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A Pilot Study on the Mirror Effect PLUS Protocol: A Standardized and Adapted Facial Rehabilitation for Acute Bell's Palsy



Une étude pilote sur le protocole *Effet Miroir Plus*, une rééducation orthophonique standardisée et adaptée à la paralysie de Bell en phase aiguë

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Abstract

Combining early facial exercises with medication may help patients with acute Bell's palsy recover significantly faster and better than patients treated with medication alone. To date, exercise therapy in acute Bell's palsy consists mostly of transferring facial rehabilitation techniques that were developed for chronic Bell's palsy, despite the differences between those stages. The aim of this pilot study was to estimate the efficacy of the Mirror Effect PLUS Protocol, the first facial rehabilitation protocol specifically designed for acute Bell's palsy. Ten patients with acute moderate-to-severe, severe, and total Bell's palsy were recruited and assigned randomly to the Mirror Effect PLUS Protocol group or the control group. Both groups received the recommended medications. In addition, patients in the rehabilitation group performed exercises that were completed using a computer that duplicated their healthy hemiface. Compared to controls, a greater number of patients in the Mirror Effect PLUS Protocol group presented better facial symmetry and greater satisfaction towards their facial function. There were no differences in recovery between the rehabilitation and control groups; however, for the subset of patients with severe palsy, the Mirror Effect PLUS Protocol improved and accelerated recovery. These preliminary results support the hypothesis that the Mirror Effect PLUS Protocol enhances the recovery of severe acute Bell's palsy. However, replication of these results with larger samples is necessary. Additionally, the intervention's precise mechanisms of action need to be investigated thoroughly to exclude the effect of spontaneous recovery.

Abrégé

Combiner une rééducation orthophonique à la prise de médicaments pourrait favoriser un rétablissement plus rapide et optimal des patients présentant une paralysie de Bell en phase aiguë, comparativement à la prise seule de médicaments. Présentement, la rééducation qui est offerte aux patients présentant une paralysie de Bell en phase aiguë consiste principalement en l'utilisation de techniques ayant été développées pour les patients ayant une paralysie de Bell chronique, et ce, malgré les différences entre ces stades de la pathologie. L'objectif de la présente étude pilote était d'évaluer l'efficacité du protocole Effet Miroir Plus, un premier protocole de rééducation orthophonique spécifiquement conçu pour la paralysie de Bell en phase aiguë. Dix patients présentant une paralysie de Bell en phase aiguë de degré «modéré à sévère» ou «sévère», ou encore, pouvant être qualifiée de «totale» ont été recrutés. Ceux-ci ont été divisés aléatoirement dans deux groupes : un groupe de patients à qui le protocole Effet Miroir Plus a été administré et un groupe contrôle. Les deux groupes ont pris les médicaments recommandés dans le traitement standard de la paralysie de Bell. Les patients du groupe à qui une rééducation orthophonique a été offerte ont également effectué des exercices musculaires en utilisant un ordinateur qui dupliquait leur hémiface saine. Lorsque comparés aux patients du groupe contrôle, un plus grand nombre de patients du groupe Effet Miroir présentaient une meilleure symétrie faciale et une plus grande satisfaction à l'égard de leur fonction faciale. En termes de rétablissement, aucune différence n'a été notée entre les groupes, sauf pour le sous-ensemble de patients ayant une paralysie de degré «sévère». Dans ce cas précis, le protocole Effet Miroir Plus a amélioré et accéléré le rétablissement. Ces résultats préliminaires soutiennent l'hypothèse que le protocole Effet Miroir Plus améliore le rétablissement des patients ayant une paralysie de Bell en phase aiguë de degré «sévère». Il sera toutefois nécessaire de répliquer ces résultats avec des échantillons plus importants. Ajoutons qu'il sera également important d'investiguer de façon approfondie les mécanismes d'action précis de la rééducation orthophonique pour exclure l'hypothèse d'un rétablissement spontané.

I idiopathic peripheral facial palsy, also called Bell's palsy (BP), is a distressing condition in which people abruptly lose their facial motor function (Prud'hon & Kubis, 2018). With an annual incidence estimated between 11 and 53.3 new cases per 100,000 persons, BP is the most frequent peripheral facial palsy (Ferreira, Marques, Duarte, & Santos, 2015). BP is thought to be caused by the reactivation of the herpes simplex type 1 virus at the level of the facial nerve (de Almeida et al., 2014). The virus causes inflammation and nerve entrapment in the internal auditory canal and/or stylomastoid foramen and can potentially lead to axonal injury (Ferreira et al., 2015). To date, the combination of corticosteroid and antiviral therapies is the "gold standard" for treating acute BP (Gagyor et al., 2015; Sullivan, Daly, & Gagyor, 2016). Complete recovery is expected without treatment in 70% of BP cases and this proportion increases with oral corticosteroid and antiviral treatment (Prud'hon & Kubis, 2018). Despite adequate medication, 5% to 30% of patients that present with acute severe and total BP are at risk of developing permanent sequelae, such as synkinesis, dysarthria, and oral dysphagia (Prud'hon & Kubis, 2018). Early facial rehabilitation could further reduce the proportion of patients with permanent sequelae (Ferreira et al., 2015); however, there are few efficiency studies on this topic and the rehabilitation programs that consider the specificity of acute BP are lacking (de Almeida et al., 2014).

Recent neuroimaging studies have shown that BP causes significant neuroanatomical changes in sensorimotor associative areas as soon as the first few days following onset (Klingner, Volk, Brodoehl, Witte, & Guntinas-Lichius, 2014; Song et al., 2017). These early changes suggest that these BP-induced cortical modifications are the result of a discordance between the motor efferents that are preserved and the sensory afferents that are affected (Klingner et al., 2014). In other words, in BP (as opposed to facial palsy caused by central injury, such as a stroke), the palsy prevents the efferent signal from reaching the muscles, but the sensory afferents that indicate muscle immobility are detected by the sensory cortex, which causes an early sensory-motor mismatch (Song et al., 2017). The speed at which these changes develop suggests that rapid intervention is desirable (Barbara, Antonini, Vestri, Volpini, & Monini, 2010; Monini et al., 2016). However, very few high-quality studies have been conducted to evaluate the effect of facial rehabilitation in acute BP, considering the high rates of spontaneous and complete recovery (de Almeida et al., 2014).

