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Review

Effectiveness and safety of the use of gracilis muscle for dynamic smile restoration in facial paralysis: A systematic review and meta-analysis



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Summary Background: Smiling is a fundamental component of social interactions. Significant challenges arise for patients with facial palsy. One of the key procedures for dynamic smile restoration is the microneurovascular transfer of a gracilis muscle. We aimed to assess the effectiveness and safety of dynamic smile reanimation surgery using the free gracilis muscle unit in patients with facial palsy.

Methods: We conducted a systematic review and meta-analysis of studies reporting surgical outcomes of dynamic smile restoration using free gracilis muscles identified from EMBASE, Medline, and Web of Science databases from their inception to March 15, 2018. Two-stage screening and data extraction were performed by two independent reviewers. Pooled proportions were calculated using random-effects models.

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Results: Thirty-one studies including 1647 patients who underwent 1739 free gracilis flaps were included. Twelve (38.7%) studies measured perioperative smile excursion change using six different tools. Six of these studies were homogeneous and were used in meta-analyses of smile excursion improvement, which revealed a mean change of 7.5 mm (95% CI 6.0-9.0 mm, I^2 86.7%) perioperatively. Twenty (64.5%) studies reported perioperative complications, and pooled proportions of flap failures were of 2.9% (95% CI 1.3-4.5%, I^2 47.7%).

Conclusions: Dynamic smile restoration using a free gracilis muscle may represent an effective procedure to regain oral commissure motion and is associated with an approximately 3% rate of flap failure. Masseteric nerve coaptations lead to larger improvements in perioperative smile excursion (10 mm) than cross-facial nerve grafts (6.8 mm). Future studies with homogeneous reporting of smile excursion and patient-reported outcome measures are needed.

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Introduction

Smiling is a fundamental component of social interactions, as it allows individuals to express their emotions to their peers. Patients affected by facial paralysis are confronted with significant functional, social, emotional, and esthetic challenges owing to the absence of oral commissure movement.¹ Treatment strategies that attempt to address these issues include the restoration of smile using the microvascular transfer of a free muscle unit. Facial reanimation procedures have proven technically successful and have been shown to improve patients' quality-of-life.²

The gracilis muscle is ideal for the purpose of functioning free muscle transplantation for the dynamic reconstruction of oral commissure movement, as it is easily accessible, it has a reliable neurovascular pedicle, and its harvest does not leave substantial functional deficits.^{3,4} These appealing characteristics have established the gracilis muscle as a widely accepted free unit transplant for dynamic smile reanimation. Outcomes resulting from this procedure have not yet been captured in a comprehensive pooled analysis and have rather been reported independently by single institutions or surgeons.⁵⁻⁷ An aggregate of data would offer facial paralysis patients, clinicians, researchers, and policy

makers with quantitative and representative outcomes data and the ability to set realistic expectations and facilitate surgical planning. Such pooled estimates would also provide benchmark outcomes data for the free gracilis muscle transfer procedure and facilitate comparison with other evolving dynamic facial reanimation techniques.

Our objective in this systematic review and meta-analysis was to assess the effectiveness and safety of the use of dynamic smile restoration surgery using free gracilis muscle transplantation in both adult and pediatric patients who have unilateral or bilateral facial nerve palsy due to any etiology.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for the reporting of this review.⁸ The protocol was registered on the PROSPERO database (registration no. CRD42018082514).⁹

Study selection

Population: We included studies of adults and children who underwent facial animation or reanimation surgery

for facial paralysis due to any etiology, including both congenital (syndromic or non-syndromic) and acquired causes (idiopathic, infectious, traumatic, post-tumor ablation, and autoimmune disease).¹

Type of studies: We planned to include experimental and observational studies (case series and retrospective and prospective cohorts). We did not identify any randomized studies. We excluded conference proceedings, letters, commentaries, and editorials that did not contain original data. Case reports, case series of less than ten cases, reviews, and qualitative studies were read to identify other potential studies but were excluded. Duplicate reports not providing additional information and non-peer-reviewed publications were also excluded.

Type of intervention: We included studies that investigated the microneurovascular transfer of a free gracilis muscle and reported any outcome of interest. All nerves selected for coaptation were included, the most common being the cross-facial nerve graft (CFNG) and motor nerve to the masseter (MNTM).¹

Outcomes: Our primary outcome was improvement in smile excursion following microneurovascular gracilis transfer, typically expressed in millimeters. All methods of measuring smile excursion were considered, but the ability to pool the data was addressed by assessing the equivalence of the actual measurements taken on a case-by-case basis. Secondary outcomes included postoperative complications, revision rates, and health-related quality-of-life. Postoperative complications were defined by the Clavien-Dindo classification,¹⁰ which proposes clear consensus definitions that facilitate interpretation and encourage consistency in reporting of surgical outcomes.¹⁰ Revision procedures were defined as any additional surgical procedure to optimize the outcome from the original smile restoration reconstruction. To evaluate health-related quality-of-life outcomes, we included validated instruments specific to facial paralysis such as the Facial Disability Index (FDI) questionnaire² and the Facial Clinimetric Evaluation (FaCE survey),¹¹ as well as tools validated in other surgical patient populations, such as the Short Form Health Survey (SF-36).¹²

Search strategy

A senior information specialist assisted the search strategy development. A comprehensive electronic search was performed using the databases MEDLINE, EMBASE, and Web of Science (from inception until March 15, 2018). No date or language restrictions were applied. Search terms were defined a priori and adapted to each specific database (eAppendix - Online Supplement 1). Additional citations were sought with a manual search of reference lists of retrieved articles. Two independent review authors (M.R. and J.P.C.) not blinded to journal, institutions, or authors assessed all citations for eligibility. Titles and abstracts were screened first, and all eligible articles, along with articles with uncertain eligibility, were retrieved for full-text review. All discrepancies were resolved by consensus or a third assessor (K.M.D).

