Efficacy of microcurrent therapy in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle: a randomized placebo-controlled trial

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Abstract
Objective: To compare the effects of a combination of therapeutic exercise and ultrasound with or without additional microcurrent therapy in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle.

Design: Prospective, randomized, placebo-controlled trial.

Setting: An outpatient rehabilitation clinic in a tertiary university hospital.

Subjects: Infants (n = 20) with congenital muscular torticollis involving the entire sternocleidomastoid muscle.

Interventions: Group 1 comprised 10 infants who received therapeutic exercise with ultrasound alone and Group 2 comprised 10 infants who received the same treatment with microcurrent therapy.

Main measures: Passive cervical rotational range of motion was measured at before treatment and one, two, three, and six months after initial treatment. Thickness, cross-sectional area, and red pixel intensity on colour histograms, which were all assessed before treatment and at three months after initial treatment. Additionally, the duration of treatment was measured.

Results: The mean passive cervical rotational range of motion measured at three months posttreatment was significantly greater in Group 2 (101.1°) than that in Group 1 (86.4°), and the thickness, cross-sectional area, and red pixel intensity of the affected sternocleidomastoid muscle were all less in Group 2 (7.8 mm, 100.3 mm², and 126.1, respectively) than those in Group 1 (9.6 mm, 121.5 mm², and 140.5, respectively). The mean duration of treatment was significantly shorter in Group 2 (2.6 months) than in Group 1 (6.3 months).

Conclusions: Microcurrent therapy may increase the efficacy of therapeutic exercise with ultrasound for the treatment of congenital muscular torticollis involving the entire sternocleidomastoid muscle.
Keywords
Congenital muscular torticollis, microcurrent, therapeutic exercise, ultrasound, sonoelastography

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Introduction

Congenital muscular torticollis of the neck is caused by shortening or excessive contraction of the sternocleidomastoid muscle.1–3 Sternocleidomastoid muscle shortness with or without a palpable mass may develop as a result of muscle trauma during birth or chronic repetitive microtrauma, such as prolonged poor intrauterine posture.4,5 Birth trauma results in the sternocleidomastoid muscle tear with hematoma formation and consequent fibrous contracture,6 whereas intrauterine constraint limits head mobility, leads to progressive contracture of the neck, and is associated with muscle fibrosis.7 Muscle trauma leads to transient changes in the calcium concentration, which is essential for muscle excitation–contraction coupling; sustained increases in the calcium concentration may contribute to structural changes in the muscle, such as fibrosis.8

One-third of cases in which fibrosis affects the entire length of the sternocleidomastoid muscle, cannot be resolved through physical therapy and require surgery to release the contracted muscles.9 Active or passive stretching of the affected muscle may be effective only in infants with involvement of less than two-thirds of the sternocleidomastoid muscle.9 Therefore, a new conservative treatment is needed for infants with congenital muscular torticollis with fibrosis of the entire sternocleidomastoid muscle. Our previous study revealed that in infants with congenital muscular torticollis, stretching exercise in combination with ultrasound and microcurrent therapy is more effective than stretching exercise with ultrasound alone, at improving the range of motion of the neck and ensuring therapeutic compliance.10

Real-time sonoelastography is a recently developed ultrasound-based technique that facilitates the evaluation of tissue elasticity in real time. Real-time sonoelastography is based on the principle that tissue compression produces strain (displacement) to a lesser degree in hard tissue than in soft tissue. Real-time sonoelastography has recently been used to assess pathologic tissues affected by various muscle disorders, and may be useful for evaluating the stiffness of the sternocleidomastoid muscle.11–14

The first aim of this study was to evaluate the therapeutic effects of microcurrent therapy in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle using clinical measurements, ultrasound, and real-time sonoelastography. The second aim was to confirm the results of a previous non-randomized study using microcurrent therapy in a randomized, controlled study.

Methods

This study was designed as a prospective, randomized, double-blinded, placebo-controlled trial. Blocked randomization was achieved by the use of a random number table generated by block randomization, which was provided by a physical therapist prior to the start of the study. The physical therapist used the randomization scheme to assign infants into two groups, the therapeutic exercise with ultrasound alone, and therapeutic exercise with ultrasound and microcurrent therapy groups. The physical therapist knew whether electrical stimulation during microcurrent therapy was turned on or off. This process ensured concealment of the group allocation from both the participating infants’ parents and the investigators who evaluated the outcome measures. Figure 1 shows an overview of the study protocol.