A literature review and meta-analysis conducted by Pereira et al. (2011) showed that data on early facial therapy were scarce and that no meta-analysis was possible on that

matter; a meta-analysis was only possible for interventions in chronic facial palsy. In a more recent systematic review, Ferreira et al. (2015) searched over 200 studies to answer the following question: Can exercise therapy and standard drug treatment have positive effects on the quality and time of recovery for acute and subacute BP? Only four clinical trials met the quality criteria to be included in the review, which confirms the need for more research. The described protocols used for acute intervention in these studies were either developed for chronic BP or were not described well enough to be replicated. The rehabilitation protocols tested in these studies included Neuromuscular Retraining, which consists in individualised facial exercises (Nicastri et al., 2013); Kabat Rehabilitation, which consists of stretching and manipulating the face (Barbara et al., 2010); the Chevalier Method, which consists of analytic muscle exercises (Penteado, Testa, Antunes, & Chevalier, 2009); and finally, electrical stimulation combined with exercise therapy (Alakram & Puckree, 2010).

These studies, however, had several methodological issues such as inadequate follow-up, a lack of blind assessors, and a lack of allocation concealment. Two of these studies did not include randomization (Alakram & Puckree, 2011; Penteado et al., 2009). Only one of these studies received a good methodological quality score (Nicastri et al., 2013), which was evaluated by the PEDro Scale (see Maher, Sherrington, Herbert, Moseley, & Elkins, 2003, for more information on the PEDro scale); the others were rated as either fair or poor (Alakram & Puckree, 2011; Barbara et al., 2010; Penteado et al., 2009). Nonetheless, based on that small sample, Ferreira et al.'s (2015) conclusions are interesting: Early facial rehabilitation combined with the gold standard medication helps patients with severe, total, and persistent BP (over 14 days post-onset) to recover significantly faster and to a better extent than patients who received the medication alone.

Development of the Mirror Effect PLUS Protocol

To date, none of the existing facial rehabilitation protocols thoroughly described in the literature were specifically designed for acute BP. Very little data support the use of facial exercise therapy in acute BP despite its potential benefits for recovery (Ferreira et al., 2015). As a result, medical guidelines cannot recommend exercise therapy for acute BP (de Almeida et al., 2014). The Mirror Effect PLUS Protocol (MEPP) was thus developed to fill this important gap. **Table 1** offers an overview of the characteristics of the MEPP.

The MEPP is the first standardized facial rehabilitation protocol designed for acute moderate-to-severe, severe,

Table 1	
Description of the Mirror Effect PLUS Protocol	
Mirror Effect Plus Protocol	
Structure	
Assessments	<p>First assessment between day 10 and 14 post-onset</p> <p>Monthly follow-up assessments. Allow adjustments of the exercises if needed and if apparition of synkinesis is detected</p>
Therapy sessions	<p>45 minutes, twice a week for 2 weeks. Add therapies weekly for trouble shooting if needed</p> <ul style="list-style-type: none"> • Education on facial anatomy and function • Description of the facial exercises and adjustments made if needed • Progressive diminution of commentaries/feedback during therapy. This should help motor learning even if it decreases spontaneous motor performance
Home exercises	<p>10 minutes of facial massages (twice a day)</p> <p>15 minutes of daily facial exercises with a specialised website using the mirror effect. (see below)</p> <p>Motor imagery sessions for total facial palsy and to help integrate the facial anatomy as well as subtle kinaesthetic cueing</p> <p>*In case of synkinesis: make target movement without eliciting the synkinesis by reducing amplitude of target movement. Repeat in series of 5 repetitions, twice a day</p> <p>Education on facial anatomy and function</p>
Exercises	
Nature	<p>Think about something surprising and rise gently the eyebrows. Release.</p> <p>Think about something frustrating and gently frown the eyebrows. Release.</p> <p>Close and open the eyes very SLOWLY while feeling progressively the opening and closing on the eyelid.</p> <p>Think about something disgusting and wrinkle your nose GENTLY and briefly. Release.</p> <p>Think about something funny and smile with closed mouth. Release.</p> <p>Think about something funny and smile with open mouth. (The index finger should follow the movement on the cheeks). Release.</p> <p>Think about someone you love and send him/her a kiss. Release.</p> <p>Think about something disgusting and make a gentle inverted smile. Release.</p>
Repetitions	5 times each
Randomization	Each exercise sequence should be done in a random order, from session to session.
Contraction/Rest time ratio	Hold contraction for 3 seconds, rest for 3 to 5 seconds.

Note. * = optional.

and total BP. It was developed as a two-step procedure. First, it is based on relevant components from two existing facial rehabilitation protocols: the Mirror Effect Protocol

(Blanchin, Martin, & Labbe, 2013; Garmi, Labbé, Coskun, Compère, & Bénateau, 2013) and Neuromuscular Retraining protocol (Diels, 1995). The Mirror Effect Protocol was

designed to help patients regain smile symmetry after corrective facial surgery. It uses modified visual biofeedback that is created by a computer application, software, or a website that duplicates the patient's healthy hemiface during facial exercises (Blanchin et al., 2013). We included the use of a modified visuo-feedback mechanism in the MEPP because it should decrease the early cortical sensory-motor disturbances that occur in acute BP, which makes the MEPP particularly well-suited for early intervention in BP. Interestingly, the Mirror Effect Protocol has been shown to be effective (Blanchin et al., 2013) and to increase patients' compliance (Martineau, Rahal, Dufour-Fournier, & Marcotte, 2018). As the Mirror Effect Protocol was developed to help regain smile symmetry, it mainly focuses on moving the muscles around the mouth (Blanchin et al., 2013). In the MEPP, exercises for different facial regions (forehead, eyes, nose, and neck) were added.

