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Evaluation of the reliability of a new non-invasive method for assessing the functionality and mobility of the spine

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For the evaluation of the functionality and mobility of the spine, several methods have been developed. The purpose of this study was to estimate the test-retest reliability of the Spinal Mouse, a new, non-invasive, computer-assisted wireless telemetry device for the assessment of the curvatures, the mobility and the functionality of the spine. Materials and methods: the test-retest reliability was evaluated in 50 adults with back or low back pain. Twenty four parameters were studied in the sagittal and frontal plane. For the characterization of the precision, the intraclass correlation coefficient and the standard error of measurement were used. Results: in the sagittal plane, 22 of the 24 parameters showed high and good reliability, while only two fair and poor. In the frontal plane, 17 parameters showed high and good reliability, five fair and two poor. Discussion: the Spinal Mouse showed excellent test-retest reliability in the sagittal plane, while a slightly inferior performance in the frontal plane, for the evaluation of curvatures, deformation and mobility of the spine.

Key words: *intraclass correlation coefficient, intra-rater reliability, mobility, range of motion, spinal mouse*

1. Introduction

Various methods have been developed for the measurement of the mobility and function of the spine and the evaluation of its curves, such as a goniometer [1], [2], a spondylometer [3], a scoliometer, a kyphometer [4], an inclinometer [1], [5], [6], a flexible curve [1], [2], [7], measurement of fingertip to floor distance [5], tape measurement method [8], [9] and the Schober index [5]. However, most of these methods either have a poor reliability or validity or are time-consuming [1], [5], [6], [10].

Methods with greater accuracy are X-ray and CT scans. There is a growing trend of using these imaging techniques for clinical studies investigating the mobility of the spine and determining the preoperative or postoperative status of patients [10]–[13]. Yet, radiation has deterministic and stochastic biologic effects, the latter being cumulative and including cancer [14], [15]. CT doses pose a statistically significant increase in cancer risk. Moreover, the increasing population dose from increased CT usage leads to concerns about future public health problems [16], [17]. Also, the use of radiography or CT allows the assessment of only a single curve (cervical, thoracic or lumbar) each time, while in cases where there is the need of imaging the entire spine, the radiation dose is considerably high. Furthermore, capturing an image in a new position requires additional radiation as well as an increasing examination time [18]. Besides, the measurement of a curve or an inclination of the spine in a radiograph is made in the classic way of recording angles (e.g., Cobb angle) by hand, which depends on the experience of the examiner and involves the risk of error due to human factor [19]. Magnetic resonance imaging

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gives a solution to the examination of the spine without the use of radiation, yet it is very cost-intensive.

In assessing the functionality of the spine and for cases where repeated examinations are required, like monitoring scoliosis, a valid, reliable, non-invasive and safe method, with low cost, short examination time and the ability of performing multiple clinical tests would be desirable. In the present study, we evaluated the Spinal Mouse, a new method for assessing the curvatures, the mobility and the functionality of the spine. The main objective was to assess the test-retest reliability of the method.

2. Materials and methods

2.1. Subjects

Eligible to participate were adults who attended the Outpatients' Spine Unit of the University Hospital of Heraklion, with symptoms of low back pain and/or back pain over a time period of at least two months. Exclusion criteria were individuals with spine surgery in the past or those with permanently limited mobility of the spine, such as Morbus Bechterew, Paget's disease and diffuse hyperostosis. All participants were informed in detail about the purpose and the procedures of the study and provided written consent, according to the Bioethics Committee of the University Hospital of Heraklion, Greece. The Scientific Committee of the University Hospital of Heraklion, Greece, had approved the study (10787/20-12-10).

2.2. Materials

The mobility of the spine was evaluated with the Spinal Mouse® (Idiag, Volkerswill, Switzerland), a computer-assisted wireless telemetry device. This portable device is guided along the spinous processes of the vertebral column. The values obtained are transferred in real time to a computer device which reproduces a two-dimensional graph of the spine. The personal computer, where the data were collected, was placed at a distance of about 1.5 metres from the registration point. While the data were being transmitted via bluetooth, there was no other radio device or mobile phone in the room where the measurements were performed, to avoid any interference. The recording frequency was 150 Hz. The mobility of the curves was calculated with a periodical algorithm.

