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WHITEPAPER

Superiority of Nano-Polished Surgical Blades: An Analysis of Their Impact on Healing and Implications for Postoperative Outcomes

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Introduction: The Evolution and Need for Enhanced Surgical Blades

The scalpel has been the foundation of surgical procedures for more than 1,000 years. Yet, the disposable scalpel blade has remained relatively unchanged since its original patent in 1915, despite the radical evolution of surgical techniques. Flaws in scalpel blade design have long been overlooked.

The conventional scalpel blade contains inherent defects from the manufacturing process. These irregularities in the bevel and edge negatively impact surgical outcomes as they snag, rip, and tear tissue. This increased tissue damage prolongs healing time, worsens cosmetic outcomes, and introduces the potential for increased postoperative complications.

For over a century, the medical community has assumed the scalpel blade's design and manufacturing were already optimized. While variations have been introduced, they have primarily focused on the ergonomics of the handle rather than improvements to the blade's effectiveness for patients and surgeons. The Planatome Polished Surgical Blade represents a paradigm shift. Registered with the FDA as a 510(k) exempt Class I manual surgical instrument for general use, Planatome combines an advanced technological process, Chemical Mechanical Planarization (CMP), used in silicon wafer manufacturing, with surgical instrument design to produce a clinically significant improvement over the conventional scalpel blade. In an era dominated by breakthroughs in medical technology, it's essential to improve the effectiveness of the surgical blade and understand the blade's role in ensuring better surgical outcomes for physicians and patients.

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The Science Behind the Cutting Edge

Planatome® Technology: Polished to Perfection

In many technology industries, from semiconductors to optics, surface finish is critical to overall product excellence. The healthcare sector should be no exception to this rule, especially for surgical instruments. Conventional scalpel blades, while effective, have suffered from a crucial limitation: primary bevel defects and edge inconsistencies left behind by archaic grinding practices. Although seemingly minuscule, roughness from bevel grinds and inconsistent edges are on the magnitude of human tissue cell size and, as such, adversely impact cutting quality, increasing tissue trauma during surgical procedures.

Applying technology from the semiconductor industry, researchers have identified CMP for the optimization of the blade's bevels and edge. Originally devised by IBM, CMP has been pivotal in refining silicon wafer surface finish to near-atomic perfection for over three decades. This precision-focused technique melds chemical reactions with mechanical forces and is equally effective when applied to surgical instruments. This has led to patented Planatome Technology producing a radically unique surgical blade with an ultra-smooth, precise, and consistent cutting surface (Figure 1).

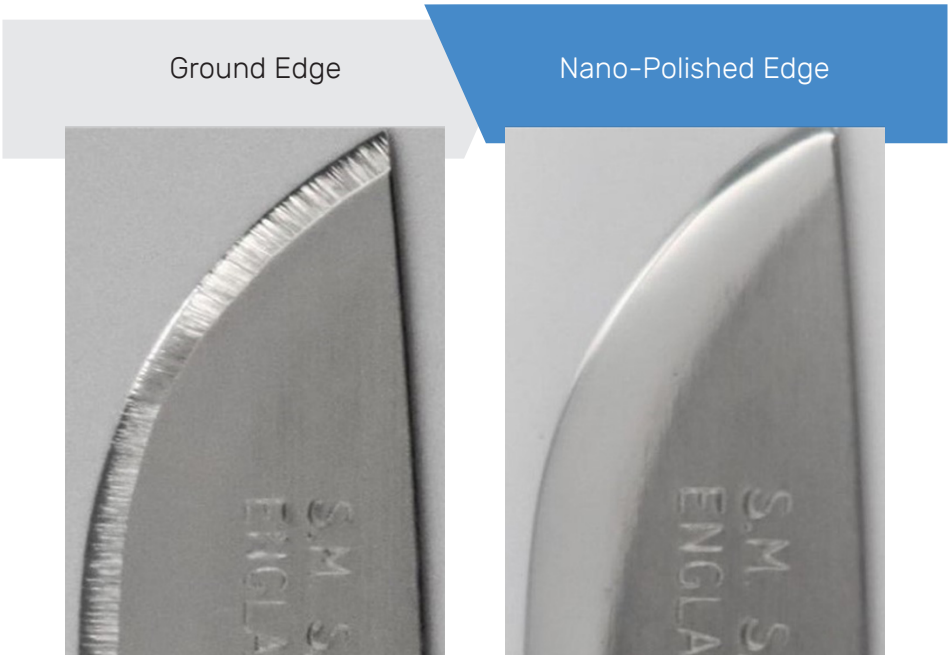

Figure 1

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From Micro-Tears to Smooth Incisions