Also, components of the Neuromuscular Retraining protocol (Diels & Combs, 1997) were included in the MEPP. For chronic BP, Neuromuscular Retraining is considered to be the gold standard for facial rehabilitation (Pereira et al., 2011). It mostly consists of re-learning adequate facial movements through individualized, slow, and specific facial exercises (Diels, 1995). Some of its components regarding the neural and motor mechanisms of the facial musculature, such as the importance of working slowly and using emotional feedback (Diels & Beurskens, 2014), are also relevant for acute BP therapy. Taking those components into account allowed us to provide more precise instructions than the original instructions for the original Mirror Effect Protocol. For example, we used "Think about something surprising and gently raise the eyebrows. Release," rather than "Lift the eyebrows."

Some parameters of both the Mirror Effect Protocol and Neuromuscular Retraining, particularly the exercises (i.e., their precise nature, the number of repetitions, and the contraction/rest time ratio), are not well-defined in the literature. Consequently, as a second step for the development of the MEPP, all the missing components were defined using motor learning principles (Caramazza, Anzellotti, Strnad, & Lingnau, 2014; Cisek & Kalaska, 2010; Eaves, Riach, Holmes, & Wright, 2016; Maas et al., 2008; Macuga & Frey, 2012; Ramachandran & Altschuler, 2009; Ramachandran, Rogers-Ramachandran, & Cobb, 1995; Shea, 2014; Shumway-Cook & Woolacott, 2017; Vogt, Di Rienzo, Collet, Collins, & Guillot, 2013; Wright, Williams, & Holmes, 2014) and based on the characteristics of the facial muscles in acute BP (Devriese, 1994; Diels & Beurskens, 2014; Mancini et al., 2014; Monini et al., 2016; Nicastrì et al., 2013; Nusser-Müller-Busch, 2015; Pohl, Anders, Schulte-Ruther, Mathiak, & Kircher, 2013; Prud'hon & Kubis, 2018;

Ranganathan, Siemionow, Liu, Sahgal, & Yue, 2004; Sittel & Stennert, 2001; Stal, 1994). By combining motor learning principles and the characteristics of the facial muscles in acute BP, we developed a well-defined protocol specifically designed for acute interventions in patients with BP.

Very few facial rehabilitation programs have been thoroughly described and there is no specific standardized re-education protocol for acute BP. The purpose of this article is to describe the MEPP, a protocol that was based on the Mirror Effect Protocol and Neuromuscular Retraining and developed based on relevant motor learning principles and the particularities of the facial muscles and issues encountered in acute BP. To demonstrate the clinical use of the MEPP, we present a pilot study to estimate the efficacy of the MEPP in acute moderate-to-severe, severe, and total BP by comparing two different conditions: medical treatment (i.e., medication) alone, which is the gold standard treatment for acute BP, and medical treatment combined with the MEPP. Our hypothesis was that the combination of medical treatment and the MEPP would enhance patients' recovery from severe and total BP, compared to medical treatment alone.

Method

Participants and Procedure

This pilot study is part of a larger study. Of the 123 referrals received between January 2017 and October 2018, 10 patients (4 men, 6 women, $M_{age} = 50.7$ years) were recruited. All patients were recruited from the emergency rooms at the Hôpital du Sacré-Coeur de Montréal and Hôpital Maisonneuve-Rosemont as well as the Otorhinolaryngology department of the Hôpital Maisonneuve-Rosemont. The participants had no other diseases or health problems and took no medications on a regular basis prior to BP onset. This was their first episode of BP, and they all received the recommended medications for severe and total BP (1000 mg of valacyclovir three times a day for 7 days and 50 mg of prednisone once a day for 10 days) within 72 hours of disease onset (Gagyor et al., 2015). Patients provided their free and informed consent to participate in the experiment, which was conducted with the approval of the ethics committee of *Centre de recherche du Centre intégré universitaire de santé et services sociaux du Nord-de-l'île-de-Montréal* (MP-32-2017-1365).

To assess the severity of facial palsy, most studies use the Facial Nerve Grading System (FNGS; Di Stadio, 2015), also called the House-Brackmann Scale (House & Brackmann, 1985). The Sunnybrook Facial Grading System (SB; Ross, Fradet, & Nedzelski, 1996) was developed a few years after the FNGS and is more sensitive to changes than

FNGS (Kanerva, Poussa, & Pitkaranta, 2006). More recently, Vrabec et al. (2009) developed the Facial Nerve Grading System 2.0 (FNGS 2.0) to incorporate regional scoring and synkinesis scoring. The FNGS 2.0 shows high intra- and inter-observer agreement with the FNGS scale, as well as better sensitivity to changes than the original FNGS (Vrabec et al., 2009). Although the FNGS 2.0 and SB facial nerve grading scales have excellent agreement and validity (Fattah et al., 2015), these scales do not evaluate the effect of the facial palsy on the patient's quality of life (Coulson, O'Dwyer, Adams, & Croxson, 2004) and its functional impact on speech and the oral stage of swallowing (i.e., lip seal and bolus preparation). The Facial Disability Index is one of the most frequently used and best-validated self-report questionnaires for the assessment of physical and social/well-being functions in facial palsy (Brach, VanSwearingen, Delitto, & Johnson, 1997). The Facial Disability Index provides additional information on the handicap caused by the facial palsy and describes how the facial palsy affects the patient's quality of life.

For the present study, a certified speech-language pathologist (SM) assessed the severity of BP, 10 to 14 days after onset, using the FNGS 2.0 (Vrabec et al., 2009) and SB (Ross et al., 1996) grading systems. Both scales were chosen for their high inter-observer agreement and validity (Fattah et al., 2015). Only patients who still presented moderate-to-severe, severe, or total BP (FNGS 2.0 grades 4, 5, or 6) on this initial assessment were recruited for the study.

To measure the patients' perception regarding their speech and swallowing impairments, each participant was asked the Facial Disability Index's first three questions on physical function during the initial assessment and at 2 months post-onset. These three questions were related to swallowing solids, drinking liquids, and making specific sounds with their mouths. A disability score for speech and swallowing was calculated at both timepoints using the formula proposed by VanSwearingen and Brach (1996):

$$\frac{\text{Total Score (questions 1-3)} - N}{N} \times \frac{100}{4}$$

where $N = 3$ (number of questions answered in the present study), which gives a score that ranges from -25 (worst) to 100 (best).