The infants’ parents provided written permission for their children’s participation in the study after receiving an explanation of the research. The study was performed after approval from the Research Ethics Committee in accordance with the Declaration of Helsinki. Our study was registered
the South Korea Clinical Trials Registry and the registration number is KCT0000778.

Infants with congenital muscular torticollis who visited the outpatient clinic of the university hospital were included in this study if they met the following criteria: (1) involvement of the entire sternocleidomastoid muscle; (2) a sternocleidomastoid muscle thickness >10 mm, as measured by ultrasound; (3) a palpable mass in the sternocleidomastoid muscle upon clinical examination; (4) age under three months; and (5) no previous rehabilitation therapy received prior to participation in this study. The exclusion criteria were: (1) congenital anomalies of the cervical spine; (2) spasmodic torticollis; (3) neurodevelopmental disorders, such as cerebral palsy or intellectual disability; and (4) ocular torticollis.

The infants’ age, sex, weight, and height did not differ significantly between the two groups. Group 1 underwent therapeutic exercise with ultrasound three times per week; this therapy consisted of the application of ultrasound diathermy to the affected sternocleidomastoid muscle, followed by therapeutic exercises. Ultrasound diathermy was applied to the affected sternocleidomastoid muscle according to the following parameters: duration, five minutes; frequency, 1.0 MHz; intensity, 0.8 W/cm²; effective radiating area, 1 cm²; and 50% duty cycle, 1:1 (five milliseconds on, five milliseconds off). The therapeutic exercises were performed for 20 minutes in each session and included range of motion exercises, postural training, and gentle manual stretch of the affected sternocleidomastoid muscle. The manual stretch followed a standardised protocol:
three repetitions of 15 manual stretches of the involved sternocleidomastoid muscle with sustained force for one second with a rest period of 5–10 seconds between each stretch. Manual stretch was performed by the other physical therapist who was blind to the group allocation and was trained in paediatric neuromuscular rehabilitation.

Group 2 underwent the same rehabilitation programme with the additional microcurrent therapy (EMI; Cosmic Co., Seoul, Korea). Microcurrent therapy was applied three times per week for 30 minutes in each session by the physical therapist. Microcurrent generator was programmed to provide an alternating current characterised by a monophasic rectangular pulse format, with polarity reversal every three seconds. The frequency was 8 Hz and the intensity was 200 µA. This level of current intensity was significantly below the infants’ threshold of sensation. The affected sternocleidomastoid muscle was isolated by turning the infant’s head toward the contralateral side to facilitate palpation of the muscle for the attachment of the electrical patch. To avoid sternocleidomastoid stretching effects during microcurrent therapy, the head was returned to the original position after the application of the electrical patch (Figure 2, available online).

In Group 1, the same electrical patches for microcurrent therapy were attached to the infants and electrical stimulation was turned off.

The parents of the infants in both groups were instructed in, and encouraged to, follow a home exercise programme for the infants consisting of two types of neck stretches, lateral flexion and rotation of the neck to both sides. The exercises were to be performed 10 times per session, six sessions every day. The home programme also included educating the parents in positioning and handling skills that would promote active neck rotation towards the affected side and discourage the infant from tilting his/her head towards the affected side. The parents were advised that the infant’s sleep position should be rotated frequently (among left lateral, right lateral, and prone). Data about home exercise were collected using monthly exercise recording sheets that were recorded by the parents. They were retrieved and reviewed by the physiatrist at each clinic visit. Good compliance was defined as the parents having completed home exercise at six times per session every day.

All infants were scheduled for routine follow-up appointments with the physiatrist every four weeks; in addition, during the treatment session, if the physical therapist detected normal passive cervical rotational range of motion on the affected side, the infant was rescheduled for evaluation by the physiatrist within one week. If normal passive cervical rotational range of motion was confirmed, the rehabilitation treatment was stopped. The duration of treatment was defined as the time between the initial treatment and the achievement of complete passive cervical rotational range of motion or when no further improvement had been noted for six months despite ongoing treatment.

