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Surface electrical stimulation for facial paralysis is not harmful

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Abstract

Introduction: Does electrical stimulation (ES) of denervated muscles delay or prevent reinnervation, or increase synkinesis? In this retrospective study we evaluate the outcome, with and without ES, of patients with acutely denervated facial muscles.

Methods: The effect of ES was analyzed in two experiments. In the first experiment, 39 patients (6 with home-based ES, median 17.5 months) underwent facial nerve reconstruction surgery. Time to recovery of volitional movements was analyzed. The second experiment involved 13 patients (7 with ES, median 19 months) during spontaneous reinnervation. Sunnybrook and eFACE scores provided functional outcome measures.

Results: No difference in time of reinnervation after facial nerve reconstruction surgery was seen between the patients with and without ES (median [interquartile range]: 4.5 [3.0-5.25] vs 5.7 [3.5-9.5] months; P = .2). After spontaneous reinnervation, less synkinesis was noted (Sunnybrook synkinesis score: 3.0 [2.0–3.0] vs 5.5 [4.75-7.0]; P = .02) with ES.

Discussion: We find no evidence that ES prevents or delays reinnervation or increases synkinesis in facial paralysis.

KEYWORDS

denervated muscle, electrostimulation, EMG, facial paralysis, reinnervation, synkinesis

1 | INTRODUCTION

Peripheral facial nerve paralysis is due to complete disruption of all motor axons innervating the facial muscles. Even when reinnervation occurs, it tends to result in a combination of muscle atrophy and aberrant reinnervation. This may have severe aesthetic, functional, and social consequences.[1] The use of electrical stimulation (ES) to reduce these symptoms has shown promising results. In 1999, using surface ES in patients with moderate to severe chronic facial palsy, Gittins et al showed an improvement in the range of voluntary eyelid movement; facial muscle tone improved subjectively and the need for artificial tears was reduced.[2]

In cases of denervated limb muscles, ES can increase mass and tetanic contractility, and provides an important cosmetic benefit for patients.[3] Home-based ES increased the volume of the stimulated muscle and normalized the composition of the quadriceps muscle in humans with lower motor neuron damage.[4,5] However, no such evidence is available concerning facial muscles. Furthermore, there are anecdotal potential negative effects of ES in terms of increased aberrant reinnervation and synkinesis. In a recent meta-analysis, the few studies published on ES for the treatment of facial palsy in humans were unable to reveal sound evidence for its potential benefits, even though some of the studies showed positive effects.[6]

Abbreviations: EMG, electromyography; ES, electrical stimulation; HFJA, hypoglossal-facial-jump anastomosis; ICC, intraclass correlation; IQR, interquartile range; NLF, nasolabial fold.

Several studies have shown that ES promotes peripheral nerve regeneration in animals[7-15] as well as in humans.[16] One animal study with low-frequency ES showed reduced synkinesis.[17] Some animal studies showed negative effects on reinnervation. Sinis et al showed, in rats with denervated facial muscles, that repetitive, sub–motor threshold ES of the intramuscular axons over a period of 2 months reduced endplate reinnervation and failed to improve the quality of muscle innervation.[18] A recent animal study suggested negative effects of ES as well. Denervated tibialis anterior muscles of rats were analyzed for changes in biochemical muscle markers such as muscle trophism markers, neuromuscular junctions, and receptors under ES for 6 or 14 days. Biochemical and histological analyses of muscle biopsies of the stimulated muscles showed that there was an increase in atrophy and that neuromuscular recovery was impaired by ES, although this was in the setting of repeated anesthesia and overall loss of body mass.[19]

We have used ES for several years in selected patients with facial palsy during the phase of spontaneous reinnervation or after facial nerve reconstruction surgery. The first aim of the present study was to evaluate whether ES for facial palsy after facial nerve reconstruction affects the timing or likelihood of reinnervation. The second aim was to test the hypothesis that there is a correlation between ES and the risk of developing aberrant reinnervation in a patient group showing spontaneous recovery (without reconstructive surgery).

2 | METHODS

After institutional ethics approval, retrospective data of patients with facial palsy were analyzed. All adult patients treated between 2005 and 2019 with denervation of the facial muscles of one side of the face, confirmed by the lack of voluntary electromyographic (EMG) activity, were screened to build a database.