After the first assessment, patients were assigned using balanced block randomization to either the MEPP intervention group ($n = 5$; 1 man, 4 women) or the control group ($n = 5$; 3 men, 2 women). Computerized randomization was performed by an external researcher who was not in direct contact with the patients. Two reassessments were conducted at 1 and 2 months post-

onset. Each assessment was video-recorded with a Samsung Galaxy S5-Neo, transferred to a PC, and converted into an MP4 video file.

The position of the camera was standardized and always positioned in front of the patient at a distance of approximately 1 meter. The video files of these two assessments were analyzed by three independent, certified speech-language pathologists who were blinded to the assessment time and group assignment. All the FNGS 2.0 grades and SB scores reported in this study were determined by the blinded assessors based on their observations of the videos.

Intervention protocols. **Table 1** provides a detailed description of the MEPP. We also provide details on each therapy session for clarity and replicability (see Appendix), including the duration, objectives pursued, and intervention techniques. Briefly, the intervention group received the MEPP, which was administered during four in-clinic sessions that took place in the first 2 weeks after the first assessment. During those four sessions, the patients received information on facial function and anatomy and practiced motor imagery (see Eaves et al., 2016). The facial exercises were then explained and executed with the help of a free web page that provides modified visual biofeedback and a symmetrical face (www.webcamtoy.com). Facial exercises were provided for each muscle group of the face with emotional cueing, a specific pace, and a contraction/rest time ratio. A written document that contained detailed information about the exercises was given to each patient. Exercises were continued at home twice a day until recovery.

The control group received basic counselling, such as instructions on how to avoid excessive facial movements, but did not attend any therapy sessions.

Outcome definition and measurement. Based on the work of Nicastrì et al. (2013), the primary outcome was the improvement in recovery at each assessment time as measured by the FNGS 2.0 and SB scales. Recovery was defined as an FNGS 2.0 grade of 2 or less (Nicastrì et al., 2013) and an SB score of 60 or more (Neely, Cherian, Dickerson, & Nedzelski, 2010). The secondary outcome was any improvement reported by the patients with regard to their speech and swallowing impairments, which were assessed using the difference (over time) in the physical function score of the Facial Disability Index. Recently, patient-related outcome measures have gained attention as important measures of satisfaction towards interventions in facial palsy (Gyori et al., 2018); however, their use remains relatively scarce compared to

the use of impairment-based scales, which are clinician-administered. Gyori et al. (2018) reported that only 12% of the professionals that worked with facial palsy patients used the Facial Disability Index. In comparison, Santosa, Fattah, Gavilán, Hadlock, and Snyder-Warwick (2017) reported that 60% of clinicians used the FNGS and 58% used the SB. Therefore, to be able to compare our findings with other studies and render them uniform with clinical and research settings worldwide, we chose to use the scores from the FNGS 2.0 and SB as primary outcomes and the Facial Disability Index score as a secondary outcome.

Statistical analysis. To illustrate the effect of the treatment between the two samples, we calculated the Cohen's *d* standardized mean effect. This descriptive statistic is based on the mean difference between two subjects, divided by the pooled standard deviation (Cohen, 1977). We calculated it for the FNGS 2.0 and SB results. According to Cohen's convention, an effect is considered large if $d = 0.8$, moderate if $d = 0.5$, and small if $d = 0.2$ (Cohen, 1977). To ensure a more reliable and accurate comparison of the two groups, we included a stratification as previously performed by Nicastrì et al. (2013). In their study, they stratified their patients by FNGS grades and showed that therapy was efficient only for patients with grade 5 (severe) and grade 6 (total) palsies and not for patients with grade 4 (moderate to severe) palsies. A similar post-hoc procedure was performed in the present study. Based on Nicastrì et al. (2013), the stratification was performed to include only initial FNGS 2.0 grades 5 (severe). We did not include grades 6 as only one patient, which was in the MEPP group, had this initial grade.

Results

Table 2 presents the demographic characteristics of both groups, their FNGS 2.0 grades, and their SB and Facial Disability Index scores, all of which were obtained during the first assessment (i.e., 10–14 days post-onset). The inter-rater agreement between the blinded assessors was measured for both the FNGS 2.0 and SB and revealed intra-class correlation coefficients of 0.98, 95% CI [0.97, 0.99] and 0.97, 95% CI [0.95, 0.99], respectively. At baseline, the MEPP group presented with more severe BP than the control group (mean FNGS 2.0 grades of 5 and 4.6, respectively, and mean SB scores of 17 and 27, respectively), but these differences were not statistically significant when evaluated by the Mann-Whitney test ($p = .643$ and $.310$, respectively).

As reported in **Table 3**, at 1 month post-onset, one patient in the MEPP group reached the primary outcome, but none of the patients in the control group reached this outcome. At 2 months post-onset, four patients in the MEPP group reached a grade of 2 or less, but only one patient in the control group reached a grade of 2. **Table 4** displays the SB scores obtained for each patient at each of the assessment times. At 1 month post-onset, two patients in the MEPP group and three patients in the control group had scores of 60 or more (i.e., recovery). At 2 months post-onset, four patients in each group had scores of 60 or more, but the MEPP group had higher scores overall. Finally, **Table 5** presents the individual scores for speech and swallowing from the physical function of the Facial Disability Index at the initial and final assessments. In the MEPP group, three patients indicated that they had no difficulties with speech

	Controls	MEPP
Sex, <i>n</i> (%)		
Female	2 (40%)	4 (80%)
Male	3 (60%)	1 (20%)
Age, <i>M</i> (<i>SD</i>) in years	43.6 (11.3)	57.8 (13.3)
FNGS 2.0 grade 10–14 D.P.O., <i>n</i> (%)		
4	2 (40%)	1 (20%)
5*	3 (60%)	3 (60%)
6	0 (0%)	1 (20%)
SB score, <i>M</i> (<i>SD</i>)	27.0 (7.6)	17.0 (8.0)
FDI score, <i>M</i> (<i>SD</i>)	39.8 (14.6)	41.5 (12.9)

Note. * identifies the 6 patients included for the stratification. Facial Nerve Grading Scale 2.0 (FNGS 2.0) scores: 6 = total palsy; 5 = severe palsy; 4 = moderate-to-severe palsy. Sunnybrook (SB) scores: minimum possible = 0 or total palsy; maximum possible = 100% or normal. Speech and swallowing scores of the Facial Disability Index (FDI): below 25 = worst function; 100 = best function. D.P.O. = Days post-onset; MEPP = Mirror Effect Plus Protocol.

