WHITE PAPER

Nonunion of Tibial Fractures

A Persistent Costly Problem

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ORTHOXEL Evolving Fracture Fixation

INTRODUCTION

Nonunion fractures are a persistent challenge in orthopaedic clinical practice. In the United States, the average total cost of care for treating a non-united tibial shaft fracture has been estimated at $53,506 per patient, with costs exceeding hundreds of thousands of dollars in complex cases.[1] When a nonunion occurs, patients experience prolonged disability and higher rates of depression, opioid use, and narcotic dependency.[1–3] The individual economic burdens resulting from nonunion disability can also be profound. Only 59% of lower-extremity nonunion patients return to work within one year.[4] Indirect costs, mainly due to lost productive work time, have been estimated up to 7-9 times the direct healthcare costs.[1,5]

The financial burden of nonunion on healthcare systems is staggering. For tibial shaft fractures, the consensus nonunion rate is at least 12%, based on data from US, UK, and European Level I trauma centers and US managed care claims databases.[1,2,6–11] In the US alone, multiplying this nonunion rate by the 53,000 tibial nails implanted each year[12] and the average per-patient treatment cost produces an estimate of the cumulative nonunion burden:

- ✔ **The estimated total cost of tibial nonunions requiring revision surgeries across the US healthcare system is $340M per year.**

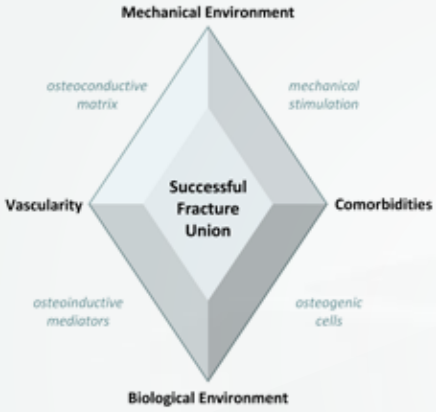

Figure 1: The diamond concept recognizes that successful fracture healing requires a biological and mechanical environment conducive to healing. When conditions are ideal, osteogenic cells proliferate in an osteoconductive matrix. Both osteoinductive mediators and the mechanical environment can stimulate the healing response, while patient comorbidities and poor vascularity can disrupt it.

Considering the individual and economic impacts of failed bone healing, the key question is whether some nonunions may be preventable. To answer this question, *the diamond concept of fracture healing*[13,14] (Figure 1) describes a framework for the interplay between four key ingredients for successful union:

1. Biological environment (availability of osteoinductive mediators, osteogenic cells, and an osteoconductive matrix),
2. Bone vascularity,
3. Physiological state of the patient (comorbidities), and
4. Mechanical environment at the location of the fracture.

If one or more of these key requirements are compromised, the patient is at risk of developing a nonunion. For most patients, the first three poles of the diamond – biology, vascularity, and physiological state – are often non-modifiable factors. Only the fourth pole of the diamond – the mechanics of fracture fixation – is clearly within the surgeon's control.

Moving the needle on nonunions will require a new approach to optimizing the fixation mechanics, setting aside the question, *"Is the fracture stable enough?"* in favor of, *"Are the mechanical conditions ideal for stimulating the biological healing response?"*

With this perspective in mind, OrthoXel has developed innovative tibial and femoral intramedullary nailing systems that optimize the mechanical environment for fracture healing through controlled micromotion.

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