Keloid and Hypertrophic Scar Reduction

Superior Healing with Low Trauma Blades

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MADE IN THE USA

Keloids & Hypertrophic Scars





- Incidence: keloids and/or hypertrophic scars develop in 30%-90% of individuals [1]; an estimated 15M each year. [15]
- Epidemiology: disproportionately affects darker skin populations (up to 15-16x more likely), as well as those under 30 and during pregnancy. [1]
- Impact: cosmetically disfiguring and commonly associated with reduced quality of life, physical status and psychological health; $4B annual treatment cost to US healthcare systems, as well as significant impact on patient reported outcomes. [1]
- Intervention: the most technologically advanced, nano-polished surgical blade.
- Response: induces the lowest trauma and superior healing.
- Result: 86% reduction in adverse scarring events at greater than 95% confidence interval (p=0.029). [17]

Keloid Research Foundation (KRF)

KRF is a group dedicated to promoting research, education and advocacy for those who suffer from keloid disorder (KD). From KRF's scientifically based, patient-focused Treatment Strategy (link) clinical practice guidelines:

- KD is a genetic disorder of the wound healing mechanism(s) of the skin.
- Surgery itself is a known cause for the formation of potentially life-changing massive keloids.
- Post-operative recurrence is observed in up to 100% of patients undergoing keloid removal surgery.
- Supplemental treatments such as radiation and laser therapy have been tried, but these can result in long-term, significant, adverse effects, including increased incidence of fatal cancers.
- Limited research and pathophysiological understanding of KD, thus most treatments have been borrowed from other areas of medicine.
- KRF's recommendations are based on reducing the risk for iatrogenic worsening of the keloids after they've formed.
- Keloid Research Foundation (link)
    - *"It is in this setting that the millennia-old concept of "Primum non nocere – first, do no harm" applies most."*
    - *"We need to focus our attention on reducing the risk of harm to the patients...".*
    - *"…support (is) needed to explore and to develop totally new treatment frontiers."*

Reduce Conditions That Create Adverse Scarring

Hypertrophic scars and keloids are caused by excessive tissue response to reticular dermal injury, local inflammation, fibroblast proliferation and collagen overproduction. [1, 12]

- Reducing Inflammation: is the predominant focus of current prevention strategies. [1]
- Reduce Mechanotransduction: gentle tissue handling reduces the associated activation of the inflammatory response. [2]
- Control TGF-β: upregulation of TGF-β increases production of collagen and extracellular matrix, thus inflammatory response. [3] HTS and Keloids have a 3- to 20-fold increase in collagen production compared to normal skin. [4] Neutralization of TGF-β results in reduced scarring. [5, 6]
- Minimize Tension During Closure: tension-free wound closure is the single most important modifiable factor in preventing scar formation. When greater tension is applied to wound edges, excessive scarring is more likely to occur. [7, 8, 9]
- Shorter Healing Duration: the duration of the inflammation, as well as the intensity and frequency, are particularly important indictors of hypertrophic scars and/or keloids. [12, 14]

Prevention Is The Key to Reduction

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Start with Surgical Prevention

- *Study 1*: Surgery with conventional blades elicits 8x higher TGF-β and 50-70% increased collagen deposition with conventional blade vs. nano-polished blade from an animal study by Lee and Zhang. [10] The authors expected similar or more significant results in a clinical setting.
- *Study 2*: Nano-polished blades have been shown to reduce inflammation, tissue trauma, TGF-β, and collagens I and III deposition vs. conventional blades in a diabetic rat study by Choi and Hong. [11] The authors expected the effect of the polished scalpel to enhance wound healing not only in patients with diabetes but also in all patients with complicated wound healing conditions. This includes the reduction of hypertrophic scarring and keloid formation.
- *Study 3*: Lee and Spiro observed significantly lower levels of macrophage infiltration (40%), resulting in reduced inflammation (50%) and 9x faster wound closure after day 3 by using nano-polished blades vs conventional blades in an animal study. [16]
- *Study 4*: It has previously been shown in a study by Ogawa, that smoother wound edges naturally attach to each other with more accurate tissue apposition and thus allow for reduced wound closure tension. [12]
- *Study 5*: Nano-polished blades produce visibly cleaner incisions and smoother wound edges vs. conventional blades in all pre-clinical test settings by Douglas and Jeffcoat. [13] Examples of this are displayed in Appendices, Slides 11 and 12.
- Study 6: 86% reduction in the incidence of hypertrophic scarring (p=0.029) for equivalent patient populations in ethnicity, age, gender, smoking and comorbidities, over a 3-year period – occurrence rate 1.8% nano-polished blade, 12.3% conventional blade (see Slide 6).

