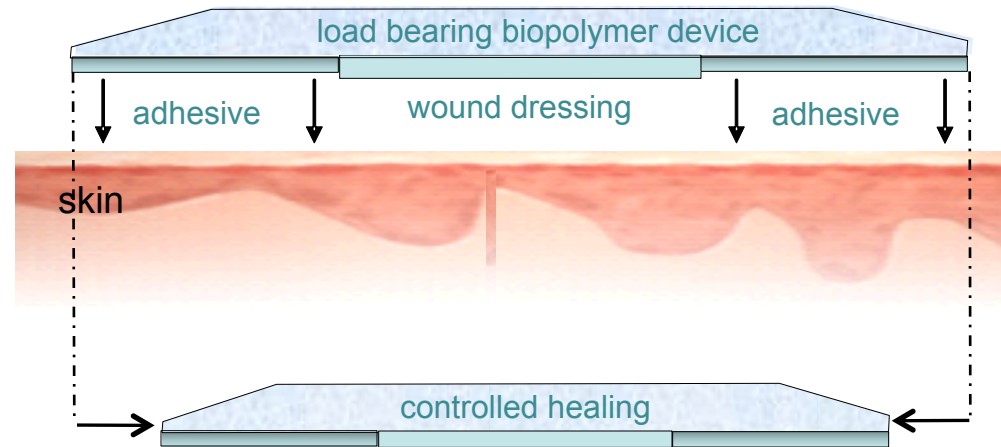
Solution: Polymer Stress-Shielding Device



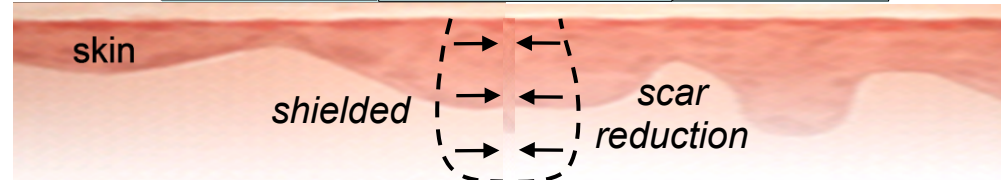
Scarring resulting from the continual forces of natural skin tension and body movement



An applicator stretches an adherent elastomeric dressing across incision site



Upon release, adhered dressing conforms to original shape, delivering an active compressive strain that buffers and protects the healing incision site.



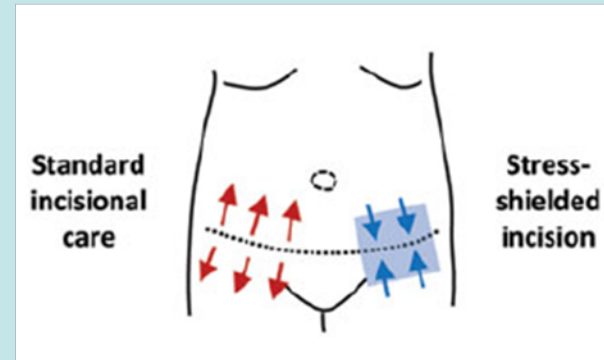
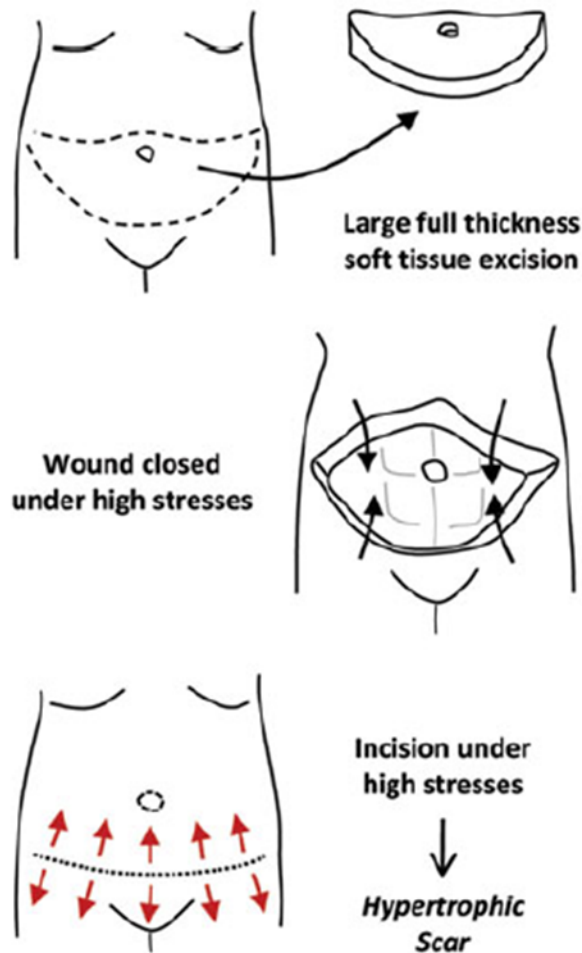
Extensive Clinical Evidence: Trials and Publications



