Measurement of shape and mobility of the spinal column: Validation of the SpinalMouse® by comparison with functional radiographs.
Dissertation Stefani Schulz, 1999, Ludwig-Maximilians University, Munich

Summary by N. Seichert

Aim: The SpinalMouse® is a novel clinical aid for the easy determination of shape and mobility of the spinal column. In the present study the validity of the Spinal-Mouse® has been tested by comparison with functional radiographs.

Methodology: The shape and mobility of the spine has been measured in the upright position and at maximal flexion/extension with the SpinalMouse® in 29 volunteers. Functional radiographs of the lumbar spine (LS) were taken with lateral incidence of the X-rays in the same standardized postures. The radiographs were evaluated in accordance with three established methods and, in large part, by two independent experts. The angle and mobility of the segments Th12/L1 to L5/S1 determined independently of each other by the SpinalMouse® and X-rays were compared by means of variance and correlation analysis. The variances were determined on segmental angles; the correlation analysis was performed for methodological reasons on the absolute angles of the spinal column relative to the plumb line. The latter are calculated from the successive summing of the segmental angles beginning with Th12/L1; they describe the total curvature of the LS from Th12/L1 to the segment observed. In addition, measurements were made concerning the reproducibility and the intra- and inter-rater reliability of the SpinalMouse® in the upright posture.

Results

1. Reliability
The reading of the same radiograph by different experts resulted in interrater differences as high as ±7° per segmental angle, while the SpinalMouse® showed deviations of maximally ±3° in repeated measurements. The averaged inter-rater correlation coefficients gave r=0.94 for X-rays and r=0.96 for the SpinalMouse®.

2. Posture
The accuracy of the determination of a segmental angle with the SpinalMouse® gives a scatter (standard deviation SD) of ±1.2° after repeated measurements on volunteers lying down (invariant spinal shape). In comparison to this the scatter on repeated evaluation of the same radiograph is of interest. Two independent readers found values of ±1.3° and ±1.6°.
In repeated measurements with the SpinalMouse® on standing volunteers the scatter is ±1.6°; and it is ±1.9° on repeated resumption of the posture. An inexperienced user of the SpinalMouse® obtains scatters only slightly greater.

The agreement of the postural and mobility measurements was tested by means of variance and correlation analysis. Before that the data was examined for systematic deviations. These were found exclusively on measurements of posture in the lumbosacral transition: The end plate procedure (EP) systematically gives a 5.7° ± 2.1° greater angle at L4/5 and an 11.0° ± 3.2° greater angle at L5/S1 than the SpinalMouse®; in the case of the posterior edge procedure (PE) the differences are as large as 9.4° ± 3.3° and 22.8° ± 2.3°. Both radiographic evaluations also show systematic deviations by 3.7° ± 1.7° at L4/5 and by 11.8° ± 1.6° at L5/S1.
Variance is the mean square of the differences between segmental angles obtained with different methods. With respect to postural measurements the SpinalMouse® gave a mean variance of 1.39 in comparison to EP; the X-ray comparison of EP with PE gave exactly the same value. With a slightly greater variance of 1.52 PE does fit the SpinalMouse® similarly well.
The correlation analysis of the postural data gave coefficients of 0.974 ± 0.022 for SM-EP, 0.969 ± 0.023 for SM-PE and 0.974 ± 0.023 for EP-PE.

3. Mobility

The mobility was measured for upright/flexion (U/F); upright/extension (U/E) and flexion/extension (F/E). The variances lay between 0.82 (SM v PE at F/E) and 1.55 (SM v Pen at U/E), when the SpinalMouse® was compared with the X-ray procedure. When an intra-radiograph comparison is made, only EP v PE should be evaluated with a mean variance of 1.06, since only these procedures are independent of each other. The correlation analysis of the comparisons SM vs EP and PE vs Pen gave a correlation coefficient of 0.963 for U/F and one of 0.966 for F/E (SD = ± 0.03 for both); this contrasts with intra-radiograph coefficients for EP vs PE of 0.985 ± 0.04. For the movement direction U/E markedly smaller coefficients of 0.892 ± 0.03 (SM v X-ray) and 0.904 ± 0.03 (EP v PE) were found.
Both for posture and for mobility the gradients $\Delta x/\Delta y$ obtained in correlation calculations all lie close to one and include this in the value range, which must be required for the identity instead of only proportionality of the methods compared.

