

Load-Bearing Features of the iBalance Implant

A Technical Overview of how the iBalance Implant Supports Compressive and Shear Loads in the Tibia

The design rationale for the iBalance Medial PEEK Implant is based on the concept of stable structural support during the healing process and an anatomic fit when implanted into the proximal tibia. The iBalance HTO instrumented technique was developed to address a need for a safe and reproducible high tibial osteotomy, and to prepare the proximal tibial osteotomy specifically for implantation of the iBalance HTO Implant. Figure 1 below shows an illustration of the iBalance HTO Implant implanted into the proximal tibia.

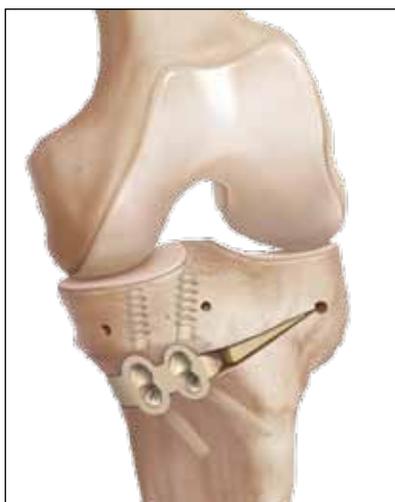


Figure 1. Illustration of the iBalance HTO Implant after implantation into the proximal tibia

The iBalance HTO Implant is unique in that it 1.) resides approximately flush with the cortical surface of the tibia, 2.) supports the open wedge osteotomy with properly oriented wedge-shaped surfaces, and 3.) is structured with unique “keys” for stable fixation and support of shear loads. The implant was designed specifically to provide a stable environment for healing of the osteotomy. See Figure 2 which shows a detailed view of the iBalance HTO Implant features.

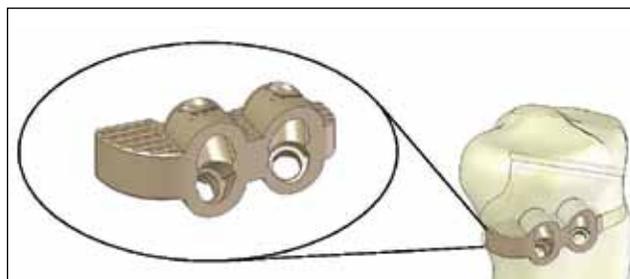


Figure 2. Illustration of the iBalance HTO Implant's wedge-shaped surfaces and “keys”

The wedge portion of the implant and the keys protruding from the wedge support the compressive and shear loads, respectively, as shown in Figure 3 below.

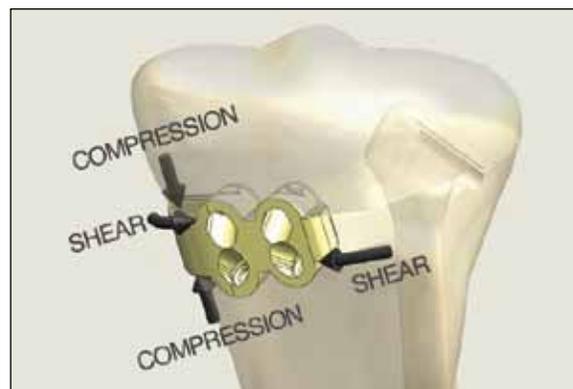


Figure 3. Force diagram illustrating the load-bearing capabilities of the iBalance HTO Implant

As illustrated above, the compressive loads are supported by the wedge and the shear loads are resisted by the keys. In addition to providing shear, or torsional load support, the keys provide a convenient location for the fixation screws to securely fixate the osteotomy construct.

Extensive biomechanical testing has shown that the iBalance HTO Implant can meet or exceed the level of fixation provided by the titanium HTO plate and screw. In static compressive testing¹ the iBalance HTO Implant exhibited over twice the static compression yield strength of the titanium HTO plate and screw system. The load levels below are much higher than normal loads observed in the human tibia², but are useful for comparison purposes. See Figure 4 below.

