



COMPANY AND TECHNOLOGY BACKGROUND

Overview

CurvaFix is a privately held medical device company headquartered in Bellevue, Washington. The company is developing implantable products to transform the treatment of fractures in curved bones, with a focus on Fragility Fractures of the Pelvis (FFP) and high-impact pelvic fractures.

The idea for CurvaFix germinated when the former division head of orthopedic trauma at the University of British Columbia, Professor Robert Meek, M.D., believed there was a simpler, stronger, and less invasive way to repair pelvic fractures.

Its first product is the CurvaFix® IM Implant, a novel solution designed to improve outcomes and decrease costs for pelvic fracture patients. The CurvaFix Implant is offered in two diameters, 9.5mm, launched in late 2021, and 7.5mm for smaller patients, launched in early 2023, and available in lengths ranging from 90mm to 180mm. Both devices have received U.S. Food & Drug Administration (FDA) clearance for the fixation of fractures of the pelvis.

The only curved intramedullary fixation devices capable of following each patient's individual bone shape, the CurvaFix Implants are designed to offer strong, curved fracture fixation with a simple, minimally invasive procedure for pelvic fracture patients, leading to a quicker recovery.

To date, over 175 patients have been treated with the CurvaFix procedure, including over 100 patients who are either geriatric and/or suffer from FFPs. Usage of over 240 CurvaFix Implants by 35 U.S. surgeons has demonstrated the advantages of a longer, wider, curved implant, which may immediately reduce pain and enable early mobility in a broad range of patients.

The patient population demonstrates the surgical utility and potential benefits in a variety of pelvic injuries and conditions, including polytrauma patients with multiple complex injuries, FFP patients with weak bone, patients with dysmorphic bony anatomy, oncology patients with pelvic fractures, revision surgery for failed pelvic fracture fixation, and patients with impeding total hip or lumbosacral spinal hardware.

About Pelvic Fractures Today

Pelvic fractures are among the most serious injuries treated by orthopedic surgeons. The primary market segments include high-impact trauma and fragility fractures. There are an estimated 150,000 people, 80% of whom are female, who suffer from FFPs every year in the U.S., a number that is growing by nine percent annually due to the rapidly aging population.¹

FFPs can dramatically change the quality of life for geriatric patients and their families due to a loss of patient autonomy, significant disability, and even death. Despite recommendations that surgical treatment should be considered for most pelvic fragility fractures, only 10% receive surgery today. For non-operative patients, conservative treatment generally consists of bed confinement, pain control, and mobility assistance while tolerating weight-bearing. Often, conservative treatment leads to lengthy hospitalizations, high nursing home admittance, and a high one-year mortality rate. In contrast, decades of innovation in hip fracture repair have enabled strong, stable surgical fracture fixation to become the standard of care. Ninety-five percent of hip fracture patients receive surgery



today, which can greatly reduce pain and often allows geriatric hip fracture patients to mobilize soon after surgery.^{2 3}

An estimated 67,000 patients suffer from high-impact trauma of the pelvis, including acetabular fractures, annually in the U.S. These injuries are often caused by serious high-energy events, such as a motor vehicle accident or a fall from height. Eighty-five percent of high-impact trauma patients receive surgery. Existing surgical fixation methods can require complex, lengthy, and morbid surgical procedures. These may result in suboptimal bone fixation, causing pain as well as a slower recovery, which may contribute to long-term disability. Current surgical procedures with straight screws can be prone to fixation failure, and procedures with bone plates can require hours of operating room time, which averages \$6,000 per hour.^{4 5}

CurvaFix IM Implant

The CurvaFix Implant is the only device that fills the intramedullary space within the bone to fix pelvic fractures in a similar way to intramedullary nails. These intramedullary fixation devices have been the gold standard in long bone fixation of the femur and tibia since their invention before WWII to speed soldiers' return to the battlefield. The implant body has interlocking segments that provide flexibility during implantation over a steerable guidewire. After implantation, the surgeon locks the CurvaFix Implant curvature (making the device rigid) by setting the patented Lock.

As multiple case studies have demonstrated, the CurvaFix procedure has the potential to overcome the limitations of existing implants used for pelvic fracture fixation in both high-impact trauma and fragility fracture patients while improving patient recovery, immediately reducing pain, and enabling earlier mobility compared to traditional techniques.

The CurvaFix IM Implant's minimally invasive implantation procedure uses a familiar, reproducible technique with standard imaging that potentially allows for a simpler and shorter surgery compared to alternatives. Implantation procedures with the CurvaFix IM Implant have been accomplished in about 20-25 minutes, offering potential savings of more than \$6,000 in operating room costs versus bone plate procedures.

The Team

The company is led by a team of industry veterans with a seasoned board of directors and advisors that are made up of distinguished key opinion leaders. Steve Dimmer, with 30 years of experience founding and building medical technology companies where he has successfully brought numerous medical device innovations from concept to commercialization, joined the company as president and CEO. Together with Bart Balkman, CMO; Jeffrey Poole, CFO; Nicole Carleo, VP of Marketing; V.J. Somasegaran, VP of Commercial Development and Carly Thaler, VP of Research and Development, the company has assembled an impressive team with in-depth medical tech expertise.

¹ Burge R, Dawson-Hughes B, Solomon DH, et al. Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005–2025. *J Bone Miner Res.* 2006;22(3):465–475 Soles G, Ferguson T, Fragility Fractures of the Pelvis. *Curr Rev Musculoskelet Med* (2012) 5:222–228

Own the Bone. Osteoporosis facts <https://www.ownthebone.org>

² Orthopedic News Network, Vol 32, No 2, May 2022

³ Rommens PM, Hofmann A. Comprehensive classification of fragility fractures of the pelvic ring: Recommendations for surgical treatment. *Injury.* 2013 Dec;44(12):1733-44

⁴ Eckardt, et. al., Good functional outcome in patients suffering fragility fractures, factors influencing outcomes, *Injury*, 2017.

⁵ Macario, A., What does one min of O.R. time cost?, *JCA*, 2010