1. Proof-of-Concept Animal Study
(Published 2011 – Annals of Surgery)
2. Proof-of-Concept Human Study “MONA LISA”
(Published 2011 – Annals of Surgery)
3. Pilot Study “LOUVRE”
(Determination of optimal compressive strain (tolerability and efficacy))
4. Pivotal Study “REFINE”
(Submitted to Plastic and Reconstructive Surgery)
5. Scar Revision Study “IMPROVE”
(Online ahead of print – Plastic and Reconstructive Surgery)



Clinical Trial Design: Abdominoplasty Challenging Indication



embrace[®] dressing randomized to one side, and physician's preferred therapy used on the other



Clinical Trial Highlights



- POSAS Results at 7 Weeks and 12 Months (*REFINE trial*)

	<i>p-value</i>	
	7 weeks	12 months
Patient overall opinion of scar	0.071	0.010
Surgeon overall opinion of scar	0.00064	0.00016

- Randomized Controlled clinical trial showed highly statistically significant difference between treated and control (* $p < 0.005$)¹
- 90% of patients were “Likely” or “Very Likely” to use embrace[®] again¹
- Clinically proven to improve scar appearance by up to 63%²
- 92% of the time, subjects rated the embrace[®] treated scar as “better” or “much better”³

¹ Lim AF, et al. The embrace Device Significantly Decreases Scarring Following Scar Revision Surgery in a Randomized Control Trial. (In press, Plastic and Reconstructive Surgery)

² Gurtner GC, et al. “Improving Cutaneous Scar by Controlling the Mechanical Environment: Large Animal and Phase 1 Studies.” Annals of Surgery 254-2 (2011): 217-225.

³ Data on File #002



Abdomen - 6 Months post-surgery



Control Side



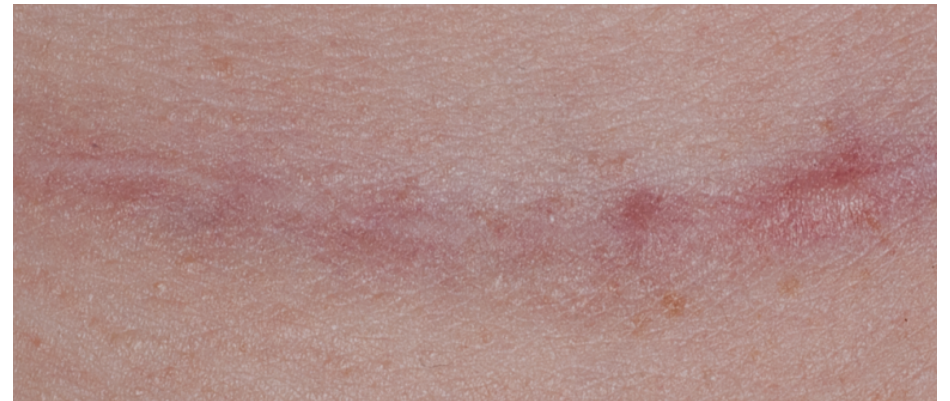
Treated Side (embrace®)



