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Pre-operative masseter muscle EMG activation during smile predicts synchronicity of smile development in facial palsy patients undergoing reanimation with the masseter nerve: A prospective cohort study[☆]

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Summary *Background:* Synchronicity of the oral commissure movement of a bilateral smile is a significant goal for reconstruction in facial reanimation and may only be guaranteed with use of the facial nerve as a donor nerve. Yet over the years several studies report some degree of spontaneity in certain patients when using a non-facial donor nerve, which indicates that synchronous initiation of the smile might be achievable with other donor nerves. We designed a prospective cohort study to evaluate whether pre-operative involuntary activation of the masseteric nerve during smile predicts development of a synchronous smile development when using the masseteric nerve for reanimation.
Methods: In a prospective cohort study unilateral long-standing facial palsy patients scheduled for dynamic smile reanimation with a free functional muscle transplant using the masseteric nerve as a donor nerve were preoperatively evaluated via EMG for involuntary activation of the masseter muscle upon smiling, which we called coactivation. Postoperatively, six months after noting the first muscle contraction smile synchronicity was evaluated. We analyzed the

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synchronicity of the bilateral smile development by analyzing slow-motion video sequences of the patients that were taken while the patients were watching funny video sequences. Results were then correlated with the pre-operative EMG.
Results: 30 patients were recruited for this prospective study and underwent facial reanimation surgery with a free gracilis transfer innervated by the masseteric nerve. 19 patients demonstrated involuntary coactivation of the masseter muscle upon smiling and 11 did not. Postoperatively all patients could demonstrate a voluntary smile. 94% of patients who had preoperative coactivation showed a synchronous movement of the oral commissure when smiling. In those patients, that did not show activation of the masseter muscle upon smiling 0% showed synchronicity. The preoperative coactivation of the masseter muscle is able to predict the outcome regarding synchronicity of the smile with a sensitivity of 99.7%, a specificity of 88.5% and 92.5% positive predictive value and 99.6% negative predictive value ($p < 0.001$ for all).
Conclusions: The lack of masseter co-activation with smile predicts a lack of spontaneous involuntary smile after dynamic smile reconstruction using the masseteric nerve.

Introduction

Current standard of care for facial reanimation in patients with long-standing facial paralysis is the free functional muscle transfer.[1,2] Re-innervation of the transferred muscle is established either by using a cross-face-nerve graft (CFNG) or the motor nerve to the masseter muscle as donor nerves,[3] the latter historically used when the contralateral facial nerve is not available.[4] However, the lower axon count of the CFNG compared to the masseteric nerve can lead to lesser muscle contraction resulting in significant smile asymmetry.[4-7] The higher axon loads, in addition to the single-stage, single-coaptation nature of the procedure, make the masseteric nerve an ideal candidate to overcome the weaknesses of the CFNG, at price of less reliable spontaneity. Thus, this motor nerve has been increasingly used for facial reanimation.[8,9] This is particularly the case in older patients, in which the outcome of facial reanimation surgery using a CFNG can be suboptimal due to decreased axonal loads.[10]

However, the major disadvantage of using the masseteric nerve for facial reanimation is that not all patients will develop a spontaneous smile. It has been suggested that approximately 59% of patients undergoing facial reanimation with a free gracilis transfer coapted to the masseteric nerve show a spontaneous smile routinely.[11] The mechanisms behind this phenomenon are not fully understood. Shaverien et al. recently described a link between the normal smile production and the activation of the masseter muscle that potentially could explain this process.[12] Data correlating coactivation of the masseter muscle with the ability to develop a spontaneous smile when using the masseteric nerve as a donor nerve is lacking. The objective of our investigation was to establish whether an existing co-activation of the masseter muscle during normal smile production in facial paralysis patients predicts the ability to generate a synchronous smile after a free gracilis muscle transfer when using the masseteric nerve. As true spontaneity is difficult to objectify we focused on the synchronous initiation of oral commissure movement upon smiling as a key-parameter for a natural smile.