Significant Scar Reduction in Clinical Practice

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Retrospective Clinical Study Series by Frank Agullo, MD, FACS (link)

Plastic surgeon in El Paso, TX

- Converted to nano-polished blades 3 years ago.
  - Patient population is 75% darker skin tones.
  - Fitzpatrick scores 4/5/6.
- Retrospective study of head and neck procedures for 3 years using nano-polished blades vs previous 3 years using conventional blades.
  - 57 patients with conventional blade; 57 patients with nano-polished blades.
  - Patient populations showed no significant statistical differences ($p>0.05$) in ethnicity, age, gender, smoking or comorbidities.
  - Hypertrophic scar occurrence rate of 1.8% with nano-polished blade (1 of 57) vs. 12.3% with conventional blade (7 of 57).
  - 86% reduction in hypertrophic scarring at greater than 95% confidence level ($p=0.029$).
- Conclusion: Significant reduction in adverse scarring events using a nano-polished blade vs. a conventional blade.

Recommendations

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Emphasize Gentle Tissue Handling:

- Adopt surgical tools and techniques that minimize tissue trauma to reduce the inflammatory response which leads to adverse scarring.

Use Nano-Polished Surgical Blades:

- Implement the use of Planatome's nano-polished blades to significantly reduce adverse scar formation, minimize trauma, reduce TGF-β levels, and promote superior healing outcomes, particularly in patients prone to keloid and hypertrophic scar formation.

Minimize Use of Elective Surgery:

- Carefully evaluate the necessity of elective surgeries in patients with a history of keloids and hypertrophic scarring, as these conditions can be exacerbated by surgical interventions.

Explore Future Areas of Research:

- Investigate the long-term outcomes of patients treated with nano-polished blades to better understand the full scope of their impact on scar formation and overall healing.
- Research potential adjunctive therapies that could be combined with nano-polished blades to further enhance scar reduction.
- Explore the genetic and molecular factors that contribute to keloid and hypertrophic scar formation to identify new prevention and treatment strategies.

