NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of free-functioning gracilis transfer to restore upper limb function in brachial plexus injury

The brachial plexus is a network of nerves coming from the neck and supplying muscles in the arm. Damage to these nerves can cause muscle paralysis, which stops the arm working properly. This procedure is done under general anaesthesia, a piece of hamstring muscle and its nerve and blood supply (free-functioning gracilis) are taken from the inner thigh, transferred to the arm and joined to the damaged nerve. The aim is to restore arm function, usually bending the elbow. Long-term physiotherapy is needed.

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Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2019.

Procedure name

 Free-functioning gracilis transfer to restore upper limb function in brachial plexus injury

Professional societies

- British Association of Plastic Reconstructive and Aesthetic Surgeons
- British Orthopaedic Association
- British Orthopaedic Sports Trauma Association
- British Society for Children's Orthopaedic Surgery

Description of the procedure

Indications and current treatment

The brachial plexus is a network of nerves that carries signals from the spinal cord to the shoulder, arm and hand. These nerves can be damaged by being stretched, compressed or torn from the spinal cord. The most severe brachial plexus injuries are often a result of road traffic accidents. Severe nerve damage can lead to paralysis of an upper limb, with a loss of function and sensation, and severe pain.

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Treatment depends on the type and severity of the injury, and the length of time since the injury. Injuries of the upper brachial plexus roots affect the muscles around the shoulder and injuries of the lower roots affect the hand. Many injuries affect both upper and lower roots. Current treatments include drugs to treat pain, and conservative care (such as physiotherapy). For some people surgical procedures (such as direct suture, nerve grafts, nerve transfer, tendon transfer and free-functioning muscle transfer) are needed to restore function.

What the procedure involves

This procedure aims to restore the function of the upper limb after brachial plexus injury, improving the patient's ability to carry out daily activities.

The procedure is performed under general anaesthesia, with the patient in a supine position. A functioning gracilis muscle, with its own nerve and blood supply, is dissected from the inner thigh. The gracilis muscle is then transferred and joined to the prepared recipient site of the upper limb, and the gracilis muscle's nerve is connected to a functioning nerve in the arm. The transfer is usually to 1 muscle group but transfer to different sites, such as the biceps or the finger flexors, may be needed depending on the nerve injury.

After the procedure, the patient needs to wear a cast or splint for about 6 weeks to immobilise the elbow and protect the transferred gracilis muscle. Then long-term physiotherapy is needed so that the patient can learn to control the transferred muscle.

Outcome measures

The Disabilities of the Arm, Shoulder and Hand questionnaire consists of 30 selfreported items to rate upper extremity disability and symptoms. Questions 1 to 21 reflect motor function, and questions 22 to 30 social and psychosomatic attributes, including pain. The scores range from 0 (no disability) to 100 (most severe disability).

The Medical Research Council (MRC) scale grades muscle power on a scale of 0 to 5: grade 0 indicates no contraction and grade 5 shows normal muscle contraction against full resistance.

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Efficacy summary

Restoration of elbow function

Muscle power

In a systematic review of 19 studies (n=347 patients with brachial plexus injuries), for elbow flexion, 87% of patients reached Medical Research Council (MRC) grade 3 or more and 65% reached MRC grade 4 or more at a minimum follow up of 12 months after free-functioning muscle transfer (FFMT)¹.

In a systematic review of 33 studies (n=103 patients with traumatic brachial plexus injuries), MRC grade 3 or more was reported in 82% (39/47) of patients (95% confidence interval [CI] 70% to 91%) who had FFMT at a median follow up of 36 months and 47% (23/49) of patients (95% CI 34% to 61%) who had nerve reconstruction at a median follow up of 24 months. This difference was statistically significant (p<0.01)². For MRC grade 4 or more, the proportion of patients was statistically significantly higher in the FFMT group (51% [24/47], 95% CI 37% to 65%) than in the nerve reconstruction group (33% [16/49], 95% CI 21% to 47%, p<0.01)².