Data extraction and methodologic quality assessment

A standardized data collection form was designed to extract data by two independent review authors (M.R. and J.P.C.). Authors were contacted for clarification or additional data. Methodologic quality was evaluated by both reviewers (M.R. and J.P.C.) using the Institute of Health Economics Quality Appraisal (IHE QA), which was developed for assessment of case series. This 20-criteria checklist evaluates studies based on study objective, study design, study population, intervention, outcome measures, statistical analysis, results and conclusions, and disclosures.¹³ This IHE QA attributes a “yes,” “unclear,” or “no” for low, moderate, and high risk of bias, respectively, for each criterion. Studies that have 14 or more “yes” scores are considered high quality and low risk of bias; those with 10 to 13 “yes” scores are considered at moderate risk of bias; those with 9 or less “yes” scores are considered at high risk of bias. Discrepancies in assessment of methodologic quality between reviewers were resolved by consensus.

Data synthesis and statistical analysis

Clinical heterogeneity was determined by the patient population (etiology of paralysis, age, and gender), the nerve used for coaptation, and the sample size (number of patients and flaps). Between-study statistical heterogeneity was assessed with the I^2 statistic.¹⁴ High, moderate, and low heterogeneity were defined as a value of I^2 of 75%, 50%, and 25%, respectively.¹⁵ We made no adjustment for multiple analyses. For the meta-analysis, data were combined in random-effects model using *OpenMetaAnalyst* vBeta 1.0.¹⁶ For continuous outcomes, pooled mean estimates were reported with 95% CI. Study weight was calculated using the DerSimonian and Laird procedure for random-effects.¹⁷ Freeman-Tukey transformations were applied to stabilize the variance of proportions and pooled estimates of proportions with 95% CI were described.¹⁸ When results in studies were missing or presented in different forms, authors were contacted to obtain original data. When unsuccessful in accessing such data, missing mean values were excluded from the pooled estimate. Missing standard deviations were calculated using the formula $SD_{\text{change}} = \sqrt{((SD_{\text{pre}}^2 + SD_{\text{post}}^2) - (2 * \text{Corr} * SD_{\text{pre}} * SD_{\text{post}}))}$, where Corr is the correlation coefficient or 0.8.

Subgroup and sensitivity analyses

We planned to perform subgroup analyses in patients undergoing coaptation with the MNTM and the CFNG based on previous reports demonstrating differences in smile excursion for both of these donor nerves.¹⁹ We also planned to carry out subgroup analyses of pediatric and adult patients. Sensitivity analyses according to the measurement tool used to assess smile excursion were intended.

