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Sagittal Shape and Mobility of the Spine-Validity and Reliability of the new MediMouse®/SpinalMouse®

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Comment: This information must be treated confidentially prior to publication.

Objective

Test for validity and reliability of the MediMouse®/SpinalMouse® (MM/SM), a new clinical device to measure the shape and mobility of the vertebral spine in the sagittal plane, by comparison with functional radiographs of the lumbar spine (XR).

Subjects

Measurements with MM/SM and XR in 29 subjects (12 female, 17 male), aged between 18 and 56 years, 9 of them with reduced mobility due to low back pain.

Design

XR with lateral incidence of X-rays were obtained in upright position (up), maximum active flexion (flex) and extension (ext) of the lumbar spine. Shape and mobility of the spine from Th11/12 to L5/S1 were extracted from the XR-pictures using established methods (endplates = EP, posterior edges = PO; mobility according to Penning = Pen). The same postures (up, flex, ext) were repeatedly measured using the MM/SM. Reliability was tested by intra- and inter-rater-comparison for each method separately. The validity of MM/SM was tested by comparing the data with those of XR, the assumed gold standard. Statistically we used variance (ANOVA) and correlation analysis.

Results

a) Reliability

The reading of the same radiograph by different experts resulted in interrater differences as high as ±7° per segmental angle, while the MM/SM showed an error of maximally ±3° in repeated measurements. The averaged inter-rater correlation coefficients gave r=0.94 for XR and r=0.96 for the MM/SM. Repeated readings (n=10) of the same radiographs by the same experts resulted in mean intrarater deviations of SD=1.6°. This must be compared with SD=1.2° for MM/SM-measurements (n=20), obtained for the subject in fixed position (lying down faced). The intra-rater-accuracy of the MM/SM in practical use is SD=1.9°, which resulted when the subjects repeatedly took their "habitually upright" position after a short walking.

b) Validity of postural measurements

The segmental angles from Th11/12 to L3/4 obtained with the different methods (MM/SM, EP, and PO) were all similar. For the lower lumbar spine the MM/SM systematically gives smaller angles by 5.7°±2.1° (EP; mean±SEM) rsp. 11.0°±3.2° (PO) at L4/5; and by 9.4°±3.3° (EP) rsp. 22.8°±2.3° (PO) at L5/S1. (There is also an inherent systematic difference between EP and PO, due to the known asymmetric shape of the vertebra L5: EP gives smaller angles than PO, namely 3.7°±1.7° at L4/5 and 11.8°±1.6° at L5/S1). After correction for these systematic deviations, one obtains averaged variances of 0.82 (EP vs. MM/SM) rsp. 1.26 (PO vs. MM/SM). They are of the same magnitude as the intra-XR-variance of 0.82 (EP vs. PO). The mean correlation between XR and MM/SM in postural data - calculated for every individual - was r=0.972±0.03, while the intra-XR correlation was r=0.974±0.02.

c) Validity of mobility measurements

There was no systematic difference between MM/SM and XR in mobility (in some subjects the MM/SM measured 3° to 5° less mobility at L4/5 and L5/S1 than XR). Variance analysis gave 1.25 (EP vs. MM/SM), 0.98 (PO vs. MM/SM), 1.33 (Pen vs. MM/SM), while the intra-XR-variance was 1.06. The mean correlation between XR and MM/SM in mobility - calculated for every individual and all positions - was r=0.967±0.029, while the intra-XR correlation (EP vs. PO, the only independent ones) resulted in r=0.965±0.053.

Conclusions

Measurements with the MediMouse®/SpinalMouse® are fast, easy and objective. The intra- and inter-rater-reliability of the MM/SM equals rsp. exceeds that of XR, although the XR-data - other than MM/SM – proceed from the same radiograph. The validity of the new method was tested by comparison with functional XR, considered as gold standard. Some systematic differences between MM/SM and XR were found in posture. These are easily explained, because XR measures the bony shape, while the MM/SM includes the soft tissue. There are no such systematic differences in spinal mobility, both methods giving practically identical results. Only at the lumbosacral region the MM/SM-data may be somewhat altered due to the displacement of soft tissue, especially in extension. The high overall correlation shows that both approaches are of equivalent validity to measure the sagittal posture and mobility. We found poor accuracy in the individual lumbar segmental mobility extracted from XR. This finding is confirmed by other authors, which makes functional XR questionable as a save "gold standard". With this in mind, the validity of MM/SM in the assessment and follow up in patients with pathological mobility, e.g. after spinal fusion, seems highly probable, but must be confirmed in further clinical investigations.