Appendices

References

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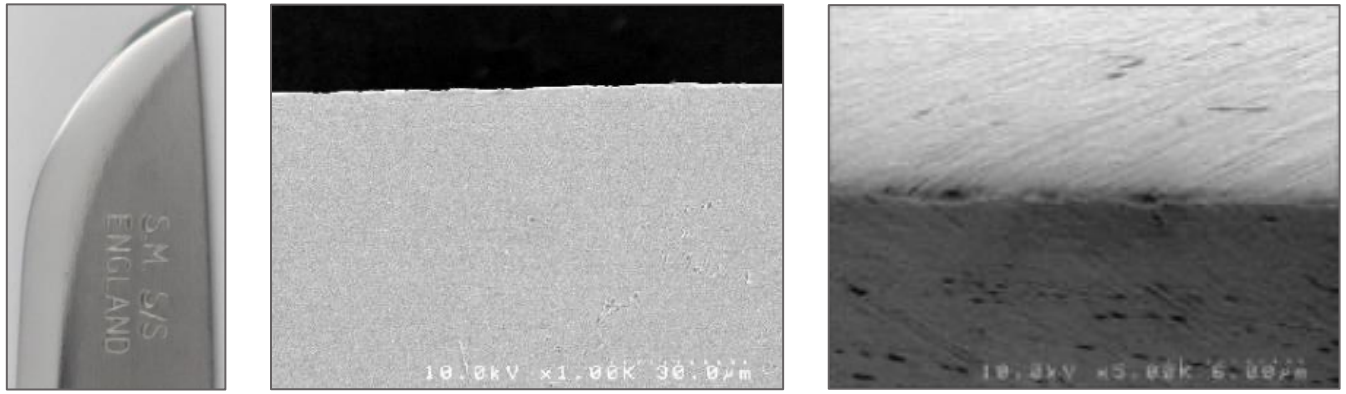
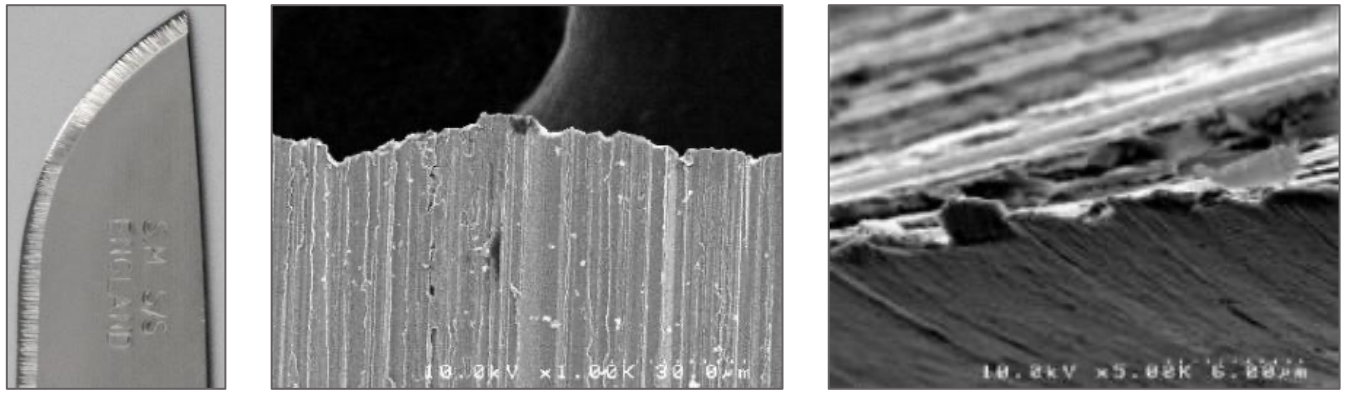
Cutting Edge

PLANATOME: is a technology platform that creates the world's most advanced surgical cutting instruments.

	Side Profile (1000x)	Top Down (5000x)
Planatome® (#10, Nano-polished)		
Conventional (#10, As Received)		

