Assessment of the efficacy of rehabilitation with concomitant use of botulinum toxin in patients with cerebral palsy qualified for this therapy by means of objective gait analysis

Ocena skuteczności leczenia rehabilitacyjnego toksyną botulinową pacjentów z mózgowym porażeniem dziecięcym przy zastosowaniu obiektywnej analizy chodu do kwalifikacji pacjentów

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Key words
cerebral palsy, botulinum toxin, gait analysis, treatment, rehabilitation

Abstract
Introduction: Botulinum toxin is more and more frequently used in rehabilitation treatment of CP patients, especially in children younger than 10 years. Its efficacy depends on several factors including proper qualification, planning of the treatment, and rehabilitation program following the injections. The aim of this paper was to evaluate the efficacy of rehabilitation treatment with botulinum toxin in CP patients using objective gait analysis as one of the qualification tools.
Material and Methods: Patients: 20 CP patients, aged from 2 to 15 years old. After the first assessment (passive ROM in joints, spasticity evaluation and assessment of motor development), patients underwent the objective gait analysis. The VICON 460 system synchronized with the 16-channel Motion Lab system for dynamic electromyography was used. Several trials were conducted and recorded in each patient (from 3 to 6). The following variables were recorded: spatio-temporal and kinematic parameters, as well as EMG of selected muscles. Based on clinical tests and results of objective gait analysis an individual treatment plan was established for each patient (dosage and sites for botulinum toxin injections). Clinical evaluation and gait analysis was repeated after 3 to 9 months. Patients underwent a rehabilitation program after the botulinum toxin injections.
Results: An improvement of gait pattern was found in all patients; there were no cases showing deterioration or no change. Both spatio-temporal and kinematic parameters were improved.
Conclusions: Botulinum toxin exerts its effects for 3 to 6 months; therefore, the second evaluation was performed after the direct effect disappeared. Appropriate planning, which takes into account results of the objective gait analysis, and the intensive rehabilitation program allow permanent improvement of gait pattern in CP children.

Słowa kluczowe
mózgowe porażenie dziecięce, botulina, analiza chodu, leczenie, rehabilitacja

Streszczenie
Wstęp: Toksyna botulinowa jest coraz częściej stosowana w leczeniu rehabilitacyjnym dzieci z mózgowym porażeniem dziecięcym (mpdz), zwłaszcza u pacjentów poniżej 10 roku życia. Jej skuteczność zależy m.in. od prawidłowej kwalifikacji pacjentów i planowania leczenia, oraz prawidłowo prowadzonej rehabilitacji po jej podaniu. Celem pracy jest ocena skuteczności leczenia rehabilitacyjnego z zastosowaniem toksyny botulinowej u pacjentów z mpdz przy wykorzystaniu obiektywnej analizy chodu do kwalifikacji pacjentów i oceny wyników postępowania skojarzonego leczenia rehabilitacyjnego.
Materiał i Metody: Pacjenci: 20 dzieci z mpdz w wieku od 2 do 15 lat. Po wstępnej kwalifikacji (badanie kliniczne: zakres ruchu biernego w stawach, ocena spastyczności oraz dużej motoryki) pacjenci przechodzili badanie analizy chodu za pomocą systemu VICON 460 współpracującego z 16-kanałowym systemem Motion Lab do elektromiografii dynamicznej. Rejestrowano kilka przejść pacjenta (od 3 do 6), a wszystkie wyniki uśredniano. Mierzono parametry czasowo-przestrzenne, kinematyczne, oraz EMG wybranych mięśni. Na podstawie wyników badań klinicznych oraz analizy chodu ustalano indywidualnie dla każdego pacjenta plan poda-

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Authors' contribution: A - project of the study, work; B - collection of the data, information; C - statistical analysis; D - data interpretation; E - preparation of the manuscript; F - literature query; G - obtaining funds

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nia toksyny botulinowej z określeniem konkretnych mięśni i dawek. Kolejne badanie i analizę chodu przeprowadzono po 3 i 9 miesiącach od podania toksyny botulinowej. Przez cały okres obserwacji pacjenci byli rehabilitowani.
Wyniki: U wszystkich pacjentów stwierdzono poprawę stereotypu chodu. Poprawa dotyczyła zarówno parametrów czasowo-przestrzennych jak i parametrów kinematycznych.
Wnioski: Prawidłowe podanie toksyny botulinowej, dzięki wykorzystaniu wyników analizy chodu, w połączeniu z intensywnym programem rehabilitacyjnym w okresie jej najsilniejszego działania wydaje się powodować trwałą poprawę stereotypu chodu u pacjentów z mpdz.

INTRODUCTION

First report on application of botulinum toxin in the therapy of spasticity in patients with cerebral palsy (CP) was published in 1993. The paper „Management of spasticity in cerebral palsy with botulinum toxin – A: preliminary investigation" was authored by Koman et al. and published in Journal of Pediatric Orthopedics[1]. Since then, the number of studies on the effectiveness and safety of botulinum toxin use has been rapidly increasing and, during the period of time between 1999 and 2002, 25 papers on this topic were published per year[1].