In a non-randomised comparative study of 65 patients with traumatic brachial pan-plexus (complete) injuries, at a median follow up of 36 months, 69% (22/32) of patients in the FFMT (gracilis) group reached MRC grade 3 or 4 compared with 64% (21/33) in the FFMT (gracilis) with neurotisation (intercostal nerve [ICN]-to-musculocutaneous nerve [MCN] transfer) group (p>0.05)⁴. In the same study, there was no statistically significant difference in the proportions of patients reaching MRC grade 3 or 4 between FFMT (gracilis) neurotised by the spinal accessory nerve (SAN; 69% [20/29]) and ICN (64% [23/36], p>0.05) (nerve transfer)⁴. However, for tendon attachment, there was a statistically significant difference in the proportion of patients reaching MRC grade 3 or 4 between gracilis to biceps tendon attachment (53% [20/38]) and gracilis to flexor digitorum profundus or flexor pollicis longus tendon attachment (85% [23/27], p<0.05)⁴.

In a non-randomised comparative study of 62 patients with traumatic brachial pan-plexus injuries, the proportion of patients reaching MRC grade 3 or 4 was statistically significantly higher in the FFMT (gracilis) group (68% [21/31]) compared with the neurotisation (ICN-to-MCN transfer) group (42% [13/31], p=0.04) 18 months postoperatively⁵. In the same study, for patients who had FFMT (gracilis), there was no statistically significant difference in the proportions of patients reaching MRC grade 3 or 4 between the 2 donor nerves (71% [15/21])

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of patients with SAN transfers compared with 60% [6/10] of patients with ICN transfers, p=0.99)⁵.

In a non-randomised comparative study of 38 patients with traumatic brachial plexus injuries, 68.4% (26/38) of patients reached MRC grade 3 or 4 at a mean follow up of 12 months. There was no statistically significant difference in the proportions of patients reaching MRC grade 3 or 4 between the 2 donor nerves (SAN 83% [15/18] compared with ulnar nerve 55% [11/20], p=0.86)⁶.

In a case series of 130 patients with brachial plexus injuries, an MRC grade of 3 or more was reported in 88% (78/89) of patients who had surgery before the procedure was modified and 98% (40/41) who had surgery after the procedure was modified, relating to placement of the gracilis on the clavicle⁷.

In a case series of 42 patients with traumatic brachial plexus injuries, 88% (37/42) of patients reached an MRC grade of 3 or more at a mean follow up of 30 months⁸.

In a case series of 68 patients with brachial plexus injuries, 77% (47/61) of patients regained MRC grade 3 or 4 at 12-month follow up^9 .

Range of motion

In the systematic review of 19 studies (n=347), at a minimum follow up of 12 months, mean elbow extension ranged from 10 degrees (0) to 33⁰ and mean elbow flexion from 88⁰ to 119⁰ (8 studies, n=109)¹. In the same study, the mean active flexion arc ranged from 58⁰ to 107⁰ (10 studies, n=164) and the median active flexion arc was 107⁰ (range 80⁰ to 116⁰; 1 study, n=42). To do most activities of daily living, a functional elbow range of motion from 30⁰ to 130⁰, or active flexion arc of 100⁰, is needed.

In the systematic review of 33 studies (n=103), at a median follow up of 36 months, the mean active range of motion was $97.1^{0}\pm33.9^{0}$, which statistically significantly improved from baseline $(5^{0}\pm5^{0}, p<0.01)^{2}$.

In a non-randomised comparative study of 81 patients with a traumatic total brachial plexus injury, the mean elbow flexion was statistically significantly higher in the double FFMT (gracilis) group (119.7^o for elbow flexion and finger extension, and then for finger flexion) at 33 months after the operation compared with the single FFMT (gracilis) group (106.9^o for elbow flexion and finger flexion) at 55 months and the nerve transfer group (113.6^o) at 45 months (p=0.018)³.

