Objective 4D-Measurements of Lumbar Spine Function in Back Pain Patients Undergoing High-Frequency Spinal Cord Stimulation at 10 kHz

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Introduction

Patients with low back pain have limitations in functional capacity due impaired back function and kinesiophobia, resulting in worsened functional status, reduced ability to work and quality of life.

The Oswestry Disability Index (ODI) is the most commonly used questionnaire to assess the functional capacity of such patients (Fairbank, Spine 2000). However, it is limited by relying on patient recollection and feedback. Therefore, objective and easy to use validated methods for measuring patients function are required. We evaluated the SPINE device (Epionics Medical GmbH, Potsdam, Germany), which allows the objective assessment of the lumbar spine motion and function in 4 dimensions in chronic back patients candidates for high-frequency Spinal Cord Stimulation at 10 kHz (HF10 SCS).

Material and Methods

Consecutive chronic back pain patients referred to our clinic and candidate for HF10 SCS were assessed pre-SCS trial (baseline), at 6 weeks, 3 months, 6 months, 9 months, and 12 months post SCS system implantation.

All patients completed an ODI questionnaire and underwent the Epionics measurements in order to measure the range of motion (angle and velocity of motion) for predefined movements, and the age- and gender specific overall flexibility score.

Epionics SPINE

The Epionics SPINE system is a CE-marked system (Fig. 1) which allows the objective evaluation of movement dynamics and function through the recording of a predetermined standard choreography and yields information on movement range and dynamics in about 15 minutes (Fig. 2)

Fig. 1: Epionics SPINE system

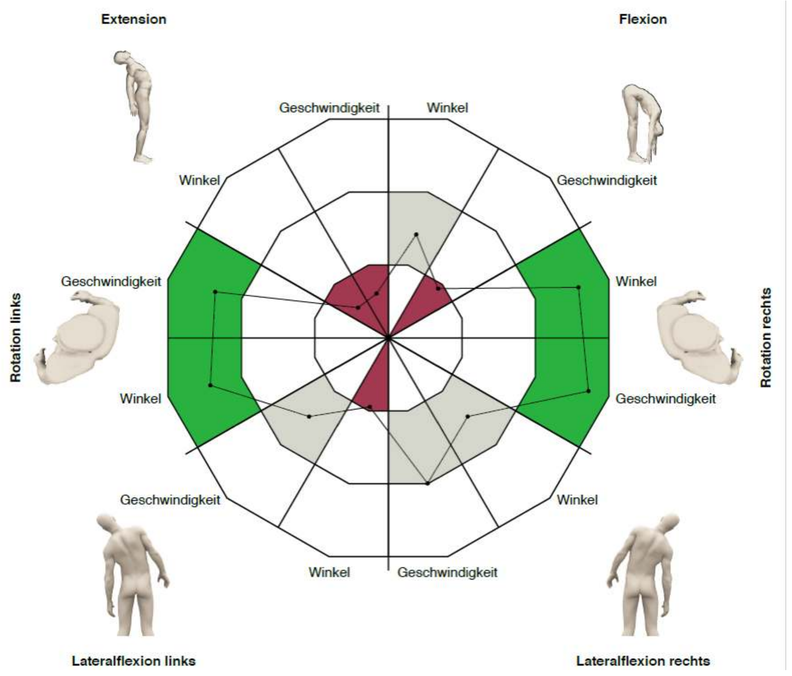
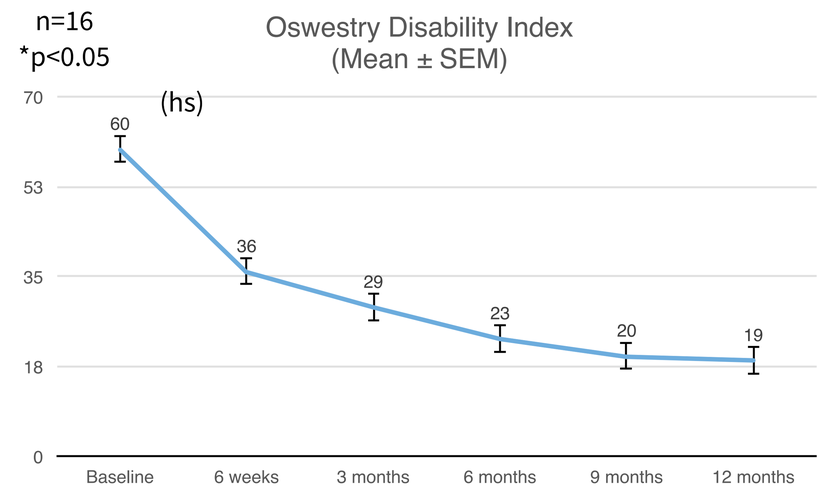
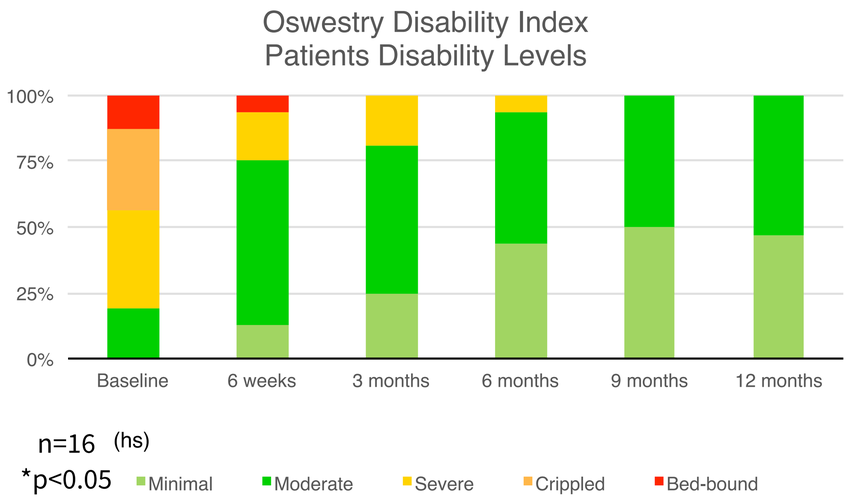


Fig. 2: Choreography outcomes

16 failed Back Surgery Syndrome patients, including 9 who had undergone fusion, and 2 patients without prior back surgery were assessed.