In numerous studies on botulinum toxin application, its effectiveness in reducing abnormal muscle tone and increasing range of motion in the joints of the lower limb has been proven; however, there have been discrepancies in the assessment of functional efficacy of botulinum toxin use. This discrepancy may have resulted from different criteria of patient qualification for botulinum toxin administration, lack of uniform protocols of drug administration, as well as use of various, incomparable patient status assessment scales[2].

Use of botulinum toxin in patients with CP aims at increasing muscle length, increasing the (limited) range of motion in the joints, preventing (or – at least – delaying) formation of fixed contractures, and at improving gait function. Its use enables delaying surgical interventions as well as limiting the range of these interventions[3].

Quantitative, objective analysis of gait is a tool more and more widely used in the evaluation of gait pathology and its use, recommended in 2000 by a consortium of 15 clinical specialists[4], allows a more detailed planning of botulinum toxin application with regard to individual patient's needs and consideration of particular administration sites and dosages[4,5].

AIM OF THE STUDY

The aim of this study is to evaluate the efficacy of rehabilitation treatment with concomitant use of botulinum toxin in patients with CP using a quantitative, objective, VICON motion analysis system-assisted gait analysis, both for patient qualification and planning their therapy, as well as for the assessment of the effects of rehabilitation.

MATERIAL AND METHODS

Study design

This study contains a description of case studies of children with CP, in whom botulinum toxin was used during rehabilitation.

Use of botulinum toxin in CP has two principle goals[5]:
- in children younger than 4 years, its administration is to aid in the development of correct gait pattern,
- in older children, it is to prevent spasticity-induced structural changes in the muscles.

Therefore, the following criteria for patient qualification for botulinum toxin treatment were formulated:
- spastic form of CP,
- lack of fixed contractures,
- presence of non-generalised (local), dynamic, spastic muscle contractures.

The exclusion criteria were: allergy to protein, muscular disorders such as myasthenia gravis, generalised or local infection, past orthopaedic surgery, use of aminoglycosides or streptomycin during 3 months preceding botulinum toxin administration, lack of cooperation of patients' caregivers.

Study group

Out of all children with CP treated with botulinum toxin at the Department of Paediatric Rehabilitation of the Institute „Monument – Centre for Children Health" in 2005-2006 (according to the criteria established by NFZ (National Health Fund)), a group of 20 patients was selected, who additionally fulfilled the following criteria:
- botulinum toxin was administered only to the lower extremities;
- patients and their caregivers conformed to the rehabilitation program designed individually for each patient during the period of time following administration of botulinum toxin, strictly according to the received guidelines;
- patients were present during subsequent follow-up visits;
- patients underwent functional assessment, including gait analysis using the VICON system, prior to and in the 3rd, 6th and/or 9th month following botulinum toxin administration.

The group of patients fulfilling all the above described inclusion criteria consisted of 20 patients aged from 2 to 15 years. Three patients were older than 7 years, 7 patients were 5 to 7 years old, while the remaining group (10 patients) was 2 to 4 years old. None of the patients ever received botulinum toxin.

Hemiplegia was found in 6 patients, diplegia in 14 (patients with spastic triplegia or tetraplegia were included in this group).

All patients underwent continuous rehabilitation, while initiation of rehabilitation treatment occurred between the 3rd and 9th month of life.

Clinical assessment

General description of patient's locomotor abilities: walking independently, assisted walking – with a walker or the patient lead using two caregiver's arms, crawling quadruped – those patients were excluded from this analysis, as they were unable to participate in the quantitative gait assessment.

Measurements of passive range of motion at isolated positions[6]. Passive motion performed slowly discloses fixed contractures at the evaluated

muscles (in clinical practice, an increase in the range of motion in the joint is frequently found after botulinum toxin administration). The same measurement performed fast aims at detection of spasticity of the evaluated muscle. The difference between the fast and the slow movement is a measure of the degree of spasticity and constitutes the so-called Tardieu test. The most widely used Ashworth scale, similarly to the Tardieu scale, is a subjective and qualitative test. According to the most recent reports published in scholarly literature, the scale is of a too low sensitivity, which renders detection of therapy-induced changes impossible[7,8]. It does not enable assessment of a correlation of the degree and type of muscle tone disturbances and patient functional status either[8,9]. Therefore, the evaluation involved the modified Tardieu test that has a higher sensitivity than the Ashworth scale[7]. In each patient, the following tests were performed:

1. Assessment of hip flexors (the iliopsoas muscle and the straight head of the quadriceps muscle of thigh) using Thomas test;
2. Assessment of the straight head of the quadriceps muscle of thigh using Duncan-Ely test;
3. Assessment of hip adductors;
4. Assessment of the gracilis muscle and the medial group of ischiocrural muscles;
5. Assessment of ischio-crural muscles (by means of measurement of the popliteal angle);
6. Assessment of the soleus muscle by measurement of dorsal flexion of the foot at the ankle joint, with the knee and hip in 90° flexion;
7. Assessment of the gastrocnemius muscle by measurement dorsal flexion of the foot at the ankle joint, with the knee and hip in the extended position.

Moreover, evaluation of the range of motion of external hip rotation (its limitations are associated with the medial group of ischio-crural muscles) and internal hip rotation, as well as of the range of flexion and extension at the knee joint in the supination and pronation positions was performed only during the slow movement.