Table 3
Individual FNGS 2.0 Grades and Means at Each Assessment Time in Both Groups

	FNGS 2.0 grade		
	10–14 D.P.O.	1 M.P.O.	2 M.P.O.
MEPP group			
Participant 1*	5	3	2
Participant 4	4	3	2
Participant 5	6	6	5.3
Participant 9*	5	2	1.6
Participant 10*	5	2.3	2
<i>M (SD)</i>	5 (0.7)	3.2 (1.5)	2.5 (1.5)
Control group			
Participant 2*	5	5	4.6
Participant 3	4	2.6	2.6
Participant 6	4	3	2.3
Participant 7*	5	3	2
Participant 8*	5	3	2.3
<i>M (SD)</i>	4.6 (0.5)	3.3 (0.9)	2.7 (1.5)

Note. * identifies the 6 patients included for the stratification. The reported FNGS 2.0 are a mean of 3 blind assessors. Scores in bold represent those who achieved recovery. Facial Nerve Grading Scale 2.0 (FNGS 2.0) scores: 6 = total palsy; 5 = severe palsy; 4 = moderate-to-severe palsy; 3 = moderate; 2 = mild; 1 = normal function. D.P.O. = Days post-onset; MEPP = Mirror Effect Plus Protocol; M.P.O. = Months post-onset.

Table 4
Individual SB Grades and Means at Each Assessment Time in Both Groups

	SB grade		
	10–14 D.P.O.	1 M.P.O.	2 M.P.O.
MEPP group			
Participant 1*	21	59.3	92.6
Participant 4	28	57.3	80
Participant 5	7	4	9
Participant 9*	24	88.3	91.3
Participant 10*	22	66.6	85
<i>M (SD)</i>	20 (7.9)	55 (31.1)	71 (35.3)
Control group			
Participant 2*	22.6	30	34
Participant 3	38	66.6	66.6
Participant 6	30.6	75	82.3
Participant 7*	25	61	87
Participant 8*	19	59.6	80
<i>M (SD)</i>	27 (7.4)	58 (17)	69 (21.5)

Note. * identifies the 6 patients included for the stratification. The reported SB mean grades are a mean of 3 blind assessors. Scores in bold represent those who achieved recovery. Sunnybrook (SB) scores: minimum possible = 0 or total palsy; maximum possible = 100% or normal. D.P.O. = Days post-onset; MEPP = Mirror Effect Plus Protocol; M.P.O. = Months post-onset.

Table 5**Individual Scores and Means for Speech and Swallowing of the Facial Disability Index at Initial and Final Assessments in Both Groups**

	Speech and swallowing scores of the Facial Disability Index	
	10–14 D.P.O.	2 M.P.O.
MEPP group		
Participant 1*	57.5	100.0
Participant 4	33.3	100.0
Participant 5	41.6	50.0
Participant 9*	50.0	100.0
Participant 10*	25.0	83.0
<i>M (SD)</i>	41.5 (12.9)	86.6 (21.7)
Control group		
Participant 2*	57.5	57.5
Participant 3	25.0	75.0
Participant 6	41.6	91.0
Participant 7*	50.0	100.0
Participant 8*	25.0	83.0
<i>M (SD)</i>	39.8 (14.6)	81.3 (16.2)

Note. * identifies the 6 patients included for the stratification. Scores in bold represent those who indicated having perfect function. Speech and swallowing scores of the Facial Disability Index scores: below 25 = worst function; 100 = best function. D.P.O. = Days post-onset; MEPP = Mirror Effect Plus Protocol; M.P.O. = Months post-onset.

or swallowing, and thus obtained the best possible score (100%). Only one patient in the control group indicated that they had no difficulties with speech or swallowing.