Thyroidectomy Scar Revision – 6 Months post-surgery



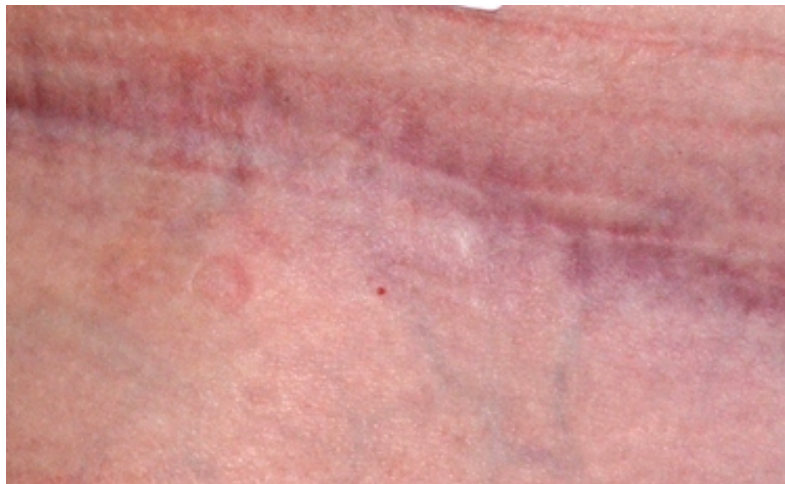
Control Side



Treated Side (embrace[®])



Abdomen Patient - 6 Months post-surgery



Treated Side (embrace®)



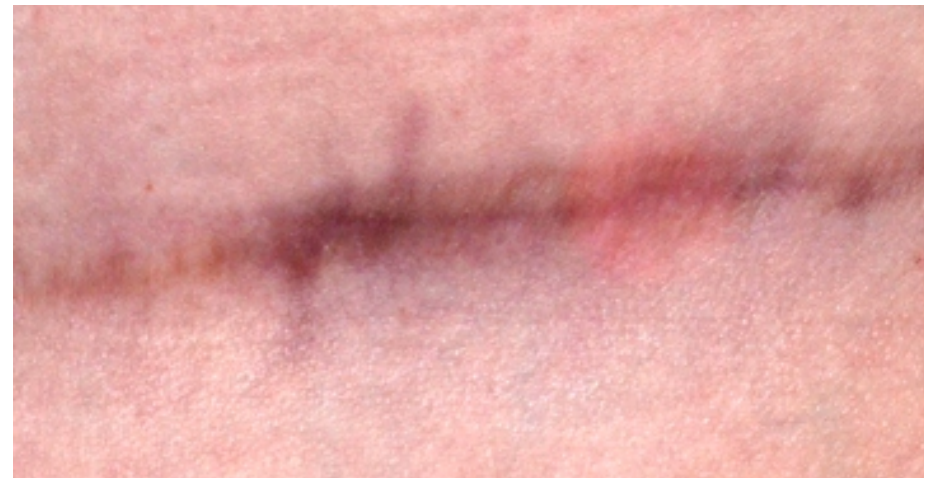
Control Side



Abdomen Patient - 12 Months post-surgery



Treated Side (embrace®)



Control Side



Scar Revision - 12 weeks post-surgery



Pre-existing scar, Marfan Syndrome



Treated with embrace[®]:
12 week follow-up



In summary...



- Very large market opportunity
- Clinically proven technology
- Weak, non-evidence based competitive set
- Publications in peer-reviewed journals
- Strong IP
- 510(K) Cleared
- Commercial launch underway





Thank You