Assessment of Reliability of the Normalcy Index for Children With Cerebral Palsy
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Introduction
Gait analysis produces copious data describing the walking pattern of an individual. Given the highly correlated nature of the data, multivariate analyses may be the most appropriate way to assess overall change in gait for outcome assessment. The Normalcy Index (NI) uses principle components analysis to reduce a set of 16 kinematic variables to a single measure quantifying a patient’s gait pattern with respect to an average normal gait [4]. The NI has been employed to assess change following multilevel surgery [3] and intrathecal baclofen pump insertion [1]. Romei et al. showed statistically significant changes in NI post-operatively [3]. Before NI is used clinically, measurement error needs to be investigated. Determining the reliability of NI is one way to ascertain measurement error. Therefore, the purpose of this study was to investigate the reliability of the NI.

Statement of Clinical Significance
Utilization of the NI as a clinical measurement tool depends upon its reliability and an understanding of “how much” change in the NI score is required for the difference to be a meaningful change.

Methodology
Subjects included 46 unimpaired children and 62 children with cerebral palsy (CP). Children with CP were classified using the gross motor function classification system (GMFCS). Gait analysis data were reduced for one left and one right gait cycle for all subjects. Right and left data were averaged to produce one NI value for each subject from which group averages were determined (Table 1). Group differences were determined using a one-way ANOVA (p-value of 0.05). To assess reliability, data were reduced for two additional left and right gait cycles for subsets of subjects in the groups to approximately equalize group sizes (new N: norm = 15; I = 12; II = 15; III = 15; IV = 6). Cycle to cycle NI reliability within patients (N = 48) was assessed using the intraclass correlation coefficient (ICC) using the (2,1) model [2]. Assessment of the measurement error of NI was achieved using a standard error of measurement (SEM) and minimal detectable change (MDC) analysis [5]. The SEM is equal to the square root of the error variance, and is a measure of within subject variability expressed in the units of the measurement tool. The MDC is related to the SEM and expresses a criterion amount of change in the measurement that assures a level of confidence in that change. The MDC is the product of SEM, the z-score for the given level of confidence (95% for this study) and \(\sqrt{2}\).

Results
Across all groups, NI values generally increased with degree of impairment, with a plateau noted between GMFCS Level III and Level IV (Figure 1). A significant group effect was found (p<0.00) and Tukey post-hoc tests revealed that average NI was significantly different among groups, with the exception of Level III and IV.

The ICC for the combined CP patient data was 0.947 indicating excellent reliability in NI between multiple gait cycles. The SEM for combined CP data was 30.6 NI units, which
resulted in an MDC of 84.6 units. Values for MDC increased with GMFCS level from 59.7 NI units for Level I to 129.1 NI units for Level IV ambulators.

Table 1. Group demographics and average NI

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Age (years)</th>
<th>NI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norm</td>
<td>46</td>
<td>10.2 (3.5)</td>
<td>15.8 (8.2)</td>
</tr>
<tr>
<td>I</td>
<td>12</td>
<td>10.9 (4.0)</td>
<td>94.6 (47.5)</td>
</tr>
<tr>
<td>II</td>
<td>26</td>
<td>10.8 (2.7)</td>
<td>162.6 (81.1)</td>
</tr>
<tr>
<td>III</td>
<td>17</td>
<td>10.0 (3.7)</td>
<td>338.3 (117.1)</td>
</tr>
<tr>
<td>IV</td>
<td>6</td>
<td>9.5 (1.5)</td>
<td>333.0 (99.6)</td>
</tr>
</tbody>
</table>

Note: Data presented as mean (SD)

Figure 1. NI scores for all subjects

**Discussion**
The NI has been shown to increase with degree of impairment and therefore it may be a useful measure for documenting overall change in gait. The reliability of NI was excellent between gait cycles, indicating that researchers and clinicians can be confident in selecting a representative gait cycle for the NI calculation. An SEM of 30.6 for the whole group of CP patients provides useful information regarding the underlying error in the measure, such that changes in NI less than 30 units must be not be interpreted as “real” change in the overall gait pattern. Results of the MDC analysis for the NI may be more clinically relevant. We have shown that a change in NI of 85 units must be achieved for the clinician to accept the change as significant with 95% confidence. Between the groups, MDC increased with GMFCS level, with the MDC for Level IV ambulators twice the magnitude of the typically less variable Level I walkers. Therefore, a greater change is necessary to interpret NI for more involved children. Future research is needed to determine if an increase in NI of greater than the MDC correlates with a clinically relevant change in function, and to assess the stability of the MDC for test-retest measures of NI.

**References**


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