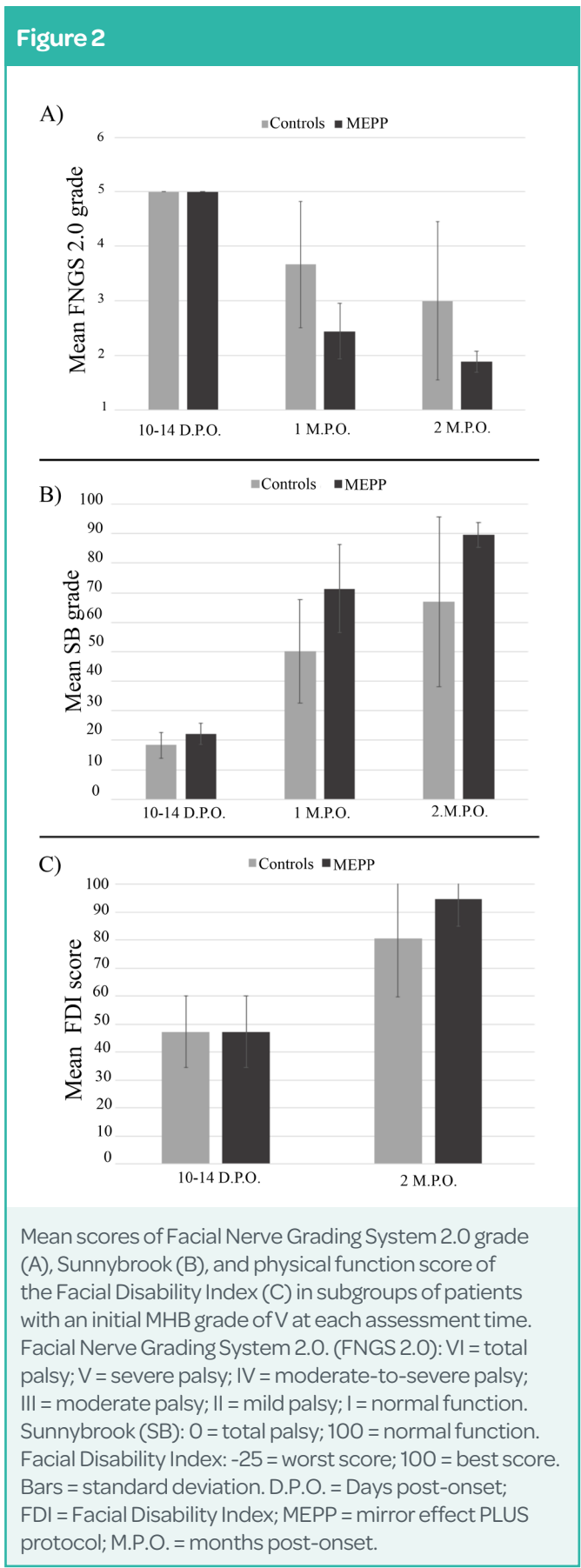
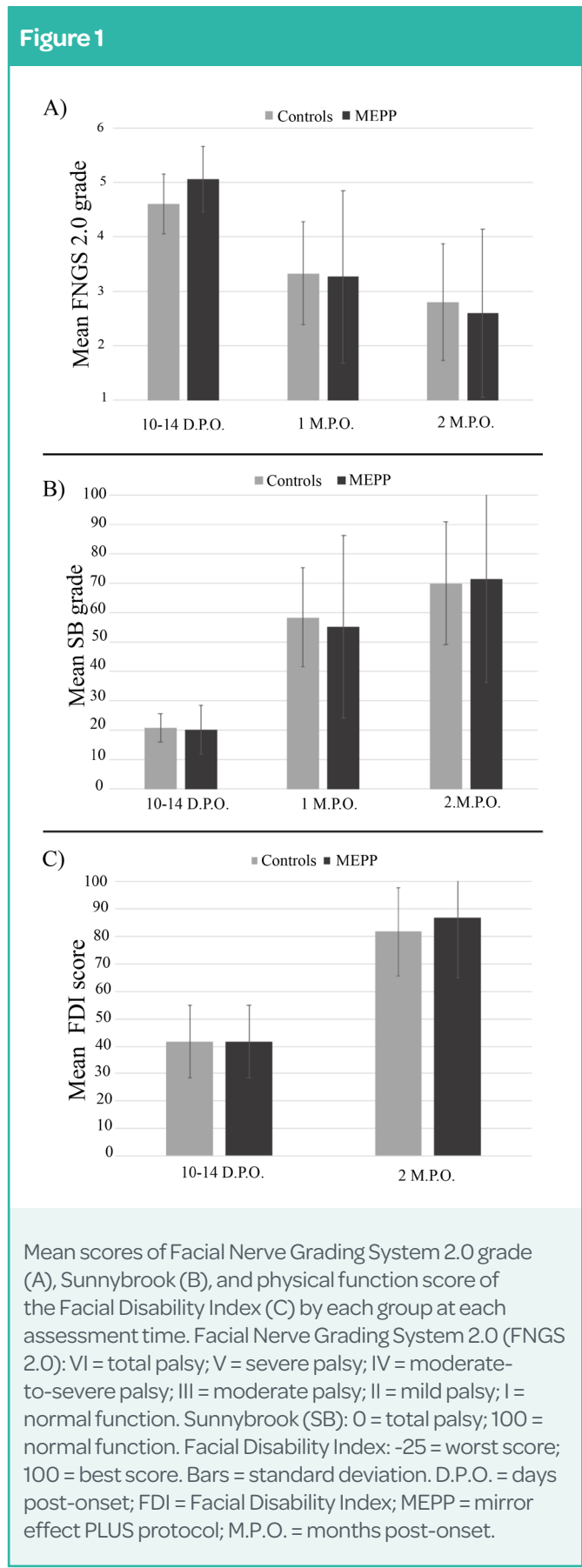
Figure 1 presents the mean FNGS 2.0 grades and SB scores obtained by each group at each assessment time, as well as the physical function score of the Facial Disability Index at the initial assessment and 2 months post-onset. There was no significant effect of MEPP treatment on the primary and secondary outcomes for the entire study sample.

As mentioned in the Method, we used a post-hoc stratification procedure, based on the work of Nicastrì et al. (2013). Three patients in each group presented with FNGS 2.0 grades of 5 at the first assessment, which constituted two-thirds of our sample. We quantified the treatment effect size on those six patients using a Cohen's *d* measure on the difference between the 2 months post-onset scores and the initial scores. Although our groups were small, the effect size for FNGS 2.0 ($d = 0.81$), SB ($d = 1.29$), and the physical function score of the Facial Disability Index ($d = 0.82$) exceeded Cohen's convention for a large effect ($d =$

0.80). **Figure 2** presents the mean FNGS 2.0 grades and SB scores obtained by each subgroup at each assessment time, as well as the physical function score of the Facial Disability Index at the initial assessment and 2 months post-onset. On the FNGS 2.0 scale, the results indicate that individuals in the MEPP group recovered to a greater extent ($M = 3.1$, $SD = 0.2$) than patients in the control group ($M = 2.0$, $SD = 1.4$). Similarly, for the SB scores, the MEPP group underwent greater changes between the 2 months post-onset assessments and the initial assessments ($M = 71.6$, $SD = 4.3$) than did the control group ($M = 44.8$, $SD = 29.0$). Patients in the MEPP group also reported greater changes in their speech and swallowing abilities between the 2 months post-onset assessments and the initial assessments ($M = 47.2$, $SD = 4.8$) than the control group ($M = 33.3$, $SD = 28.9$) on the physical function score of the Facial Disability Index.

