White Paper 3 – The BoneWelding® fixation process provides superior fatigue and long-term stability

Introduction and background

Long term stability of an implant is not so much about maximum strength, but ***fatigue***, i.e., the resistance against repetitive loading as during each step and ***creep***, the ability of an implant to withstand constant pulling load to prevent the formation of gaps between ligament and bone or loosening of a fixation.

Comparative fatigue and creep resistance of the Weldix® anchor (*in vitro*)

In vitro comparison between the Weldix® Anchor and a commercially available, resorbable 2.5mm barbed anchor was performed to investigate fatigue strength and resistance against creep, modelling three months of implantation. The fatigue test represents a repetitive tensile loading in the first three months. The test comprised 150'000 loading and unloading cycles, corresponding to 50'000 cycles per month. To compare, the fatigue strength has been normalized to the control (barbed anchor), as shown in *Figure 1*. The inverse to the creep resistance is the creep rate. The latter was investigated by subjecting the anchor to a constant pulling force and measuring the anchor's dislocation rate (mm/h), as shown in *Figure 2*. Again, the barbed anchor was taken as control. (Please note that since the Weldix® anchor's dislocation rate is three orders of magnitude lower, the data are displayed on a logarithmic scale).

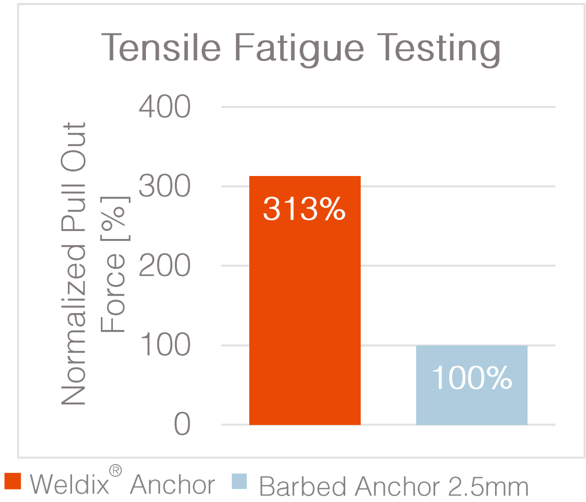

Figure 1: Tensile fatigue Test on specimens aged for three months. The Barbed Anchor has been taken as a 100% reference.

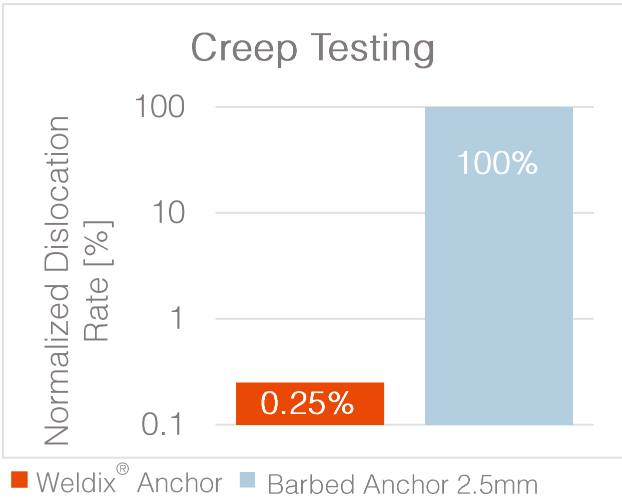

Figure 2: Creep Test performed at 20N for 12 weeks proving that BoneWelding® prevents micro-motion.

Discussion

Due to the method of placement using ultrasonic energy, the Weldix® Anchor forms a more robust interface with the bone, and suture tension continues to hold, even under conditions of repetitive loading when used in appropriate indications. The importance of good creep and fatigue strength has been impressively illustrated in a spine study [1, 2]; they subjected PLDLLA spinal cages in ovine or caprine models to excessively high loads inducing creep and fatigue-related failure of the implants. The consequence was accelerated implant disintegration, causing an intense inflammatory reaction and, most importantly, leading to faster degradation and osteolysis. The observed unwanted tissue reaction is a direct consequence of overloading induced accelerated disintegration not an effect of material volume nor the device size, as sometimes speculated.

To conclude, for dynamic tests, the Weldix® Anchor (drill hole 1.8mm) possesses three times higher pull-out force than the resorbable 2.5mm barbed anchor (drill hole of 2.5mm). Additional creep tests showed 400 times better creep performance of the Weldix® Anchor compared with the barbed anchor. Both are of essential importance to ensuring the upkeep of suture tension even under challenging conditions while minimizing the size of the anchor.

Bibliography

[1] T. H. Smit, M. R. Krijnen, M. van Dijk, and P. I. Wuisman, “Application of polylactides in spinal cages: studies in a goat model,” *J Mater Sci Mater Med,* vol. 17, no. 12, pp. 1237-44, Dec, 2006.

[2] P. Wuisman, and T. Smit, “Bioresorbable polymers: heading for a new generation of spinal cages,” *European Spine Journal,* vol. 15, no. 2, pp. 133-148, 2006.