

## ORIGINAL ARTICLE

# Is an Instrumented Spasticity Assessment an Improvement Over Clinical Spasticity Scales in Assessing and Predicting the Response to Integrated Botulinum Toxin Type A Treatment in Children With Cerebral Palsy?

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## Abstract

**Objective:** To compare responsiveness and predictive ability of clinical and instrumented spasticity assessments after botulinum toxin type A (BTX) treatment combined with casting in the medial hamstrings (MEHs) in children with spastic cerebral palsy (CP).

**Design:** Prospective cohort study.

**Setting:** Hospital.

**Participants:** Consecutive sample of children (N=31; 40 MEH muscles) with CP requiring BTX injections.

**Intervention:** Clinical and instrumented spasticity assessments before and on average  $\pm$  SD 53 $\pm$ 14 days after BTX.

**Main Outcome Measures:** Clinical spasticity scales included the Modified Ashworth Scale and the Modified Tardieu Scale. The instrumented spasticity assessment integrated biomechanical (position and torque) and electrophysiological (surface electromyography) signals during manually performed low- and high-velocity passive stretches of the MEHs. Signals were compared between both stretch velocities and were examined pre- and post-BTX. Responsiveness of clinical and instrumented assessments was compared by percentage exact agreement. Prediction ability was assessed with a logistic regression and the area under the receiver operating characteristic (ROC) curves of the baseline parameters of responders versus nonresponders.

**Results:** Both clinical and instrumented parameters improved post-BTX ( $P \leq .005$ ); however, they showed a low percentage exact agreement. The baseline Modified Tardieu Scale was the only clinical scale predictive for response (area under the ROC curve=0.7). For the instrumented assessment, baseline values of root mean square (RMS) electromyography and torque were better predictors for a positive response (area under the ROC curve=.82). Baseline RMS electromyography remained an important predictor in the logistic regression.

**Conclusions:** The instrumented spasticity assessment showed higher responsiveness than the clinical scales. The amount of RMS electromyography is considered a promising parameter to predict treatment response.

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Cerebral palsy (CP) is the most common cause of physical disability in children. Spasticity, occurring in 80% to 90% of these children, was described by Lance<sup>1</sup> as being a velocity-dependent increase in tonic stretch reflexes resulting from hyperexcitability of the stretch reflex. However, the term spasticity is often used to represent multiple positive symptoms of the upper motor neuron syndrome. Spasticity is considered to play an important role in the development of secondary muscle contractures and bone deformities.<sup>2</sup> Consequently, spasticity management in children with CP aims to prevent these secondary problems and delay or avoid the need for surgery.<sup>3</sup>

Intramuscularly injected botulinum toxin type A (BTX) is effective in temporarily decreasing spasticity,<sup>4</sup> although a large variability in response has been reported in children with CP (37%–80%, depending on the outcome measure used).<sup>5,6</sup> Common outcome measures include the Modified Ashworth Scale (MAS)<sup>7</sup> and the Modified Tardieu Scale (MTS).<sup>8</sup> However, the intrinsic subjective character of these clinical scales restricts their reliability.<sup>9–12</sup> Additionally, it remains unclear whether their predictive ability is sufficient for clinical decision making.<sup>13–16</sup> The value of clinical scales may be questioned because they cannot differentiate between neural and nonneural components of increased resistance.<sup>10,17–21</sup> This may be essential information to support treatment planning and help understand treatment response.

Instrumented tests that integrate biomechanical and electrophysiological measures of spasticity collect quantitative data.<sup>20,21</sup> These have been shown to be reliable and valid to measure spasticity in the medial hamstrings (MEHs) of children with CP.<sup>22,23</sup> However, it has yet to be assessed if parameters obtained from these instrumented assessments are more sensitive than clinical scales in detecting treatment response and if these could provide further insights that help explain response variability.

In this study, we used instrumented and clinical spasticity assessments to define the effect of BTX in the MEHs of children with CP. For both assessments, we analyzed first their responsiveness to change and then their ability to predict it. We hypothesized that an instrumented assessment was more responsive and could better predict the effect of BTX on spasticity in the MEHs of children with CP.