2.1 | Experiment 1: Effect of ES after facial nerve reconstruction surgery

In experiment 1 we aimed to analyze a group of patients that was as homogeneous and comparable as possible. For analysis of reinnervation, only patients undergoing a hypoglossal-facial-jump anastomosis (HFJA) in the last 12 years were selected. HFJA is a surgical procedure to reinnervate the facial muscles by means of nerve bypass, grafting axons from a minor part of the hypoglossal nerve.[20] All HFJA surgical procedures were performed by the same surgeon (O.G.L.). After HFJA, all patients had follow-up visits every 3 months. Time until onset of reinnervation and the degree of reinnervation were compared between the ES and control groups. All patients who underwent HFJA in recent years were offered surface ES unless there were contraindications. Thus, the main criterion determining whether a patient was in the ES or in the control group was the time of HFJA. Data from six ES patients with sufficient follow-up were included.

While waiting for reinnervation, ES aimed to elicit contraction of the facial muscles and was delivered to the middle and lower portions of the affected side using external stimulators that generate biphasic triangular impulses, namely Paresestim (Krauth + Timmermann, Hamburg, Germany), PierenStimParese (Schwa-Medico, Ehringshausen, Germany), or Stimulette r2x (Dr. Schufried, Vienna, Austria). Each patient used only one device for the entire period of training. Detailed instructions were given to the patients to place two self-adhesive surface electrodes (40 × 60-mm Flextrode Plus; Krauth + Timmermann) over the facial muscles to be trained. They practiced positioning the electrodes in the hospital with the help of a mirror. Pictures were taken of the patients with correct placement of the electrodes. Figure S1 (online) shows typical placement of the electrodes. Each patient was given instruction on the function of their take-home device and on how to adjust the duration and amplitude of the pulses to achieve a visible muscle contraction. The impulse frequency was kept constant with an inter-impulse gap of 1000 milliseconds for the Paresestim. The PierenStimParese had a phase duration of 300 milliseconds and an inter-impulse gap of 3000 milliseconds. For the Stimulette r2x, an inter-impulse gap of the same length as the phase duration was used. The amplitude and the phase duration were set individually for each patient based on visual inspection of the contraction of the zygomaticus muscle, depressor anguli oris muscle, and depressor labii muscle. The average phase duration for the Paresestim was 110 (range 100-500) milliseconds. The average amplitude using the Paresestim and the PierenStimParese devices was 14 (range 5-27) milliamps. The average amplitude with the Stimulette r2x was 18 (range 12-22) milliamps. The patients were advised to perform the home training twice per day for 10 minutes, 5 days per week. Participants recorded deviations from the protocol and reported them at the next follow-up visit. It was recommended not to stimulate more than 10 minutes at a time to avoid fatigue of the muscles. The patients in the ES group were instructed to stop the ES and inform the principal investigator if severe fatigue of the stimulated muscle occurred (ie, loss of visible movement as the session progressed). At each visit, the parameters for the stimulation were checked with the patients and changes during their home-training were documented.

Reinnervation was confirmed by recruitment of voluntary motor unit potentials on needle EMG or later with stronger innervation by the presence of visible volitional movements. Needle EMG was performed on the zygomaticus major, orbicularis oculi, orbicularis oris, and frontalis muscles. The grading system described by Volk et al for laryngeal EMGs was used.[21] Reinnervation was defined as a single motor unit action potential in at least one muscle based on EMG. If there were single-fiber patterns in additional muscles or other reinnervation activity in the subsequent EMG, the first EMG was taken as the time of reinnervation.

2.2 | Experiment 2: Effect of ES under spontaneous facial nerve regeneration

Experiment 2 aimed to evaluate differences in long-term functional outcome with and without ES. Outcomes were quantified using Sunnybrook[22,23] and eFACE[24] scores. Only patients without reconstructive facial nerve surgery and a follow-up of at least 1 year after

reinnervation were included. This decision was made because adequate time after reinnervation is needed to identify stable muscle innervation resulting in sufficient muscle activity to quantify synkinesis. Reinnervation grade was evaluated by needle EMG. The ES group performed ES at an average amplitude of 14 (range 6-20) milliamps and an average pulse duration of 110 (range 100-280) milliamps. The devices used for ES were the Paresestim and the Stimulette r2x. The average amplitude for the patient with the Stimulette r2x was 20 milliamps. Parameters of ES with the Paresestim and the stimulation protocol were set as described in the first experiment.

