A comparison of Range Of Motion (ROM) and Forces in a single level vs. multi-level lumbar Posterior Dynamic Stabilization (PDS) implant – Finite Element (FE) study

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Introduction

Stabilimax® is a pedicle screw based lumbar PDS implant indicated for lumbar spinal stenosis (Figure 1). The aim of the study was to compare the Range of Motion (ROM) and Maximum forces (MaxF) generated in the Stabilimax PDS in single-level (L4-L5) and multi-level (L3-L4-L5 and L4-L5-S1) scenarios, using FE analysis.

Figure 1. Stabilimax ® PDS

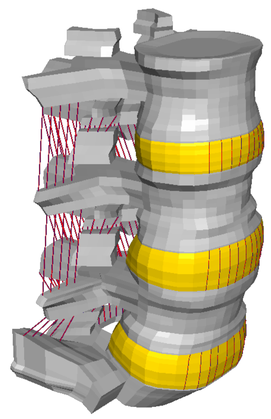

Figure 2. L3-S1 FE model

Methods

An experimentally validated, 3-D ligamentous FE model of the L3-S1 segment from previous studies was used [1] (Figure 2). A 400 N compressive follower load and a pure bending moment of 8 Nm were applied to the intact model. A combination of total nucleotomy, bilateral partial facetectomy and laminectomy injury was simulated at the index level (s), followed by stabilization. The direction of loading included Flexion (Flex), Extension (Ext), Lateral Bending (LB) and Axial Rotation (AR). ROM and MaxF generated in the implant at the index level(s) were computed for all loading scenarios.

Results

The MaxF for Flex, Ext and LB in the single-level implant are reported in Table 1. AR resulted in a small MaxF for both the single and multi-level implants (**< 8 N and < 33 N respectively**). **There was a 55% increase in MaxF in LB and a 19% reduction in Flex of the L4-L5-S1 multi-level case, in comparison to the single-level case.** The ROM for Flex+Ext, LB and AR at index level for all cases are reported in Table 2. In the table, ROM has been averaged for the two index levels for the injury and stabilized multi-level models. Intact motion for the multi-level cases (not shown) was similar to the single-level case. There was a greater reduction in ROM for both multi-level stabilization cases as compared to the single-level case, except in AR.

MaxF	Flex	Ext	LB
L4 – L5 Stabilimax	54 N	74 N	71 N
L3 – L4 – L5 Stabilimax	47 N	72 N	78 N
L4 – L5 – S1 Stabilimax	44 N	83 N	110 N

Table 1. Maximum Force (MaxF) in Newtons generated in single-level and multi-level implants

ROM	Flex+Ext	LB	AR
L4 – L5 Intact	6.7˚	3.6˚	2.0˚
L4 – L5 Injury	8.1˚	4.1˚	2.4˚
L4 – L5 **Stabilimax**	3.5˚	2.2˚	2.3˚
L3 - L4 – L5 Injury	7.8˚	4.2˚	2.5˚
L3 – L4 – L5 **Stabilimax**	2.6˚	1.3˚	2.2˚
L4 – L5 – S1 Injury	8.5˚	3.7˚	2.3˚
L4 – L5 – S1 **Stabilimax**	2.3˚	1.6˚	2.2˚

Table 2. Range of Motion (ROM) in single-level and multi-level implants

Discussion

A PDS in a multi-level scenario sees significantly more load than the single-level scenario, especially in LB. The level of treatment also has an impact on the forces generated in the implant. While this study examined the Stabilimax, this information may be useful in designing and testing different dynamic stabilization systems, particularly in multi-level applications.

Stabilimax® is an Investigational Device, limited by Federal law to investigational use

REFERENCES

Goel V.K., et al., *Effects of charite artificial disc on the implanted and adjacent spinal segments mechanics using a hybrid testing protocol.* Spine, 2005. **30**(24):p. 2755-64.