Biomechanical Evaluation of the Transpedicular Nucleotomy with Intact Anulus Fibrosus

Fabrizio Russo¹, Gianluca Vadala², Robert Allen Hartman, MS³, Kevin M. Bell, MS³, Gwendolyn A. Sowa⁴, Nam Vo, Ph.D⁵, Vincenzo Denaro, MD⁶, James D. Kang, MD⁶.

¹University Campus Bio-Medico of Rome, Rome, Italy, ²department of Orthopedic and Traumatology - University Campus Bio-Medico of Rome, Rome, Italy, ³University of Pittsburgh, Pittsburgh, PA, USA, ⁴ferguson Laboratory for Orthopedic and Spine Research - University of Pittsburgh, pittsburgh, PA, USA, ⁵Department of Orthopedic and Traumatology - University Campus Bio-Medico of Rome, rome, Italy, ⁶Ferguson Laboratory for Orthopedic and Spine Research - University of Pittsburgh, Pittsburgh, PA, USA.

Disclosures:

Introduction: Low back pain is a significant socioeconomic burden and intervertebral disc degeneration (IDD) has been implicated as a main cause. Significant research has been performed with the goal of regenerating the intervertebral disc (IVD) via injection of therapeutic agents (growth factors/cells/hydrogels).

Mechanical loading represents an integral part of IVD homeostasis. Knowledge of the functional role of the NP is critical for the development and evaluation of a novel model to study IVD regeneration. Indeed, regeneration strategies must also aim to restore the mechanical properties of the native, healthy NP tissue by introducing replacement materials combined with regenerative cells. However, traditional regenerative strategies require violation of the annulus fibrosus (AF) which results in significant alteration of the joint mechanics. The transpedicular nucleotomy represents a suitable method to create a reproducible cavity into the NP by mechanical discectomy trough the endplate, as a model to study IVD regeneration strategies with intact AF as previously described (Vadalà et al. 2013).

The aim of this study is to explore how the transpedicular approach and the novel mechanical nucleotomy affect the biomechanical behavior of the NP in terms of range of motion (ROM), segmental stiffness, neutral zone and axial loads.

Methods: Biomechanical testing was conducted on the lumbar spines of 15 skeletally matured sheep. All muscles and soft tissues were dissected. Three functional spinal units (FSUs) from each ovine spine (L1-L2, L3-L4, L5-L6) were obtained for a total of 60 FSUs. The vertebral bodies of each FSU were then fixated in Epoxy Resin (Bondo) for secure attachment to the testing system. Sheep motion segments were randomly assigned to 5 groups: control, transpecicular tunnel (TT), TT + polymethylmethacrylate (PMMA), TT + Nucleotomy, TT + Nucleotomy + PMMA. Under fluoroscopy, the transpedicular approach was performed to access the NP. A 2 mm diameter resector powered by an arthroscopy shaver unit and connected to a vacuum pump, was introduced through the 2mm tunnel and NP tissue was removed.

After specimen preparation all samples were hydrated in a refrigerated 4°C phosphate buffered saline solution for 18h prior to testing. The samples were placed in fixtures designed for robot testing. The tissue hydration of the motion segments was maintained during the testing procedure by covering specimens with saline-soaked gauze.. The robotics-based spine testing system consists of a robotic manipulator (Staubli RX90), with an on-board six-axis load cell (JR3 Inc.) and is controlled via MATLAB (Mathworks, Inc.). The testing system operates under adaptive displacement control to a pure moment target of 5.0 Nm for flexion and extension (FE), lateral bending (LB), and axial rotation (AR). Three consectutive cycles were perfromed (preconditioning) and the data from the third cycle was reported. Immediately after robot testing, axial compression was applied for 15 cycles of preconditioning followed by 1 h constant compression. Axial forces were applied to achieve 0.25 MPa of intradiscal pressure based on cross-sectional area measurements of the discs made with Vernier calipers. Creep properties were determined using a two-phase exponential model to identify changes in elastic and viscous structural properties.

Results: The transpedicular approach itself has minimal effects on ROM, NZ stiffness and displacement width in FE, LB and AR compared to control. The mechanical nucleotomy increases ROM and NZ displacement width while decreasing NZ stiffness in all degree of freedom. The transpedicular tunnel filled with PMMA has small effects in terms of ROM. The injection of PMMA in the tunnel of IVDs that underwent mechanical nucleotomy brings the ROM back to the control, increases NZ stiffness and decreases NZ displacement width in both FE and LB. The transpedicular approach and nucleotomy primarily altered the early creep response: nucleotomy resulted in decrease in the early elastic and viscous damping coefficients, S1 and η1. The use of PMMA reduced viscosity (S2) and increased stiffness (η2) in late creep.

Discussion: Biomechanical properties of healthy and degenerated NP are crucial for future regenerative strategies for intervertebral disc (IVD) repair. The results from this testing quantify the effects of the transpedicular approach and nucleotomy on spinal biomechanics. The testing was conducted under constant hydration condition since it strongly correlates with IDD.
The small transpedicular tunnel alone did not affect segmental stability, though it did appear to alter segmental time-dependent properties. This underscores the clinical need for adequate restoration of the tunnel following surgery. The mechanical and structural changes that occur with nucleotomy (e.g. increased ROM, increased neutral zone deformation and decreased stiffness) are similar to changes that occur in early degeneration. In particular the NP play a crucial role in the early creep response, while the late creep response may be determined more by the annulus fibrosus and endplate.

**Significance:** These results could provide fundamental information for understanding the mechanism of injuries caused by IVD degeneration. Moreover, the testing results can be used to guide the selection of appropriate surgical treatments in the context of IVD degeneration and to validate and optimize biomaterials based on the biomechanical and biological requirements of the IVD. ROM, neutral zone characteristics, viscoelastic creep biomechanics are sensitive to specific alterations in the NP pressurization, AF and endplate integrity and must be addressed for an effective functional repair. Meeting mechanical and biological compatibilities are necessary for the efficacy and longevity of the repair.

**Acknowledgments:**

References:
Lateral Bending

ROM

NZ displacement width

NZ Stiffness

Transpedicular tunnel filled with PMMA