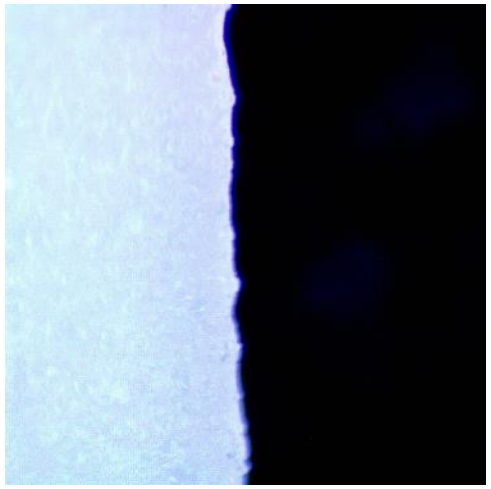
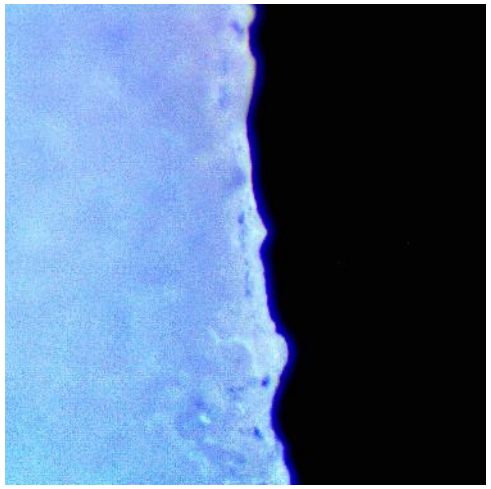
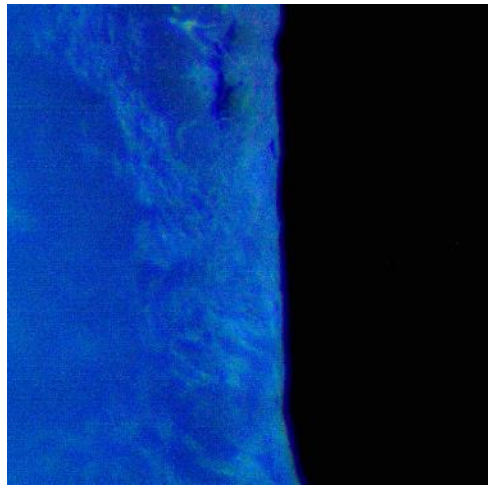
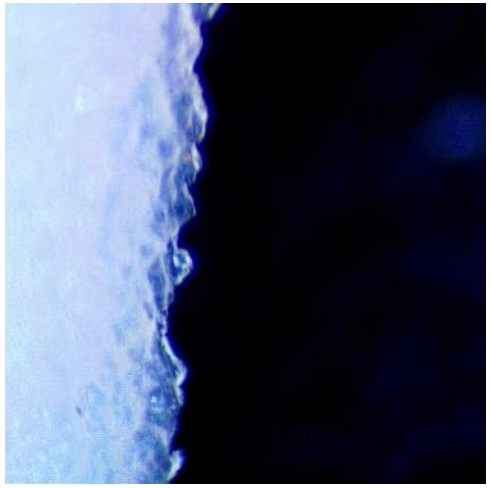
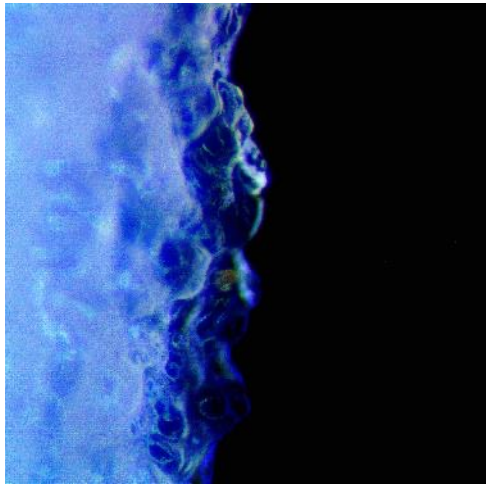
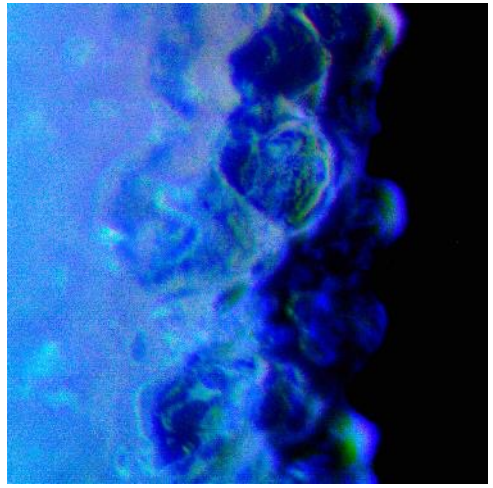
Edge Roughness (R_a of *Cutting Edge*)	
Planatome®	5-20 nm
1,000x More Precise	