2.3. Measurement procedure

All measurements followed the same procedure and were performed in the same order. First, the processus spinosus of C7 was determined with palpation and signed with a permanent marker. Then a sign was placed at the height of S1-S2, with palpation of the inferior aspect of the posterior superior iliac spine [20]. After completing the first set of measurements in the sagittal plane and the frontal plane, all skin marks were completely removed and the examinees were asked to stay in the waiting room for 30 minutes. This waiting time was deemed sufficient [21], [22] to expect that no adjustment of spinal motion to the measurements, thus no increase in the range of motion, as a result of repeated measurements, occurred. Then the examinee came back to the room, the skin marks were placed anew and the second set of measurements was performed. All measurements took place during morning hours, at a constant ambient temperature of 26–27 °C.

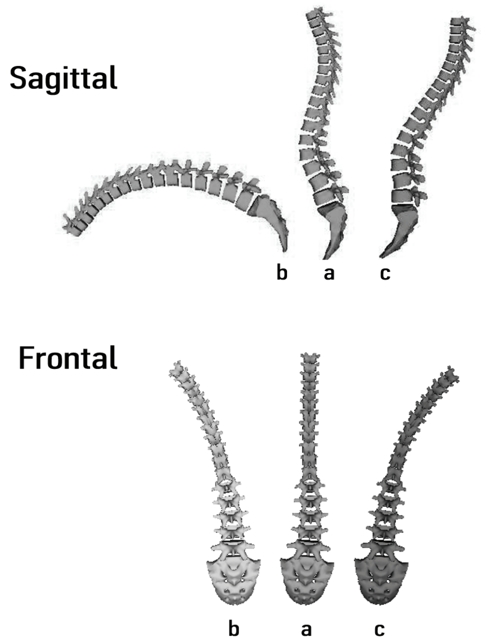

Fig. 1. Graphical reproduction of the spine in its neutral and maximally possible positions in the sagittal and frontal plane. The images are derived from real measurements in one patient. Sagittal plane: (a) upright position, (b) full flexion, (c) full extension. Frontal level: (a) upright position, (b) left lateral bending, (c) right lateral bending

The measurements involved (Fig. 1):

- Sagittal plane: (a) In the upright position. With the feet parallel to each other shoulder-width apart, the hands in anatomical position parallel to the torso and the head straight. (b) In full flexion. The examinee was requested to bend as much as possible from the upright position and with the knees extended, let the hands fall downwards parallel to each other, as if to touch the tips of the toes, and remain in this position for a few seconds. (c) In full extension. With the knees stretched, the examinee was requested to perform full extension of the trunk backward, with his head in a neutral position and to remain in this position.

- Frontal plane: A) In the upright position. With the feet parallel to each other shoulder-width apart, the hands in the anatomical position parallel to the torso and the head straight. B) Left lateral bending. The examinee was requested to perform a lateral flexion of the trunk to the left, having equal weight distribution on both feet. C) Right lateral bending. The examinee was requested to perform a lateral flexion of the trunk to the right, having equal weight distribution on both feet.

Overall, 24 parameters of the functionality of the spine and posture were counted and calculated for each plane:

- In the sagittal plane: The thoracic curvature (T1-T12), the lumbar curvature (L1-L5), the hip-sacral angle and the angle of the trunk inclination. These parameters were measured by the examiner in all positions: The upright position (Auf), full flexion (Flex) and full extension (Ext). Moreover, the mobility of the spine and the above parameters was determined with the software of the device for the following movements: From the upright position to full flexion (AF), from the upright position to full extension (AE) and from full bending to full extension (FE).
- In the frontal plane: The thoracic curvature (lateral curvature) (T1-T12), the lumbar curvature (lateral curvature) (L1-L5), the hip-sacral angle, the angle of the trunk inclination. These parameters were measured by the examiner in all positions: The upright position (Upright), left lateral flexion (Left), right lateral flexion (Right). Moreover, the mobility of the spine and the above parameters was calculated with the device software for the following movements: From the standing position to full left lateral bending (SL), from the standing position to full right lateral bending (SR) and from full left lateral bending to full right lateral bending (LR).