Each range of motion measurement was performed 1-2-3 times, dependently on the degree of child cooperation.

Quantitative, objective gait assessment

Quantitative, objective gait assessment was conducted using the VICON 460 system (ViconPeak, formerly Oxford Metrics) including 6 6M camcorders collecting the data at 60 Hz frequency. The system was linked to a 16-channel system Motion Lab used for dynamic electromyography. Acquisition and preliminary data processing was performed using Workstation software (ViconPeak), while further analysis was conducted using the program Polygon (ViconPeak).

A set of 15 markers (the so-called Helen Hayes marker set – a model constituting a part of the Polygon software) was used for the studies. The markers were placed at predefined body points over the hip girdle and the lower extremities. Based on their position and principle anthropometric data (patients underwent basic measurements prior to the testing), the following variables were calculated (during walking): orientation of the pelvis in space at all three planes, angles at the hip joints in the saggital, frontal and transverse planes, motion of the knee joints in the saggital plane, motion of the ankle joints in the saggital and transverse planes, as well as position of the feet with regard to the gait direction line. Moreover, spatial-temporal parameters, such as: gait velocity, stride rate, stride length, as well as percentages of the particular phases of the gait cycle were calculated. Gait velocity, stride rate and their length were presented as % of the age-adjusted normal value[10,11,12].

During walking, activity of the antagonistic muscles of the right and left body half were simultaneously assessed by means of dynamic EMG recording (bilaterally in the following muscles: tibialis anterior, lateral head of the gastrocnemius, biceps of thigh, rectus of thigh, gluteus maximus, and ischio-crural). In the patients, where it was possible, ground reaction forces were additionally recorded during walking using dynamographic Kistler platform. All three measurement systems (video, dynamic electromyography and the platform) were synchronised with each other. Several walks were recorded in each patient (3 to 6) and all the results were averaged. Number of walks depended on the age and patients' willingness to cooperate during the measurements.

Patients were scheduled for the quantitative, objective evaluation of gait three times: during qualification for botulinum toxin, and, subsequently - 3 and 6 months after botulinum toxin administration; whereas, when clinical examination revealed persistence of the effects of botulinum toxin after 3 months, then the second assessment was rescheduled for the 6th month and the third – for the 9th month following administration of botulinum toxin.

Treatment program

The program of rehabilitation of CP children using botulinum toxin, including patient qualification principles, is based on the program designed by professor Jules Becher from the Department of Rehabilitation Medicine, VU Amsterdam, The Netherlands[5].

Following conduction of the first quantitative gait assessment, sites for botulinum toxin injections were determined according to the following criteria:

- total botulinum toxin dose must not exceed the maximum acceptable dose,
- dose administered to a given muscle must not exceed the maximum acceptable dose for this muscle,
- muscles to be injected with botulinum toxin were selected based on abnormal muscular activity (associated with spasticity), inducing disturbances of gait kinematics (e.g. excessive activity of the rectus muscle of thigh, evident in EMG, causing failure of hip extension during the support phase and excessive hip flexion at the beginning of the support phase); the abnormal activity was evident in the EMG
- spasticity, as demonstrated in the Tardieu test, was found on clinical examination of a given muscle

Botulinum toxin was administered at a single level in 2 casaes, in 5 cases, it was given at multiple levels in one lower extremity. In the remaining 13 cases, botulinum toxin was administered at multiple levels in both lower limbs.

Botulinum toxin dose was:

– for single-level administrations (2 cases) – 20 units/kg body weight as calculated for Dysport (4 units/kg body weight for Botox)
– for 12 multi-level administrations – 40-50 units/kg body weight as calculated for Dysport (8-10 units/kg body weight for Botox)
– for 6 multi-level administrations – 30-35 units/kg body weight as calculated for Dysport (6-7 units/kg body weight for Botox)

Following botulinum toxin administration, patients had rehabilitation for 3 weeks during rehabilitation-associated hospitalisations and, subsequently, continued rehabilitation at home. Each patient had an individual rehabilitation program, „designed" specifically for particular patient's motor deficits. A significant part of the program was oriented towards improvement of gait pattern. During single-day hospitalisations, patients additionally had exercises in a swimming pool (individual exercises in a small pool, with carer's assistance), hydrotherapy and task therapy.

RESULTS

The obtained results are listed in the Table 1.

In studies of range of motion during slow passive movement at isolated positions (indirectly indicating the length of a muscle or muscle group), botulinum toxin and rehabilitation-induced changes in length of the following muscles were assessed: ischio-crural, gracilis, soleus, and gastrocnemius.

An improvement in the length was achieved in:
– ischio-crural muscles in 38% (13),
– gracilis muscle in 44%5 (15),
– soleus muscle in 50% (17),
– gastrocnemius muscle in 35% (12).

Further, when relating the obtained results to particular patients, the improvement was found in all:
– 4 parameters in 15% of patients (3),
– 3 parameters in 20% of patients (4),
– 2 parameters in 45% of patients (9),
– 1 parameter in 20% of patients (4).

No differences in the results of the modified Tardieu test were found in any of the patients.

In all studied patients, gait pattern was improved. However, the range of those changes was very different: from small, e.g. an improvement in position and a reduction in the range of motion of the pelvis in the saggital and transverse planes (1 patient) to very pronounced, encompassing near all spatial-temporal and kinematic parameters (2 patients).