The passive cervical rotational range of motion of the affected side was measured using an arthrodial protractor by a single physiatrist who was blinded to the group allocation throughout the study. The infant was placed in the supine position on the examination table with the shoulders stabilised. The examiner supported the head and neck in the neutral position over the edge of the examination table. With the infant in this position, the neck could be rotated and moved freely in all directions. A previous study found a correlation coefficient of inter-examiner reliability of 0.71 for the measurement of the passive range of motion of the neck in infants by this method. On the basis of an earlier study, we defined ≥100° as the reference value for normal passive cervical rotational range of motion.

A physiatrist (DRK) performed the ultrasound and real-time sonoelastography using a commercially available ultrasound system equipped with a 5–13 MHz multifrequency linear transducer (Antares™; Siemens Healthcare, Erlangen, Germany). The frequency of the transducer during scanning was 11.43 MHz. At the time of the study, the physiatrist had 10 and four years of experience in performing musculoskeletal ultrasound and sonoelastography, respectively. The same physiatrist reviewed all ultrasonographic imaging. Ultrasound was performed after the infants had fallen asleep with their mothers’ help. For the examination, the infant was laid across the examination couch in such a manner that the operator could observe from
above the infant’s head. A small bolster was used to extend the neck maximally, and the head was rotated contralaterally to the examined side. Ultrasound was discontinued if the infant became tense and uncooperative.

Both longitudinal (along the long axis of the muscle) and transverse (perpendicular to the long axis of the muscle) scans of the affected sternocleidomastoid muscle were performed on each infant. The transverse scans included the levels of origin (clavicle and sternal head) and insertion (mastoid process) as well as the belly of the muscle. The location of the mass in the sternal or clavicular portion of the muscle and its site in the lower, middle, or upper third of the sternocleidomastoid muscle, were recorded.

The thickness (Figure 3(A), available online), was defined as the distance from the superficial to the deep aponeurosis in the thickest part of the muscle, and the cross-sectional area (Figure 3(B)) of the affected sternocleidomastoid muscle, was measured on the transverse image.

The position of the infant and transducer for real-time sonoelastography were identical to those described for ultrasonographic imaging. The ultrasonographic image was displayed on the right side of the screen, while the colour-coded real-time sonoelastography was depicted on the left side of the screen (Figure 4(A) and (B), available online).

Using the ultrasonographic display for guidance, a region of interest including the affected sternocleidomastoid muscle and the normal surrounding tissue was selected. No external compression was applied for real-time sonoelastography, because the pulsation of the carotid artery was used as the compression source. On the colour-coded real-time sonoelastography images, purple indicated soft tissue, green and yellow indicated intermediate-stiffness tissue, and red indicated hard tissue. The recorded real-time sonoelastography images were replayed to select the best representative image, which was defined as the best depiction of the tissue structure that was consistent with the majority of the scanned images. The colour patterns of the two representative images were analysed quantitatively by another physiatrist (GYP) using Image J software (National Institutes of Health, Bethesda, MD, USA). The region of interest of the colour histogram was selected to include the entire sternocleidomastoid muscle (excluding its hyperechoic epimysium), and the pixel colours ranged from 0 to 255. The colour histogram represented the number of pixels coloured in each of a fixed list of colour ranges; the intensity of each colour component of the pixels within the region of interest was calculated, with higher values representing greater colour intensities (Figure 4(c), available online). Median red pixel intensity values were obtained from the colour histograms. Real-time sonoelastography scanning was performed twice, and one representative image from each scan was used to determine the intra-rater reliability of the red pixel intensity.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 19.0 (SPSS, Inc., Chicago, IL, USA) with a level of significance of <0.05. Data are presented as the mean value and standard deviation. The intra-class correlation coefficient was used to examine the intra-rater reliability of the repeated red pixel intensity measurements. Wilcoxon’s signed-rank test was used to evaluate the intra-group differences in the parameters before and after treatment. Intergroup differences in the clinical and real-time sonoelastography parameters (passive cervical rotational range of motion, thickness and cross-sectional area of the sternocleidomastoid, duration of treatment, and red pixel intensity) were evaluated using the Mann–Whitney $U$ test.

Results

Total 25 infants were enrolled and allocated to two groups. The 13 infants (Group 1) who received therapeutic exercise with ultrasound were compared with the 12 infants (Group 2) who received therapeutic exercise with ultrasound and microcurrent therapy.