2.4. Statistics

Statistical analysis was performed with PASW Statistics 18. Paired *t*-tests were used to examine differences between the two measures for each parameter. Significance level was accepted at 5%. No adjustments were performed for multiple testing [23]. The intraclass correlation coefficient (ICC) and standard error of measurement (SEM) (or "typical error of measurement"), each with 95% confidence intervals, were calculated to characterise precision [24]. A measurement is considered to be useful if it shows an ICC of >0.6 [25]. However, in the present study, the more strict criteria of Currier [10], [26] were applied: 0.90–0.99 = high reliability, 0.80–0.89 = good reliability, 0.70–0.79 = fair reliability, ≤0.69 = poor reliability. The standard error of measurement (SEM) was calculated for each variable as $SD\cdot\sqrt{(1 - ICC)}$, where SD is the standard deviation. The smaller the SEM value, the better the reliability [24].

3. Results

The experimental group consisted of 50 adults (12 males, 38 females; age 58.4 ± 13.4 years, height 163.4 ± 8.2 cm, weight 72.3 ± 12.1 kg, BMI: 27.1 ± 4.0 kg m^{-2}).

The average values and the standard deviation of the first and the second measurement, the *p* value of the paired *t*-test, the ICC and the SEM for all parameters in the sagittal and frontal plane are shown in Table 1 and Table 2, respectively.

Sagittal plane

There was no statistically significant difference between the first and the second measurement for all parameters in the sagittal plane. Twenty two out of 24 parameters showed a high reliability with the highest ICC for the following ones: Upright position-lumbar curvature (Auf Lumbar), full flexion-lumbar curvature and angle of trunk inclination (Flex Lumbar, Flex Incl), from the upright position to full flexion-angle of trunk inclination (AF Incl) and from full flexion to full extension-angle of trunk inclination (FE Incl). Five parameters showed good, while two fair reliability. The other two parameters which exhibited poor reliability are not measured data, but calculated by the software of the device.

The SEM ranged from 0.322° for the lumbar curvature in full flexion (Flex_Lumbar) to 4.965° for the range of flexion of the thoracic spine (AF Thor) (Table 1).

Frontal plane

There was no statistically significant difference between the measurements for almost all parameters,

Table 1. Parameters of the functionality and mobility of the spine in the sagittal plane, determined by the Spinal Mouse

Parameter	1st measure (degrees)	2nd measure (degrees)	*p*-value	ICC (95% CI)	SEM (degrees)
Auf_Sac_Hip	20.935 ± 10.260	21.194 ± 10.294	0.674	0.972 [0.942–0.987]	0.567
Auf_Thor	46.839 ± 13.362	46.097 ± 13.407	0.443	0.959 [0.915–0.980]	1.075
Auf_Lumbar	–37.839 ± 13.067	–38.355 ± 12.981	0.374	0.985 [0.969–0.993]	0.390
Auf_Incl	0.871 ± 2.754	0.548 ± 2.815	0.385	0.845 [0.679–0.925]	0.803
Flex_Sac_Hip	66.677 ± 16.877	65.677 ± 16.088	0.276	0.976 [0.951–0.989]	0.777
Fex_Thor	62.516 ± 12.127	62.581 ± 11.416	0.964	0.877 [0.745–0.941]	2.735
Flex_Lumbar	13.613 ± 19.849	13.000 ± 20.852	0.351	0.992 [0.984–0.996]	0.322[b]
Flex_Incl	94.613 ± 20.652	93.032 ± 23.702	0.123	0.984 [0.967–0.992]	0.701
Ext_Sc_Hip	14.387 ± 12.986	13.516 ± 13.966	0.331	0.966 [0.929–0.983]	0.906
Ext_Thor	39.677 ± 15.873	38.645 ± 16.109	0.311	0.969 [0.935–0.985]	0.983
Ext_Lumbar	–45.742 ± 12.543	–44.871 ± 13.438	0.344	0.961 [0.919–0.981]	0.996
Ext_Incl	–15.677 ± 11.906	–16.161 ± 9.374	0.474	0.959 [0.915–0.980]	0.752
AF_Sac_Hip	45.871 ± 17.703	44.516 ± 16.858	0.200	0.972 [0.941–0.986]	0.963
AF_Thor	15.677 ± 11.906	16.419 ± 13.273	0.701	0.783 [0.549–0.895]	4.965[c]
AF_Lumbar	51.355 ± 16.165	51.258 ± 17.784	0.916	0.977 [0.953–0.989]	0.769
AF_Incl	93.742 ± 21.169	92.516 ± 23.840	0.228	0.985 [0.968–0.993]	0.679
AE_Sac_Hip	–6.419 ± 7.140	–7.613 ± 9.308	0.210	0.892 [0.775–0.948]	1.704
AE_Thor	–7.161 ± 6.724	–7.613 ± 7.013	0.718	0.663 [0.301–0.837][a]	4.005
AE_Lumbar	–8.032 ± 6.706	–6.484 ± 7.375	0.087	0.864 [0.718–0.934]	1.799
AE_Incl	–16.613 ± 8.958	–16.710 ± 9.107	0.878	0.961 [0.920–0.981]	0.689
FE_Sac_Hip	52.290 ± 20.627	52.290 ± 21.185	1.000	0.974 [0.947–0.988]	1.066
FE_Thor	22.935 ± 13.631	24.065 ± 15.629	0.536	0.867 [0.725–0.936]	3.660
FE_Lumbar	59.355 ± 19.683	57.742 ± 21.133	0.165	0.976 [0.949–0.988]	0.978
FE_Incl	110.387 ± 27.409	109.129 ± 29.864	0.272	0.988 [0.975–0.994]	0.686