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Restoration of shoulder function in upper brachial plexus lesions

In the non-randomised comparative study of 81 patients, the mean external rotation of the shoulder was statistically significantly better in the double FFMT (gracilis) group (-14.5^o) at 33-month follow up compared with the single FFMT (gracilis) group (-20.7^o) at 55-month follow up and the nerve transfer group (-40.0^o) at 45-month follow up (p=0.004)³. In the same study, the mean arc of rotation was also statistically significantly better in the double FFMT (gracilis) group (65.1^o) compared with the single FFMT (gracilis) group (47.3^o) and the nerve transfer group (32.6^o, p=0.002)³. However, the mean shoulder abduction (double FFMT [gracilis] 34.6^o, single FFMT [gracilis] 28.1^o, nerve transfer 32.8^o; p=0.632) and flexion (double FFMT [gracilis] 26.4^o, single FFMT [gracilis] 25.4^o, nerve transfer 14.2^o; p=0.188) were comparable in all 3 groups.

Restoration of finger function in lower brachial plexus lesions

In the non-randomised comparative study of 81 patients, the mean total active finger movement (TAM) was 46.8° (range 0° to 142°) in patients who had double FFMT (gracilis) at a mean follow up of 33 months, 13.5° (range 10° to 24°) in patients who had single FFMT (gracilis) at 55 months and 0° in patients who had nerve transfer at 45 months³. For patients who had double FFMT (gracilis), the TAM consisted of a mean 30° arc at metacarpophalangeal joint (from -11° in extension to 40° in flexion) and mean 16° at proximal interphalangeal joint (from -61° in extension to 77° in flexion)³.

In the case series of 68 patients, 69% (42/61) of patients were capable of finger flexion between 35° and 60° at 12-month follow up⁹.

Patient-reported outcomes

Improvement in disability and symptoms

In the systematic review of 19 studies (n=347), the mean improvement in Disability of the Arm, Shoulder and Hand (DASH) scores was 27 points (4 studies, n=86) at a minimum follow up of 12 months¹.

In the non-randomised comparative study of 81 patients, the mean improvement in DASH scores was statistically significantly better in the double FFMT (gracilis) group (31.2 points) at 33 months after the operation compared with the single FFMT (gracilis) group (19.7 points) at 55 months and the nerve transfer group (18.3 points) at 45 months (p=0.0096). All 3 groups showed improvement in functional measures of more than the minimum clinically important difference of 17 points, which implies genuine clinical improvement in patients' activities of daily living³.

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In the non-randomised comparative study of 65 patients, at a median follow up of 36 months, the FFMT (gracilis) group reported a non-statistically significant improvement in the mean score (4.6±17 points, p>0.05), whereas the FFMT (gracilis) with neurotisation (ICN to MCN transfer) group showed a statistically significant improvement (18.9±15.8 points, p<0.05)⁴.

In the non-randomised comparative study of 62 patients, the mean improvement in DASH scores was 5.5 ± 15.6 in the FFMT (gracilis) group (p=0.09) and 6.3 ± 14.5 in the neurotisation (ICN-to-MCN transfer) group (p=0.08) at 18-month follow up⁵. There was no statistically significant difference in the mean changes between groups (p=0.77)⁵.

In the case series of 42 patients, the mean DASH score was 43.09 ± 14.9 at a mean follow up of 30 months⁸.

Reduction in pain

The mean pain score (using a visual analogue scale [VAS]) ranged from 3.6 to 49 postoperatively (3 studies, n=90) in the systematic review of 19 studies $(n=347)^{1}$.

The mean VAS score for pain was 51 in patients who had double FFMT (gracilis) at a mean follow up of 33 months, 49 in patients who had single FFMT (gracilis) at 55 months and 49 in patients who had nerve transfer at 45 months in the non-randomised comparative study of 81 patients³. The difference between treatment groups was not statistically significant (p=0.953).

The mean VAS score for pain was 3.6 ± 3.0 at a mean follow up of 30 months in the case series of 42 patients⁸.

Return to work or school

In the systematic review of 19 studies (n=347), the proportion of patients who returned to work ranged from 75% to 83% (3 studies, n=78) at a minimum of 12 months after the operation¹.

In the non-randomised comparative study of 81 patients, the proportions of patients who had returned to work were 83% (39/47) in the double FFMT (gracilis) group at a mean follow up of 33 months, 75% (12/16) in the single FFMT (gracilis) group at 55 months and 75% (13/18) in the nerve transfer group at 45 months³. The difference between treatment groups was not statistically significant³.