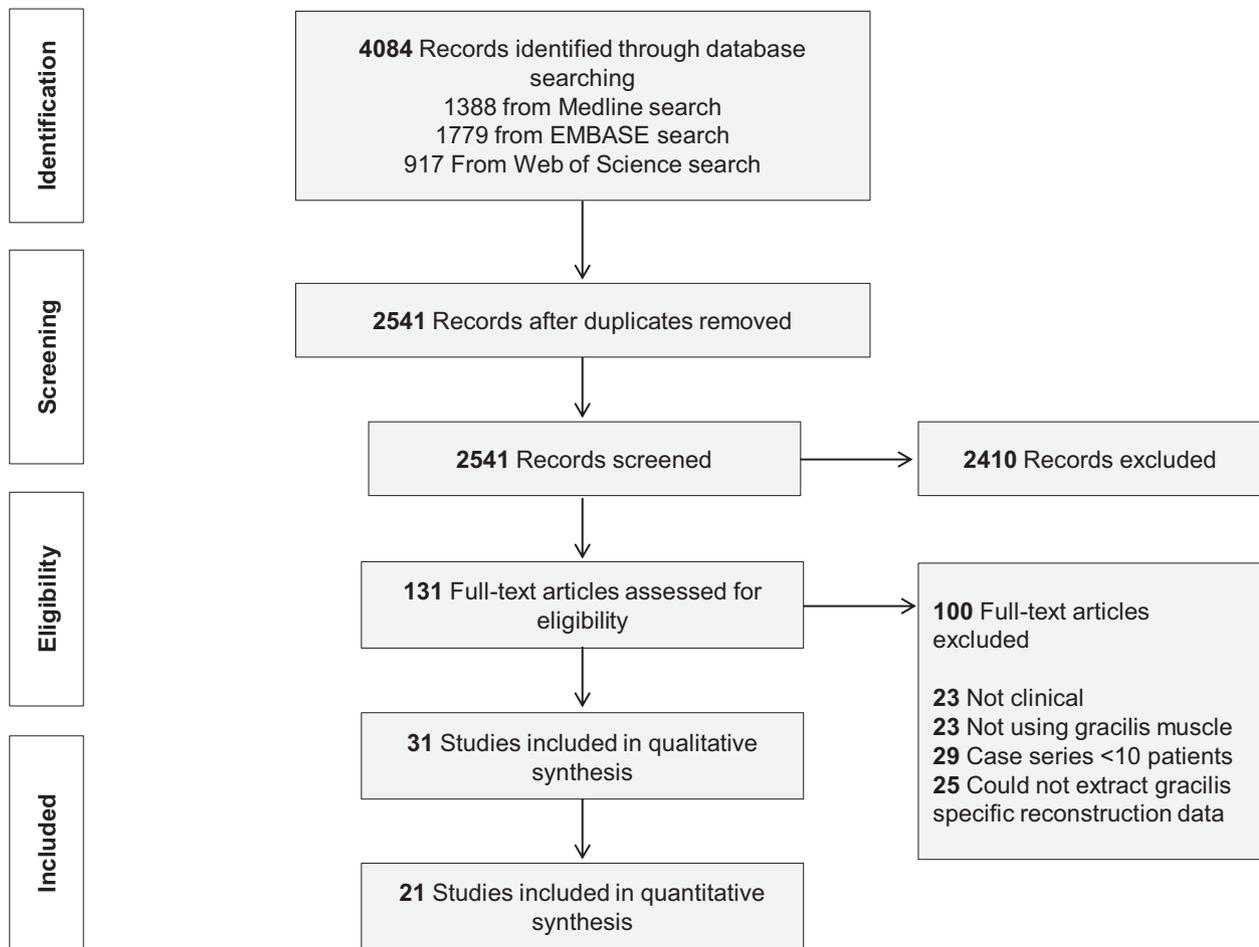


Figure 1 PRISMA flow diagram.

Results

Our electronic database search identified a total of 4084 articles. Removal of 1543 duplicates took place, and 2541 titles and abstracts were screened. Of these articles, 131 full texts were reviewed for eligibility and 31 met inclusion criteria for systematic review (Figure 1).

Study and patient characteristics

Table 1 summarizes the 31 included studies meeting eligibility criteria. Studies were published between 1991 and 2018, and 13 (41.9%) originated from Europe, 12 (38.7%) from USA, and 6 (19.4%) from Asia. Based on the reported data, these studies included 1647 patients (from 30 studies) with an average age of 31.2 ± 13.4 years old (range 4-80 years old) and a female-to-male ratio of 1:1.2. A total of 1739 gracilis muscle transplants were performed for facial paralysis owing to a congenital cause in 320 (39.1%) cases, iatrogenic or following a tumor resection in 332 (40.6%) cases, and after trauma in 61 (7.5%) cases. Only 14 (45.2%) studies reported the severity of facial paralysis (complete or incomplete). When reported, the vast majority of cases were found to be complete paralysis ($n=357$ out of 403 cases, 88.6%). The gracilis muscle was re-innervated by the contralateral

facial nerve ($n=1047$, 60.2%), the MNTM ($n=523$, 30.1%), the spinal accessory nerve ($n=60$, 3.5%), or the hypoglossal nerve ($n=13$, 0.7%) nerve. Dual innervation to the gracilis muscle was provided in 36 (2.1%) cases.

Methodologic quality assessment

A full summary of methodologic quality assessment is available (eTable - Online Supplement 2). Most studies were of moderate to high quality as assessed by the IHE QA, with 11 (35.5%) studies having a low risk of bias, 19 (61.3%) studies have a moderate risk, and 1 (3.2%) study having a high risk.

Outcomes of interest

Smile excursion: A total of 25 studies (80.6%) reported smile excursion assessments. One¹¹ was excluded from the smile excursion analysis, as it represented the same patient population as in another included study.³⁹ Of the remaining 24 studies, 12 (50.0%) reported postoperative smile outcomes without exact smile excursion measures. In this group, nine tools were used to evaluate smile excursion, including Terzis's⁵⁰ Aesthetic and Functional Grading System,^{32,36} O'Brien's⁵¹ evaluation criteria,^{24,30} the

Table 1 Characteristics of the included studies in the qualitative synthesis.