Average surface roughness (Ra) measures and quantifies the defects in surface smoothness. Conventional scalpel blades, with their grind marks, exhibit significant surface roughness when examined at the microscopic level. In contrast, Planatome polished scalpel blades show a remarkably reduced average surface roughness in both blade bevels and cutting edge of up to 1,000x compared to conventional blades (Figure 2). The jagged features and increased roughness cause micro-tearing of tissue during incision, which, while invisible to the naked eye, slows the healing process, worsens cosmetic outcomes, and may result in increased surgical complications. The elegance of such an advancement is that without a change in workflow, doctors and surgeons can significantly improve healing while utilizing a surgical tool to which they are already very accustomed.

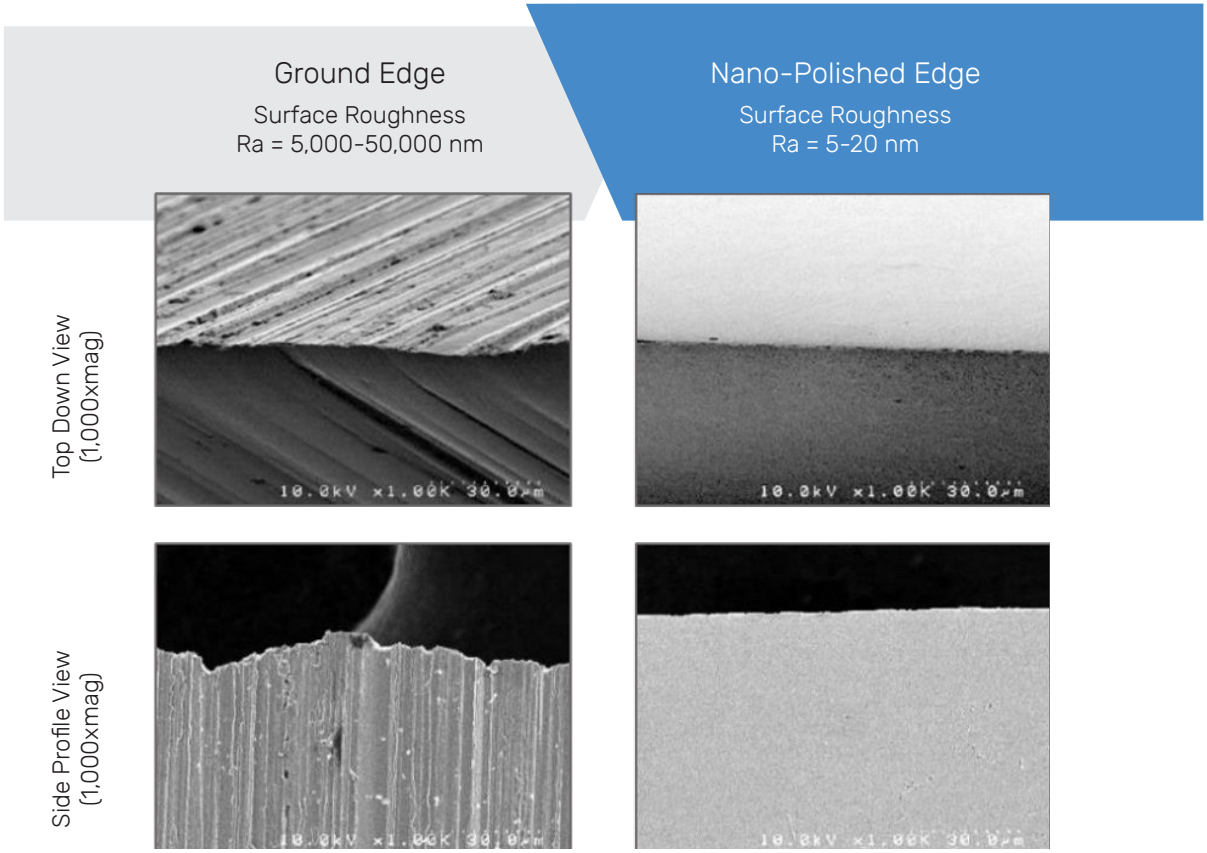

Figure 2

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Improved Postoperative Outcomes