Improvement in gait velocity was observed in 6 patients, in stride rate – in 4 patients. Stride length increased in 8 patients (in a part of them, stride rate was concomitantly reduced thus

Table 1

Summary of results

Patient number	Toxin	Number of muscles*	Gait velocity	Stride rate	Stride length	Step width	Percent**	Pelvis#	Range of motion in the hip joints in the saggital plane	Position of the hip jopints in the transverse plane	Motion of the knee joints in the saggital plane	Position of the feet during the phase	Position of the feet with respect to the shanks in the transverse plane
1	W1	4	+	+	+	+	+	+	+	+	+	+	+
2	W1	4	+	+	+	+	+	+	+	+	+	+	+
3	W1	4					+	+		+			+
4	W1	4						+			+		
5	W2	3	+		+		+		+				+
6	W1	3	+					+		+	+		+
7	W1	3	+				+	+					
8	W1	3	+										+
9	W2	2					+						
10	W1	2			+				+				+
11	W1	2					+	+					
12	J	2					+	+				+	+
13	W1	2			+			+	+				
14	W1	2		+	-					+			+
15	W1	2			+			+					
16	W2	2								+		+	+
17	J	2			+			+					
18	W2	1		+							+		
19	W2	1			+				+				
20	W2	1						+					

Toxin indicates the method of administration of the botulinum toxin: J – one-level, W1 – multi-level at Dysport dose of 40-50 mass units/kg body weight, W2- multi-level at a dose of 30-35 mass units/kg body weight, *number of muscles indicates number of muscles, where an improvement in length was achieved, **percent contribution of particular phases in the gait cycle, # position of the pelvis in the saggital and transverse planes, the "+" sign indicates an improvement. The patients were ranked from the best to the worst result.

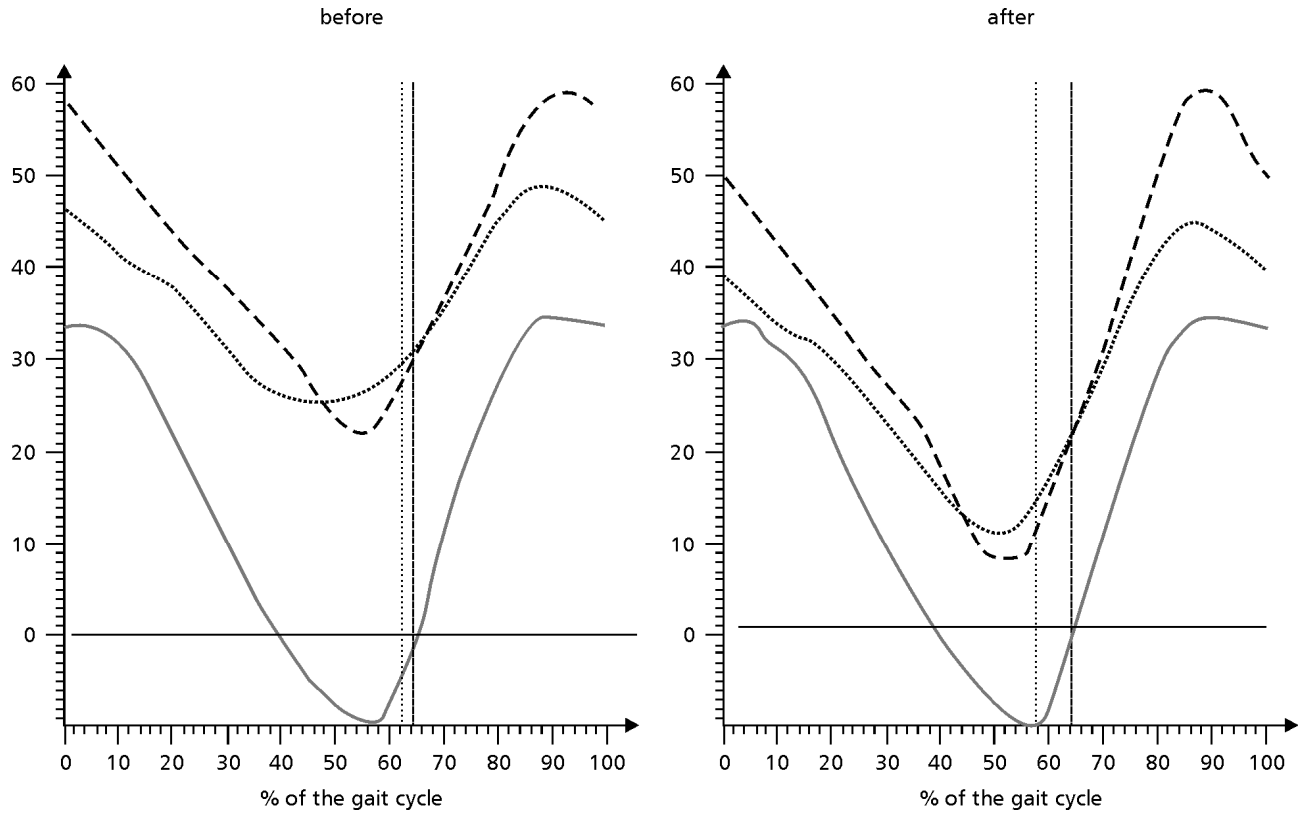

Figure 1

An example of improved range of motion in the hip joints in the saggital plane, and decreased flexion at the beginning of the stance phase following treatment with botulinum toxin. Dashed line – left lower limb, dotted line – right lower limb, grey solid line – normal reference.

gait velocity was not affected). In 2 patients, stride width decreased.