Studies	Country	Patients n	Flaps n	Etiology				Mean age years (range)	Nerve coaptation		
				Congenital	Iatrogenic/oncologic	Trauma	Other		CFNG	MNTM	Other
Sassoon et al., ²⁰ 1991	UK	12	12	2 (16.7)	6 (50.0)	1 (8.3)	3 (25.0)	31.3 (6-59) ^a	12 (100)	0	0
Ueda et al., ²¹ 1998	Japan	21	21	9 (42.9)	6 (28.6)	1 (4.8)	5 (23.8)	10.2 (4-15)	21 (100)	0	0
Ueda et al., ²² 1999	Japan	28	28	7 (25.0)	8 (28.6)	2 (7.1)	11 (39.3)	23.9 (6-57) ^a	0	0	28 (100)
Zuker et al., ³ 2000	Canada	10	20	10 (100)	0	0	0	7.5 (4.5-13)	0	20 (100)	0
Schliephake et al., ²³ 2000	Germany	15	16	2 (13.3)	10 (66.7)	3 (20.0)	0	31.2 (6-59) ^a	3 (18.8)	0	13 (81.3)
Kumar and Hassan, ²⁴ 2002	UK	25	25	11 (44.0)	9 (36.0)	2 (8.0)	3 (12.0)	36.4 (7-60) ^a	25 (100)	0	0
Terzis and Noah, ²⁵ 2003	US	14	19	14 (100)	0	0	0	- ^b	7 (36.8)	3 (15.8)	9 (47.4)
Bae et al., ⁴ 2006	Canada	120	164	93 (77.5)	17 (14.2)	5 (4.2)	5 (4.2)	9.5 (-)	70 (42.7)	94 (57.3)	0
Manktelow et al., ²⁶ 2006	Canada	27	45	12 (44.4)	6 (22.2)	2 (7.4)	7 (25.9)	34.4 (16-61) ^a	0	45 (100)	0
Faria et al., ²⁷ 2007	Brazil	80	80	-	-	-	-	28.3 (5-63) ^a	58 (72.5)	22 (27.5)	0
Frey et al., ²⁸ 2008	Switzerland	31	31	-	-	-	-	18.2 (8-62) ^a	31 (100)	0	0
Gur et al., ²⁹ 2010	Israel	60	60	-	-	-	-	- ^b	55	5	0
Bianchi et al., ³⁰ 2010	Italy	20	30	20 (100)	0	0	0	- ^a	7 (23.3)	23 (76.7)	0
Gousheh and Arasteh, ³¹ 2011	Iran	505	505	-	-	-	-	-	505	0	0
Lin et al., ³² 2011	Taiwan	24	24	0	24 (100)	0	0	43.0 (28-63)	0	0	24 (100)
Hadlock et al., ³³ 2011	US	17	19	-	-	-	-	11.5 (4-18)	13 (68.4)	6 (31.6)	0
Lee et al., ³⁴ 2012	US	105	107	9 (8.4)	58 (54.2)	14 (13.1)	26 (21.7)	32.8 (6-69) ^a	60 (56.1)	47 (43.9)	-
Hontanilla and Vila, ³⁵ 2012	Spain	41	41	0	25 (61.0)	15 (36.6)	1 (2.4)	55.8 (-) ^b	41 (100)	0	0
Biglioli et al., ³⁶ 2012	Italy	10	10	2 (20.0)	8 (80.0)	0	0	42.3 (16-63) ^a	0	10 (100)	0
Hontanilla et al., ³⁷ 2013	Spain	47	47	5 (10.6)	32 (68.1)	7 (14.9)	3 (6.4)	41.3 (-) ^b	20 (42.6)	27 (57.4)	0
Chuang et al., ³⁸ 2013	Taiwan	36	42	9 (25.0)	11 (30.6)	2 (5.6)	14 (38.9)	22 (4-63) ^a	0	0	42 (100)
Bhama et al., ³⁹ 2014	US	138	141	-	-	-	-	35 (6-80) ^a	62 (44.0)	70 (49.6)	7 (5.0)
Lindsay et al., ¹¹ 2014	US	66	66	6 (9.1)	41 (62.1)	2 (3.0)	17 (25.8)	40.1 (14-80) ^a	28 (42.4)	34 (51.5)	4 (6.1)
Doménech Juan et al., ⁴⁰ 2014	Spain	10	9	0	7 (70.0)	0	3 (30.0)	44 (38-52)	0	9 (100)	0
Snyder-Warwick et al., ¹⁹ 2015	Canada	-	68	-	-	-	-	10.0 (-)	45 (66.2)	23 (33.8)	0
Sforza et al., ⁴¹ 2015	Italy	13	13	1 (7.7)	12 (92.3)	0	0	41.0 (9-75) ^a	0	0	13 (100)
Bianchi et al., ² 2016	Italy	42	42	23 (54.8)	13 (31.0)	0	6 (14.3)	33.5 (6-61) ^a	42 (100.0)	0	0
Cardenas-Mejia and Palafox, ⁴² 2017	Mexico	76	-	76 (100)	0	0	0	- ^a	0	54 (71.1)	22 (28.9)
Braig et al., ⁴³ 2017	Germany	22	22	2 (9.1)	15 (68.2)	4 (18.2)	1 (4.5)	9.5 (-)	70 (42.7)	94 (57.3)	0
Bianchi et al., ⁴⁴ 2017	Italy	20	20	7 (35.0)	12 (60.0)	1 (5.0)	0	34.0 (6-62) ^a	0	20 (100)	0
Faris et al., ⁴⁵ 2018	US	12	12	0	12 (28.6)	0	0	53.8 (27-67)	4 (33.3)	7 (58.3)	1 (8.3)
Total	-	1647	1739	320	332	61	105	31.2 (4-80)	1047	523	169

Only values representing gracilis free flap reconstructions are presented.

Values are frequencies (percentages) unless otherwise indicated.

CFNG, cross-facial nerve graft; MNTM, motor nerve to masseter.

^a Data reported for both adult and pediatric patient populations.

^b Unclear whether or not data represent a combination of adult and pediatric patients.

Table 2 Studies reporting quantitative smile excursion outcome of the reconstructed paretic side(s).

Studies	Tool	Flaps n	Pre Mean (SD) mm	Post Mean (SD) mm	Change Mean (SD) mm
Hadlock et al., ³³ 2011 ^{a,b}	FACEgram ⁴⁶	19	-	=	CFNG/MNTM 8.8 (5.0)
Lee et al., ³⁴ 2012 ^a		6	-0.7 (3.7)	2.3 (6.8)	CFNG/MNTM 3.0 (4.4 ^c)
Bhama et al., ³⁹ 2014 ^a		74	-0.86 (3.6)	Overall 7.8 (3.3)	Overall 8.66 (2.2 ^c)
Faris et al., ⁴⁵ 2018 ^a		35		CFNG 6.5 (2.9)	
		43		MNTM 8.7 (3.5)	
		12	-2.2 (2.4)	8.0 (2.6)	Overall 10.2 (1.6 ^c)
		4	-1.4 (1.5)	7.2 (3.4)	CFNG 8.5 (2.4 ^c)
Frey et al., ²⁸ 2008 ^a	3D Video analysis ²⁸	7	-3.0 (2.7)	8.6 (2.4)	MNTM 11.6 (1.6 ^c)
		1	-0.08 (-)	6.4 (-)	Dual 6.5 (-)
		22	-0.2 (4.7)	6.9 (5.3)	1 CFNG 7.1 (5.5)
Snyder-Warwick et al., ¹⁹ 2015 ^{a,b}	SMILE ⁴⁷	9	-0.9 (2.7)	7.4 (5.8)	2 CFNGs 8.3 (6.7)
		13	-	-	CFNG 4.1 (2.9)
Hontanilla and Vila, ³⁵ 2012	FACIAL	41	-	CFNG 5.8 (2.9)	-
Hontanilla et al., ³⁷ 2013	CLIMA ⁴⁸	20	-	CFNG 5.1 (2.6)	-
		27	-	MNTM 7.7 (2.8)	-
Manktelow et al., ²⁶ 2006	FaceMS ⁴⁹	31	-	MNTM 13.0 (4.7)	-
Zuker et al., ³ 2000	Tragion to	20	-	MNTM 13.7 (-)	-
Bae et al., ⁴ 2006 ^b	commis- sure distance	32	-	MNTM 14.2 (4.3)	-
		20	-	CFNG 7.9 (3.9)	-
Braig et al., ⁴³ 2017		22	-	No exact values reported	-