## Methods

### Participants

In this prospective cohort study, participants were recruited from the multidisciplinary clinic for patients with CP of the University Hospital Leuven. Children aged 3 to 18 years and scheduled for

BTX of the MEHs (semitendinosus and semimembranosus muscles) were screened for inclusion. Exclusion criteria were the presence of ataxia or dystonia, severe muscle weakness (<2+ on the Manual Muscle Test<sup>24</sup>), poor selectivity,<sup>8</sup> bone deformities or contractures compromising the performance of purely sagittal plane passive knee flexion/extension movements, cognitive problems that could impede the measurements, previous lower limb orthopedic surgery, intrathecal baclofen pump, or selective dorsal rhizotomy. Children's parents signed an informed consent for participation. The experimental protocol was approved by the university hospital's ethical committee (B32220072814).

BTX dosage was based on patient history, findings of a clinical examination [MAS,<sup>7</sup> MTS,<sup>8</sup> range of motion (ROM), strength,<sup>24</sup> selectivity<sup>8</sup>], three-dimensional gait analysis, and the clinicians' experience. Injection was done under short anesthesia, and ultrasound was used for visual identification of muscles and needle depth control.<sup>25</sup> Post-BTX, all patients received casting for a period of 10 days (lower-leg cast and optional removable, upper-leg night splint used as a knee-extension device), intensive physical therapy, and orthotic management (day and night), as previously described.<sup>26</sup>

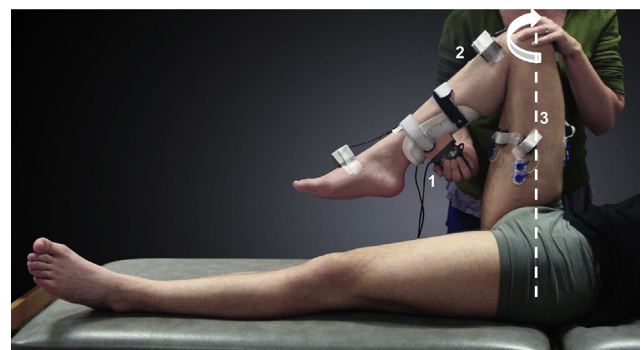
### Data acquisition

Spasticity assessments were performed before injection and between 14 and 90 days after injection. Clinical and instrumented spasticity assessments<sup>22</sup> were performed consecutively by 2 independent assessors on the same day. The MAS was used to assess the quality of muscle reaction to passive stretch.<sup>7</sup> The MTS was only performed in those muscles with an MAS score  $\geq 1+$ , whereby the angle at which a spastic catch was felt during a quick passive stretch (R1 value) was noted.<sup>8</sup> In children with unilateral CP, only the affected side was tested. In children with bilateral involvement, both sides were tested.

The setup of the instrumented assessment is presented in figure 1. All evaluations were conducted as previously outlined.<sup>22</sup> Surface electromyography electrodes were placed according to standardized procedure on the MEHs and the rectus femoris muscle.<sup>27</sup> Data from the rectus femoris muscle were used to ensure the absence of active assistance during passive muscle

#### List of abbreviations:

AOC (%)	angle of catch expressed as a percentage of the full range of motion
BTX	botulinum toxin type A
CP	cerebral palsy
IQR	interquartile range
MAS	Modified Ashworth Scale
MDC	minimal detectable change
MEH	medial hamstring
MTS	Modified Tardieu Scale
RMS	root mean square
ROC	receiver operating characteristic
ROM	range of motion



**Fig 1** Test starting position, direction of stretch (white arrow), and instrumentation for the instrumented spasticity assessment of the MEHs. Overview of the test instrumentation: a 6 degrees of freedom force sensor attached to a shank orthosis on the posterior aspect of the lower leg was used to measure torque (1); 2 inertial measurement units measured joint angle characteristics (2); and surface electromyography measured muscle activity of the agonistic and antagonistic muscle groups (3).

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