In 8 patients, percentages of particular gait phases were improved. In most cases, percentage of the double-support phase decreased, while percentage of the single-support phase increased; in some patients, also percentage of the support phase of gait cycle was reduced.

In 11 patients, position of the pelvis was improved. In the majority of cases, the improvement involved a reduction in the excessive anteversion of the pelvis and a reduction in pelvic torsion at the transverse plane with regard to gait direction line. Range of movements of the pelvis (excessive prior to botulinum administration) also decreased in both planes.

In 6 patients, range of motion in the hip joints increased; in some of them, the excessive flexion in these joints occurring at the beginning of the support phase and at the end of the swing phase was also improved (decreased) (Figure 1 – an example illustrated in the patient WR).

In 5 patients, external rotation of the hip joints decreased (Figure 2 – an example illustrated in the patient KP).

In 5 patients, an improvement in the form of movements in the knee joints was found. It involved a reduction of flexion in these articulations at the moment of ground contact, as well as an increase in the maximum flexion during the swing phase (Figure 3 – an example illustrated in the patient MW).

In 4 patients, position of the feet during the swing phase was improved, in 2 of them, the premature lifting of the heel during the support phase occurs later and has a smaller range (Figure 4 – an example illustrated in the patient ST).

In 10 patients, internal rotation of the feet with regard to the shin in the transverse plane was decreased (Figure 5 – an example illustrated in the patient MA).

DISCUSSION

Duration of botulinum toxin effects ranges from 3 to 6 months[1,3]. The third evaluation of gait was conducted at the time, when direct action of botulinum toxin was terminated (dependently on the results of clinical examination – this occurred 6 or 9 months following botulinum toxin administration). Its correct application, thanks to use of gait analysis results, in combination with an intensive rehabilitation program conducted early after botulinum administration, results in a permanent improvement of gait pattern in patients with CP. However, the range of those changes is very variable.

The improvement in feet position with regard to the shins in the transverse plane is associated with administration of the botulinum toxin into the ischio-crural muscles. However, such a simple association of the site of injection and the character of improvement is not always true: in 15 patients, the toxin was also administered into the triceps muscles of calf, while the improvement in feet position occurred only in 4 patients. Nonetheless, in those 15 patients, a reduction in knee flexion during ground contact was observed, which constitutes a significant improvement in gait pattern.