Patients and operative procedure

Pilot study

A pilot study was designed to evaluate the feasibility of our EMG set-up and correlate outcome with existing data, which was required for subsequent approval from the ethic committee for the following cohort study. In this pilot study, we analyzed 30 healthy volunteers for co-activation of the masseter muscle upon smiling. Standardized masseteric muscle electromyography (EMG) was performed bilaterally with an Inomed nerve-monitor. After placing the needle in the masseter muscle, the volunteers were asked to clench their teeth to confirm correct positioning of the needle in the masseter muscle. The volunteers were then asked to completely relax the masseter muscle. They were then asked to smile normally without clenching their teeth. All these events were recorded. After the pilot-study confirmed the masseter coactivation and feasibility of the technique in a healthy population, we started recruiting patients for the SMILE trial.

The SMILE trial-study design, setting and participants

Inclusion criteria: all patients presenting with long-standing facial paralysis (>18 months) for facial reanimation surgery using free functional muscle transfer using the masseteric nerve as a donor nerve were included in the study according to the study protocol depicted in Figure 1. Co-activation of the masseter muscle upon smiling was assessed by needle EMG upon clenching of the teeth, relaxing and then smiling without clenching teeth as established in the pilot study (Figure 2). Exclusion criteria were age under 18, previously failed facial reanimation surgery, patients scheduled for facial reanimation using other donor nerves than the masseteric nerve and patients with combined NVII and NV paralyzes.

Patients were divided in two groups: the first included patients that demonstrated coactivation of the masseter

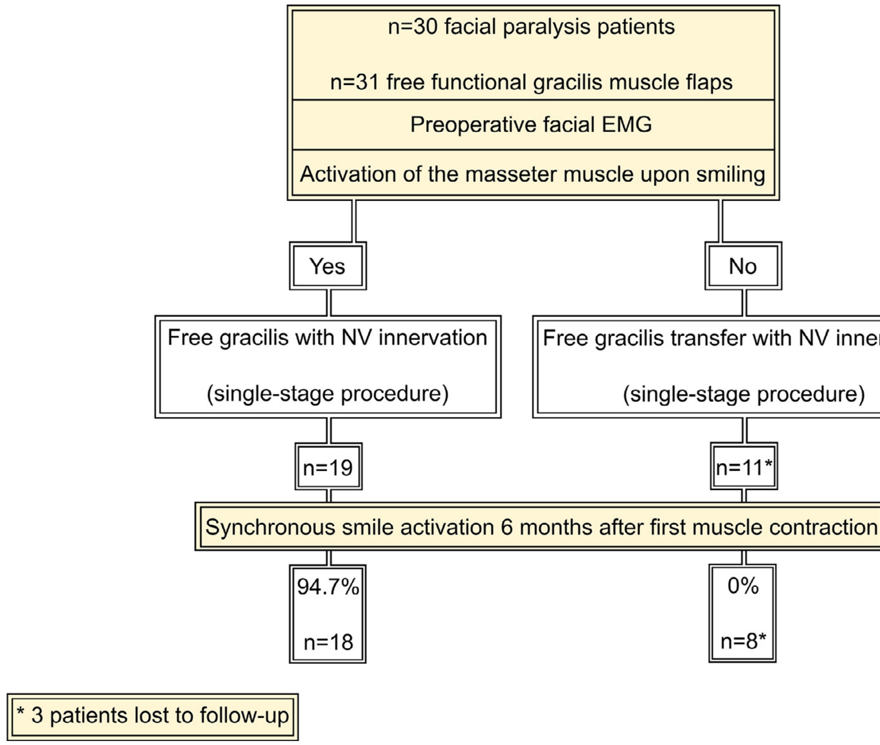

Figure 1 Study inclusion protocol and outcome.