To minimize detection bias, the data were rated by two independent raters: one having no knowledge about the study design and one involved in the study. Photographs used for evaluating the scores were taken by a professional photographer following a standardized protocol, originally developed for facial palsy video evaluation.[25,26] Nine to 12 different standardized facial movements were performed or attempted by the patients for the photographs. The last available picture set of the patients was used for Sunnybrook and eFACE scoring. In both groups, the photograph sets were taken between 1 and 3 years after first signs of reinnervation.

The resting symmetry section in the eFACE score evaluates the height of the brow, the palpebral fissure, the depth and orientation of the nasolabial fold (the fold of the skin between nose and lip, NLF) and the height of the oral commissure. These are all visual landmarks of the human face and therefore indirect markers for muscle tone. In the dynamic section brow movement, full and gentle eye closure, NLF depth, and orientation and oral commissure movement while smiling were measured. The original eFACE score only uses the expression causing the worst synkinesis in each region. The synkinesis section was modified to evaluate synkinesis more accurately: Each movement from the dynamic score of the eFACE was used to evaluate the specific synkinesis in each region. Ocular synkinesis was evaluated in smiling, brow elevation, and when vocalizing the syllable "ee." Midfacial synkinesis was evaluated in brow elevation and gentle and full eye closure. Mental and platysmal synkinesis were evaluated in brow elevation, during gentle and full eye closure, while smiling, and when vocalizing the syllable "ee." These extended scoring systems were aimed at increasing the sensitivity of the eFACE to grade aberrant reinnervation in pictures of the patients. The total eFACE score is defined as the average difference from 100 over all items. In our results, the total eFACE score is not used because it does not differentiate between denervated, hypotrophic, and aberrant reinnervated, hypertrophic muscles. The Sunnybrook score was evaluated as the total Sunnybrook score and the component subscales, namely resting symmetry, movement, and synkinesis.

2.3 | Statistics

In the first experiment, the Kaplan–Meier method was applied to compare the time until reinnervation between the two groups. The Mann–Whitney *U* test was used to measure the difference in time until reinnervation between both groups because the data were not normally distributed.

For evaluation of group differences in the second experiment, the results of both scores were analyzed using the Mann–Whitney *U* test because the data were not normally distributed. For the eFACE score in resting symmetry and movement, the differences from 100 (being the value of a healthy face) were also compared, whether positive or negative, with the Mann–Whitney *U* test, to demonstrate whether one group is significantly closer to normal than the other group. Testing of the absolute values was done to evaluate whether there was a significant difference in the muscle tone of the resting face or a significant hypermobility or hypomobility in the dynamic score. For synkinesis, this was not relevant because the score ends at 100 (healthy face). For both scores, the intraclass correlation (ICC) between the two raters was measured.[27]

The level for significance was set at 5% for both experiments. Due to non-normal distribution of data, median and interquartile range (IQR, 25th-75th percentile) are reported for the group differences in both experiments.

3 | RESULTS

3.1 | Experiment 1: Effect of ES after facial nerve reconstruction surgery

In the first experiment, 6 patients (3 women) received ES and 33 patients (16 women) had no ES. Facial paralysis was caused by surgical removal of benign tumor (n = 5) or malignant tumor (n = 1) in patients with ES. Age ranged from 18 to 68 (median 57, IQR 45-66) years. The patients without ES (range 26-72, median 46, IQR 33-61.25) years developed facial paralysis due to surgical removal of benign tumor (n = 19), malignant tumor (n = 10), infection (n = 1), idiopathic (n = 1), birth trauma (n = 1), or traumatic injury (n = 1). Primary reconstruction of the facial nerve was only performed when the surgeon was certain to have caused complete facial nerve discontinuity. In most cases, no immediate surgical nerve reconstruction was performed, but a conservative observation strategy was started. All patients underwent HFJA between 10 months and 7.4 years after the onset of the paralysis when no spontaneous recovery was observed during this observation period.

All patients with ES regularly completed the home training without reporting any adverse events. The ES training started between 7 and 91 (median 10, IQR 7-48.25) days after HFJA and between 13 months and 7 years after the onset of the paralysis. The ES home training was performed for a median duration of 17.5 (IQR 13.75-23) months after HFJA surgery (range 10-29 months).