Discussion

The reproducibility of the measurements obtained with the SpinalMouse® is markedly better than that of the X-ray evaluations in the inter- and intra-rater comparison. This provides a sound basis for the validity of the SpinalMouse®. In addition an unexpectedly good reproducibility was found on repeated resumption of a standardized posture. Evidently man possesses a “posture consciousness” which allows him to reproduce his individual upright posture well at short notice. The generally known variability of individual posture, the result of multiple influences, is probably manifest only over longer time intervals of hours or days.
The segmental angles of the measurement of posture gave large systematic deviations (inherent in the procedure) at the level of L4/5 and L5/S1. These can be explained by the irregular shape of LSB4, LSB5 and sacrum, on the one hand, and by the influence of soft tissues, on the other. They can be corrected without difficulty as systematic errors of measurement of the postural data.

Systematic deviations do not appear in mobility measurement since this relative data is calculated from the difference of postural data.
When the different methods of evaluation of radiographs (EP, PE, Pen) were compared, great differences were manifest which cast serious doubt on the utility of functional radiographs of the LS for the determination of segmental angles. Unfortunately, this is particularly valid for both segments of the lumbosacral transition which are of particular clinical importance. Even the evaluation according to Penning, considered as the best one, performs no better in this respect. It is probably impossible to define clear-cut contours in the two dimensional projection of complex three-dimensional structures. Stokes (1987), Hanley (1975), Dvorak et al.(1991) and Tallroth (1994) were also compelled to recognize this in the case of the clinical validation of the functional radiographs of the LS. We had selected the X-ray evaluation as reference procedure for the validation of the SpinalMouse®, since in general it serves as the “gold standard”. Owing to the failure of this “gold standard” the validity of the SpinalMouse® can be determined only within the limits of accuracy of the reference (X-ray).
After correction of the systematic deviations found in posture the variance and correlation analyses gave equally good agreement in the inter-procedural and in the intra-X-ray comparison. The SpinalMouse® thus does not make the agreement given by the X-ray inaccuracy any worse. The postural measurement with the SpinalMouse® may therefore either correspond to the (unknown) true situation or exhibit a defined linear relation to this latter.
Variance analysis gave the same good result for segmental mobility as for posture. In contrast, in the case of the correlation analysis the intra-X-ray procedure showed a slightly better agreement than the inter procedure comparison. This is adequately explained by the fact that the inter-process comparison refers to the same posture, but independently taken at different times; whereas the X-ray evaluations of posture are made on the same radiograph. Thus correlation analysis leads to an equally good agreement among the different processes.
The excellent agreement relative to mobility is valid for the absolute angles with which the correlation analysis was performed, and that in the clinical sense means an identical total mobility of the LS with the SpinalMouse® and with X-rays. This is not true for the segmental angles because, alone owing to its inaccuracy, the X-ray evaluation for L4/5 and L5/S1 can not be in good agreement with an independent measuring procedure. Whether the SpinalMouse® is a closer approximation to the true situation can not be known with certainty owing to the poor quality of the reference procedure. All that can be said is that the SpinalMouse® is of (at least) equal value with the X-ray evaluation for the determination of segmental mobility.
Possibly it is not at all the quantitative extent of a mobility impairment which is clinically relevant, but rather its unequivocal presence and the position at which it is located. The SpinalMouse® offers a very promising basis from which to answer these kinds of clinical questions. Its definitive validity for assessment and follow-up in such cases can only be checked in further clinical studies suitably designed.