

Evaluation of selective dorsal rhizotomy for the reduction of spasticity in cerebral palsy: a randomized controlled trial

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Selective dorsal rhizotomy (SDR) is widely used to treat spasticity in children with diplegic cerebral palsy (CP) but has never been shown conclusively to improve functional outcome. The study was designed to measure changes in gross motor function in children 1 year following rhizotomy compared with a control group receiving equivalent physiotherapy (PT) and occupational therapy (OT) with the exception that the rhizotomy group initially underwent a 6-week postoperative in-patient therapy program. Twenty-four children (mean age 58 months) with mild to moderate CP with spastic diplegia were randomly assigned to a therapy-only control group (CG) ($N=12$) or rhizotomy and therapy group (RG) ($N=12$). The Gross Motor Function Measure (GMFM) was administered at the baseline, 6-, and 12-month assessments. Extremity tone, range of motion (ROM), biomechanics of the ankle-stretch reflex, isometric contraction, and temporal gait components were also evaluated. GMFM scores in the RG improved by 12.1 percentage points versus 4.4 percentage points in the CG ($P<0.02$). RG knee and ankle tone was significantly reduced ($P<0.005$), associated with increased passive ankle ROM ($P<0.001$), and decreased soleus EMG reflex activity on forced dorsiflexion ($P<0.008$). Foot-floor contact pattern improved in the RG compared with the CG ($P<0.05$). In conclusion, SDR combined with PT and OT leads to significantly greater functional motor improvement at 1 year following surgery compared with PT and OT alone. This was achieved in part through reduced knee and ankle tone, increased ankle dorsiflexion ROM, and more normal foot-floor contact during walking.

The optimal management of functionally significant lower-limb spasticity remains controversial (McLaughlin et al. 1994). Non-surgical means of reducing spasticity have met with limited long-term success (Peacock et al. 1987). Orthopaedic surgery, such as muscle-lengthening procedures, is often effective in alleviating the effects of spasticity, but not the cause (Peacock and Arens 1982). Over the past two decades, partial division of the posterior lumbar roots (selective dorsal rhizotomy [SDR]) has become a common surgical treatment (Fasano et al. 1978, Peacock and Arens 1982, Abbott et al. 1993). Reduction in lower-extremity tone (Peacock and Arens 1982, Berman et al. 1990, McLaughlin et al. 1994, Steinbok et al. 1997, Sienko Thomas et al. 1997), increase in joint range of motion (ROM) (Cahan et al. 1987, 1990; Walker 1991; Marty et al. 1995; Steinbok et al. 1997), improved gait (Vaughan et al. 1988, 1991; Berman et al. 1990; Sienko Thomas et al. 1997), reduction in the incidence of progressive hip dislocation (Heim et al. 1995), and improved gross motor (Steinbok et al. 1997) and functional abilities (Bloom et al. 1994, Dudgeon et al. 1994, McLaughlin et al. 1994, Buckon et al. 1996) have all been reported.

Before the 1997 study by Steinbok et al. none of the published rhizotomy studies had used control subjects to account for the effects of growth, motor development, physiotherapy (PT), or occupational therapy (OT). Their conclusions can only suggest the effectiveness of rhizotomy. Critics have also argued that reduction in tone will not influence motor control, and hence not lead to any improvement in functional outcome (Landau and Hunt 1990, Gaskill et al. 1992). Controversy has also surrounded the electrophysiological criteria used to identify 'abnormal' posterior rootlets for division (hence the term 'selective') (Peacock and Arens 1982, Fasano et al. 1988, Cohen and Webster 1991, Weiss and Schiff 1993, Logigian et al. 1994, Steinbok et al. 1994). Immediate or delayed side effects of SDR that have been reported in various studies have included hypotonia, underlying muscle weakness, sensory changes, bladder dysfunction, and spinal deformity (McDonald 1991).

This study was designed to determine whether SDR leads to improved functional outcome after 1 year in children with spastic diplegia compared with a control group receiving the equivalent amount of PT and OT. Functional abilities were evaluated by the Gross Motor Function Measure (GMFM) (Russell et al. 1989), a widely used assessment that has demonstrated strong reliability, validity, and responsiveness to clinically important change in motor function (McLaughlin et al. 1994, Bower et al. 1996).

Method

SUBJECTS

Thirty-one children out of a possible 100 seen in the rhizotomy clinic met the study's main eligibility criteria (Table I). Of these, 24 (10 female and 14 male) with CP were enrolled over a 24-month period. The other seven declined to participate in the trial as their families wanted the rhizotomy procedure to occur at the earliest possible date. All participants had spastic diplegia that interfered with functional tasks such as sitting, standing, or walking, and this spasticity was considered to be a major limiting factor to gross motor progress. Four children also had spasticity of the upper extremities that was strongly evident during functional activities. The mean age at enrolment was 58.0 months \pm 12.7 months (SD).