The rate of functional reinnervation was 100% with ES. Median reinnervation time was 4.5 (range 3.2-6.5) months after HFJA surgery. The reinnervation rate was 91% without ES. Three patients without ES were not successfully reinnervated during the follow-up period of at least 1 year after HFJA. The median reinnervation time in patients without ES was 5.7 (range 2.2-21.9) months (Figure 1). The slightly earlier reinnervation with ES was not significant ($P = .2$; Table 1).

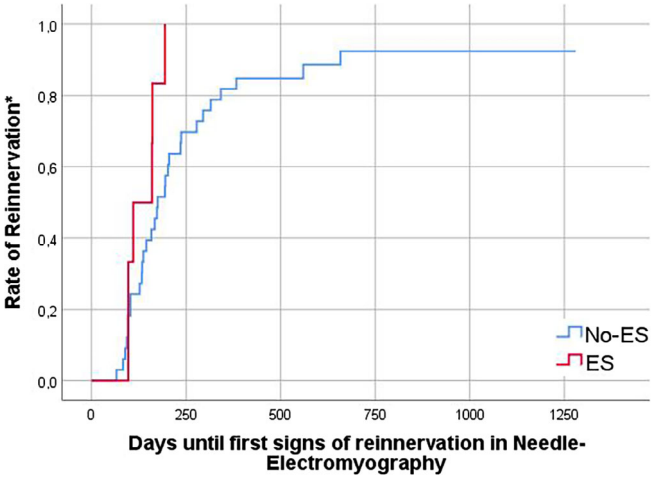

FIGURE 1 Time between hypoglossal-facial-jump anastomosis and first signs of reinnervation in 33 patients without ES vs 6 patients with ES therapy. All patients with ES were reinnervated, and 90.9% without ES were reinnervated (*rate of reinnervation = patients reinnervated / patients without reinnervation). Abbreviation: ES, electrical stimulation [Color figure can be viewed at wileyonlinelibrary.com]

3.2 | Experiment 2: Effect of ES under spontaneous facial nerve regeneration

In the second experiment, 13 patients (10 women) with facial palsy and aberrant reinnervation were analyzed. Seven (6 women) of 13 patients performed ES home training. ES started between 4.7 and 13.2 (median 8, IQR 7-11) months after palsy onset. The individual ES training was performed for a median of 19 (IQR 16-33, range 13-37) months. Six patients had no ES.

All patients with ES had completely denervated facial muscles at the beginning of their facial palsy. In the group without ES, four patients with complete denervation and two patients with severe but incomplete denervation of their facial muscles by needle EMG were enrolled to increase the size of the group. In these 13 patients, no surgical nerve reconstruction was performed, but a conservative wait-and-see strategy was started.

In the ES group, facial palsy was caused by surgical removal of a benign tumor (n = 7). Ages ranged from 35 to 68 (median 48, IQR 36–66) years. In the control group (38-70 years, median 57 years, IQR 42.5-68.5 years), facial palsy was caused by surgical removal of

TABLE 1 Experiment 1: Reinnervation time in patients with HFJA surgery with and without ES

	With ES		Without ES		
	Median (IQR)	Mean ± SD	Median (IQR)	Mean ± SD	*P* value
Time between onset of facial palsy and HFJA (months)	22.5 (13.5-76)	38.2 ± 33.3	12 (4-25.5)	24.3 ± 53.4	.08
Time between HFJA and first ES (days)	26.5 (7-48.3)	10 ± 33.3	—[a]	—[a]	—[a]
Time between HFJA and reinnervation (months)	4.5 (3.0-5.3)	4.5 ± 1.3	5.7 (3.5-9.5)	6.9 ± 8.6	.2

Abbreviations: ES, electrical stimulation; HFJA, hypoglossal-facial-jump anastomosis; IQR, interquartile range; SD, standard deviation.
[a]The second line has no *P* value and no values for the control group because they did not have ES therapy.