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Satisfaction with surgery

In the systematic review of 19 studies (n=347), 15% to 91% of patients (in 4 studies, n=88) were satisfied with the surgery¹.

In the non-randomised comparative study of 81 patients, the proportions of patients who were satisfied with the treatment and outcome were 71% (33/47) in the double FFMT (gracilis) group after a mean follow up of 33 months, 50% (8/16) in the single FFMT (gracilis) group at 55 months and 50% (9/18) in the nerve transfer group at 45 months³. The difference between treatment groups was not statistically significant.

Using the reconstructed limb for activities of daily living

In the systematic review of 19 studies (n=347), 25% to 96% of patients used their reconstructed limbs for activities of daily living (in 2 studies, n=52) at a minimum follow up of 12 months¹.

In the non-randomised comparative study of 81 patients, the proportions of patients who used their reconstructed limbs for activities of daily living were 43% (20/47) in the double FFMT (gracilis) group, 25% (4/16) in the single FFMT (gracilis) group and 25% (5/18) in the nerve transfer group at a minimum follow up of 24 months³. The difference between the groups was not statistically significant³.

Safety summary

Flap failure

Flap failure was mentioned in 13 studies in the systematic review of 19 studies (n=347). Of these 13 studies, a failure rate ranging from 4% to 17% was reported in 7 studies and 0 in 6 studies (number of patients was not reported)¹.

Flap failure was reported in 8% (7/89, 95% CI 3% to 16%) of patients who had surgery before the procedure was modified and 2% (1/41, 95% CI 0% to 13%) of patients who had surgery after the procedure was modified in the case series of 130 patients⁷. The difference in failure rates before and after the procedure modification was not statistically significant (p=0.434), and all the affected muscles were removed within 34 days postoperatively.

Flap failure was reported in 10% (4/42) of patients in the case series of 42 patients⁸. The failed flaps were removed within 1 week of the initial transfer and all 4 patients did not consent to another muscle transfer.

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Infection

Infection was reported in 4 patients (2 studies, n=36) in the systematic review of 19 studies (n=347)¹.

Infection was reported in 2 patients (1 in the upper limb and 1 in the donor thigh) in the non-randomised comparative study of 38 patients. The infections resolved with simple superficial debridement without harming the flap⁶.

Infection in the upper limb was seen in 2 patients in the case series of 130 patients and caused flap failure⁷. The affected muscles were removed within 34 days postoperatively.

Recipient site complications

Thrombosis

Thrombosis was reported in 6 patients (4 arterial and 2 venous; 2 studies, n=52) in the systematic review of 19 studies $(n=347)^{1}$.

Thrombosis was reported in 4% (5/130) of patients (arterial thromboses, n=2; arterial and venous thromboses, n=1; venous thrombosis, n=1; vessel thrombosis, n=1) in the case series of 130 patients⁷. Thrombosis caused flap failure and the affected muscles were removed within 34 days postoperatively.

Arterial thrombosis was seen in 2 patients and caused flap failure in the case series of 42 patients⁸. The failed flaps were removed within 1 week of the initial transfer and these 2 patients did not consent to another muscle transfer.

Necrosis

Necrosis was reported in 6 patients (3 skin necrosis and 3 gracilis partial necrosis; 3 studies, n=90) in the systematic review of 19 studies (n=347)¹.

Skin flap necrosis happened in 2 patients at months 22 and 36 respectively in the case series of 42 patients⁸. Of the 2 patients, 1 had inspection of anastomosis within 24 hours after surgery with no revision of anastomosis done, and 1 had the skin flap excised with small windows for muscle monitoring, and delayed closure within 1 week.

Haematoma

Haematoma was reported in 3 patients (1 study, n=42) in the systematic review of 19 studies (n=347)¹.

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Haematoma was reported in 1 patient in the case series of 130 patients⁷. This caused flap failure and the affected muscle was removed within 34 days postoperatively.

Vascular impairment

Vascular impairment of the skin monitor was reported in 2 patients in the nonrandomised comparative study of 38 patients⁶. The gracilis muscle maintained adequate perfusion after the skin monitors were excised; both patients had skin grafts.