Values are expressed as mean ± SD for the first and second measurement. ICC = Intraclass correlation coefficient. CI = Confidence interval. SEM = Standard error of the measurement.
[a] Parameter with poor reliability.
[b] Parameter with lowest SEM.
[c] Parameter with highest SEM.

except for the variables Right_Thor (right lateral flexion for the thoracic curvature) and LR_Thor (full left lateral to full right lateral bending) (Table 2). The calculation of the ICC showed a lower reliability compared with measurements in the sagittal plane (Table 2). More specifically, eight parameters exhibited high reliability. Nine parameters showed good and five fair reliability. Poor reliability was observed in the measurement of hip-sacral angle mobility from upright position to left (SL Sac Hip) and to right bending (SR Sac Hip). The SEM ranged from 0.958° for upright angle of trunk inclination (Upright Incl) to 4.820° for range of full lateral left bending to full lateral right bending for the lumbar curvature (LR Lumbar).

4. Discussion

Great emphasis is put on the conformation and the mobility of the spine in many fields of orthopaedics and rehabilitation [1], [5]. For this reason, there are various methods of evaluating and imaging the spine that are radiographic or non-invasive, the latter being mostly surface devices. The recommendations for the reduction of the exposure of the population and the patients to radiation stimulated the development of other evaluation methods [27]. Most of these methods do not study the spine as an entity. Instead, they record a part of it, mostly only the thoracic or lumbar spine. At the same time they provide results in only one plane. Moreover, the study of the mobility of the spine should include the orientation of the pelvic, as part of the structure and the mechanics of the spine [28].

In the present study, the reliability of an innovative method, the Spinal Mouse, was investigated. This method determines the curvatures and the mobility of the thoracic spine and the lumbar spine, the mobility of the pelvis and the hip and the inclination of the trunk in a non-invasive way [10], [12], [29].

The research on the Spinal Mouse has focused so far on the inter-rater reliability regarding the sagittal

Table 2. Parameters of the functionality and mobility of the spine in the frontal plane, determined by the Spinal Mouse