Faster Healing

Histological studies provide a window into the microscopic world of healing. Comparisons of incisions made with conventional blades to those made with nano-polished blades reveal a stark contrast. While conventional blades achieve a meager 10% wound closure rate within 72 hours, the nano-polished blade boasts a staggering 90% closure rate in this same time (Figure 3).[i] This faster healing not only results in quicker recovery but also supports reduced opportunities for surgical site infections.

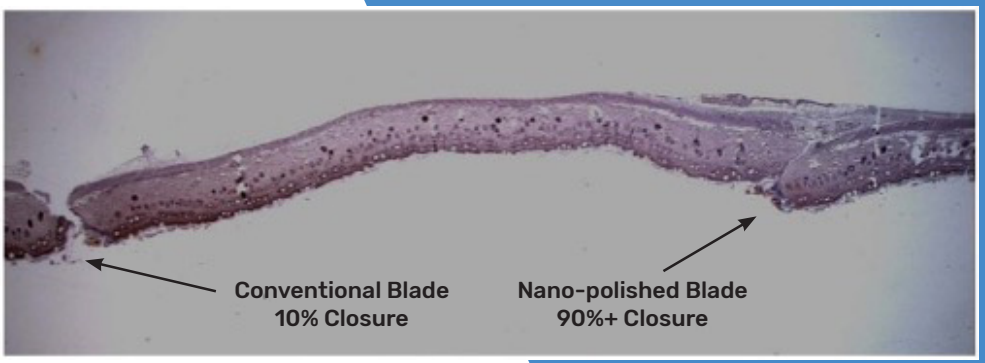


Figure 3

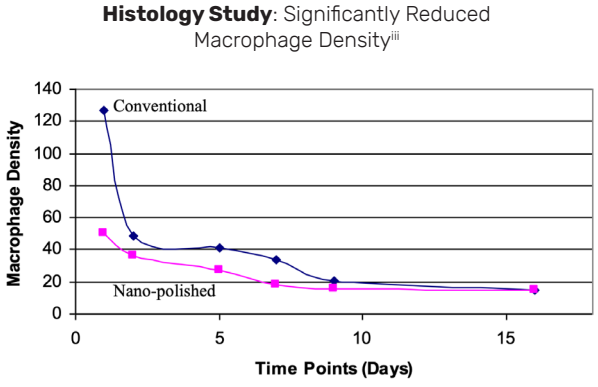


Figure 4

Less Pain with Reduced Nerve Damage

Lower macrophage inflammatory response is also linked to a reduction in pain.[ii] In a histologic evaluation of macrophage density one day after wound closure, the burden created from a conventional blade was significantly higher compared to a nano-polished blade. The macrophage density from the nano-polished blade also returned to baseline faster (Figure 4). This results in less postoperative pain.

[i] Bigdelle V, Ling MX, Clifford L. Spiro CL, Lee RC. "Effect of Scalpel Cutting Edge Roughness on Surgical Incisional Inflammation and Scarring." [Manuscript in Preparation]. American Journal of Obstetrics and Gynecology.