Discussion

Here we described a detailed intervention protocol adapted for acute moderate-to-severe, severe, and total BP, called the MEPP. Although facial rehabilitation for chronic BP has been a research topic for more than 40 years, this is



the first protocol specifically designed for the rehabilitation of acute BP. The MEPP was developed based on some principles of two other facial rehabilitation protocols (i.e., the Neuromuscular Retraining and the Mirror Effect Protocol) that were designed for chronic facial palsies (Blanchin et al., 2013; Garmi et al., 2013; Martineau et al., 2018; Teixeira, Valbuza, & Prado, 2011) as well as relevant motor learning principles that accounted for the characteristics of the facial muscles in acute BP. We also provided a detailed description of the clinical parameters of this new rehabilitation for a clear clinical overview and to make the protocol easy to replicate (see Appendix). This pilot study showed that, when comparing homogeneous groups, the MEPP improves and accelerates the patient's recovery from acute and severe BP. This is a promising start for establishing the potential efficiency of the MEPP.

In order to compare our results with previous studies, our primary outcome measures were the improvement in recovery, as measured using the FNGS 2.0 and SB scales at three different assessment times. The results from the FNGS 2.0 scale showed that more patients in the MEPP group had recovered at the final assessment, compared to the patients in the control group. As for the SB scale, at 2 months post-onset, the same number of patients reached the recovery criterion in the two groups, but the scores were higher (i.e., better recovery) in the MEPP group. Taken together, these results suggest that the MEPP may improve the recovery from acute BP. However, the functional impacts on speech and swallowing are not covered by these grading systems (Marsk, Hammarstedt-Nordenvall, Engstrom, Jonsson, & Hultcrantz, 2013), which provides an incomplete picture of the effect of our facial rehabilitation (Gyori et al., 2018). Therefore, the physical function questionnaire of the Facial Disability Index on speech and swallowing was included as a secondary outcome. The number of participants who indicated being 100% satisfied with their speech and swallowing was higher in the MEPP group than in the control group. This suggests that the MEPP could not only be effective in reducing the severity of the facial palsy, but could also improve speech and swallowing functions. Also, the results of the present pilot study support the idea that future studies that measure the impact of facial rehabilitation on BP symptoms must also include measures of functional impairments (Moverare, Lohmander, Hultcrantz, & Sjogreen, 2017).

Strict inclusion criteria were established for this study, particularly with regard to the severity of BP, the medication given, and the time post-onset. This procedure helped us to control for the high number of spontaneous recoveries encountered in BP (Fujiwara, Hato, Gyo, &

Yanagihara, 2014; Mancini et al., 2014), but it also reduced the number of patients that could be included in the study and, consequently, affected our statistical power and generalization capacity. The strict inclusion criteria were meant to control for patient variability. Furthermore, we applied a stratification strategy, as did Nicastrì et al. (2013), that allowed us to consider even more homogeneous groups (e.g., only patients with initial FNGS grades of 5). The results following that procedure showed greater changes in the MEPP group on both scales at 1 and 2 months post-onset, suggesting that the MEPP reduced the severity of the facial palsy and accelerated the patient's recovery from severe BP, which is a promising start for establishing the potential efficacy of the MEPP.

However, our results still displayed high standard deviations. It is generally accepted that severe BP has a poor prognosis (Prud'hon & Kubis, 2018), but the variation of recovery within this group remains unclear because the exact pathogenesis of the disease has not yet been elucidated (Bucak et al., 2014). Our results also highlight the fact that, as the exact mechanisms of BP recovery are largely unknown, larger samples must be recruited for studies that evaluate therapeutic strategies in order to compensate for the unexplained variability in recovery.

One of the central tenets of the MEPP is that it is based on modified visual feedback, or mirror feedback, as originally described by Ramachandran and Altschuler (2009). There are two main reasons why this feature is of great importance during facial rehabilitation for acute BP. First, the visual mirror biofeedback is a concrete application of motor learning principles, even if this was not originally (explicitly) mentioned in the Mirror Effect Protocol literature. The visual mirror biofeedback is an example of using and controlling a sensory stimulus to sustain motor (re)learning. This reflects bottom-up processing, which is the basis of all motor rehabilitation (Shumway-Cook & Woolacott, 2017).

Recently, studies on motor learning principles have precisely identified action observation as a form of motor learning reinforcement and motor imagery as another form. A large body of research supports the use of these two means in motor rehabilitation to improve motor skills (e.g., Berends, Wolkorte, Ijzerman, & van Putten, 2013; Eaves et al., 2016; Vogt et al., 2013; Wright et al., 2014). Action observation involves the observation of the movement, whereas motor imagery involves a mental practice that involves the internal visual and kinesthetic representations of the movement (Eaves et al., 2016). When applied together, action observation and motor imagery are thought to enhance motor learning by activating a neural

signature that resembles that of motor execution (Vogt et al., 2013). For example, Wright et al. (2014) reported that single-pulse transcranial magnetic stimulation of the cortical representation of the hand produced greater motor-evoked potentials when stimulation was given during combined action observation and motor imagery than during action observation alone. These results suggest that simultaneously applying action observation and motor imagery facilitates corticospinal excitability.

When this idea is applied to the field of facial re-education, it suggests that visual and kinesthetic inputs, along with instructions that promote concrete mental representations of movements (motor imagery), should be used during facial exercises to enhance motor learning and to compensate for altered facial motor execution. These principles were therefore included in the MEPP with the use of a mirror-effect visual display, which allows action observation. Moreover, motor imagery sessions and the type of instructions provided for facial exercises (i.e., "... concentrate on muscular contractions and try to visualize the movement, even though the face doesn't move") were chosen to facilitate motor execution. Also, based on the available evidence, there is no indication that the MEPP could be deleterious if used to rehabilitate patients with chronic BP.

Second, as mentioned previously, the early cortical modifications that follow BP demonstrate a change in sensorimotor areas, which is thought to be caused by discrepancies between the preserved motor commands and impaired sensory feedback that prevail in the cortex after BP (Song et al., 2017). Indeed, a recent neuroimaging study of acute BP revealed decreased functional connectivity in the secondary somatosensory cortex, insula, thalamus, and cerebellum between 2 and 5 days post-onset (Klingner et al., 2014). Because the MEPP uses modified visual biofeedback during facial exercises, we hypothesize that it could correct these early discrepancies, thus helping to maintain normal functional connectivity and sustain recovery in a bottom-up manner (Blanchin et al., 2013; Garmi et al., 2013). Although we did not collect imaging data in this pilot study, it would be interesting to investigate the neurobiological mechanisms of the MEPP using functional neuroimaging.