SD, Standard deviation; CFNG, cross-facial nerve graft; MNTM, motor nerve to masseter; SMILE, Scaled Measurement of Improvement in Lip Excursion.

^a Included in smile excursion improvement meta-analysis.

^b Pediatric-only patients.

^c Calculated standard deviations.

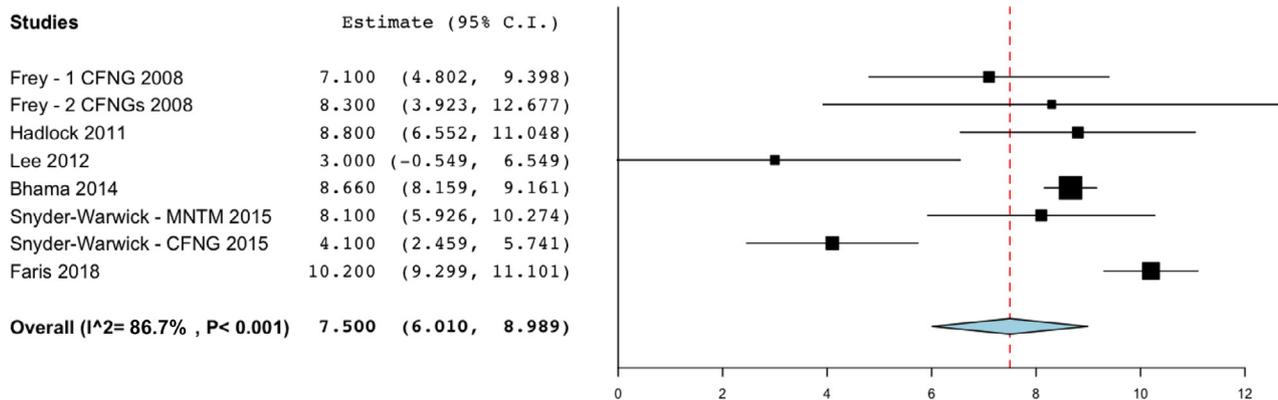


Figure 2 Forest plot of pooled estimate of mean smile excursion change of paretic side(s) following gracilis muscle transfer.

optoelectronic 3D motion analyzer,⁴¹ and other quantitative^{23,32,39,41} and qualitative^{21,22,27} customized tools. Twelve (50.0%) studies estimated smile excursion quantitatively using six different methods (Table 2). Four of the 6 (66.7%) quantitative outcome measures were validated, including the FACEgram,⁴⁶ FACIAL CLIMA,⁴⁸ the Scaled Measurement of Improvement in Lip Excursion (SMILE),⁴⁷ and the FaceMS.⁴⁹

Pooled estimate using a random-effects model was calculated from studies reporting the mean change in perioperative smile excursion and associated (or calculated) standard deviation. The pooled estimate was found to be 7.5 mm

(95% CI 6.0-9.0, I² 86.7%) (Figure 2) representing six studies and 167 gracilis flaps. Nerve coaptation has been shown to substantially influence smile excursion.^{4,19} Subgroup analyses based on nerve coaptation were performed for CFNG and MNTM groups. The CFNG group consisted of three studies and 47 flaps for a pooled estimate of 6.8 mm (95% CI 4.4-9.1, I² 73.9%), whereas the MNTM group consisted of two studies and 20 flaps for an estimate of 10.0 mm (95% CI 6.5-13.4, I² 86.8%) (eFigures - Online Supplements 3 and 4). Comparison of individual studies' mean smile excursion values between CFNG and MNTM did not demonstrate statistical significance

Table 3 Studies reporting operative complications.

