

# An analysis of PostOp performance of the Stabilimax<sup>®</sup> posterior dynamic stabilization (PDS) implant through measurement of Range of Motion (ROM) and InterPedicular Travel (IPT)

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## Introduction

Pedicle screw based PDS systems are intended to provide stability and permit motion when used in conjunction with decompression to treat patients with degenerative lumbar stenosis. The Stabilimax<sup>®</sup> was designed to stabilize ROM while providing near normal quality of motion (IPT) and is the subject of an ongoing IDE study. The purpose of this study was to measure the PostOp ROM, IPT and IPT/ROM at the index level in one-level IDE patients treated with Stabilimax.

## Methods

Maximum voluntary flexion-extension (F-E) radiographs were obtained PreOp and PostOp (12 months) from 49 single-level patients from the IDE study. PreOp measurements have been reported separately. The radiographs included a calibration marker to account for radiographic magnification. The F-E radiographs were assessed using validated, computer assisted methods accurate to better than 1° and 1 mm [1]. ROM was measured as the change in angle between adjacent endplates of the index level from flexion to extension. Interpedicular distance was measured between the mid-pedicular axes of adjacent vertebrae using points slightly posterior to the superior articular process of each vertebra, representing the typical location of the junction between the posterior rod and pedicle screw in dynamic systems. Interpedicular travel (IPT) was calculated as the change in interpedicular distance from flexion to extension.

## Results

The average age of the patients was 58 years of age (range: 35-82), including 22 males and 27 females. **The L4-L5 level represented 78% of the index levels**, with the remainder at L5-S1, L3-L4 and L2-L3. ROM and IPT were non-normally distributed, so medians and ranges are reported. **At 12 month follow-up, the median PostOp ROM was 1.9° (range 13.4°), the median PostOp IPT was 1.4 mm (range 10.0 mm) and the ratio of median IPT to ROM was 0.74.** PostOp ROM and IPT data has been presented in Figures 1 and 2 respectively.

## Discussion

A predominantly older population of stenotic patients tends to have limited PreOp motion at the index level. The goal of Stabilimax is to stabilize the stenotic level while maintaining near normal quality of motion. PostOp, patient stability was maintained at the treated level, as indicated by a median reduction in ROM. The ratio of IPT to ROM was similar to that of PreOp (0.66) [2], suggesting that the quality of motion is near normal. This data is indicative of the desired mechanical performance of the Stabilimax system.