In South Korea, the pregnant women usually return to their hometown in order to give birth to a child under the care of their parents. They usually have stayed at hometown with their infants for one to two months after childbirth. Therefore, five of the 25 infants dropped out since they had returned home
after delivery recuperation (Figure 1). Passive cervical rotational range of motion, red pixel intensity, thickness, and cross-sectional area at baseline of the affected sternocleidomastoid muscle in five infants (three boys and two girls, the mean age was 18.1 ± 4.5 days) were 63.5° ± 10.4°, 156.2 ± 9.1, 13.2 ± 1.6, 174.7 ± 61.2, respectively.

Finally, 20 infants with congenital muscular torticollis were enrolled in the study. Group 1 comprised 10 infants (four boys and six girls; mean age, 17.9 ± 4.5 days), and Group 2 comprised 10 infants (five boys and five girls; mean age, 18.3 ± 4.7 days). The infants' age, sex, weight, and height did not differ significantly between the two groups.

All parents in both groups showed good compliance for the home exercise programme. The mean duration of treatment was significantly shorter in Group 2 (2.6 ± 1.1 months) than in Group 1 (6.3 ± 1.2 months; \( p = 0.002 \)).

There was no significant difference in passive cervical rotational range of motion at baseline between groups. However, the passive cervical rotational range of motion at one month, two months, and three months after initial treatment was significantly greater in Group 2 than in Group 1. There was no significant difference in passive cervical rotational range of motion at six months after initial treatment between groups.

In Group 1, the passive cervical rotational range of motion significantly increased at two months, three months, and six months after initial treatment compared with that at baseline. In Group 2, the passive
cervical rotational range of motion significantly increased at all posttreatment time points compared with that at baseline (Table 1).

All clinically palpable masses were detected on ultrasound and real-time sonoelastography. There were no significant differences in thickness, cross-sectional area, or red pixel intensity of the affected sternocleidomastoid muscle at baseline between the groups. In both groups, the thickness, cross-sectional area, and red pixel intensity of the affected sternocleidomastoid muscle significantly decreased at three months posttreatment compared with those at baseline. Additionally, at three months posttreatment, the thickness, cross-sectional area, and red pixel intensity of the affected sternocleidomastoid muscle were significantly smaller in Group 2 than in Group 1 (Table 2). The intraclass correlation coefficient values for repeated red pixel intensity measurements were $r = 0.902$ and $r = 0.908$ for Groups 1 and 2, respectively.

**Discussion**

The duration of treatment in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle decreased significantly after the addition of microcurrent therapy to the treatment programme that included therapeutic exercise and ultrasound. The mean treatment duration was 2.6 months in infants who received microcurrent therapy in addition to therapeutic exercise and ultrasound versus 6.3 months in infants who received therapeutic exercise and ultrasound alone. Passive cervical rotational range of motion was improved as early as one month posttreatment after the addition of microcurrent therapy in Group 2. On the other hand, passive cervical rotational range of motion showed improvement at two months posttreatment in Group 1.

The way in which microcurrent therapy caused the discrepancy between the two groups is not known. However, several mechanisms of the therapeutic effect of microcurrent therapy have been proposed in the treatment of muscle damage. First, the therapeutic effect of microcurrent therapy is likely related to the maintenance of intracellular Ca\textsuperscript{2+} homeostasis after muscle damage.\textsuperscript{10,18} In a previous study,\textsuperscript{18} microcurrent therapy reduced the severity of muscle damage compared with placebo. The investigators in that study suggested that the increased intracellular calcium concentration might alter membrane integrity and cause functionally deleterious morphological changes in the contractile machinery of the muscle.\textsuperscript{19} This finding can be applied to congenital muscular torticollis, in which prolonged isometric contraction of the sternocleidomastoid muscle interferes with normal blood circulation and ionic interchange at the cell membrane.\textsuperscript{20,21}

Second, microcurrent therapy might increase the synthesis of adenosine triphosphate, amino acid transportation, and protein synthesis, which are involved in decreasing inflammation and promoting tissue healing.\textsuperscript{22,23} The beneficial effects of electric current on soft tissue repair have been described in a previous study.\textsuperscript{24}

Last, microcurrent therapy may affect the function of cell nuclei, and activate the genes that adjust collagen breakdown and induce the relief of fibrosis. After microcurrent therapy was initiated in the treatment of radiation-induced fibrosis in patients with head and neck cancer, the cervical rotational range of motion improved significantly.\textsuperscript{22} This finding is in accordance with our results.