Studies	Patients		Flaps Complications					Total
	<i>n</i>	<i>n</i>	Flap failure	Thrombosis	Hematoma/seroma	Infection	Others ^b	
Sassoon et al., ²⁰ 1991	12	12	0	0	2 (16.7)	0	0	2 (16.7)
Schliephake et al., ²³ 2000	15	16	0	0	-	-	-	0
Zuker et al., ³ 2000	10	20	0	1 (10.0)	1 (10.0)	2 (20.0)	0	4 (40.0)
Kumar and Hassan, ²⁴ 2002	25	25	0	0	2 (8.0)	3 (12.0)	11 (44.0)	16 (64.0)
Terzis and Noah ²⁵ 2003	14	19	0	1 (7.1)	1 (7.1)	2 (14.3)	0	4 (28.6)
Manktelow et al., ²⁶ 2006	27	45	0	0	1 (3.7)	6 (22.2)	0	7 (25.9)
Faria et al., ²⁷ 2007	80	80	0	0	4 (5.0)	0	3 (3.8)	7 (8.8)
Gur et al., ²⁹ 2010	60	60	3 (5.0)	0	5 (8.3)	7 (11.7)	0	15 (25.0)
Bianchi et al., ³⁰ 2010	20	30	1 (5.0)	0	1 (5.0)	1 (5.0)	4 (20.0)	7 (35.0)
Gousheh et al., ³¹ 2011	505	505	0	12 (2.4)	6 (1.2)	0	5 (1.0)	23 (4.6)
Lin et al., ³² 2011	24	24	0	0	0	1	1 (4.2)	2 (8.3)
Hadlock et al., ³³ 2011	17	19	1 (5.9)	^a	-	1 (5.9)	0	2 (11.8)
Lee et al., ³⁴ 2012	105	107	-	-	-	6 (5.7)	-	6 (5.7)
Chuang et al., ³⁸ 2013	36	42	1 (2.8)	0	0	0	14 (38.9)	15 (41.7)
Bhama et al., ³⁹ 2014	138	141	14 (10.1)	-	-	-	-	14 (10.1)
Doménech Juan et al., ⁴⁰ 2014	10	9	0	0	3 (30.0)	2 (20.0)	1 (10.0)	6 (60.0)
Sforza et al., ⁴¹ 2015	13	13	2 (15.4)	-	-	-	-	2 (15.4)
Bianchi et al., ⁴⁴ 2017	20	20	0	0	0	0	0	0
Cardenas-Mejia and Palafox, ⁴² 2017	76	-	6 (7.9)	8 (10.5)	1 (1.3)	0	4 (5.3)	19 (25.0)
Faris et al., ⁴⁵ 2018	12	12	0	0	0	0	0	0
Total Clavien-Dindo Grade	1219	1199	28 (IIIb)	22 (IIIb)	27 (IIIa or b)	31 (II)	40 (I, II, and IIIa)	147

Values are frequencies (percentages) per patient unless otherwise indicated.

^a The failed flap initially had an arterial thrombosis.

^b Other complications included muscle tethering to skin, muscle graft failure, hypertrophic scars, localized swelling (not infected and not from fluid collection), donor site shoulder pain (accessory nerve harvest), salivary fistula, dyskinesia, and not recognized preoperatively ligated facial vein impeding anastomosis.

($p = 0.20$). Although a subgroup analysis of pediatric versus adult patients was planned, it could not be performed due to the conglomeration of data in the included studies and inability to obtain these data upon contacting authors. Sensitivity analyses according to the measurement tool used to assess smile excursion could not be performed due to the heterogeneity in tools used.

Symmetry: Symmetry was reported in 17 (54.8%) studies. Ten studies (32.3%) described quantitative estimates of symmetry using various tools (FACEgram,^{11,39} tragion to commissure distance,^{4,28,43} FaceMS,²⁶ SMILE,¹⁹ optoelectronic 3D motion analyzer,⁴¹ FACIAL CLIMA,³⁵ and interpupillary distance system²³). The quantitative estimates produced were heterogeneous and included asymmetric index,⁴¹ vertical and horizontal directions reached from nonparetic side,²³ improvement in excursion symmetry in millimeters,¹⁹ measured paretic and nonparetic values compared for statistical significance,^{4,26} comparison of tragus to commissure distance,^{28,43} percentage difference between the two sides,³⁵ and subtraction of smile excursion of both sides.^{11,39} One study reported both quantitative and qualitative smile symmetry.²³ Qualitative symmetry reporting from 8 (25.0%) studies was performed using Terzis' Aesthetic and Functional Grading System,^{32,36} O'Brien's criteria,^{24,30} Harii's evaluation criteria,²³ and customized tools.^{21,22,31} In all cases, symmetry was a component of a grading scale most commonly encompassing commissural movement and was not assessed as a unique reanimation feature.

Complications: Twenty (64.5%) studies reported operative complications (Table 3). Only flap failures were pooled, as this specific complication has the most relevance to patients and clinicians.⁵² Pooled estimate of flap failures from 19 studies whether due to an anastomotic problem or due to lack of reinnervation was 2.9% (95% CI 1.3-4.5%, I^2 47.7%) (Figure 3). Gousheh et al. was identified as an outlier having no failures and a very large sample size. Sensitivity analysis without this one particular study showed a failure rate of 3.3% with low heterogeneity (95% CI 1.8-4.9%, I^2 15.8%). Of the studies reporting flap failure rates, all but two reported partial or complete reinnervation failures only and no microvascular failures. Cardenas-Mejia et al. and Bhama et al. did not specify the type of reconstructive failure. A total of 13 (3.6%) out of 360 reported failures occurred in CFNG, 7 (1.9%) in coaptations with MNTM, 1 (0.3%) with spinal accessory nerve, and 7 (1.9%) with unknown nerve coaptations. Based on the available data, comparisons of reinnervation failure in CFNG versus MNTM coaptations could not be performed due to heterogeneous reporting.