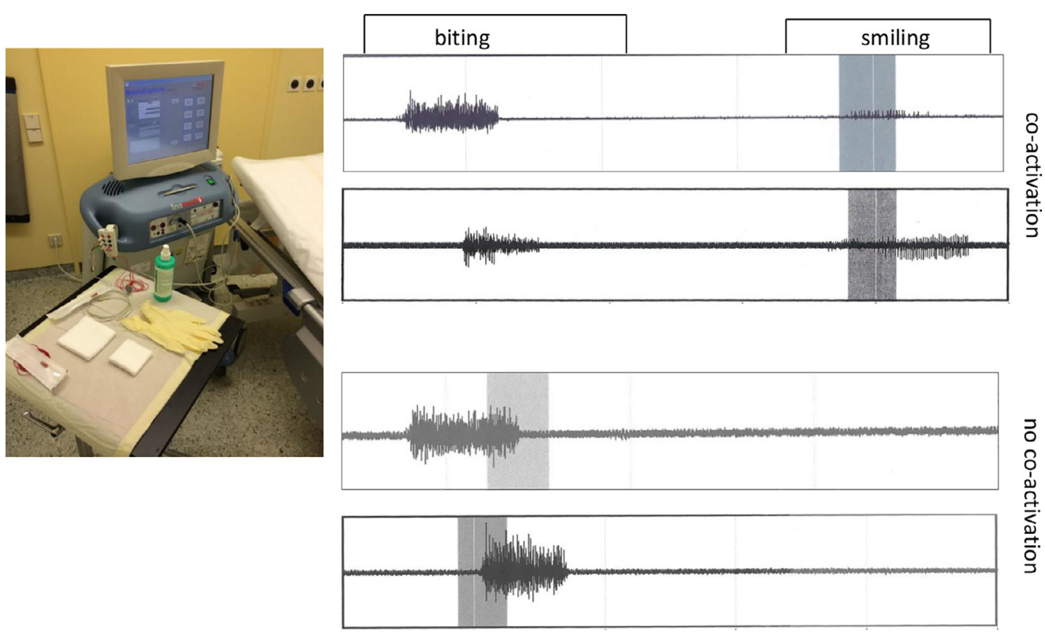

Figure 2 Needle EMG set up and representable measurements of 4 patients. Two results showing co-activation of the masseteric muscle upon smiling (upper) and two showing no co-activation (lower).

muscle upon smiling, the second consisted of patients that did not demonstrate a coactivation.

Institutional review board approval was obtained prior to data acquisition (approval # 487/15). The prospective trial was conducted in accordance with the Declaration of Helsinki (revised 59th General Assembly, Seoul, South Korea, 2008) and registered with the German clinical trial registry *(DRKS00009899)*. All data obtained in the context of the clinical trial was subject to data protection. Informed consent was obtained from every patient. Power calculations for the pilot study, as well as the SMILE trial were done by the Center for Clinical Trials at the University of Freiburg Medical Center and calculations performed with the n-query software (www.statsols.com).

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Surgical technique

The surgical procedure for single-stage smile reconstruction has been described previously.[9] Briefly, after preparing the pocket for the gracilis muscle segment, the facial artery and vein are dissected. We then identify and expose the masseteric nerve in its usual position.[9,13] Next, we harvest a gracilis muscle segment and transfer it to the face. We then insert the muscle at the oral commissure and lower lip and fixed it in the layer of the atrophied facial musculature. Afterward, nerve coaptation and microvascular vessel anastomosis are performed, and an implantable Cook-Doppler probe is sutured to the facial vein to allow for monitoring of flap perfusion.

Table 1 Patient demographics of the pilot study.

Characteristics	Value (%)
Total patients	30
Gender (f/m)	20 (66.7) 10 (33.3)
Age, yr	
Average	24.5
Range	15-43
Activation of the masseter muscle upon smiling determined by EMG	
Yes	
No	18 (60.0)
	12 (40.0)

f - female, *m* - male, *yr* - year(s).

Follow up and data collection

All patients were advised to present in our outpatient clinic upon first noticing of muscle movement. They were then examined and instructed with muscle training, which consisted of two crucial steps: first, patients were asked to train smiling in front of the mirror with a particular emphasis on smiling with open mouth and without clenching the teeth. This exercise was used to provide neural feedback to the appearance of their new smile and improve regulation of the strength of their smile. Second, patients were asked to "use" the smile voluntarily as often as possible in social situations to trigger a positive feedback loop and strengthen the automatism of smiling. We did not use specialized physiotherapy or external muscle stimulation in any of our cases.