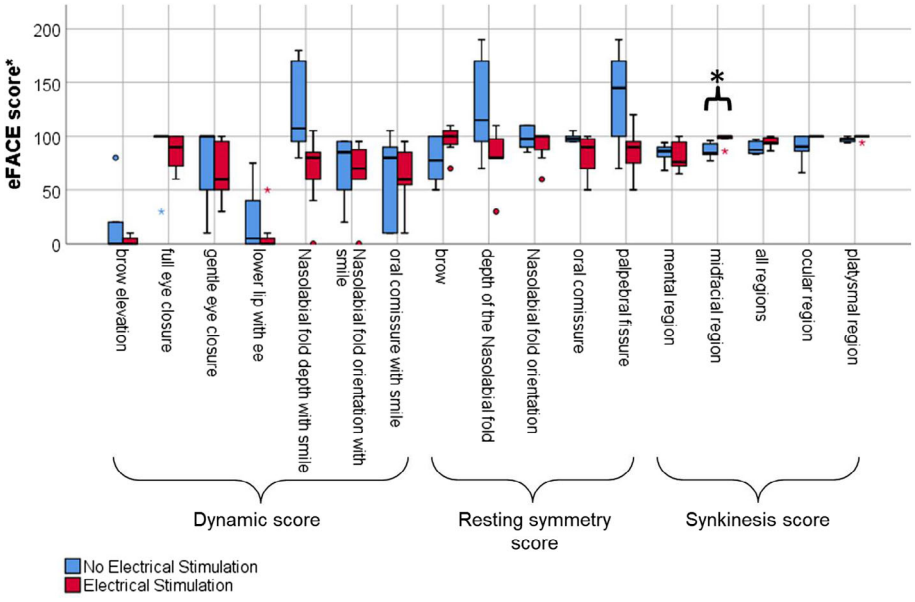

FIGURE 2 eFACE score. *eFACE score: the resting symmetry scores and the NLF depth and orientation in the dynamic score have values from 0 (low muscle tonus), to 100 (healthy face), to 200 (extremely high muscle tonus). The other scores range from 0 to 100 (100 = healthy face). Patients with electrical stimulation showed a significantly lower rate of midfacial synkinesis than patients without electrical stimulation (*P* = .01, black asterisks). Abbreviation: NLF, nasolabial fold [Color figure can be viewed at wileyonlinelibrary.com]

benign tumor (n = 2), was idiopathic (n = 2), or was due to infection (n = 2).

Using the Sunnybrook synkinesis score for grading, patients with ES had a significantly lower score for synkinesis than the control group (P = .02). The other subscales of the Sunnybrook score did not show significant differences between the two groups. The ICC for the Sunnybrook score between the two raters varied between 0.59 (synkinesis), 0.71 (total), 0.72 (movement), and 0.78 (resting symmetry), indicating good reliability.

All eFACE results are shown in Figure 2. These scores showed no significant differences in the resting symmetry section. For the dynamic score, there was a significant difference (P = .02) in NLF depth while smiling between the two groups: patients had a less deep NLF than a healthy face (by default 100). Patients without ES had a deeper NLF than a healthy face. The other six subsections in the dynamic score did not differ significantly. In the synkinesis section the original eFACE evaluation showed a significant difference in midfacial synkinesis: Patients with ES had a significantly lower rate of synkinesis than the patients without ES (P = .01). In the extended eFACE synkinesis evaluation there was a significantly lower rate of synkinesis in the midfacial region during full eye closure with ES than without ES (P = .02). With ES, synkinesis in the mental region in brow elevation was significantly lower compared with no ES (P = .01). When comparing the absolute differences from both groups to a healthy face for the eFACE score for movement and resting symmetry, no significant differences between ES and no ES were found. Table S1 (online) presents the Sunnybrook and eFACE results in detail.

The ICC was measured for each item of the eFACE score. For the resting symmetry section, ICCs varied from 0.29 to 0.84. In the dynamic section, ICCs varied from 0.26 to 0.99. ICCs varied from 0.23 to 0.77 for the original synkinesis section.

4 | DISCUSSION

There was no evidence of any negative effect of ES in terms of prevented or delayed reinnervation or increased aberrant reinnervation or synkinesis, neither after spontaneous facial nerve recovery nor after facial nerve reconstruction surgery. There also was no clear statistical evidence of improved or reduced facial symmetry and muscle response to physiological stimuli. This may be have been due to the lack of standardization of the stimulation protocols, which permitted interindividual differences in the stimulation parameters, training time, and electrode position.[28]

4.1 | Comparisons with published data

Prior studies, even ones with similar ES protocols, showed conflicting results. Pinhero-Darvis et al showed negative effects of ES on denervated tibialis anterior muscle in rats. ES was done only for 6 or 14 days daily at 20 Hz, and pulse duration of twice the measured chronaxie time, 3 seconds on and 6 seconds off, and stimulation was performed under daily repeated anesthesia. The stimulation parameters, the outcome measures and the duration of the stimulation were also different those in our study. Similar to our study, the ES amplitude was set at the level when contractions of the muscles were seen.