The minimum age was 41 months and the maximum age 91 months.

The children were initially reviewed by the rhizotomy team's neurosurgeon (JMD), orthopaedic surgeon (JHW), a physiotherapist, and an occupational therapist in the rhizotomy clinic at Bloorview MacMillan Centre, and suitability with reference to the rhizotomy study's eligibility criteria was determined.

EXPERIMENTAL DESIGN

Children were randomly assigned to either the therapy-only control group (CG) or to the rhizotomy plus therapy group (RG). When a child met the study criteria, an information sheet was provided to parents that included mention of the use of random assignment to group. Informed consent was obtained from parents. The order in which a child's name was entered into the randomization process was based on the post-marked date of the signed consent form when it was returned through the mail by parents. Before randomization, blocking was performed on the basis of age, i.e. less than 6 years of age, and age 6 years and over, to ensure an even distribution of ages between the two groups. A simple randomization scheme based on the assignment of values from a uniform distribution on the interval (0,1) was used to generate two groups of 12 children.

Following randomization, the baseline PT and biomechanical assessments were conducted. In the RG, the assessments occurred no more than 3 weeks before the child's rhizotomy surgery date. The date of surgery indicated the start of the study's 1 year of follow-up. In the CG, completion of the child's baseline assessment signalled the beginning of the child's 1-year study period of outpatient therapy.

SURGICAL PROCEDURE

SDR was performed under general anaesthesia. No neuromuscular-blocking agents were used. A urinary catheter was inserted following induction of anaesthesia. Surface electrodes were placed over the quadriceps, hamstrings, anterior tibial, and gastrocnemius muscles and EMG activity was recorded. Following a L2 to L5 partial laminectomy, the posterior roots of L2 to S2 were gently isolated. After confirmation that the roots were indeed sensory (by increased threshold to stimulation as compared with the motor roots), they were subdivided along natural planes into between 2 and 6 rootlets, according to the size of the root. The rootlets were tested in sequence for their threshold to constant current stimulation at 50 Hz (pulse duration 100 μ s). Those rootlets with the lowest threshold were divided. On average, approximately 50% of each dorsal root was divided. All procedures were performed by the same neurosurgeon (JMD).

The stimulation protocol of Peacock and Arens 1982 and Fasano et al. 1988 was modified as described above, as their published criteria were unproven. We suspected that the roots with the lowest threshold might carry a higher proportion of Ia afferents, and thus lead to a greater reduction in spasticity. A number of publications (Cohen and Webster 1991, Steinbok et al. 1992, Rivera et al. 1995) have shed doubt on the validity of the stimulation criteria reported by Fasano and Peacock, and the whole notion of whether or not a 'selective' rhizotomy is possible is still unresolved.

Postoperative analgesia was managed initially with intravenous morphine by constant infusion (typically 30 μ g/kg/hr)

usually for 3 or 4 days. Patients were nursed in bed during this time and were turned from side to side every 4 hours. The urinary catheter was left in place during this time. Physiotherapy to maintain ROM was commenced on the second or third postoperative day.

PHYSIOTHERAPY AND OCCUPATIONAL THERAPY PROGRAMS

The child's local physiotherapist and occupational therapist developed a list of prerandomization therapy goals and the behaviours that would indicate goal accomplishment (Palisano et al. 1992) for the next 3 to 6 months. This ensured that the children who were ultimately assigned to the CG had an unbiased set of treatment goals that would be used at the start of their participation in the study. The children who were assigned to the RG had a new set of short-term goals determined postoperatively by the in-patient physiotherapist/occupational therapist team at Bloorview MacMillan Centre.

Children in the CG followed the treatment goals set by their local physiotherapist and occupational therapist before randomization. These children received two therapy sessions per week (approximately 120 minutes in total), and the balance of PT and OT treatment within this time was determined based on the treatment goals set for the child. The PT/OT therapy program components concentrated on ROM, strengthening through functional activities, facilitation of normal movement patterns and postural control, standing and gait-related activities, and work on fine motor skills and functional abilities. The physiotherapists' focus was generally on these treatments as they related to the lower extremity, while the occupational therapists concentrated on therapy directed towards the upper extremity and functional skills.

For the RG, the initial postoperative program was structured and consistent for all children, and followed the clinical guidelines that have been established at our facility for initial post-SDR rehabilitation. The same physiotherapist and occupational therapist treated each of the 12 RG children during their 6-week postoperative in-patient stay at the Bloorview MacMillan Centre. Each child received a 45-minute PT session daily and a 45-minute OT session twice weekly. The focus of the postrhizotomy program was initially on ROM and positioning, upper- and lower-extremity strengthening, particularly of the trunk musculature, hip extensors and abductors, and knee extensors via work on isolated movements, and facilitation of more normal movement patterns and postural control (Elk 1984, Irwin-Carruthers et al. 1985, Sled 1991). This strong emphasis on strengthening and postural control is critical as muscle weakness is very apparent and physically limiting in conjunction with reduction of spasticity in the early recovery weeks post-SDR (McDonald 1991, Sled 1991, McLaughlin et al. 1994, Damiano et al. 1995). Standing- and gait-related activities, and work on fine motor skills and functional activities were gradually introduced as the child's strength and control improved. Other services such as speech therapy and psychology were continued with the child only if they had been provided preoperatively.