Parameter	1st measure (degrees)	2nd measure (degrees)	*p*-value	ICC [95% CI]	SEM (degrees)
Left_Sac_Hip	–2.981 ± 4.004	–3.990 ± 3.961	0.092	0.804 [0.593–0.905]	1.428
Left_Thor	23.387 ± 15.085	20.839 ± 13.205	0.116	0.895 [0.781–0.949]	2.837
Left_Lumbar	18.913 ± 6.367	18.294 ± 7.539	0.355	0.926 [0.846–0.964]	0.998
Left_Incl	23.619 ± 7.385	23.368 ± 6.911	0.704	0.93 [0.855–0.966]	0.967
Upright_Sac_Hip	2.455 ± 3.140	2.658 ± 3.325	0.679	0.787 [0.559–0.897]	1.250
Upright_Thor	–8.652 ± 5.999	–8.255 ± 6.184	0.612	0.857 [0.703–0.931]	1.631
Upright_Lumbar	5.545 ± 3.569	5.903 ± 4.096	0.566	0.751 [0.483–0.880]	1.713
Upright_Incl	0.103 ± 1.719	0.290 ± 1.894	0.548	0.719 [0.399–0.860]	0.909[b]
Right_Sc_Hip	7.103 ± 3.831	6.790 ± 3.540	0.588	0.772 [0.526–0.890]	1.519
Right_Thor	–31.158 ± 11.349	–28.352 ± 9.898	0.038	0.871 [0.732–0.938]	2.586
Right_Lumbar	–14.281 ± 8.140	–14.210 ± 8.582	0.937	0.902 [0.798–0.953]	1.561
Right_Incl	–26.000 ± 7.653	–24.916 ± 6.752	0.111	0.931 [0.956–0.967]	0.965
SL_Sac_Hip	–5.435 ± 3.961	–6.648 ± 4.183	0.133	0.596 [0.163–0.805][a]	2.777
SL_Thor	32.039 ± 14.695	29.094 ± 12.301	0.122	0.831 [0.649–0.918]	4.237
SL_Lumbar	13.368 ± 6.761	12.390 ± 6.140	0.209	0.879 [0.749–0.942]	1.475
SL_Incl	–23.516 ± 7.636	–23.077 ± 7.304	0.586	0.903 [0.799–0.953]	1.383
SR_Sac_Hip	4.648 ± 4.294	4.132 ± 3.243	0.556	0.325 [–0.399–0.675][a]	3.968
SR_Thor	–22.506 ± 11.418	–20.097 ± 11.051	0.133	0.825 [0.636–0.915]	3.631
SR_Lumbar	–19.826 ± 8.774	–20.113 ± 9.521	0.815	0.841 [0.670–0.923]	2.706
SR_Incl	26.103 ± 7.352	25.206 ± 6.317	0.171	0.928 [0.850–0.965]	0.954
LR_Sac_Hip	10.084 ± 5.275	10.781 ± 5.285	0.409	0.761 [0.505–0.885]	2.266
LR_Thor	–54.545 ± 23.048	–49.190 ± 20.006	0.042	0.882 [0.755–0.943]	4.820[c]
LR_Lumbar	–33.194 ± 12.685	–32.503 ± 13.982	0.570	0.933 [0.861–0.968]	1.731
LR_Incl	49.619 ± 14.006	48.284 ± 12.931	0.253	0.941 [0.877–0.971]	1.550

Values are expressed as mean ± SD for the first and second measurement. ICC = Intraclass correlation coefficient. CI = Confidence interval. SEM = Standard error of the measurement.

[a] Parameter with poor reliability.

[b] Parameter with lowest SEM.

[c] Parameter with highest SEM.

plane in healthy adults or young children [10], [12], [30]. In contrast, the present study examined the test-retest reliability which was performed in patients with back pain or low back pain. Furthermore, it also included the frontal plane.

Sagittal plane

The evaluation in the sagittal plane exhibited excellent reliability. These results confirm the results of other investigators in the healthy population [10], [31] and in individuals with spinal fractures [12]. On the contrary, evaluations in children have shown a slightly lower reliability [30] which may be the result of the different methods that were used in these studies, such as not using skin marks.

In the present study, the only values that exhibited fair or poor reliability concerned the measurements of the mobility of the thoracic curvature from an upright position in full flexion (AF Thor) and upright full extent (AE Thor). A similarly low reliability has been shown in exactly the same measurements of the thoracic spine in the study of Mannion et al. [10]. A possible explanation for their and our observations is the extraction of the particular values via an algorithm that uses the device's software and not a direct measurement and recording by the examiner. Kellis et al. [30] emphasize that this poor reliability regarding the spinal range of motion results in an inappropriate method of monitoring the changes of the spinal range of motion over time. Therefore, we recommend further studies of the range of motion of the thoracic curvature to draw more accurate conclusions.