Revision procedures: Ten (32.3%) studies reported subsequent revision procedures (Table 4). Pooled proportion estimate of revision procedures such as muscle debulking and insertion site repositioning was not performed considering the high heterogeneity of revision rates described, ranging from 3% to 75%. This extensive variation in reporting may be explained by individual surgeons' and patients' thresholds. It may also stem from reporting bias⁵³ or lack of long-term

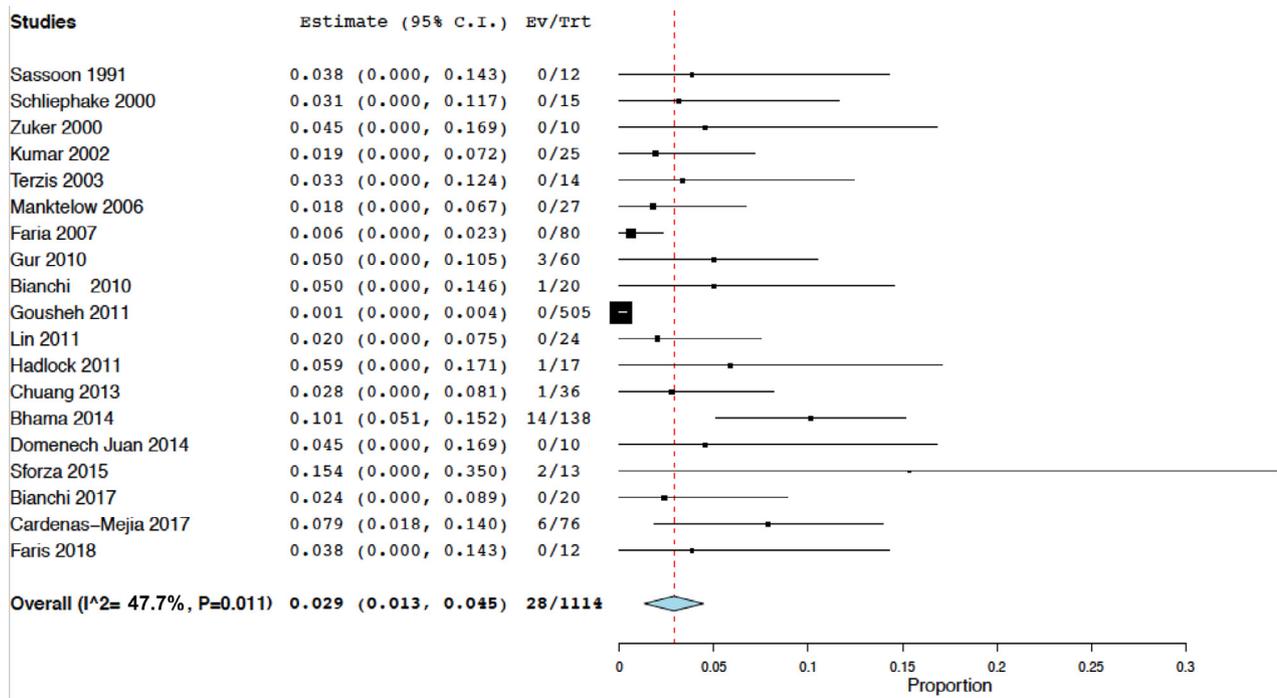


Figure 3 Forest plot of pooled proportion of flap failure.

Table 4 Studies reporting postoperative revision procedures.

Studies	Patients <i>n</i>	Flaps <i>n</i>	Revision procedures			Total
			Muscle debulking	Insertion sites rearrangements	Others	
Sassoon et al., ²⁰ 1991	12	12	4 (33.3)	5 (41.7)	0	9 (75.0)
Schliephake et al., ²³ 2000	15	16	6 (40.0)	-	-	6 (40.0)
Zuker et al., ³ 2000	10	20	0	0	1 (10.0) hypertrophic scar	1 (10.0)
Kumar and Hassan, ²⁴ 2002	25	25	0	2 (8.0)	10 (40.0) sling (3); fat injection (2); others (5)	12 (48.0)
Terzis and Noah, ²⁵ 2003	14	19	3 (21.4)	0	1 (7.1) muscle plication	4 (28.6)
Gur et al., ²⁹ 2010	60	60	-	3 (5.0)	-	3 (5.0)
Bianchi et al., ³⁰ 2010	20	30	-	1 (5.0)	-	1 (5.0)
Lin et al., ³² 2011	24	24	-	-	1 (4.2) coverage of partial skin paddle loss	1 (4.2)
Bianchi et al., ² 2016	42	42	0	3 (7.1)	5 (11.9) adherence removal (3); fat injection (2)	8 (19.0)
Braig et al., ⁴³ 2017	20	20	5 (25.0)	0	0	5 (25.0)
Total	242	268	18	14	18	50

Values are frequencies (percentages) per patient unless otherwise indicated.

follow-up. Five (50.0%) studies^{2,23,24,32,43} reporting revisions also indicated length of follow-up (1-5 years).

Health-related quality-of-life: Seven (22.6%) studies assessed patients' change in quality-of-life using the FaCE⁵⁴ (Facial Clinimetric Evaluation) instrument,^{11,33,40,45} the Facial Disability Index (FDI) questionnaire,^{2,44} and the SF-36.²³ The FaCE instrument revealed statistically significant improvements ranging from 13.7 to 17.7 (pre- to postoperative score differences). The FDI also showed statistically significant perioperative score improvements (5.5-7.5). The tool selection heterogeneity and absence of reported standard deviations did not allow for data pooling.