It should be noted that the PT regimen in the RG initially emphasized strengthening because of the postoperative weakness in the trunk and lower extremities. These children would otherwise have been compromised with regard to strength in comparison with the CG.

At the time of transfer to outpatient care with the child's

regular community therapists, therapy frequency was reduced to two sessions per week (approximately 120 minutes in total) for the remainder of the child's study year. Specific treatment guidelines were sent to the child's local therapist(s) who then set individual treatment goals for the child based on this information.

ASSESSMENT PROCEDURES

Assessments were conducted at baseline, 6, and 12 months for all children. Assessments were divided into clinical (PT) and biomechanical assessments. While the 12-month assessment was intended as the primary outcome period, the 6-month assessment was conducted primarily to see if there were adverse effects, and to document the rate of any measurable change over time. A 2- to 3-day assessment period was required to complete the assessment protocol.

PRIMARY OUTCOME MEASURE

The primary functional outcome measure was the GMFM (Russell et al. 1989). This 88-item observational assessment has been successfully validated with children with CP, and has also demonstrated convincing responsiveness to small increments of change (Russell et al. 1989, Bower et al. 1996). Reasonably strong correlation has also been established between abilities on the GMFM and muscle performance (Parker et al. 1993), and between GMFM and time-distance components of gait (Damiano and Abel 1996, Drouin et al. 1996), although this does not mean that they measure the same thing (Damiano and Abel 1996). The GMFM's five gross motor dimensions (lie/roll, sit, crawl/kneel, stand, and walk/run/jump) are suitable areas for assessment post-rhizotomy. Scores are expressed as a percentage and are computed for each of the five dimensions as well as for the total scale. A change of 6 percentage points in the total score or within a dimension is considered to be clinically important (Russell et al. 1989). In ambulatory children with spastic diplegia, the stand and walk/run/jump dimensions may be the most indicative of comparative abilities and change (Damiano and Abel 1996). Eighteen of the 24 items in the walk/run/jump dimension pertain to dynamic standing- or walking-based activities, i.e. walking forwards on a straight line, stepping over a stick, kicking a ball, climbing stairs. The remaining six items are jumping- or running-based.

SECONDARY OUTCOME MEASURES

Physiotherapy assessments

The PT outcomes included assessment of tone (elbow flexion-extension, hip/knee flexion-extension, and ankle dorsiflexion-plantar flexion) using the modified Ashworth Scale (Bohannon and Smith 1987), active and passive lower-extremity ROM (Hoppenfeld 1976), and distance walked in 60 seconds with the child's usual gait device. These outcomes were selected to permit evaluation of physical changes that might underlie functional gains, and to monitor for any adverse effects.

Biomechanical assessments

Assessments were performed at baseline and 12 months later. The stretch-reflex test permitted quantitative evaluation of the hyperactivity of the stretch reflex in the soleus muscle, thereby providing a measure of tone. Surface electrodes were used to measure the stretch-reflex response

obtained from triceps surae while imposing a sudden dorsiflexion of the ankle at a rate of 180° per second over a 10 to 15° range by an ankle actuating device under computer control (Apkarian and Naumann 1991). The range through which the ankle moved was recorded in degrees. Joint torque was recorded in newton-meters (N·m). Surface EMG electrodes were attached to the skin over the triceps surae muscle just below the gastrocnemius belly and over the tibialis anterior muscle. The EMG signals were low-pass filtered at a cut-off frequency of 200 Hz and sampled at a rate of 400 Hz by the controlling computer.

The isometric-contraction test evaluated muscle force and the ability of the subject to perform independent contractions of antagonist muscles. The foot of the subject was strapped to the fixed platform of the ankle actuating device. EMG signals were measured and sampled from the soleus muscle and the tibialis anterior muscle at 200 Hz. The joint moment was monitored through strain gauges. The subject performed maximum contractions in both the plantar flexion and dorsiflexion directions as well as fast oscillatory movements of the foot.

Gait analysis was performed using a VICON (Oxford Metrics Ltd, Oxford, UK) system (Apkarian et al. 1989). The children were also video recorded during each session while they walked across the gait laboratory. Measurements of stride length, stride time, step length, stance/swing ratio, and foot-floor contact (FC) pattern were obtained to provide a temporal analysis of gait. FC patterns were scored according to whether contact of the foot with the floor was first with the toe, foot-flat, or heel.