Frontal plane

The evaluation of the method in the frontal plane showed slightly inferior reliability compared with the sagittal plane. The best results were obtained when we measured the lumbar spine in flexion of the torso left and right and the angle of the trunk inclination in all positions (left and right assessments, range of motion) except for the upright position, whereas all measurements of the thoracic spine and the analysis of its parameters showed good reliability. The only fair or poor reliability shown for all measurements concerning the hip-sacral angle may be based on the difficulty in assessing whether examinees equally distribute their weight on both feet when performing the flexion of the trunk.

Summarizing the results concerning the frontal plane, the present method is a very good evaluation tool for deformations of the lateral curvatures of the spine, such as scoliosis and also for trunk impairment and postural disorders [4], [32].

Reliability

The Intraclass Correlation Coefficient (ICC) was used for the estimation of the test-retest correlation. The SEM is mainly a standard deviation of the error that was made during the prediction of a true score of an individual measurement. It is used for the estimation of an absolute measurement of the reliability in cases where the ICC is a relative and dimensionless variable [24], [33].

Even with the very strict reliability limits of Currier that were applied in the present study [10], 22 parameters out of a total of 24 parameters that were studied in the sagittal plane exhibited high and good reliability and 17 parameters of the 24 parameters that were studied in the frontal plane exhibited high and good reliability. This indicates the validity of this method in repeated measurements of the spine.

Another method which characterizes the precision is the evaluation of the ICC according to Fleiss, where the cut-off value between excellent and fair-to-good reliability is 0.75, while the one distinguishing between fair-to-good and poor reliability is 0.4 [34]. Based on this evaluation, the method that was studied would exhibit an even better and almost excellent reliability. Specifically, in the sagittal plane, all but one parameter would present excellent reliability, only one parameter would present fair to good reliability whereas no parameter would present poor reliability. Similarly, in the frontal plane, 21 parameters out of a total of 24 parameters would present excellent reliability, two parameters fair to good reliability and only one parameter poor reliability. Alternatively, Sleivert and Wenger [35] characterized the ICC within stricter thresholds compared to Fleiss' definition but still more flexible than Currier's limits. In particular, good reliability was defined with ICC values 0.80–1.0, fair reliability with ICC values 0.6–0.79 and poor reliability with ICC values <0.6. Applying the thresholds by Sleivert and Wenger, our investigation of the Spinal Mouse would present good reliability for 22 parameters and fair reliability for only two parameters in the sagittal plane. In the frontal plane the results would also be satisfying with 18 parameters out of a total of 24 parameters presenting good reliability, four parameters presenting fair reliability and two parameters presenting poor reliability.

Another study, where the inter-rater reliability of the Spinal Mouse was evaluated only in the sagittal plane in the healthy population and in individuals who had chronic spinal fracture with no neurological deficits, showed that the ICC was 0.92–0.95 in the measurements that concerned the inclination, the flexion and the extension [12]. Moreover, the ICC was 0.76 in the measurements from full flexion to full extension [12]. In the present study, the parameters that were explored for the mobility of the spine in the sagittal plane, from full flexion to full extension, presented an ICC in the range of 0.86–0.98. However, the present study examined the intra-rater reliability and therefore the results cannot be compared. Generally, the results of the ICC cannot be compared with other studies [10], [30] because the parameters that are explored, the methodology and the population that is examined differ. Also, there is no other study that explores the reliability in the frontal plane.

Regarding other methods that examine the mobility of the spine, the flexible curve exhibits an ICC value of 0.82–0.97 for an intra-rater evaluation. However, this particular method can evaluate only the lumbar spine in the sagittal plane and the sample size of the participants in the study was very limited [2]. Another study that explored the inter-examiner and intra-examiner reliability of three types of inclinometers revealed poor inter-examiner reliability and an intra-examiner reliability below 0.90 for the total of the measurements. Also, this method evaluated only the lumbar curvature of the spine [36]. Finally, another study, where the goniometer was evaluated only for the lumbar spine and in the sagittal plane as a method of evaluation of the spine compared with the double inclinometer and the Shober method, revealed that both the inter-examiner and the intra-examiner variability of the goniometer were statistically significantly lower compared with the other methods in almost all motions [37]. Specifically, the ICC presented values from 0.76 to 0.84 [37].

Conclusion

In conclusion, the Spinal Mouse showed a high test-retest reliability for the evaluation of curvatures, deformation and mobility of the spine and the position of the body in both the sagittal and the frontal plane in patients with back or low back problems.

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