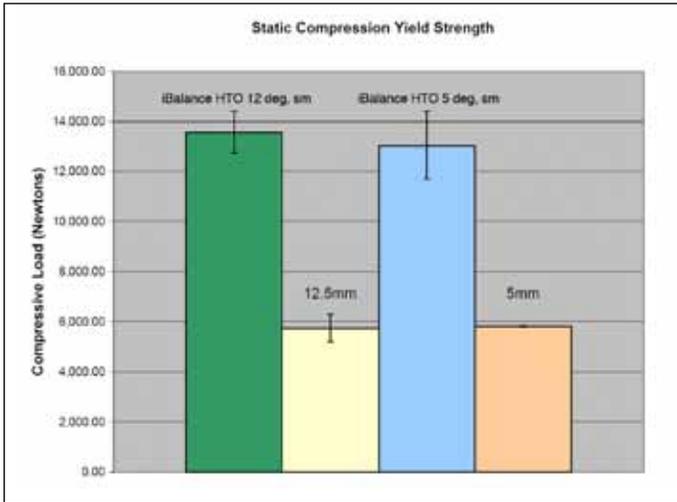


Figure 4. Static Compressive Yield Strength

In cyclic compressive testing, the results were even more differentiated¹. The compressive load that can be supported for 5 million cycles without failure, or the “run-out value” is 15 times greater for the iBalance Medial PEEK Implant. The nominal dynamic load in a tibia during normal walking is typically 3x body weight². This equates to 2268N of force. The iBalance HTO Implant exceeded the typical values that would occur during normal walking, as shown in Figure 5.

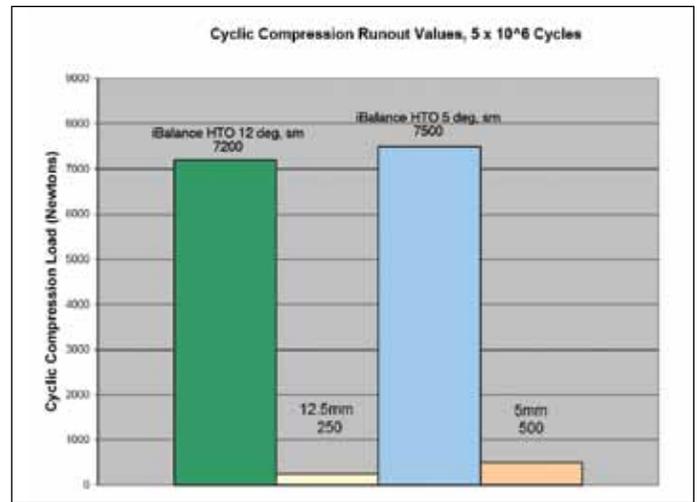


Figure 5. Cyclic Compression Testing

The fact that the static and cyclic test results for the iBalance HTO Implant (an implant made entirely of PEEK), exceed that of an implant made of titanium, is a result of the design features of the implant itself. The iBalance HTO Implant supports the osteotomy surfaces over a broader area than typical plates and screws. The iBalance HTO Implant itself bears the majority of load, rather than the fixation screws carrying the load. Furthermore, the keys provide shear resistance, rather than the metal screws of a typical plate and screw system¹. Also, during the implantation of the iBalance HTO Implant, the fixation anchors pull the proximal and distal portions of the tibia into intimate contact with the implant, ensuring that the implant, rather than the fixation anchors, are bearing the biomechanical loads.

REFERENCES:

1. TR-0003, *Comparative Analysis iBalance HTO Medial Opening Wedge Tibial System and Competitive HTO System Comparative Analysis Verification Summary Report*, Document on file at Arthrex, Inc., July 2009.
2. Dorsey, *The Stability of Three Commercially Available Implants Used in Medial Opening Wedge High Tibial Osteotomy*, Journal of Knee Surgery, 2006 Volume: 19 pp 95-98.