Six months after the first visible contraction of the muscle, all patients were examined in our outpatient clinic. We recorded the patients using the Apple Photo Booth software (Version 8) while showing them a video sequence that has been validated to trigger a smile in most patients.[14] The captured video sequences were then modified to a slow-motion setting running on 20% of the original speed and replayed for analysis by two independent reviewers. The synchronous initiation of the smiling movement represented by the synchronous movement of the oral commissures was the key parameter that was analyzed. Any delay of the initiating movement between the healthy and the reanimated side observed was rated as non-synchronous. With focusing on the initiation of the movement, potential confounding factors, such as the amplitude of the oral commissure excursion, which can vary between both sides, could be omitted. For clarification, the supplemental digital content demonstrates two patients, one rated as a synchronous smile (See Video, Supplemental Digital Content 1) and one rated as a non-synchronous smile (See Video, Supplemental Digital Content 2). These videos are in contrast to the typical pre- and postop video documentation of these patients that reveal almost identical results (See Video, Supplemental Digital Contents 3 and 4) and underline the importance of observing and documenting patients not only in still photographs and videos taken under lab conditions when analyzing the quality of facial reanimation surgery. Still photographs of the same patients (Figure 3) are also provided.

Statistical analysis

The information we gained from the video analyses represents a yes/no answer (synchronous smile/non-synchronous smile) that was statistically analyzed using a chi-squared test with Yates' correction for continuity. An unpaired t-test for normally distributed data after normalization confirmation with a Shapiro-Wilk test was used to analyze the comparability of the two treatment groups regarding age and comorbidities. Data are presented as a percentage, mean values $\pm$ standard deviation, medians, and ranges. A p value of less than 0.05 was regarded as statistically significant.

Results

Pilot study

In the pilot study, we assessed the activation of the masseter muscle upon smiling in 30 healthy volunteers (20 females, 10 males, mean age 24.5 $\pm$ 4.4; Table 1) by EMG as described above (Figure 2). The measurement was performed bilaterally and revealed that 18 persons (60%) involuntarily activated the masseter muscle when demonstrating a smile without clenching their teeth, which we termed co-activation of the masseter muscle while smiling. In all cases, the test result did not differ between sides. Furthermore, the assessment of the masseteric co-activation upon smiling proved to be reliable, technically feasible, and fast to perform in an outpatient setting.

SMILE trial

Between January 2014 and December 2016, we prospectively recruited 30 patients for this clinical trial 18 females, 22 males, mean age 42.6 $\pm$ 14.5; Table 2) in the Smile trial receiving a total of 30 free functional gracilis muscle transfers for facial reanimation surgery (Figure 1). Preoperative EMG assessment revealed a positive co-activation of the masseter muscle in 19 patients (47.5%). 11 patients did not show a pre-operative co-activation. Both groups were comparable regarding age and comorbidities ($p = 0.08$ and $p = 0.35$, Table 2). All patients presented with a history of facial paralysis for at least 18 months. Surgical treatment of

Figure 3 Results of two study patients. The patient on the left demonstrated a synchronous smile, the patient on the right did not show a synchronous smile. The difference in the quality of reconstruction is only distinguishable in the spontaneous smile video but not in still photographs or video sequences taken under instructions of the photographer. Patient 2 reprinted from Braig et al.[20]

head and neck related neoplasms and congenital anomalies were the most common causes of facial paralysis among the study patients (Table 2).