Abnormal position of the pelvis and increased range of its move-

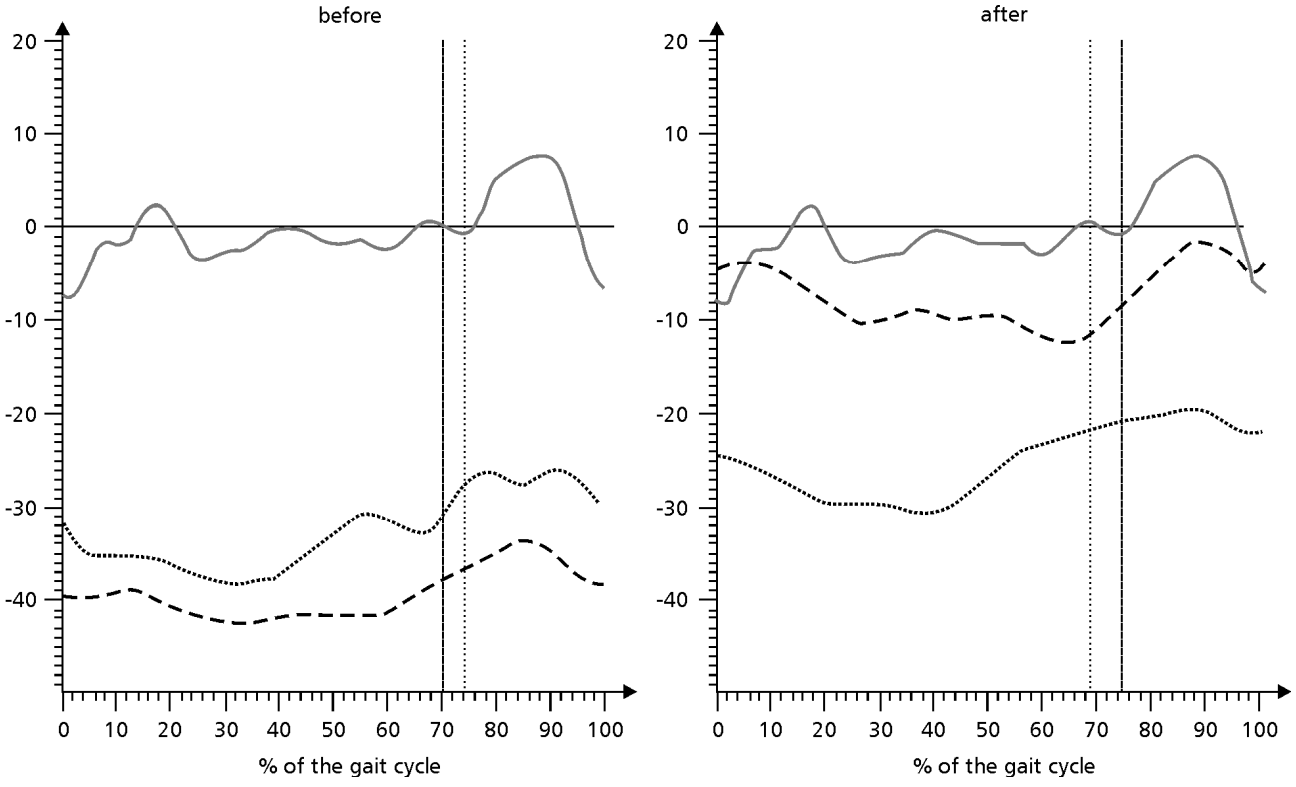

Figure 2

An example of decreased external rotation of the hip joints following treatment with botulinum toxin. Dashed line – left lower limb, dotted line – right lower limb, grey solid line – normal reference.

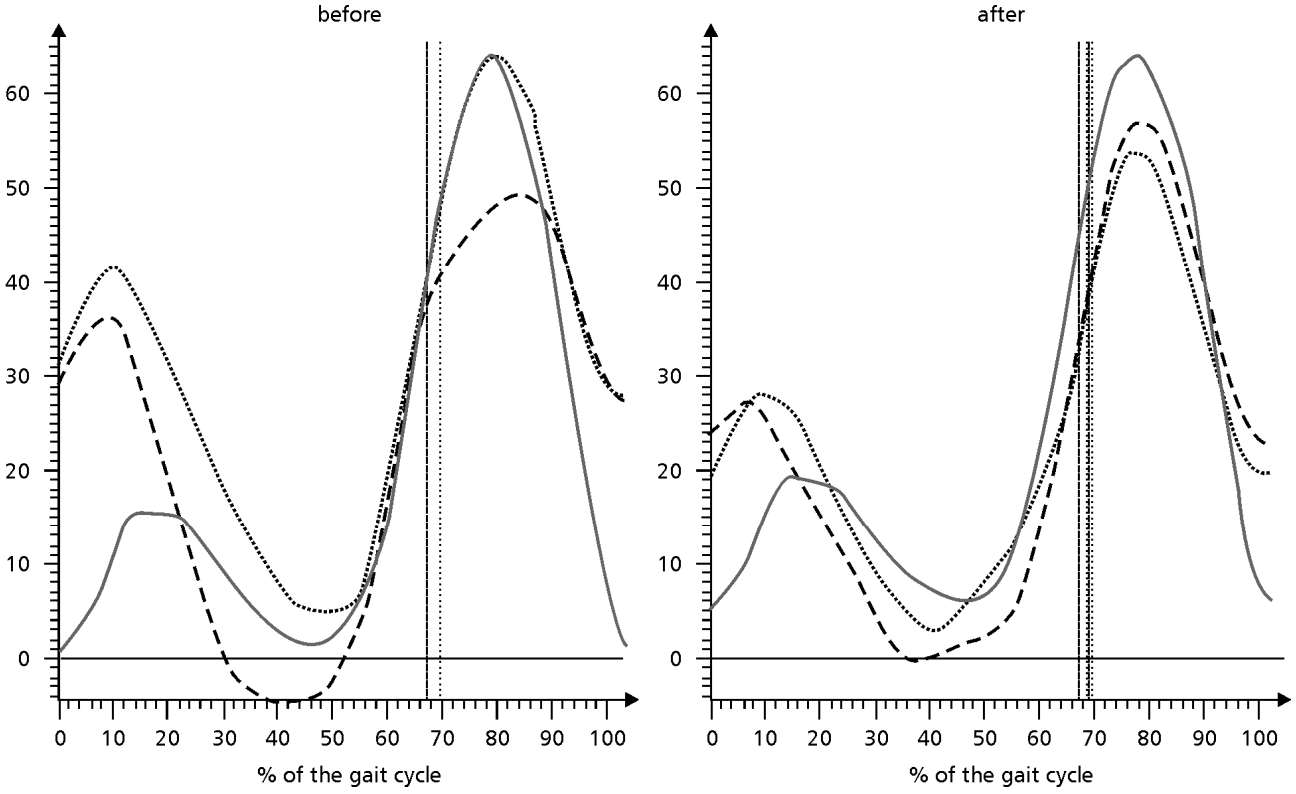

Figure 3

An example of improved movement of the knee joints in the saggital plane following treatment with botulinum toxin (decreased flexion at initial contact, increased flexion during the swing phase). Dashed line – left lower limb, dotted line – right lower limb, grey solid line – normal reference