EMG during gait evaluated both the timing and strength of muscle contractions. Four EMG signals (tibialis anterior, soleus, vastus lateralis, and medial hamstrings) were measured through surface electrodes along with two foot switches. The measured EMG signals were low-pass filtered at a cut-off frequency of 200 Hz, full-wave rectified, filtered at 15 Hz, and sampled at a rate of 100 Hz.

THE ASSESSORS

The individual tests within the PT and biomechanical assessment protocol were administered in the same order in both groups for each child such that the tests that required the most cooperation from the child were administered at the start of the session, i.e. GMFM and timed walk. Each child was assigned to an assessor team (PT assessor and gait laboratory assessor). The PT assessors had all successfully passed the standard criterion testing on the GMFM. They were responsible for conducting baseline and follow-up assessments. The assessors were not told to which treatment group the child had been assigned and the children wore occlusive clothing to hide the surgical incision. However, at the time of the 6-month assessment all assessors were able to identify the children who had undergone surgery because of the obvious decrease in lower-extremity tone of children in the RG. To minimize assessor bias, none of the assessors was involved in any aspect of the care of children post-rhizotomy, nor did they work directly with any of the therapists involved in the rhizotomy program. During follow-up assessments, the assessors were not given access to the child's previous assessment data.

Administration of the GMFM was video recorded. A randomly-selected set of seven GMFM tapes were viewed and

scored by an independent PT assessor to conduct a check on the interrater reliability of the GMFM scoring and thereby confirm the absence of bias in scoring.

STATISTICAL ANALYSIS

One-way analysis of variance (ANOVA) was used to test baseline equivalence of the RG and CG for age, GMFM, tone, ROM, timed walk, and biomechanical variables.

The primary analysis was conducted for the total GMFM scores at 12 months after the baseline assessment by analysis of covariance (ANCOVA) with baseline GMFM total scores as the covariate was used to determine between-group differences at the 12-month point. A P value of 0.05 was used to indicate statistical significance. Interrater reliability of the GMFM scoring was confirmed using ANOVA and an intraclass correlation coefficient (ICC) (Shrout and Fleiss 1979). The secondary analyses of PT and biomechanical outcomes consisted of descriptive and inferential statistics for the 12-month data. All data were treated as parametric with the exception of the tone scores which were measured via an ordinal scale. For parametric data, ANCOVA was used with baseline scores as the covariate. For non-parametric tone-score data, a Mann-Whitney *U* test was used. For secondary outcomes, the P value was adjusted to 0.001 to handle test-

ing of multiple outcomes and reduce the chance of type I error. The data for the 6-month PT outcomes were summarised using descriptive statistics only. Inferential analyses were not conducted given the risks of statistical error for repeated measures testing with a small sample.

The strength of the relation between GMFM change scores (12-month minus baseline scores) and baseline scores for variables such as tone, ROM, timed walk, and GMFM was evaluated using Pearson correlation coefficients. All data were analysed using the Minitab statistical software package (Minitab Inc, Pennsylvania, USA, 1994).

Results

SUBJECTS

All parents accepted the randomization assignment for their children. Parents whose children were assigned to the CG indicated that they were satisfied to have another year for their child to make functional gains. There were no drop-outs from the study in either group during the 1 year of follow-up. There was no significant difference between groups in terms of mean age (RG=57.8 months and CG=58.3 months) or in the balance of males and females (five females and seven males in each group). With the age group blocking before randomization, there were six children in the younger age stratum (less than 6 years of age) in each group, and six children in the older age stratum (age 6 years and over) in each group. Baseline scores for GMFM, tone, ROM, and walk velocity are provided in Tables II, III, and IV.

THERAPY FOLLOW-UP DURING THE STUDY

Therapy services, aside from the 6-week in-patient stay in the RG, were received in an outpatient treatment facility by six children in the RG and five children in the CG. Three children in the RG and four in the CG received therapy in a specialized class at school. Three children in each group received therapy by home care in their local school.

There was no difference in the combined PT/OT treatment weekly time received in the two groups ($P=0.22$). The RG received a mean of 126.8 ± 20.5 (SD) minutes per week and the CG a mean of 116.4 ± 17.6 (SD) minutes weekly. Of a maximum 104 treatment sessions expected during the course of the year, there was a mean of 88.1 ± 21.9 (SD) in the RG versus a mean of 87.4 ± 22.2 (SD) in the CG ($P=0.94$).