All patients showed an uneventful postoperative course. Contraction of the transferred muscle when clenching the teeth was notable three to four months postoperatively. After noticing the first muscle contraction, patients were seen in the outpatient clinic and advised to train smiling as described above. Unfortunately, three patients, all of whom showed no pre-operative masseteric co-activation upon smiling, were lost to follow-up. Six months after the first muscle movement, we tested all remaining patients for development of spontaneous smiling using the standardized video analysis described above and in the Supplemental Digital Content (See Video, Supplemental Digital Contents 1 and 2). 18 out of 19 patients (94.7%, $p < 0.05$, Figure 1, Table 2), who preoperatively demonstrated co-activation of the masseter muscle upon smiling showed a synchronous triggering of the movement of the oral commissure between the healthy and the reanimated side. None of the patients that showed no co-activation of the masseter muscle on the preoperative EMG test, developed a synchronous smile. Thus, the preoperative EMG assessment seemed to be highly sensitive in predicting postoperative synchronicity (test sensitivity: 99.7%, test specificity: 88.5%, positive predictive value: 92.5%, negative predictive value: 99.6%, $p < 0.001$ for all parameters).

Discussion

This is the first prospective clinical cohort study attempting to preoperatively predict the chances of achieving a synchronous smile development postoperatively when using the masseter motor nerve as the donor nerve for facial reanimation. We suggest a possible algorithm for donor nerve

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Table 2 Patient demographics of the SMILE-trial.

Characteristics	Value	
Total patients	30	
EMG of the masseter muscle upon smiling preoperatively		
Positive co-activation	19 (63.3%)	
No co-activation	11 (36.7%)	
Gender (f/m)		
Co-activation group	13	6
No co-activation group	3	8
Age, average and range, yr		
Study population	44.8 [19-67]	
Co-activation group	44.4 [19-67]	
No co-activation group	45.6 [24-63]	
Cause of facial paralysis		
Neoplasia (benign or malignant)	21 (70.0%)	
Congenital	6 (20.0%)	
Trauma injury	2 (6.7%)	
Unknown	1 (3.3%)	
Charlson comorbidity index		
Co-activation group	1.9 ± 1.2	
No co-activation group	2.0 ± 1.5	
Perioperative complications		
Co-activation group	0	
No co-activation group	0	
Synchronous smile 6 months after first muscle contraction determined by standardized video analysis		
Co-activation group	18 (94.7%)	
No co-activation group	0 (0.0%)	

f - female, *m* - male, *yr* - year(s).

selection in smile reconstruction using a simple EMG assessment preoperatively, possibly helping with patient selection or at least providing a more informed pre-operative consultation. Furthermore, we observed that 60% of healthy volunteers show a co-activation of the masseteric muscle upon smiling. This result is of particular interest because it matches the percentage of cases in which previous studies have reported spontaneity of the smile when using the masseteric nerve as the donor nerve for free functional gracilis transfer.[11] Our results vary slightly from the initial study of Schaverien and coworkers who have reported masseteric co-activation to be present in 40.0% of their healthy study population, which was not bilateral in all cases.[12] Presumably, these differences are due to the higher number of test persons assessed in our study or a more sensitive EMG setup.

Facial reanimation surgery is a complex and challenging field. The two-stage reanimation of the smile using a CFNG followed by a free functional muscle transfer with coaptation of the motor nerve to the CFNG is the gold standard. This complex procedure usually has a reliable success rate[15] with complication rates described as low as 2%. However, the success not only depends on the survival of the free tissue transfer but also on whether the coaptation to the CFNG and the consecutive muscle reinnervation is sufficient to generate a smile that is symmetrical to the healthy, non-paralyzed side. With increasing age, the CFNG delivers less myelinated axons compared to the masseteric nerve resulting in a lesser muscle excursion.[5,7] Especially in patients that present with a strong excursion of the oral commissure upon smiling on the healthy side, this circumstance can lead to non-satisfactory results. These limitations have prompted the increasing use of the masseteric nerve for facial reanimation as it overcomes the shortcoming of the limited axon load and weak oral commissure excursion.[7] However, significant disadvantages regarding the spontaneity of the smile remained. Other limitations, such as synkinetic smiling upon mastication, usually weaken over time and do not seem to be disturbing to most patients.[16]