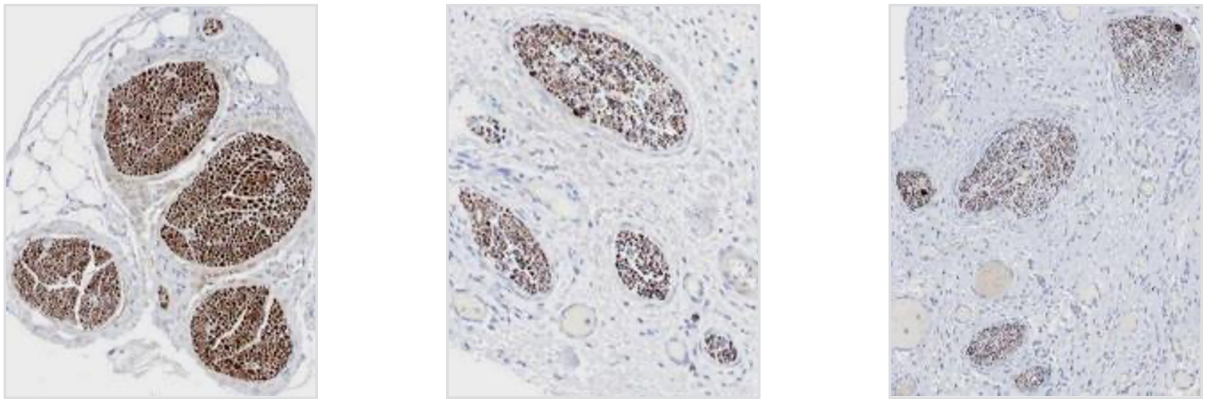
[ii] Raoof, Willemen, Eijkelkamp (2017). "Significantly reduced macrophage density, linked to pain development through the production of inflammatory mediators." British Society for Rheumatology, Aug 2017.

[iii] Planatome. (2020). Macrophage density post-nano-polished blade incision w/ Lee RC. Unpublished internal company document. 2020.

This same inflammatory reaction impacts the complex regeneration process between severed nerve segments. A study evaluating the regeneration of nerves cut with a nano-polished blade compared to those with a conventional blade demonstrated accelerated structural and functional recovery after complete nerve transection when using a nano-polished blade.

Stained nerve images illustrate nerve axon regeneration (Figure 5). The dark brown areas of the "Never Cut" image show a normal nerve axon. The center image shows a nerve cut by a nano-polished blade, and the image to the far right shows a nerve cut by a conventional blade. The darker brown areas of the nerve cut with a nano-polished blade indicate improved nerve axon regeneration. After surgery, the degree of functional recovery relies on the rapid regeneration of nerves to prevent irreversible muscle denervation.[xii]

Stained Nerve Tissues: Improved Axon Regeneration with Nano-Polished Blade



Never Cut | Nano-polished Cut | Conventional Cut

Figure 5

Electrical Impulse Data: 25% recovery after five weeks with a nano-polished blade

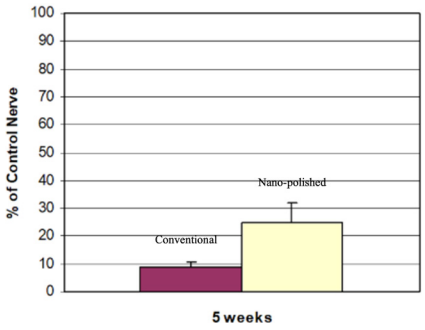


Figure 6

The same study used advanced nerve stimulus detection techniques to collect electrical impulse data from nerves cut with nano-polished and conventional blades. Nerves cut with a nano-polished blade showed 25% recovery at five weeks, while nerves with a conventional blade showed only 9% recovery. At 12 weeks, the nerves cut with a nano-polished blade showed a 92% recovery postoperatively (Figure 6).[xii]

[xii] Prescher H, Ling MX, Bigdelle V, et al. "Scalpel edge roughness affects post-transection peripheral nerve regeneration." Surg Open Sci, 2021, 4:1–6

Scarring: The Silent Aftermath

Beyond the immediate concerns of surgical site infection lies the long-term cosmetic outcomes of surgical scaring, which directly relate to the degree of tissue trauma. As surgical incisions damage tissue, it triggers an array of inflammatory signaling, specifically IL-1, TGF-b, and an increase in macrophage count, leading to collagen deposition and, eventually, scar formation. Notably, the macrophage plays a pivotal role during the inflammatory phase, guiding the deposition of new tissue via the secretion of growth factors and cytokines.[iv] However, the severity of the inflammatory response varies with the incision tool. Incisions made with nano-polished blades result in a reduced inflammatory environment, evidenced by a macrophage density that is at least 40% less compared to conventional blades.[v]

The differences are apparent on macroscopic and microscopic levels when we contrast this with incisions made using the ultra-smooth, nano-polished blade. Incisions made by a nano-polished blade result in a less traumatized wound edge (Figure 7).[iv, xi] This leads to a cleaner environment due to minimized tissue damage and reduced inflammation, hastening the return to baseline conditions. The scar that forms is less prominent and boasts a more uniform appearance due to the balanced collagen distribution enabled by the nano-polished blade. Choosing the right surgical tool can significantly mitigate the lasting impact of surgical scars.