Table I: Eligibility criteria for inclusion in or exclusion from the study

Inclusion criteria	Exclusion criteria
1 Diagnosis of cerebral palsy	1 Major fixed contractures of lower extremity i.e. $>30^\circ$ at hips and knees
2 Predominant spastic diplegia that interferes with functional tasks such as sitting, standing, and walking	2 Major previous orthopaedic surgery e.g. rectus femoris transfers
3 Ability to walk at least 3 m with an assistive device or underarm support	
4 Adequate trunk control to allow at least 60 s of independent sitting	
5 Reasonable underlying lower-extremity strength (minimum grade 3 at hip and knees)	

Table II: GMFM scores (percentage points) by category for the control and rhizotomy groups at the baseline, 6-month, and 12-month assessments

GMFM dimensions	Control group (N=12)			Rhizotomy group (N=12)		
	Baseline Mean (SD)	6 mo Mean (SD)	12 mo Mean (SD)	Baseline Mean (SD)	6 mo Mean (SD)	12 mo Mean (SD)
Lie/roll	91.2 (8.3)	95.9 (2.8)	96.2 (3.1)	92.8 (9.4)	94.4 (6.7)	98.7 (1.9)
Sit	83.7 (16.1)	85.6 (17.9)	87.9 (15.8)	74.3 (22.2)	87.9 (15.1)	87.7 (15.2)
Crawl/kneel	71.1 (19.4)	76.3 (15.8)	76.9 (10.4)	62.9 (26.9)	68.4 (24.0)	77.3 (19.2)
Stand	19.6 (17.2)	23.7 (12.1) ^a	27.1 (19.6)	21.8 (15.9)	30.1 (23.4) ^a	33.1 (23.5)
Walk/run/jump	13.2 (14.2)	14.5 (15.4)	15.7 (17.1) ^a	10.6 (8.2)	14.8 (7.8)	23.4 (19.5) ^a
Total	56.5 (12.2)	58.5 (10.7)	60.9 (12.5) ^a	51.9 (13.4)	58.7 (13.5)	64.0 (13.2) ^a

^a $P < 0.05$ between groups.

PRIMARY GMFM ANALYSES

There was no significant difference between groups for the GMFM dimension or total scores at baseline (minimum $P=0.07$). Since the CG's mean total GMFM score was 5 percentage points higher than the RG, ANCOVA was used to adjust for this baseline difference.

GMFM dimension and total scores are shown in Table II, and the children's individual total scores are listed in Table III. The increase in GMFM total scores was 12.1 percentage points in the RG and 4.4 percentage points in the CG ($P=0.02$). When the five individual dimensions of the

GMFM were compared, only gains in the walk/run/jump dimension were greater in the RG at the 12-month assessment ($P=0.03$) (see Table II). From baseline to 12 months, five children in the RG and two in the CG showed mean score improvements of at least 10 percentage points (Table III). Children in the RG demonstrated gains of between 1 and 31.0 percentage points at the 12-month point. In contrast, in the CG, three children demonstrated mean score decreases by 1 to 2 percentage points, and the highest gain in this group was greater than 10 percentage points. The ICC for interrater reliability of the GMFM assessment was

Table III: Subjects' individual GMFM total scores at the baseline, 6-month, and 12-month assessments

Subject ^a	Control group			Subject ^a	Rhizotomy group		
	Baseline	6 mo	12 mo		Baseline	6 mo	12 mo
1	29.7	33.3	31.3	13	30.3	32.6	45.5
2	47.4	62.6	62.1	14	38.6	54.3	69.9
3	50.8	45.4	55.0	15	41.0	47.0	56.2
4	53.0	54.0	56.0	16	43.2	49.6	53.5
5	54.7	61.7	66.0	17	43.2	53.0	50.6
6	56.0	58.0	56.0	18	46.1	52.5	53.6
7	56.3	60.5	63.6	19	55.2	56.9	56.4
8	57.1	61.4	63.9	20	55.6	61.9	64.7
9	60.0	59.4	59.9	21	62.3	78.2	87.0
10	63.0	66.0	66.0	22	66.9	71.6	75.0
11	66.1	62.0	64.0	23	70.8	72.4	77.4
12	81.8	76.5	86.8	24	70.0	74.7	78.3

^aSubject numbers do not refer to the children's actual assigned study number.

Table IV: Physical therapy outcomes of tone, active ROM, and passive ROM at the baseline, 6-month, and 12-month assessments for the control and rhizotomy groups