Vascular insufficiency with apparently patent vessels at exploration happened in 1 patient and caused gracilis graft failure in the case series of 130 patients⁷. The affected muscle was removed within 34 days of the operation.

Fat liquefaction

Fat liquefaction was reported in 2 patients (1 study, n=42) in the systematic review of 19 studies $(n=347)^{1}$.

Bowstringing

Bowstringing at the elbow happened in 8 patients (1 study, n=42) in the systematic review of 19 studies $(n=347)^{1}$.

Bowstringing was reported in 13.5% (12/89, 95% CI 7.2% to 22.4%) of patients who had surgery before the procedure modification and 0% of patients who had surgery after the procedure modification in the case series of 130 patients⁷. The difference was statistically significant (p=0.018).

Dehiscence

Recipient site dehiscence was reported in 1 patient (1 study, n=26) in the systematic review of 19 studies $(n=347)^{1}$.

Wound dehiscence happened in 3 patients at a follow up of 13 to 32 months in the case series of 42 patients. Of these 3 patients, 2 had dehiscence done near the skin flap closure and 1 had local debridement and closure done⁸.

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Donor site complications

Transient sensory disturbance around the knee

Transient sensory disturbance around the knee happened in 2 patients at 12 months after the operation in the case series of 42 patients⁸. Both patients did not have additional surgery and this resolved after 3 and 5 months.

Transient peroneal palsy

Transient peroneal palsy was reported in 1 patient who had gracilis-adductor muscle transfer at 23-month follow up in the case series of 42 patients⁸. This event completely disappeared after a further 3 months.

Knee instability

Subjective knee instability was reported in 1 patient (1 study, n=10) in the systematic review of 19 studies $(n=347)^{1}$.

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, the professional expert did not list any anecdotal adverse events and theoretical adverse events.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to free-functioning gracilis transfer to restore upper limb function in brachial plexus injury. The following databases were searched, covering the period from their start to 24 October 2019: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the <u>literature search</u> <u>strategy</u>). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

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Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies.
	Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study.
	Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with brachial plexus injury.
Intervention/test	Free-functioning gracilis transfer.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Table 1 Inclusion criteria for identification of relevant studies

List of studies included in the IP overview

This IP overview is based on 929 patients from 2 systematic reviews^{1, 2}, 4 non-randomised comparative studies³⁻⁶ and 3 case series⁷⁻⁹.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) are listed in the <u>appendix</u>.

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Table 2 Summary of key efficacy and safety findings on free-functioning gracilistransfer to restore upper limb function in brachial plexus injury

Study 1 Yi Lee (2019)

Details

Study type	Systematic review				
Country	Not reported for individual studies				
Recruitment period	Publication years for included studies: 1990 to 2017				
Study population and	n=19 studies (347 patients)				
number	Patients with traumatic brachial plexus injuries				
Age and sex Up to 60 years with a mean age of injury less than 35 years (15 of the 19 articles); gender was not reported					
Patient selection criteria	Inclusion criteria: studies included patients who sustained traumatic brachial plexus injuries, published up to July 2017; FFMT predominantly for adults and for injuries related to brachial plexus injuries.				
	Exclusion criteria: single case reports, articles not published in English, as well as articles on FFMT performed predominantly on obstetric brachial plexus injuries were excluded.				
Technique	The most common muscle transferred was the gracilis (n=309), followed by the latissimus dorsi (n=17), rectus femoris (n=15) and a combination of gracilis and adductor longus (n=6).				
	Popular sites of FFMT proximal anchorage were the clavicle (8 studies, n=26) and coracoid process (4 studies, n=64), and popular sites of FFMT distal insertion were the biceps tendon or bicipital aponeurosis for elbow flexion (6 studies, n=87), and the long finger flexors or extensors for elbow and digital motion (9 studies, n=142). The most commonly chosen recipient vessel was the thoracoacromial artery (7 studies, n=138), followed by the brachial artery (4 studies, n=51). The most common donor nerve was SAN (13 studies).				
Follow-up	12 to 89 months				
Conflict of interest/source of funding	No potential conflicts of interest and no financial support				

Analysis

Follow-up issues: All patients were followed up for a minimum of 12 months and maximum of 89 months after freefunctioning muscle transfer (FFMT) surgery, with most patients being followed up for at least 24 months. Losses to follow up were not reported. Of the 364 patients, 17 complete flap failures because of vascular issues were reported, leaving 347 patients in this review.