Conventional	5,000-50,000 nm
Human Tissue (φ)	*10,000-100,000nm*

Tissue Damage

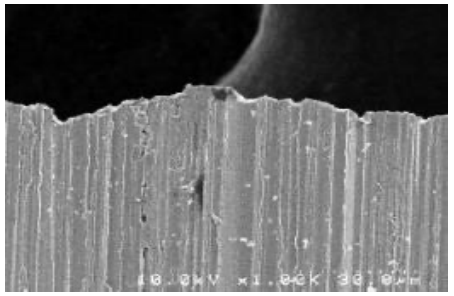
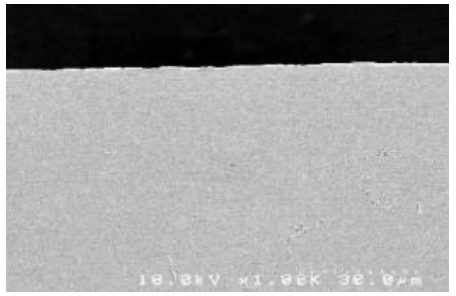
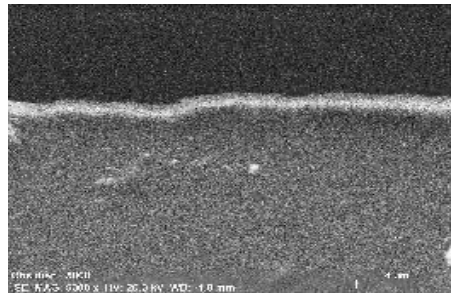
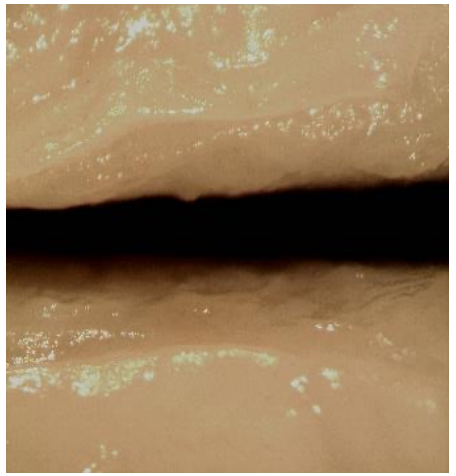
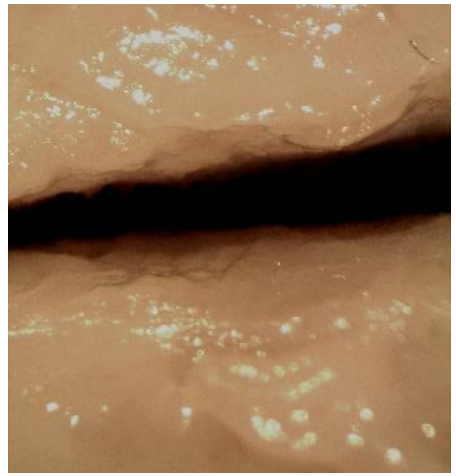
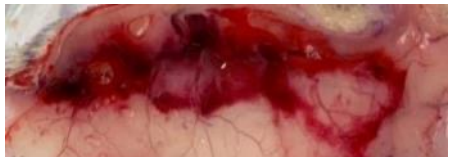
PLANATOME®

Side by Side Incisions in Porcine Abdomen Tissue

	60x Mag	120x Mag	180x Mag
Planatome® (#10, Gray)			
Conventional (#10, Bard Parker)			

Incision Comparison

PLANATOME®

	Conventional	*Planatome*	*Obsidian*
Blade Edge *(SEM @ 1000x)*			
Incision Image *(@ 22.5x, pig feet)*			
Healing *(@ 24 hrs, guinea pig)*			*NOT AVAILABLE*