Outcome	Control group (N=12)			Rhizotomy group (N=12)		
	Baseline Mean (SD)	6 mo Mean (SD)	12 mo Mean (SD)	Baseline Mean (SD)	6 mo Mean (SD)	12 mo Mean (SD)
Tone (7)						
Elbow	5.0 (0.5)	4.0 (0.6)	4.0 (0.6)	4.0 (1.3)	4.0 (0.7)	4.0 (1.2)
Knee	5.0 (0.7)	5.0 (0.6)	5.0 (0.7) ^a	5.0 (1.2)	4.0 (0.9)	4.0 (0.7) ^a
Ankle	6.0 (0.4)	6.0 (0.4)	6.0 (0.4) ^a	5.0 (0.7)	4.0 (0.7)	4.5 (0.7) ^a
Active ROM						
Hip extension	-44.2 (31.3)	-28.6 (15.3)	-38.3 (27.9)	-22.5 (25.3)	-26.5 (20.0)	-20.3 (18.7)
Knee extension	-32.5 (17.4)	-28.6 (15.3)	-24.3 (14.9)	-26.7 (18.7)	-10.2 (10.9)	-11.3 (15.4)
Ankle dorsiflexion	-27.9 (21.4)	-32.7 (20.1)	-35.4 (19.9) ^a	-25.8 (18.1)	-13.0 (19.9)	-6.3 (10.3) ^a
Passive ROM						
Hip extension	-20.4 (12.7)	-18.6 (7.7)	-12.9 (12.7)	-15.0 (10.2)	-7.7 (9.1)	-7.5 (9.9)
Knee extension	-12.1 (12.7)	-11.1 (11.3)	-8.7 (11.1)	-12.9 (18.3)	-8.4 (15.9)	-6.5 (12.5)
Popliteal angle	46.7 (14.4)	50.5 (14.7)	46.8 (9.8)	37.1 (17.5)	32.5 (16.6)	32.5 (19.3)
Ankle dorsiflexion (knee extended)	-9.6 (17.9)	-11.8 (17.6) ^a	-12.0 (16.4) ^a	-5.0 (20.2)	6.9 (13.7) ^a	3.8 (11.5) ^a
Timed walk (m/60 s)	30.1 (25.1)	38.1 (25.9)	26.6 (18.6)	23.9 (25.9)	28.9 (27.7)	39.8 (32.2)

^aIndicates a significant difference between control and rhizotomy groups ($P<0.001$)
ROM; range of motion.

0.97 showing evidence of excellent interassessor agreement, and absence of PT assessor bias.

SECONDARY PT OUTCOMES

Descriptive statistics for these outcomes for baseline, 6 and 12 months are provided in Table IV.

Tone

Median scores in the RG for tone at the knee decreased by one entire grade unit at 12 months ($P=0.002$) and ankle tone by 0.5 grade units ($P=0.001$). The CG was unchanged. No differences were noted between groups for tone at the elbow ($P=0.39$).

Passive ROM

Passive ankle dorsiflexion (knee extended) had increased by 8.8° in the RG as compared with a mean decrease of 2.4° in the CG ($P=0.001$). In both groups, the mean hip flexion contracture had decreased by approximately 8° at the 12-month assessment. Passive knee extension had increased by 6° in the RG and 3.4° in the CG ($P=0.44$). The mean popliteal angle had decreased by 4.6° in the RG. There was no change in the CG ($P=0.09$).

Active ROM

Active ROM for ankle dorsiflexion was greater for the RG at 12 months ($P=0.0001$). No difference was detected between groups for hip extension, knee flexion, or extension active ROM (minimum $P=0.07$). However, generally the RG's mean 12-month scores were 10 to 30° better than the CG scores.

Timed walk

Timed walk scores (meters covered in 60 seconds) improved by 16.0 m (or 0.26 m/s) in the RG from baseline to 12 months while there was a decrease of 3.5 m (or 0.08 m/s) in the CG. This difference was not significant ($P=0.16$). The SDs on the mean scores were large, reflecting marked differences between children.

CORRELATIONAL ANALYSES:

The strength of correlations between GMFM total 12-month change scores and baseline data for age, tone, ROM, and timed walk were weak ($r<0.4$), as was the correlation between GMFM total baseline scores and GMFM total 12-month change scores ($r=-0.32$).

ASSISTIVE DEVICE USE

Four RG children changed to a less supportive device during the 12 months of follow-up (Table V): two children who used walkers at baseline used two canes at the 12-month point; one child who was unable to walk at baseline used a walker at 12 months; and one child who required a walker at baseline walked independently at 12 months. None of the children in the CG changed assistive device.

BIOMECHANICAL OUTCOMES

The results from the video analysis (see Table V) revealed that, while statistically significant within-group differences between baseline and 12-month assessments occurred in the RG for stride length ($P=0.04$), velocity ($P=0.01$), and FC pattern ($P=0.001$) (Table VI), differences were not observed between groups except for FC patterns ($P=0.004$). The FC pattern mean score of 3.1 in the RG indicated toe-first contact with foot flat, and was in contrast to the mean score of 1.14 in the CG indicating persistent toe-walking at 12 months.

The stretch-reflex test results (Table VII) showed statistically significant differences between the RG and CG in the number of bursts of soleus muscle and of tibialis anterior activity (maximum $P<0.05$). The isometric-contraction test results (Table VII) showed a statistically significant difference between groups for the amount of cocontraction of soleus with respect to tibialis anterior ($P=0.02$). The magnitude of these changes were minimal and likely not of clinical importance.

ADVERSE EFFECTS

No major negative effects were detected following the SDR procedure. There were no complaints of sensory changes, or bladder dysfunction. One child experienced a urinary-tract infection postoperatively associated with the indwelling Foley catheter.

During the trial, laminectomies were performed. Over the last several years since the trial we have been performing laminotomies and replacing the bone. There have been no spinal deformities as a result of these procedures.