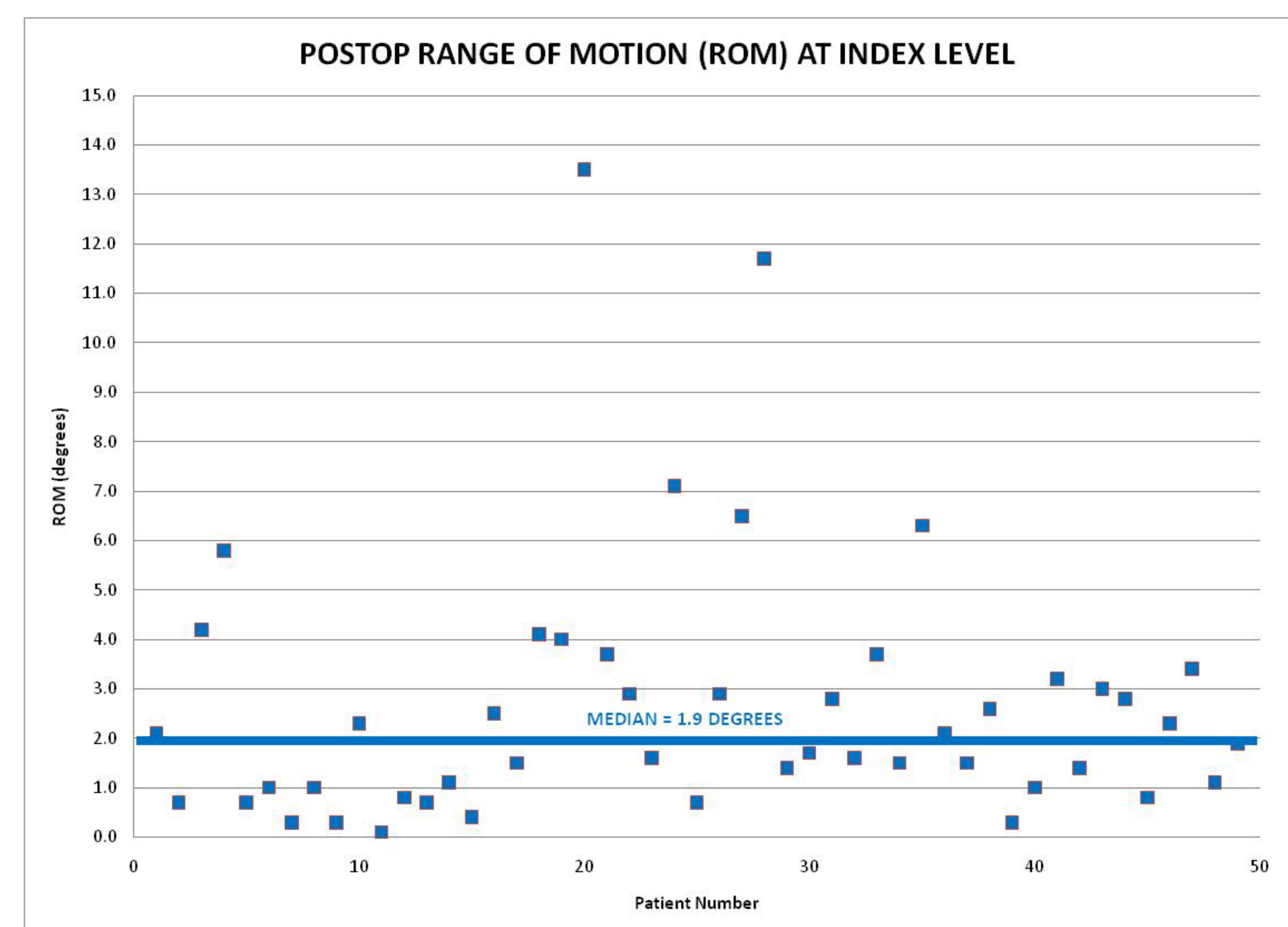


Figure 1. PostOp ROM distribution for stenotic patients treated with Stabilimax<sup>®</sup>

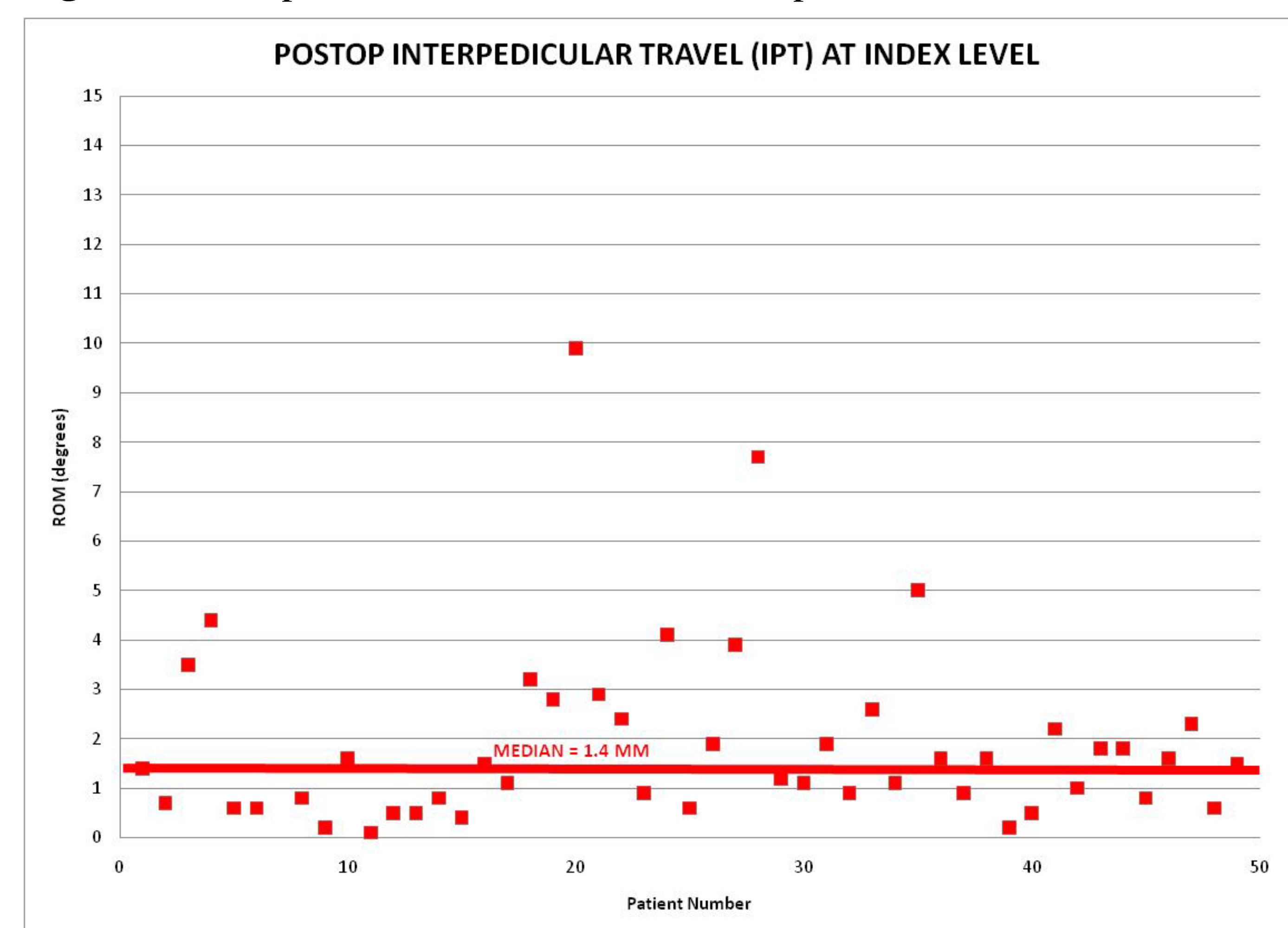


Figure 2. PostOp IPT distribution for stenotic patients treated with Stabilimax<sup>®</sup>

## REFERENCES

1. Pearson, et al., *Precision of Lumbar Intervertebral Measurements: Does a Computer Assisted Technique Improve Reliability ?*. ISSLS Conference, 2007.
2. Anand N, et al., *Quantity and Quality of Motion in Stenosis Patients*. Spine Arthroplasty Society Conference, 2010. Abstract 373.

