Response to Letter by Page and Chae

Response:
We would challenge the view of Professors Page and Chae that our study is seriously flawed. The study is a pragmatic clinical trial to answer a clinically relevant question—does surface neuromuscular electrical stimulation (sNMES) applied to the shoulder within 10 days of stroke improve upper limb function?1 Features of the study include a placebo-control blinded-outcome assessment and measurement of carryover effect. The study has adequate statistical power.

During rehabilitation, stroke patients wish to regain useful upper limb function. As Page and Chae rightly point out, sNMES has been shown to improve glenohumeral subluxation and range of movement but it should not be assumed that this translates into sustained functional benefits or important clinical gain.2-4

Because our research question related to upper limb function, it was appropriate to use the Action Research Arm Test, which is a validated measure of arm function, as the primary outcome measure. Page and Chae wrongly state that we used the Frenchay Activities Index as a secondary outcome measure.

We do not accept that there is a mismatch between the intervention and our outcome measures. In our study, sNMES was applied to the shoulder because there are sound scientific reasons to study the effect of this intervention on distal as well as proximal upper limb recovery: recovery of proximal function precedes distal upper limb recovery,5 and therefore an effective intervention applied at the shoulder could have effects on the rate of whole arm recovery without being applied to other muscle groups. The ARAT has 4 subsections and allows, albeit crudely, measurement of both proximal and distal recovery.

We do not find our choice of sNMES regimen perplexing. Recent evidence suggests that subsensory cyclical sNMES has the potential to modify cortical plasticity6 and facilitate recovery of arm function.7 We decided to focus on a simple cyclical sNMES protocol as early evidence,8,9 and a theoretical analysis suggested that such a protocol may be of benefit to patients.

The clinically relevant outcome is the longer term effects of treatment—hence our outcomes at 1 and 3 months. We would suggest that recording treatment effects at a point of maximum intensity is likely to overestimate the utility of an intervention and be clinically misleading.

Although there were no significant differences in total ARAT score between intervention and control groups at 1 and 3 months, differences in favor of the control group were seen in the grasp (reaching) and gross (shoulder movement) subsections at 3 months. These subsections involve predominantly proximal rather than distal movement and are those most likely to have been influenced by the intervention.

We did not ignore the importance of careful patient selection—176 participants were recruited from 1226 patients admitted with acute stroke. Our study was more pragmatic than many previous studies and selected patients on the basis of any upper limb impairment. Although there is evidence that electrical stimulation is beneficial in improving joint alignment and reducing spasticity,2,3 these were not measured in our study. There is often confusion when trying to define subluxation,10 and its measurement is unreliable and of dubious clinical significance.4 There is also no validated measure of spasticity about the shoulder joint.11

Like Page and Chae, we were surprised by the possible negative effect of sNMES for more severely impaired participants and can only speculate on the mechanism. There is a growing body of evidence to suggest cyclical electrical stimulation protocols have the potential to influence cortical plasticity. Although it may appear that sNMES has benefits for subluxation and range of movement by direct action on the shoulder musculature, it may not be a useful influence on plasticity through sensory feedback.

We acknowledged that other clinical confounding factors could influence the subgroup analysis. Differences in favor of the control group were found at 3 but not at 1 month, which does not fit with a simple model of causality but would be consistent with sNMES influencing cortical plasticity. We also considered an effect through learned disuse attributable to patient protection of the stimulated arm. Whatever the explanation, it would be wrong of us not to report a potential negative effect of an intervention in clinical use and with a very limited evidence base.

Although Page and Chae may be surprised and disappointed by the findings, we do agree—and have put clearly in our conclusion—that sNMES can still be used as an intervention in selected patients under specialist supervision. Our study, however, suggests that sNMES to the shoulder should not be assumed to be a treatment without risks which can be applied to any stroke patient in the acute phase.

Disclosures
None.

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