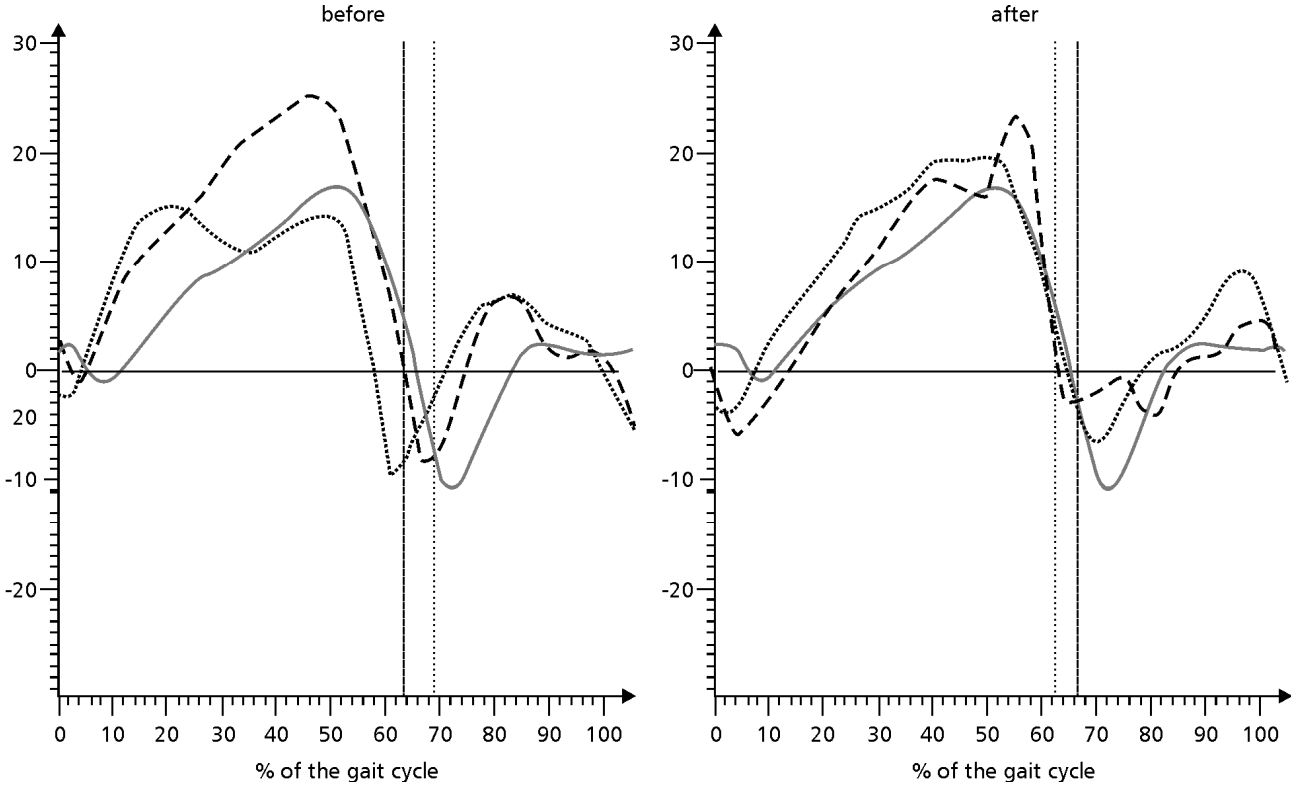

Figure 4

An example of improved position of the ankle joint during the swing phase (left limb) and much delayed premature heel rise during the stance phase (right limb). Dashed line – left lower limb, dotted line – right lower limb, grey solid line – normal reference.