In another study, Zealear et al showed in denervated canine laryngeal muscles that low-frequency (10 Hz) ES reduced synkinetic reinnervation and paradoxical closure in the larynx.[17] The lower rate of synkinetic activity correlates with a lower rate of reinnervation in the stimulated muscle. ES was delivered via implanted electrodes for 90 days after denervation. In contrast, high-frequency ES (40 Hz) increased aberrant reinnervation. This long-term stimulation of a denervated muscle is comparable to that in our study. Similar to our results, the authors found that ES did not prevent reinnervation. ES as a tool to modulate reinnervation and promote selective reinnervation as postulated by Zealear et al is not supported by our results, but should be the focus of further research.

In terms of human studies, ours is based on modifications of the stimulation protocol used in the EU Project RISE for paraplegic patients, stimulating the quadriceps muscle 5 days per week.[3,4,29] In contrast to their study, our study patients only used one program for stimulation and did not vary between four programs of different duration and intensity of the pulses. Adjustments of the parameters of each patient in our study were based on the visible contraction of the muscles in the face. Unlike paraplegic patients, in whom sensory function was absent in the stimulated region, in our study sensory innervation through the trigeminal nerve was preserved. Nevertheless, ES strong enough to stimulate denervated muscle fibers was tolerated well in the face. Most commercially available stimulators for home use can only provide low-frequency stimulation for denervated muscle (less than 1 Hz); therefore, our stimulation parameters differed from those used in Project RISE. Higher frequencies are tolerable in the face and would be preferable to increase the training effects. Kern et al showed in computed tomography scans and histology of muscle biopsies that ES improved muscle mass and structure.[3] In our study, we have provided no quantitative outcome measures of muscle morphology.

In a randomized, controlled trial, Tuncay et al reported positive effects in patients with Bell palsy and repetitive ES during the time of spontaneous recovery.[30] The treatment group received ES beginning in the fourth week of acute palsy for 3 weeks with monophasic pulses of 100 milliseconds, a pulse interval of 300 milliseconds, at a rate of 2.5 Hz, until muscle contraction was visible. After 3 months, the House-Brackmann grade was better in the ES group than in the control group. Although needle EMG examination to confirm complete denervation was not performed, House-Brackmann grades V and VI (complete palsy) were excluded. In contrast, in our study, we only included patients with complete paralysis confirmed by needle EMG.

4.2 | Limitations

One limitation of our study is that only retrospective data were analyzed. In future studies, the number of patients should be increased, and the length of follow-up and stimulation devices used should be

standardized. The electromyographer was involved in the patient's ongoing care and therefore not blinded. Although a surgical learning curve is a potential concern, the surgeon in this study had more than 20 years of experience in HFJA surgery, so this possibility is unlikely.

In summary, our study has shown that home-based ES is safe, easy, and comfortable for patients with facial palsy. Studies have shown that atrophy of muscles as well as an increase in muscle cross-section after exercising can be followed with ultrasound, magnetic resonance imaging, and three-dimensional scanners.[31-34] A standardized study with regular planned follow-up visits, a standardized stimulation protocol, and use of patient questionnaires would be needed to verify the subjective improvement in symmetry and demonstrate the impact of ES in muscle response and psychological influence.[35] A larger sample size would be helpful to detect the between-group differences more accurately. To quantify the synkinesis and the movement in ES more specifically, it would also be useful to rate standardized videos developed for facial palsy evaluation rather than pictures.[25,26] Accordingly, these preliminary results need to be followed up in systematic studies aimed to standardize the stimulation protocol; ease the quantification of potential benefits linked to ES, such as reduction of muscle atrophy[36]; as well as increase symmetry and subjective benefit in quality of life.

ETHICAL PUBLICATION STATEMENT

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

CONFLICT OF INTEREST

The authors declare no potential conflicts of interest.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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