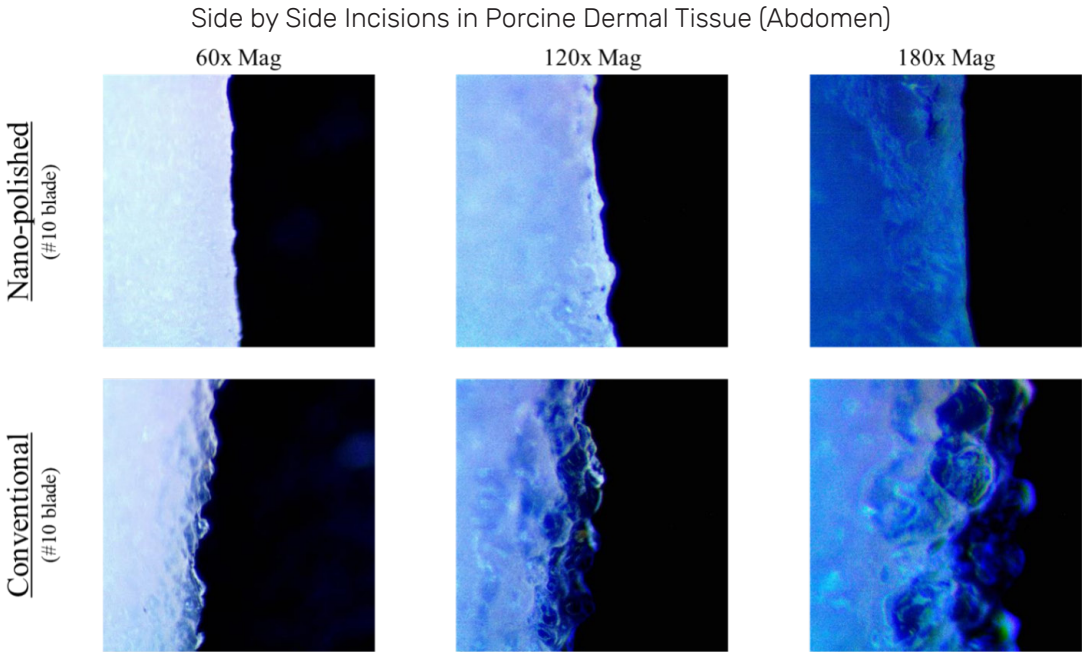


Figure 7

[iv] Chen P, Piao X, Bonaldo P. "Role of macrophages in Wallerian degeneration and axonal regeneration after peripheral nerve injury." Acta Neuropathol, 2015, 130, 605–618.

[v] Bigdelle V, Ling MX, Clifford L. Spiro CL, Lee RC. "Effect of Scalpel Cutting Edge Roughness on Surgical Incisional Inflammation and Scarring." [Manuscript in Preparation]. American Journal of Obstetrics and Gynecology.

[xi] Planatome. (2023). Microscopy Study 10062023. Jeffcoat KL. Unpublished internal company document. Oct 2023.

Continuous Midline Laparotomy in Human Dermal Tissue (Abdomen)