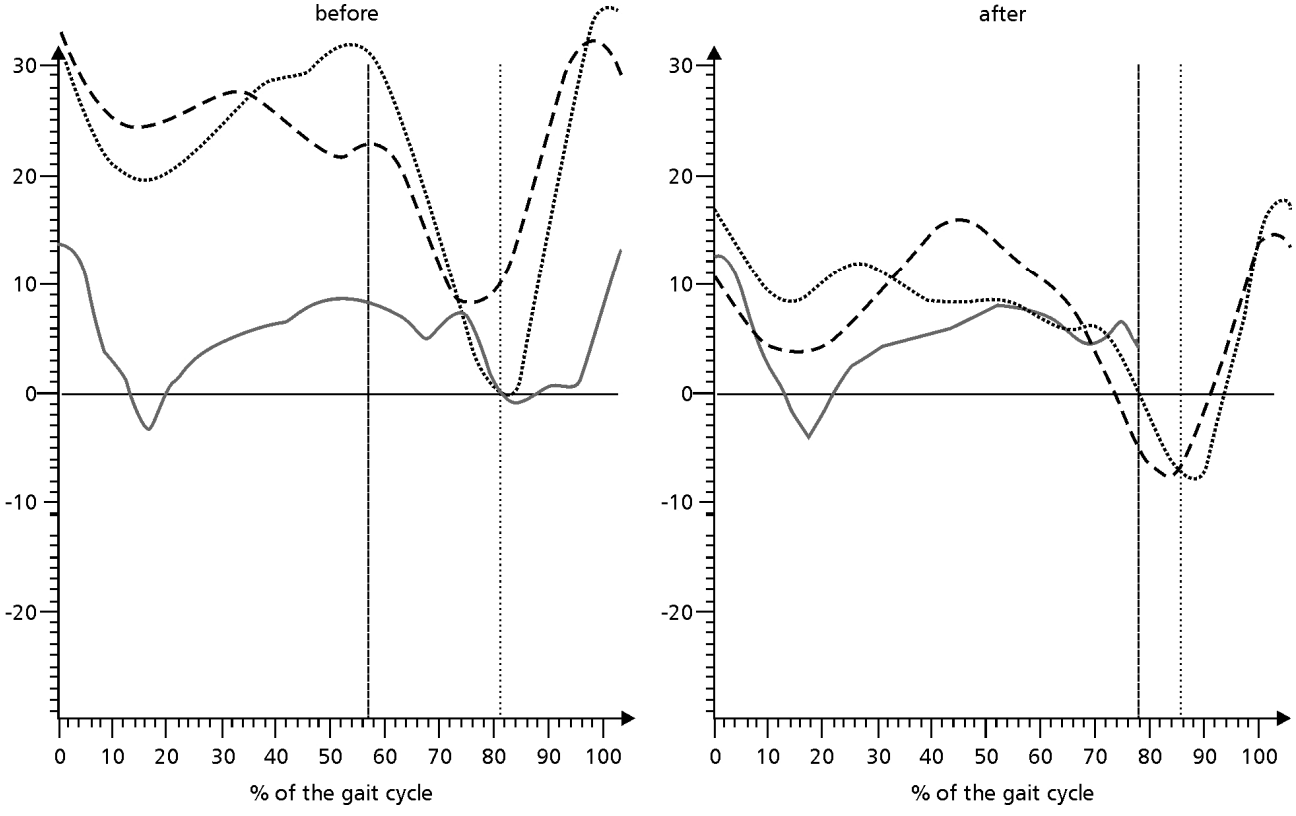

Figure 5

Decreased internal rotation of the feet with respect to the shanks in the transverse plane following treatment with botulinum. Dashed line – left lower limb, dotted line – right lower limb, grey solid line – normal reference.

ments in the saggital and transverse planes frequently constitute compensatory mechanisms (in children with CP, compensation of dysfunctional distal segments occurs in the proximal segments[6]). Improvement in position and range of movements of the pelvis observed in 10 patients is a result of improved kinematics of the lower extremity joints and patient's resignation on some compensatory mechanisms.

External rotation in the hip joints is also a compensatory mechanism improving position of the feet with regard to the gait line, which is used by patients demonstrating large internal rotation of the feet with respect to the shins (provided patients demonstrate good control over and strength of the muscles causing external rotation in the hip articulation). In all 5 patients, in whom this rotation was reduced, position of the feet with respect to the shins was improved.

Based on the results of this study, it can be concluded that the obtained degree of improvement depended on factors including the severity of spasticity and the amount of botulinum toxin administered into the particular muscle. At multi-level application of the toxin, the number of muscles involved in the therapy ranged from 4 to 12, and was 6 to 8 in the majority of cases, with 2 injections in each muscle. Better effects were achieved in patients, where doses of 40-50 units/kg body weight as calculated for Dysport (8-10 units/kg body weight for Botox) per one session were used.

There were two cases, where an improvement in gait pattern was observed only with regard to one parameter, who had the most severe form of CP: tetraplegia.

Patients assessment following use of botulinum toxin was based not only on the clinical examination but also on the quantitative, objectiv assessment of gait. Improvement in CP patients' status after botulinum toxin treatment is most frequently assessed by means of clinical evaluation, such as range of motion in particular joints[13], using the Gross Motor Function Measure[13,14], or by means of an observational gait analysis based on observation of walking on video recordings[13,15]. Despite recommendations to use a quantitative, objective gait analysis as an objective tool enabling objective assessment of changes in functional status of a patient with CP[16,17,18], it is rarely used, because many centres do not have access to this type of studies; moreover, these studies require patient's cooperation, which – especially in small children – is not always easy to obtain. In this study, all patients underwent quantitative gait analysis that was performed three times. Testing performed prior to botulinum toxin use, apart from the clinical examination, constituted the basis for decision making as to the muscles, where botulinum toxin should be administered to, and the comparison of results of this testing to those obtained after 6 or 9 months allowed objective evaluation of changes in gait pattern.

Duration of botulinum toxin effects is limited: in the scholarly literature, it is most often considered that its effects are terminated after 3-4 months[19], yet, in some patients, they can persist for up to 6 months[20]. In the majority of studies, evaluation of botulinum toxin-induced changes in CP patients' functional status is performed within a period of time shorter than 4 months: in a review by Crouchman, the majority of testing discussed by this author was conducted between the 2nd and the 8th week following administration of botulinum toxin[14]. In a study by the group led by Sarioglu[15], the changes were evaluated after 8 weeks, while Sutherland's group assessed changes in gait pattern after 4 weeks[18]. All the observed changes could, therefore, have been attributed to the direct effects of botulinum toxin.

In this study, patients were evaluated during the period of time, when direct botulinum toxin activity already stopped (i.e. after more than 3 months following its administration, and cessation of this activity was confirmed during clinical examination); therefore, the observed changes in muscle length or gait pattern were not due to direct botulinum toxin effects but seem to have resulted from a stable improvement associated with concomitant activity of botulinum toxin and the intensive rehabilitation treatment conducted during the period, when botulinum toxin was exerting its direct effects.

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