The results presented here are limited to 10 patients, and a subset of six patients after stratification, which prevents generalization and does not allow us to distinguish our results from spontaneous recovery. Larger samples will help control for patient variability during the evolution of BP and to draw clearer conclusions regarding the effect of early facial rehabilitation. Moreover, our randomized

allocation to the experimental and control groups led to a sex imbalance. To our knowledge, two studies have tested the influence of sex on BP. First, Hsieh, Wu, Wang, and Lee (2009) investigated the factors that correlate with the degree of nerve involvement in early BP and the factors that predict the evolution of the disease. Using a group of 563 patients, no sex effect was found. This finding was confirmed by Fujiwara et al. (2014) who reported that the disease prognosis was not influenced by sex. Therefore, it is unlikely that the sex imbalance in the present study could affect our results.

In future studies, it will be important to assess the progression of patients with a longer follow-up (6 months to 1 year post-onset) in order to determine the stability of the therapeutic effect and its impact on preventing the development of synkinesis (involuntary movements during volitional facial movements), which normally appear 3 to 4 months post-onset (Nicastri et al., 2013). Because recovery was defined by an FNGS 2.0 grade of 2 or less (as in Nicastri et al., 2013) and an SB score of 60 or more, recovery occurred at different times. Therefore, the therapy length differed between patients. It will be important to assess the length of therapy as a potential confounding variable in a larger study that includes more patients in order to measure how this variable influences the stability of recovery during the longitudinal follow-up. The results from these patients serve as a starting point for investigating the efficacy of the MEPP.

Conclusion

The MEPP is the first standardized re-education protocol specifically designed for acute moderate-to-severe, severe, and total BP. Our preliminary results support the hypothesis that the MEPP is effective in enhancing patients' recovery from acute severe BP. This study also highlights the need for the recruitment of a larger population and longer follow-up times as well as better computing tools in order to obtain a more complete understanding of the effects of the treatment.

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Disclosures

No conflict of interest, financial or otherwise, are declared by the authors.

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Appendix

Clinical Structure of the MEPP

Session 1 (75 min approximately)	
Objective 1: Teaching on facial muscles and massages (45 min)	
Means	<ul style="list-style-type: none"> • Use any facial muscles schema that details the facial muscles and their innervation with the facial nerve. Begin with education on anatomy and function of each muscle region. • Demonstration and practice of facial massages following the schema: <ul style="list-style-type: none"> » For each muscular region (forehead, eyes, cheeks, nose, mouth, neck) follow muscle fibers orientation and retain the muscle at its anchor point. Apply a considerable pressure, so that discomfort can be felt (but won't last after massage is done). » Apply a considerable pressure. A discomfort could be felt (but won't last after massage is done).
Objective 2: Teaching of Motor Imagery Sessions Developing the ability to lightly and specifically move on muscle region at a time. (30 min)	
Means	<ul style="list-style-type: none"> • Relax the face, close the eyes and concentrate. • Every day until the next appointment, realize 10 minutes of motor imagery as follows: <ul style="list-style-type: none"> » Imagine doing ample complete and symmetrical movements of the face. Activate lightly and selectively each different muscle region. Refer to the schema if needed. » Repeat 5 times each with a 5 second pause between each visualization: Lift the eyebrows, Frown the eyebrows, Close the eyes, Open the eyes, Wrinkle your nostrils, Smile with closed mouth, Give a kiss, Stretch the lower lip downwards.

Session 2 (60 min approximately)	
Objective 1: Return on the massages (15 min)	
Means	<ul style="list-style-type: none"> • Execution of the massages by the patient. Corrections/Troubleshooting if needed
Objective 2: Teaching the exercises on the website (45 min)	
Means	<ul style="list-style-type: none"> • Instructions: <ul style="list-style-type: none"> » The healthy side is the reflected side. Stabilize your head with your hand or any other support. The exercises should be done slowly 5 times each, with a 5 second pause between each. While doing the exercises, concentrate on the specific facial movements and try to feel them even though the face doesn't move. Don't force! The other parts of your face should be relaxed. During the exercise, if you feel any movement, you have to touch your paralysed side with your thumb and index finger. Your fingers should follow the ongoing movement for more kinesthetic input. Everyday, mix the order of the exercises given, in a random way. • Exercises: <ul style="list-style-type: none"> » Think about something surprising and rise gently the eyebrows; Think about something frustrating and gently frown the eyebrows; Close and open the eyes very slowly while feeling progressively the opening and closing on the eyelid; Think about something disgusting and wrinkle your nose gently and briefly; Think about something funny. Smile with the mouth closed; Think about something funny and smile with open mouth. (The index finger and the thumb should follow the movement on the cheeks); Think about someone you love and send him/her a kiss; Think about something disgusting and make an inverted smile.

Session 3 (60 min approximately)	
Objective 1: Return on the exercises with the website (45 min)	
Means	<ul style="list-style-type: none"> Invite the patient to do his exercise session in front of you. Make any necessary correction on speed, precision, and use of sensitive biofeedback. Decrease verbal instructions to promote motor learning. When improvement occurs, progressively modify the exercises in order to treat only the remaining impairments.
Objective 2: Counselling regarding specific problems (15 min)	
Means	<ul style="list-style-type: none"> Invite the patient to ask any questions about how to do his/her exercises or how to manage its difficulties regarding eating, drinking, and speaking.

Session 4 (45 min)	
<ul style="list-style-type: none"> Idem as session 3 but with less verbal instructions during exercises, to promote motor learning. 	

Extra material (30 min)	
<ul style="list-style-type: none"> Procedure to inhibit synkinesis (approximately around 3-5 months post-onset): Relax face. Do the target movement till the synkinesis is felt. Then relax the synkinesis while holding the target movement. OR Do the target movement with reduced amplitude and hold it just before the synkinesis starts. <ul style="list-style-type: none"> * If synkinesis are still present at 6 months post-onset, management in the chronic phase should be considered. 	