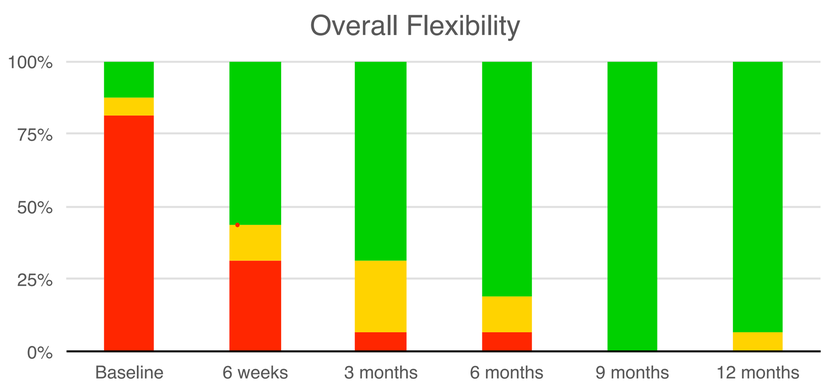
At baseline, their ODI was 61 ± 4 (mean ± SEM) and 75% of the patients had a poor overall flexibility status as assessed with the SPINE system. All the patients had a successful HF10 SCS trial and were implanted with an Implantable Pulse Generator. During their follow-up, their ODI score decreased from 64 ± 4 to 37 ± 4 at 6 weeks, 29 ± 4 at 3 months, 21 ± 4 at 6 months and 17 ± 4 ($p<0.001$ compared to baseline Graph 1), with the proportion of patients with severe disability or crippled decreasing from 81% down to 0% at 9 months and 0% at 12 months (Graph. 2)





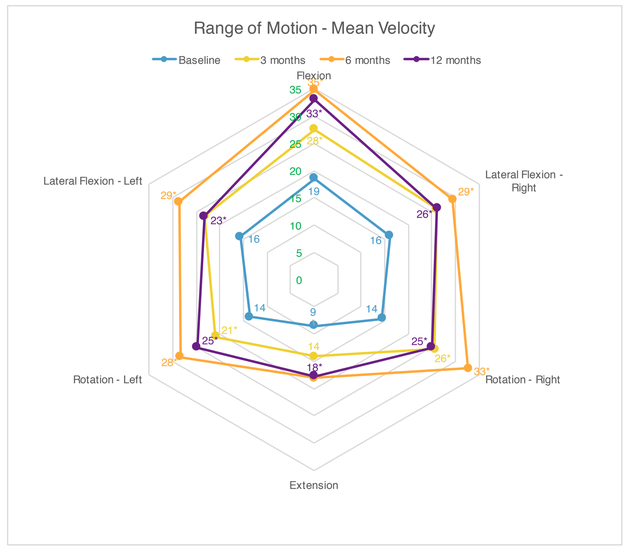
Graphs 1 and 2: Oswestry Disability Index

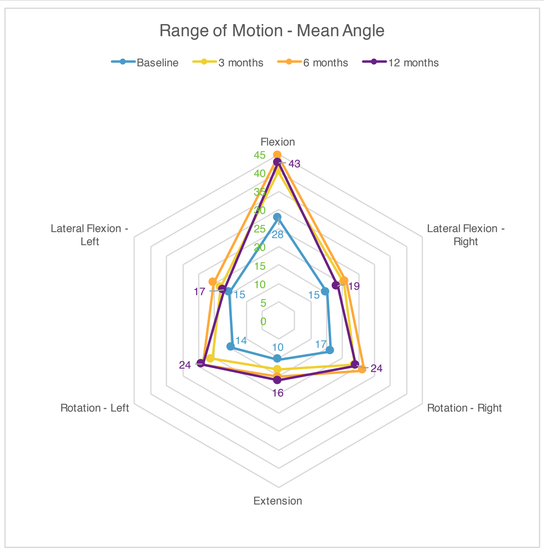
The Epionics overall flexibility score improved significantly, with the proportion of patients being classified as Poor/Average/Good improving from baseline 75% / 12.5% / 12.5% to 12,50% / 0% / 87,50%. at 6 months, 0% / 0% / 100% after 9 months to 0% / 12,5% / 100% at 12 months (Graph. 3)



Graph 3: SPINE Overall Flexibility Score

Significant improvements were observed in all 4 dimensions: in spinal movement velocities at 6 weeks, 3 months, 6, 9 and 12 months and in range of motion at 3 months, 6, 9 and 12 months (Graphs 4 and 5)





*: P < 0,05 compared to baseline

Conclusions

The Epionics functional measurements are easy to perform in routine practice and provide objective, clinically relevant information on 4 dimensional lumbar spine function in chronic back pain patients. In SCS patients, this device provides objective information demonstrating the significant impact of HF10 SCS in improving patients function. Further research is needed to confirm these results.