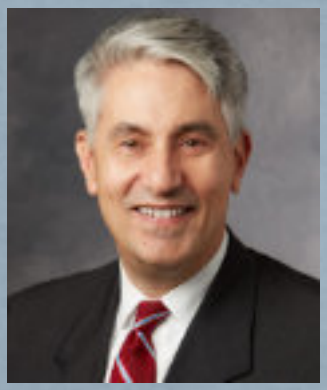
# Local injection of Verteporfin to promote wound repair via regeneration without scarring



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## Clinical Need

Clefts of the lip and/or palate (CL/P) are the second most common congenital anomaly in the USA, affecting 7.9/10,000 babies annually. While surgery is the standard of care, patient outcomes are marred by post-operative scarring that compromises both form and function. We seek to eliminate scarring and augment the lives of CL/P patients and their families.

## Solution

Our approach is to deliver a one-time, local Verteporfin injection at the time of cleft lip scar revision surgery. This will prevent scarring and reduce the need for future surgeries and psychosocial and developmental sequelae. Treatment using a one-time local injection would be technically straightforward with minimal impact on anesthesia time, making it attractive for both patients and clinicians. Given that no other treatments exist to reduce scarring post CL/P repair, as well as the large biomedical burden associated with such scarring, our approach would meet a significant clinical need and has potential for rapid transition to clinical studies.

## Competitive Advantage

Currently, there is no targeted small molecule (drug) therapy to reduce the significant biomedical burden of scarring post CL/P repair. Our team brings together expertise in craniofacial surgery (specifically, CL/P repair), wound healing, and translating devices from laboratory into commercial products. Our team members have proven track records and are key opinion leaders in regenerative medicine and cleft repair.

## Target Market

The initial target market is CL/P revision, which affects approximately 7,000 children per year in the USA, making it an orphan indication. Once we have secured FDA approval for Verteporfin in CL/P scar revision, we intend to pursue the use of Verteporfin in adult and pediatric scarring (research already supports this application).

## Regulatory Pathway

We are pursuing an orphan indication with repurposed 505(b)(2) pathway.

## Intellectual Property

Dr. Longaker has filed IP on Verteporfin in both the US and OUS for the indication of scar reduction.

## Related Publications

(1) Rinkevich Y, Walmsley GG, Hu MS, Maan ZN, Newman AM, Drukker M, Januszyk M, Krampitz GW, Gurtner GC, Lorenz HP, Weissman IL, Longaker MT. Skin fibrosis. Identification and isolation of a dermal lineage with intrinsic fibrogenic potential. Science. 2015;348(6232):aaa215. (2) Mascharak S, desJardins-Park HE, Davitt MF, Griffin M, Borrelli MR, Moore AL, Chen K, Duoto B, Chinta M, Foster DS, Shen AH, Januszyk M, Kwon SH, Wernig G, Wan DC, Lorenz HP, Gurtner GC, Longaker MT. Preventing Engrailed-1 activation in fibroblasts yields wound regeneration without scarring. Science. 2021;372(6540):eaba2374. (3) Mascharak S, Talbott HE, Januszyk M, Griffin M, Chen K, Davitt MF, Demeter J, Henn D, Bonham CA, Foster DS, Mooney N, Cheng R, Jackson PK, Wan DC, Gurtner GC, Longaker MT. Multi-omic analysis reveals divergent molecular events in scarring and regenerative wound healing. Cell Stem Cell. 2022;29(2):315-327.e6.