SURGICAL INTERVENTIONS AFTER THE 12-MONTH ASSESSMENT

The 24 children were reviewed again in the rhizotomy clinic after completion of their 12 months in the study. All children in the CG received a surgical procedure. Seven of these children (four females and three males) underwent a dorsal rhizotomy within 3 months of completion of the trial. The

Table V: Video analysis of gait

Outcome	Control group (N=12)		Rhizotomy group (N=12)	
	Baseline Mean (SD)	12 mo Mean (SD)	Baseline Mean (SD)	12 mo Mean (SD)
Stride length (m)	0.41 (0.08)	0.48 (0.12)	0.46 (0.08)	0.52 (0.18)
Velocity (m/s)	0.38 (0.25)	0.58 (0.33)	0.38 (0.27)	0.54 (0.33)
Assistive device	1.17 (0.94)	1.17 (0.94)	1.17 (0.72)	1.42 (0.99)
Foot-floor contact pattern	1.00 (0.0)	1.14 (0.38)	1.40 (0.70)	3.10 (1.16) ^a

^aIndicates a significant difference between control and rhizotomy groups ($P<0.005$).

other five children in the CG underwent orthopaedic surgery (soft tissue releases at hips, knees, or ankles).

None of the children in the RG had undergone orthopaedic surgery at the last follow-up (2 years after the last child completed the study). One child did however receive serial casting for tightened ankle plantar flexors 3 years post-rhizotomy, and may ultimately be a candidate for tendon releases.

Discussion

The results of this trial indicate that SDR, combined with PT and OT, leads to significant improvement in gross motor function beyond the developmental and therapy-based gains made by those in the CG. The increase in GMFM score (12.08 percentage points) in the RG exceeds what is regarded as large change (Russell et al. 1989) and is similar to the 9.8 percentage points increase measured in a similar group of rhizotomy subjects (McLaughlin et al. 1994). The 4.44 percentage points mean increase in the CG represents what might be expected on the basis of maturation and regular therapy over a 1-year period in young children with diplegic CP (Russell et al. 1989, Bower et al. 1996). In both groups, there was a steady increase in abilities from baseline to 12 months. Steinbok et al. (1997) found a similar comparative change in their rhizotomy plus therapy group (11.3 percentage points total GMFM score change) versus a therapy-only group (5.2 percentage points change) at the 9-month follow-up.

In the RG, there were also significant reductions of spasticity at ankle and knee, increased passive and active ROM at the ankle, less cocontraction of soleus in relation to tibialis anterior, and a decrease in toe-walking gait. There was a reduction in the amount of support required for walking from assistive devices in four of the 12 children in the RG. Significant reductions in lower-extremity spasticity were also observed by Steinbok et al. (1997) in their rhizotomy study, and they also identified a reduction in the support required for three of 15 children in the rhizotomy group only. ROM differences between rhizotomy and control groups in Steinbok et al.'s study were significant at both the knee and ankle and were larger than in our study.

There was a pattern of increased gait velocity and stride length in the RG similar in magnitude to those reported in other studies (Cahan et al. 1990, Vaughan et al. 1991). While the mean gain of 0.26 m/s in walking velocity (based on the timed walk over a 60-second distance) in the RG was not statistically significant, this magnitude of change may be clinically important from a functional viewpoint. Steinbok et al. (1997) did not find a significant difference between rhizotomy and control groups in the physiological cost of walking (a measure that combines walking speed and heart rate)

($P=0.89$) although, as the authors indicate, there were technical difficulties with this test and only 10 of the 30 children were evaluated with it.

The improvements in underlying physical attributes such as tone and reduced joint stiffness (increased ROM) are similar to those that have been observed in previous single-group studies. For example, McLaughlin et al. (1994) also noted mean improvements post-SDR of at least one grade in muscle tone on the modified Ashworth Scale in the lower extremities of children with spastic diplegia, but minimal change in upper-extremity spasticity. Walker (1991) and Marty et al. (1995) described improvements in range of hip abduction, knee extension, and ankle dorsiflexion.

The stretch-reflex measurements impartially confirm the clinical findings of decreased tone about the ankle joint in the RG. None of the biomechanical results suggested that the rhizotomy procedure affected the profile of muscle activation during gait or muscle contraction, but rather a change in the strength of muscle contraction appears to underlie the functional gains that were attained. A decrease in clonus as a result of SDR, indicating a decrease in spasticity about the ankle joint, was demonstrated by the stretch-reflex test. Here the number and magnitude of oscillations in response to the rapidly imposed stretch on the triceps surae decreased. An improvement in foot-floor contact pattern was seen as a result of the rhizotomy procedure with children achieving toe-first foot contact with foot flat in stance in contrast to persistent toe-walking in the CG.

