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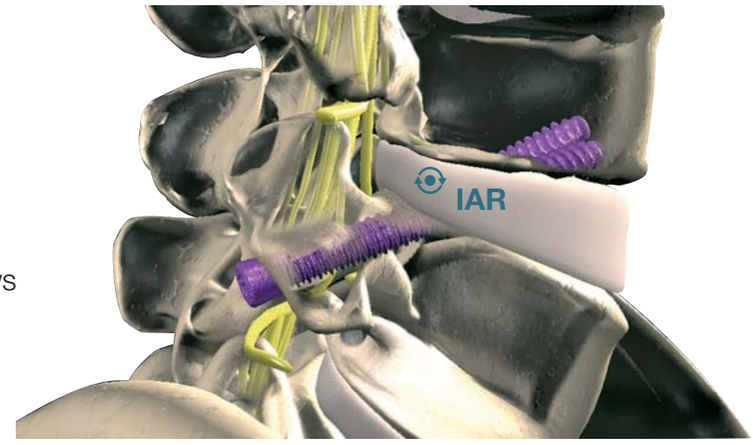
GO-LIF
Imagine Simplicity

Biomechanical Validation for the GO-LIF Technique and Implants

The trans-pedicular, trans-discal procedure was described in the literature 13 years ago by Grob *et al.*[1]. There have been few sporadic reports in the literature prior[2] and following[3,4,5] Grob's publication. The first major study of this technique, with a long term follow-up, was recently published by Zagra *et al.*[6]. The study presented a 7-year average follow-up on 62 patients operated using this technique, free-hand in an open approach. The clinical results were excellent or good in 96.8% of the cases.

The key advantages of this surgical technique are:

- Optimal primary stability [6]
- Creating the best biomechanical conditions to obtain a solid fusion [6]
- Simplicity [6]
- Only two implants rather than 4 screws & 2 rods
- Bone sparing
- Percutaneous or MIS approach



(Figure 1) Instantaneous Axis of Rotation relative to GO-LIF implant

Yet despite the significant advantages, this method was not widely adopted. Two key reasons are:

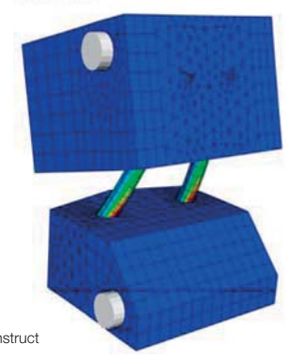
- Lack of biomechanical data to support the empiric findings
- Difficulty in proper placement of the implants, especially in Minimally Invasive (MIS) approach

Mazor Surgical Technologies together with the Cleveland Clinic Foundation have performed the necessary biomechanical testing and developed the surgical technique, as well as developed a new dedicated implant to optimize clinical outcome.

- By combining the procedure with a guidance system (SpineAssist®, Mazor Surgical Technologies Ltd. Caesarea, Israel), the difficulties in safe trajectory and accuracy of implant placement have been eliminated.
- Specially designed implants were developed to withstand and accommodate the different biomechanical environment (Onyx Spinal System® and Amethyst Spinal System®, Mazor Surgical Technologies Ltd. Caesarea, Israel)
- Extensive biomechanical tests were performed by independent and accredited labs in order to validate the procedure and implants. They have demonstrated conformance with the relevant industry standards of the GO-LIF procedure as a stand-alone stabilization method.

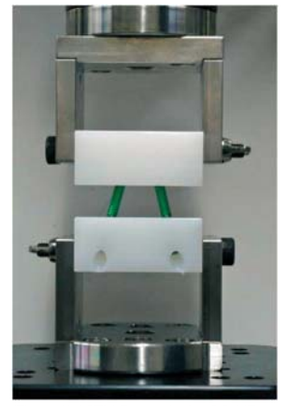
Comprehensive bio-mechanical testing of the GO-LIF stabilization has assured the rigidity, safety and durability of the construct. A synopsis of the biomechanical tests follows:

1. Comparative FEA tests clearly demonstrated that GO-LIF spinal stabilization, achieved by Onyx and Amethyst implants, are equivalent to the standard four screws and two rods construct.