Superior Healing

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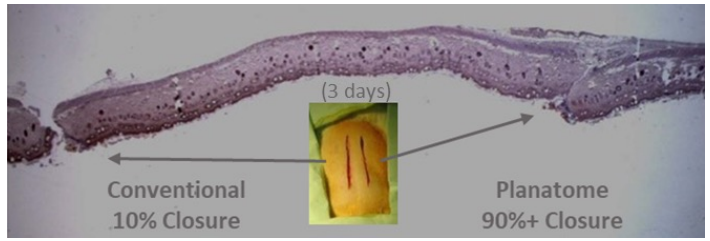
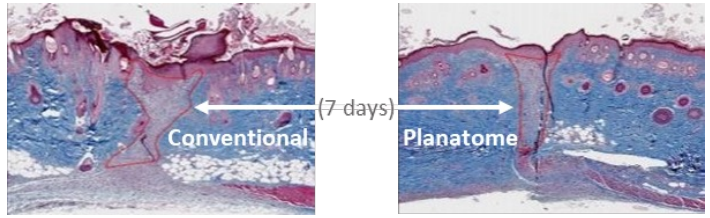
Faster Recovery

- Wound closure of 90% vs. 10%.
- Reduced bleeding and trauma.



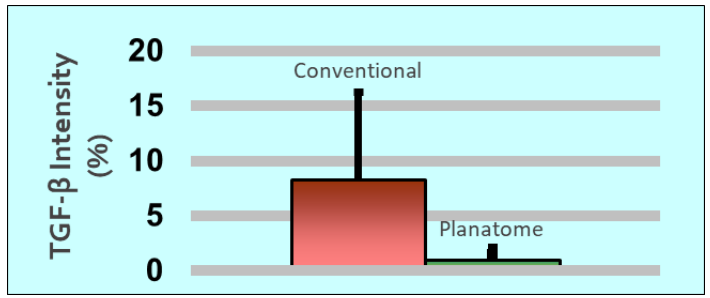
Lowest Inflammation

- 8x reduction in TGF-β; 2.5x reduction in macrophage.
- 50-60% less collagen deposited.



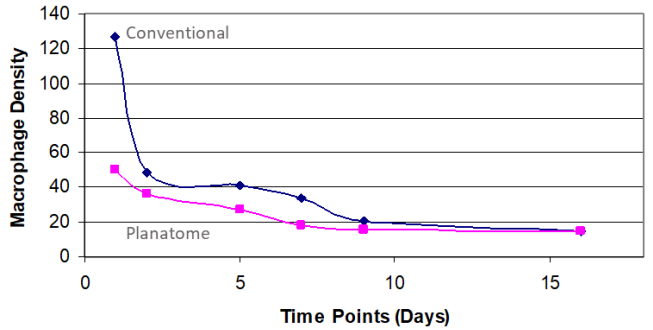
Reduced Scarring

- Smaller scars and reduced variability.
- 86% reduction in adverse scarring events (>95%, p=0.029).



Improved Immunocompromised Healing

- Diabetic healing as good or better than non-diabetic control group.
- Expected to enhance all compromised wound healing conditions.



Visibly Superior

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Clinical Study

(Dr. Frank Agullo, El Paso, TX)

Bilaterally Symmetric Incisions: Patient BRC-02-009, Age 44, Fitzpatrick IV

Conventional Blade — Planatome Blade

Bilaterally Symmetric Incisions: Patient BRC-02-015, Age 30, Fitzpatrick II

Conventional Blade — Planatome Blade

Clinical Case Work

(Dr. JW Choi & Dr. JP Hong, Asan Medical Center, Seoul, South Korea)

Medial Epicanthoplasty:

Conventional Blade — Planatome Blade

Laparotomy:

Planatome Blade

Conventional Blade

Planatome Product Pipeline

PLANATOME

2024 2025 2026

PRODUCTS	 **COMPLETE:** Blades	 **COMPLETE:** Scissors	 ***IN QUEUE:*** MIP, Rongeurs, etc.
MARKETS	MEDICAL: Surgical Blades, Scissors, MIP, etc.		
PROTECTION	US Patent 7,037,175	2x US-PCT Patent Pending	New IP