In some cases, statistically significant improvements for the biomechanical outcomes in the RG were accompanied by similar changes in the CG resulting in few statistically significant differences between groups. The possibility of type II error should be considered for all clinical and biomechanical outcomes that failed to reach statistical significance but for which large clinical changes at 12 months in the RG as compared with the CG were apparent, i.e. the stand dimension of the GMFM, active knee flexion and ankle dorsiflexion, and

Table VI: Scoring for the foot-floor contact pattern

Contact pattern	Score
Unable to walk	0
Purely a toe-walker	1
Toe-first contact with foot with foot-flat contact approximately 50% of the time	2
Toe-first contact with foot-flat	3
Foot-flat	4
Heel-first contact	5

Table VII: Ankle-stretch reflex and isometric contraction

Outcome	Control group (N=12)		Rhizotomy group (N=12)	
	Baseline Mean (SD)	12 mo Mean (SD)	Baseline Mean (SD)	12 mo Mean (SD)
Nr bursts in tibialis anterior	1.67 (0.5)	1.89 (0.9)	1.63 (0.7)	0.43 (0.79) ^a
Nr bursts in soleus	1.78 (0.67)	1.78 (1.3)	1.88 (0.64)	0.86 (0.69) ^a

^aIndicates a significant difference between control and rhizotomy groups ($P<0.05$).

timed walk. The power of all of these comparisons was between 0.40 and 0.50 with the sample size of 24 subjects.

The large degree of variability between children in the GR in the extent of improvement should be noted (Table III). There was, however, no pattern of gross motor change based on either the age, severity, or prerrhizotomy functional abilities in our sample of children with spastic diplegia. This was in contrast to studies by Arens et al. (1989) and Berman et al. (1990) who found that in a sample of non-ambulatory and ambulatory children with CP, the better the child's function before surgery the greater were the gains after surgery. In ambulatory children with spastic diplegia, factors such as motivation, and availability of PT/OT services likely play a strong role in outcome (Peacock et al. 1987, Arens et al. 1989, Dudgeon et al. 1994).

When individual items within the GMFM stand and walk/run/jump dimensions were reviewed to determine any items for which change consistently occurred during the 12-month follow-up, no pattern was evident. It appeared that independent standing balance which occurred by 6 months was a necessary precursor for improvements in the walking-based items that the children were able to perform in the walk/run/jump dimension of the GMFM.

There are several limitations of the GMFM that should be considered when interpreting the results. First, the GMFM does not evaluate quality of the child's movement. It looks at how much of an activity a child can perform rather than at attributes of quality such as speed, coordination, and smoothness of movement. Parents and therapists frequently comment on these changes in quality of movement following rhizotomy. A measure such as the Gross Motor Performance Measure (GMPM) (Boyce et al. 1991) might have allowed evaluation of these characteristics. Unfortunately, at the time of the rhizotomy study, the GMPM was undergoing initial stages of validation, and it was felt that its use was premature.

Second, the GMFM does not attempt to look at a child's higher level of functional skills or endurance, for example, typical playground or gym activities, or ascending a long flight of stairs at school. Third, many of the items in the GMFM allow the child to use their arms and therefore may not be optimally sensitive to the sequence of changes in spasticity in the lower extremity.

The relation of GMFM scores to performance of everyday activities has not yet been established. However work by Dudgeon et al. (1994) and McLaughlin et al. (1994) provides evidence of carry-over of basic motor skills (evaluated by the GMFM) into daily functional activities, as evaluated by the Pediatric Evaluation of Disability Inventory (PEDI) (Haley et al. 1992). Gross motor assessment in the SDR study by McLaughlin et al. (1994) was by means of the GMFM. There was a mean gain of 9.0 percentage points in total scores for children with spastic quadriplegia, and of 9.8 percentage points in children with spastic diplegia. The children with spastic diplegia made their gains predominantly in standing- and walking-based activities, while those with spastic quadriplegia made greatest progress in sitting and crawling skills. In a separate study (Dudgeon et al. 1994) with a partial sample of children in McLaughlin et al.'s study (1994), there were mean improvements of 7.8 percentage points and 16.8 percentage points respectively in the 1-year post-SDR scaled scores (range of 0 to 100) for the self-care and mobility domains on the PEDI for the 11 children with spastic diple-

gia. Scaled score change was less than 4 percentage points on these domains for the five children with spastic quadriplegia. While the strength of the correlation between the GMFM and the PEDI scores was not reported, it would appear that the changes in the spastic diplegic group were parallel and similar in magnitude.

Conclusions

SDR in children with spastic diplegia leads to a clinically and statistically significant increase in gross motor function compared with controls who did not receive surgery but who had 1 year of therapy of equivalent frequency. This change is brought about by a significant decrease in lower-extremity tone and increased ankle ROM. There was no evidence of altered motor control, and the tone of the upper limbs was unaffected. Further studies should address the long-term effects of the surgery, as well as the impact on daily functional activities. This information is crucial for both parents and health-care providers when initial decisions about the appropriateness of SDR surgery are being made.

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