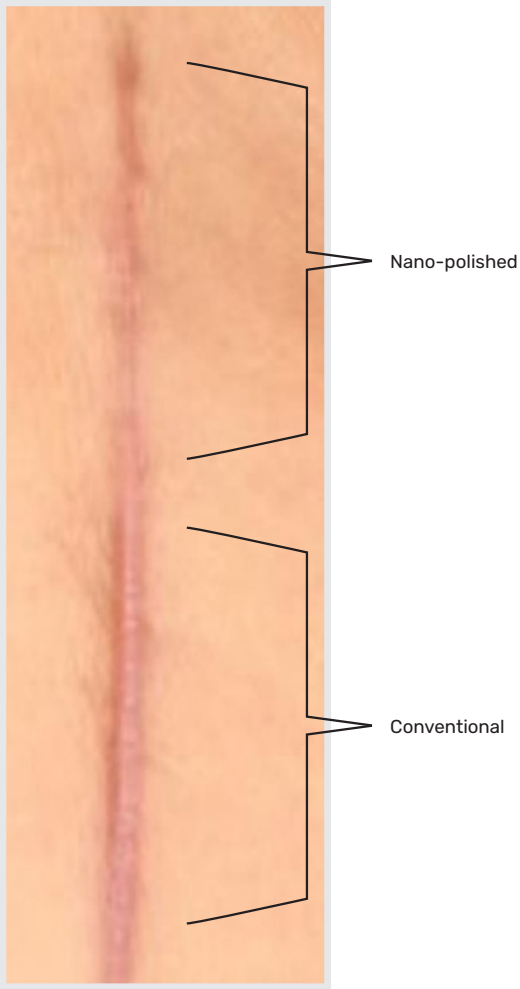


Figure 8[vii]

Several studies have shown how inflammation magnitude and mechanical tension influence scar formation. The findings revealed that by minimizing unnecessary tissue disruption around incisions with an ultra-smooth, nano-polished blade, there is a marked decrease in macrophage infiltration[iv] and reduced inflammatory response compared to conventional blades.[vi] The result is decreased collagen deposition and an aesthetically superior outcome (Figure 8).[vii] Further clinical evaluations are warranted. However, the macro-evaluation and trajectory are clear: **precision in tool selection can redefine postoperative outcomes.**

Tackling Surgical Site Infections (SSIs)

Patients and surgeons alike are universally concerned by the risks associated with postoperative complications,[viii] including concern of surgical site infections (SSIs) that occur in 2% to 4% of all patients who undergo surgical procedures.[ix] SSIs are the most common hospital-acquired infections, representing 20% of all reported infections, and also contribute to an increased hospital length of stay between 7-11 days. These infections add $10 billion in US hospital costs annually but, more importantly, jeopardize patient health and recovery by increasing the risk of death up to 11 times.[x] Conventional surgical blades, by virtue of their jagged edges, lead to undue tissue trauma, prolonged healing times, and increased chances of complications. Planatome Technology provides a solution promising a future where surgeries lead to faster recoveries, reduced pain, minimal scarring, and supports fewer postoperative complications.

[iv] Chen P, Piao X, Bonaldo P. "Role of macrophages in Wallerian degeneration and axonal regeneration after peripheral nerve injury." Acta Neuropathol, 2015, 130, 605–618.

[vi] Zang Z, Despa F, Yu N, Chioffe M, Spiro C, Bodnar EN, Lee RC. "Effect of scalpel cutting edge roughness on wound healing response." [Manuscript in Preparation]. American Journal of Obstetrics and Gynecology. 2019.

[vii] Planatome. Initial Human Case Midline Laparotomy Study. Choi JW. Unpublished internal company study. 2017.

[viii] Centiment Survey of potential patients considering plastic surgery in the next 12 months [n=208].

[ix] Berrios-Torres SI, Umscheid CA, Bratzler DW. "Centers for Disease Control and Prevention guideline for the prevention of surgical site infection." JAMA Surg. Aug 2017; 152:784-791.

[x] Ban KA, Minei JP, Laronga C, Harbrecht BG, Jensen EH, Fry DE, Itani KMF, et al. "Surgical site infection guidelines." Journal of American College of Surgeons, Jan 2017; 224(1), pp. 60-74.

PLANATOME®

Looking Ahead: A New Dawn in Surgical Procedures

The Planatome blade is the first significant improvement to the surgical scalpel blade in over a century. It is also the first to focus on the patient-based clinical benefits of better surgical blade design. Conventional blades have long been accepted as the norm, with their primary bevel defects and edge inconsistencies resulting from grinding. The emergence of the Planatome nano-polished blade symbolizes a significant milestone in the evolution of surgical instruments. Its ultra-smooth surface finish reduces tissue trauma at the microscopic level, improving wound closure and paving the way for healthier, stronger postoperative tissue response. From reduced postoperative pain due to lower inflammatory responses to minimized scarring resulting in better aesthetic outcomes to accelerated nerve regeneration, Planatome technology stands to positively impact patients' lives.

Planatome Technology provides a solution promising a future where surgeries lead to faster recoveries, reduced pain, minimal scarring, and supports fewer postoperative complications.