(Figure 2) FEA for GO-LIF construct

2. Biomechanical stability and implant rigidity validation tests:



(Figure 3) ASTM F1717-04 for GO-LIF

a. ASTM F1717-04 testing was conducted to determine the mechanical properties of the GO-LIF construct and implants.
   - Static testing of load-to-failure in axial compression mode
   - Static testing of load-to-failure in torsional mode
   - Cyclic testing of axial compression. Run-out of 5M cycles

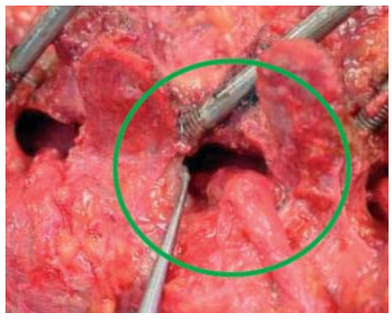
   The GO-LIF construct and implants were as rigid as regular pedicular constructs in all 3 tests.

b. ASTM F543 testing determined that the pullout strength of GO-LIF implants is higher then an average pedicle screw with comparable insertion torque.

This is attributed to GO-LIF implants' special threading which provides optimal bone purchase and to the fact that each implant traverses 3 cortices.

3. Cadaveric tests were performed to validate in-situ results. Lumbar motion segments were instrumented (St. Clair and Lieberman[7]) with either pedicle screws or GO-LIF implants. Pure moment tests were carried out and range of motion and neutral zone were compared. A final load-to-failure test was carried out on specimens instrumented with GO-LIF implants.
   The results demonstrated that static load bearing and stiffness of GO-LIF are comparable to pedicle screw fixations.

Testing the biomechanical performance of Onyx Spinal System and Amethyst Spinal System conducted at Empirical Testing Corp., Colorado Springs, CO, has been found to be comparable with pedicle screws. There was no significant difference in failure load between the GO-LIF technique and pedicular fixation technique.



The guided, oblique, trans-pedicular, trans-discal technique (GO-LIF) is a stable construct that can be performed safely without damage to nerve roots and epidural space. A generous corridor exists from the junction of the pedicle and transverse process at the base of the facet, across the pedicle, into the disc space and then into the cephalad vertebral body.

Of key importance is that in all the dynamic tests of the GO-LIF implants, despite the loads applied, no pedicular or pars interarticularis fractures were observed. The bio-mechanical data support the peer-reviewed publications, which include long-term clinical follow-up [6], demonstrating that it is indeed the optimal methodology for obtaining solid fusion in the Lumbar spine.

1. Grob *et al: "Direct Pediculo-Body Fixation in Cases of Spondylolisthesis with Advanced Disc Degeneration",* European Spine Journal 5. 281-285, 1996;
2. Abdu W.A., Wilber R.G., Emery S.E.: *"Pedicular Transvertebral Screw Fixation of the Lumbosacral Spine in Spondylolisthesis:* A *New Technique for Stabilization",* Spine 19 (6), 715-715, 1994;
3. Minamide *et al: "Transdiscal L5-S1 Screws for the Fixation of Isthmic Spondylolisthesis: A Biomechanical Evaluation",* Journal of Spinal disorders and Techniques16 (2), 144-149, 2003
4. François *et al: "Treatment of High-Grade Spondylolisthesis by Posterior Lumbosacral Transfixation with Transdiscal Screws: Surgical Technique and Preliminary Results in Four Cases",* Acta Orthopedica Belgica 71, 334-341, 2005;
5. Beringer *et al: "Anterior Transvertebral Interbody Cage with Posterior Transdiscal Pedicle Screw Instrumentation for High-Grade Spondylolisthesis. Technical Note.",* Neurosurgery Focus 20 (3), E7, 2006;
6. Zagra A., Giudici F., Minoia L., Corriero A.S., Zagra L.: *"Long-term results of pediculo-body fixation and posterolateral fusion for lumbar spondylolisthesis",* European Spine Journal 18 (Suppl 1), S151-S155, 2009.
7. St. Clair S., Lieberman I.H. *Minimally Invasive Guided Oblique Lumbar Interbody Fixation. A biomechanical study to compare against pedicle screws fixation.*