The intensity of microcurrent therapy is important in the treatment of muscle damage. In one study, when an intensity of 100–500 µA was applied after muscle damage, the healing process, including amino acid transport, triphosphate generation, and protein synthesis, increased by 30–40% above the control level.\textsuperscript{23} On the contrary, when the intensity exceeded 1000 µA, these stimulatory effects were reversed.\textsuperscript{22} Therefore, an intensity of 200 µA was used in our study. Additionally, this level of microcurrent intensity was significantly below the infants’ threshold of sensation, and they felt nothing during the microcurrent therapy. Our study revealed good compliance of microcurrent therapy when used as an adjunct to therapeutic exercise and ultrasound. There were no adverse effects or untoward events, since microcurrent stimulation works at the microampere level and mimics the electrical intensity found in living tissue.\textsuperscript{25–27}
The infants in both groups began the treatment programme before one month of age, as it is well known that the prognosis for congenital muscular torticollis depends on the age at which treatment is initiated.\textsuperscript{3,16} A previous study\textsuperscript{9} demonstrated that the nature of the tissue that replaces degenerated muscle fibres varies according to the patient’s age. In young infants with congenital muscular torticollis, muscle fibres are replaced by cellular fibrous tissue with an immature appearance that become more solid and mature over time. Additional microcurrent therapy might increase the rate at which fibrotic sternocleidomastoid muscle is replaced by normal muscle fibres and contribute to structural muscle change. Therefore, it eventually contributes to a reduction in the duration of treatment in infants with congenital muscular torticollis.

In vivo ultrasound and real-time sonoelastography have been applied as useful imaging methods to assess the morphology and stiffness of muscles in the human body. The increased muscle stiffness associated with congenital muscular torticollis relates to the high level of dense fibrous tissue. Because real-time sonoelastography can measure muscle stiffness, we used it to indirectly estimate the amount of fibrous tissue in infants with congenital muscular torticollis.\textsuperscript{14} In our study, all imaging parameters, including muscle thickness, cross-sectional area, and red pixel intensity of the sternocleidomastoid muscle, measured at three months posttreatment, were significantly lower in infants who received microcurrent therapy than in those who did not. These favourable changes in muscle properties were successfully semi-quantified using ultrasound and real-time sonoelastography, and confirmed by the change in the passive cervical rotational range of motion.

Our study has some limitations. First, the small number of infants in our study precludes the definite results regarding the therapeutic effect of the addition of microcurrent therapy to therapeutic exercise and ultrasound. Further investigation, preferably with a larger population, is needed to assess the usefulness of microcurrent therapy as an adjunct treatment for congenital muscular torticollis involving the entire sternocleidomastoid muscle. Second, we could not evaluate inter-rater reliability of the ultrasound and real-time sonoelastography measurements. Ultrasound and sonoelastography is considered to be operator-dependent, has an inherently long learning curve, and poses technical problems in the reproducibility of images depending on the experience of the examiner. To overcome this problem, a physiatrist with 10 years of musculoskeletal ultrasound and four years of sonoelastography experience performed all examinations at the time of study. Third, infants needed to be immobile during ultrasound and sonoelastographic examination owing to motion artefact, but it is sometimes very difficult. In this study, all images were obtained after the infants had been fallen asleep. Last, we did not contemplate the influence of age since it is known that the prognosis for congenital muscular torticollis depends on the age at which microcurrent therapy is initiated. Further studies are needed to evaluate the effects of microcurrent therapy according to the age at which the therapy is started for achievement of the best and most durable results.

In conclusion, the addition of microcurrent therapy to therapeutic exercise and ultrasound, significantly decreased the duration of treatment required to achieve a normal passive cervical range of motion in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle. Therefore, therapeutic exercise and ultrasound with additional microcurrent therapy may be more effective than therapeutic exercise and ultrasound alone in treating congenital muscular torticollis. Additionally, ultrasound and real-time sonoelastography might be useful imaging methods for assessing architectural changes in the sternocleidomastoid muscle after treatment.

### Clinical messages

- Microcurrent therapy might increase the efficacy of rehabilitation treatment in infants with congenital muscular torticollis involving the entire sternocleidomastoid muscle.
- Quick intrinsic architectural changes (stiffness and size of the sternocleidomastoid muscle) in congenital muscular torticollis after addition of microcurrent therapy have been demonstrated on ultrasound and real-time sonoelastography.
Conflict of interest
No other financial support was provided for the creation of this manuscript, and no author had any conflict of interest.

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