True spontaneity of the movement of the facial muscles is difficult to assess. The facial movement consists not only of smile production, but also of movement of the mimic muscles during speaking and eating, which in their complexity are difficult to reconstruct. Therefore, while our results show a synchronous initiation of the movement of the oral commissure between a healthy side innervated by NVII and the reanimated side innervated by NV this still does not represent a truly spontaneous and independent movement of the NV innervated gracilis muscle. While videos and pictures taken under laboratory conditions suggest a comparable outcome between patients, only a detailed video analysis using a spontaneous smile assay[14] reveals the true quality of the reconstructive outcome. Not achieving a synchronous smile can lead to a disfiguring result upon involuntary smiling that resembles the preoperative state and thus might be devastating for the patient. In our opinion, despite growing popularity of other donor nerves, the most natural result in long-standing facial reanimation is still attained with a CFNG, if a sufficient and symmetrical oral commissure excursion can be achieved. This is particularly the case in the pediatric and adolescent patient population. Therefore, the CFNG remains the gold standard for donor nerve selection in these patients in which we expect sufficient axonal loading of the CFNG and a better nerve regeneration.[7,10] Therefore, we excluded these cases from our study.

In contrast, older patients have a significantly decreased chance to develop perfect oral symmetry due to the limitations of the CFNG as a donor nerve. According to the study results, we now advise older facial paralysis patients to use the masseteric nerve if co-activation of the masseter muscle upon smiling is present preoperatively. At this stage, however, we cannot define a cut-off age at which we would not recommend the use of a CFNG. In our practice, we now base the indication for single-stage reconstruction more liberally, even in patients less than 30 years of age if masseteric co-activation is present. We cannot answer the question which procedure is ideal for patients that are unlikely to develop a spontaneous smile with masseteric innervation and which patients belong to an age group in which use of a CFNG alone will unlikely produce a symmetrical smile. In our experience, it is difficult for patients to comprehend the importance of true spontaneity fully. Thus, patients are more likely to agree to the masseteric nerve procedure because sufficient smile development can be guaranteed in most cases. Subsequently, most of these patients are very satisfied once they regain the ability to smile voluntarily. However, the level of satisfaction might decrease over the years as the limitations and lack of true spontaneity become more apparent. One possible solution to this problem, as suggested by multiple groups around the world, is the use of duel innervation techniques, using both a CFNG and a masseteric nerve for innervation, with the idea that the masseteric nerve will provide a sufficient axonal load and the CFNG triggers spontaneous smiling.[17]

Assessing true spontaneity of the smile after facial reanimation surgery is difficult and most described methods have limitations, such as the tickling test which has been introduced by Chuang et al.[18] and was further implemented into a grading system to evaluate the outcome of smile reconstruction surgery.[19] While this is a simple test, it relies on a physical rather than an emotional initiator. Therefore, for the evaluation of our results we evaluated playbacks of video sequences showing the patient while watching a previously established spontaneous smile assay[14] in slow motion and focused in our analysis on the synchronous initiation of the oral commissure movement in the developing smile. Whereas a truly spontaneous movement is more complex, the synchronous initiation of the smile might be one key parameter of spontaneity. On assessment, we only focused on the initiation of the upward movement of the oral commissure of the affected side in comparison to the healthy side. The synchronicity of this initial movement is the key indicator of our analysis and is independent of confounding factors that might impede the assessment, such as asymmetrical oral commissure excursions. Therefore, we believe that the method presented is more sufficient than questionnaire based assays.

All our patients underwent postoperative training with bio-feedback in order to strengthen the potentially preformed ability to achieve a spontaneous smile by recruitment of new neuronal tracks to preexisting centers and thereby to potentially improve the quality of the reanimation result, as suggested by Manktelow et al.[11] However, we did not specifically evaluate the role of biofeedback training in our study and therefore cannot draw any conclusions about its impact on the outcome of our results, as all groups underwent a similar post-operative regimen.

In conclusion, the results of this study suggest that coactivation of the masseter muscle during smile can help to identify suitable candidates for facial reanimation surgery using the masseteric nerve because these patients are more likely to develop a synchronous, more natural appearing smile. Our findings also show that patients will not develop a synchronous smile if the masseter muscle does not show co-activation upon smiling on the preoperative EMG.

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Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2018.11.011.

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