Discussion

Dynamic smile restoration using free gracilis muscle requires careful planning and surgical precision, as well as comprehensive postoperative therapy. Results obtained following such a reconstruction lead to functional, emotional, and esthetic improvements.¹ This comprehensive systematic review and meta-analyses of nonrandomized studies provides a thorough representation and interpretation of reported surgical outcomes. Major clinical heterogeneity was found in the nerves used for coaptation and the age of patients. Pooled estimates revealed significant perioperative

improvement in smile excursion of the paretic mouth commissure of 7.5 mm because a meaningful oral commissure excursion is described as anything higher than 3 mm.^{39,47} We also determined that 97% of patients had a viable re-innervated free gracilis flap that should allow them to smile and better perform daily activities such as chewing and speaking. This very high success rate sets a reference for the use of the gracilis muscle for dynamic smile reanimation. Smile restoration using the free gracilis muscle sometimes requires subsequent revision procedures, but the involved risks may be overridden by the anticipated improvements in quality-of-life. Nerve regeneration remains less predictable, and further investigations examining strategies to optimize axonal load may better guide nerve coaptation selection.

Our subgroup analysis comparing MNTM and CFNG groups identified that MNTM coaptations may be associated with greater smile excursion (10.0 mm versus 6.8 mm).⁴ However, despite providing less commissural movement, the CFNG generally produces a more spontaneous and coordinated smile. The quest for a symmetric, synchronous smile with normal excursion may require further exploration of the role of dual innervation and enhancement of nerve regeneration or axonal load.^{55,56} Further research investigating outcomes of incomplete facial paralysis would also help guide preoperative planning and nerve coaptation selection. We planned to perform subgroup analyses according to patients' age (pediatric versus adults). However, the outcomes' reporting of included studies precluded this analysis, and original data could not be obtained by contacting authors. Sensitivity analysis based on the smile excursion measurement tool selected was not performed, as due to unexpected diversity in instruments used, only limited data were represented per tool.

This meta-analysis highlights the lack of universally adopted outcomes' measurement tools for smile reanimation procedures. Although there is no shortage of proposed tools to measure smile motion, some requiring more complex methodology or ancillary support equipment,⁵⁷ a definite absence of standardization exists.^{1,58} In our review, fifteen different tools or assessment methods were reported. This diversity in smile outcome assessments may be explained by smile mobility's multifactorial character. Both three-dimensional and two-dimensional approaches can be considered because of the multivectorial nature of movements. Because of the natural continuum between a fully rested mouth and maximal contraction,⁵⁴ videos may allow a more accurate measure of smile excursion than pictures. It is essential to recognize that regardless of the tool used, subtle differences in oral movements and function may not be fully captured with grading instruments nor be clinically relevant to patients.⁵⁹ Effectiveness should be defined by objective, comparable, and standardized smile excursion and facial symmetry measures and with patients' experiences of their condition.

Patient-reported outcome measures (PROMs) have emerged as key assessment tools to better capture the impact of procedures and their value to patients. Motion should be distinguished from the concept of facial disability.⁵⁴ With regard to that, PROMs may represent the only reliable approach to gain understanding of patients' psychosocial status, highly relevant to the facial paralysis

population.⁶⁰ This unique perspective has been further investigated in the facial paralysis patient population,⁶¹ and specific validated instruments exist. Only 23% of our included studies assessed patients' quality-of-life using patient-reported questionnaires. General health-related quality-of-life instruments have previously been shown to lack sensitivity for the assessment of facial nerve-related impairments.⁶² Tools that have been specifically developed and that should be considered in smile reanimation research are the Facial Clinimetric Evaluation⁵⁴ (FaCE), the Facial Disability Index² (FDI), and the FACE-Q.⁶³ The FaCE is a reliable and validated scale with a focus on disability. It consists of 15 items measured on 5-point Likert scales. Similarly, the FDI is a reliable and validated self-reported 10-item questionnaire. The FACE-Q is a psychometric scale originally developed for esthetic procedures. A module specifically pertaining to facial paralysis is currently under development. It is understandable that these instruments involve additional patient commitment and organization. Their added value allowing for comprehensive evaluation of patients' perspective outweighs the technical challenges. The integration of PROMs to routine clinical practice enables the capture of patient satisfaction and quality-of-life toward a best-practice surgical care approach.⁶⁴

Unlike previously published reviews,⁵⁻⁷ this meta-analysis attempted to assess the outcomes of gracilis muscle transplantation for smile reanimation with pooled data providing a more complete understanding of expected outcomes. Strengths of the review include a comprehensive literature search, rigorous methodological approach including contact made with authors to obtain original data, and careful selection of clinically relevant outcomes. We acknowledge the limitations such as the lack of standardized timing for outcomes' assessment, especially smile excursion, in included studies. We ensured that follow-up of appropriate length was evaluated through our risk of bias assessment and present when capturing outcomes of interest. The timing of assessments was not uniform, but it was overall appropriate to perform data collection such as smile excursion post reinnervation. The methodologic limitations of the published evidence with variable and often small sample sizes, the heterogeneity in the eligible patient population, and the variable measurement tools used for smile excursion reduced the power of the meta-analysis in drawing conclusions. The efficacy and safety conclusions are derived from non-randomized studies, and as such, the evidence remains of low quality. Future studies are needed in well-delineated patient populations in terms of age (pediatric versus adults), sides of paresis (unilateral versus bilateral), and nerve used for coaptation (CFNG versus MNTM).

Conclusions

Dynamic smile restoration using a free gracilis muscle may offer facial paralysis patients a strategy to regain oral commissure motion and to improve their quality-of-life with modest risks of failure and an acceptable rate for further revision procedures. Masseteric nerve coaptations lead to larger improvements in perioperative smile excursion (10 mm) than with cross-facial nerve grafts (6.8 mm). This review highlights a critical need for universal outcome

assessment, integration of PROMs, and better designed studies to facilitate interpretation of results and improve patient care.

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Conflict of interest

None.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2019.05.027.

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