Study design issues: This systematic review assessed the results of FFMT for elbow flexion in traumatic brachial plexus injuries. The outcome measures included flap failure rate, MRC power grade, elbow range of motion, sensory restoration, functional score, pain and patient rated outcome measures. This review was conducted in accordance with the PRISMA guidelines. Six databases were systematically searched, and titles and abstracts were screened by 3 authors independently. Postoperative management was not described.

Study population issues: Of the 19 studies, 8 reported on the use of FFMT purely for elbow flexion and the rest reported on the use of FFMT for simultaneous elbow flexion and digital motion or had additional procedures performed, such as nerve transfers. One study included both types of surgeries with separate data analysis and this was broken down into 3 separate components for analysis. Although patient selection was targeted at those who sustained traumatic brachial plexus injuries, 13 children with obstetric brachial plexus injuries and 1 adult with upper limb paralysis due to polio from a

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single study of 26 patients were included. FFMTs were most commonly performed in patients with total brachial plexus injuries, with time from injury to surgery ranging from 2 to 106 months.

Key efficacy and safety findings

Efficacy					Safety				
Number of patients a	analysed: 19 st i	udies (347 patien	ts)		Flap failur	e was menti	oned in 13 studies		
Muscle power for e	bow flexion:				• 7 studies: ranging from 4% to 17% in 7 studies				
 MRC grade 	e ≥4: 65% of 347	7 patients			• 6	studies: 0%			
 MRC grade 	e ≥3: 87% of 347	7 patients							
					Complicat		1		
A sub-analysis of 8 s hat 62% of patients power grade of ≥3.						Number of patients	Complications		
Elbow range of mo	tion (degrees):	: 11 studies (206 p	oatients)		Yang et al., 2016	42	Thrombosis (4, 2 arterial and 2 venous);		
	Number of patientsMean elbow extensionMean elbow flexionMean active flexion arc						gracilis partial necrosis (3); fat liquefaction (2);		
Doi et al., 1991	4	30	88	58			haematoma		
Doi et al., 1995	10	19	107	88			(3); bowstring at elbow (8)		
Surgpet et al., 2003	3	10	110	100	Potter and	16	Re-exploration (1, successful)		
Barrie et al., 2004	14	19	100	81	Ferris, 2017		excision of skin paddle for		
Gousheh and Arasteh, 2010	17	-	-	87	Vekris	s 10	cosmesis (6) Skin necrosis		
Coulet et al., 2011	10	29	115	86	et al., 2008		and infection (1)		
Dodakundi et al., 2013	36	33	119	86	Kay et al.,	26	Donor site infection (3);		
Estrella and Montales, 2016	38	-	-	107	2010		recipient site dehiscence, skin grafted (1)		
Yang et al., 2016	42	-	-	80 to 116 (median 107)	Coulet et al.,	10	Arterial thrombosis s/p		
Satbhai et al., 2016	16	30	107	77	2011	l	revision (2); MRC 1 for		
Potter and Ferris, 2017	16	23	112	89			both. Subjective		
Sensory recovery o							knee instability (1) d in Estrella and		
		ents achieved reas		ry recovery	Montales (2016) were (detailed in study 8		
		gained protective							
Elzinga et a	ai. (2014): n=2 r	egained protective	e sensation						
DASH scores: 8 stu	· ·	,							
		SH scores: 27 poin cores before and a		36 patients] that					

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	Number of patients	DASH score
Coulet et al., 2011	10	32 for complete BPI, 42 for partial (no preop)
Maldonado et al., 2017	32	Mean preop 43.5 (SD=21.4), mean postop 38 (SD=19), mean improvement 5.5
Dodakundi et al., 2013	36	Mean preop 66 (SD=14), mean postop 36 (SD=15), mean improvement 30
Elzinga et al., 2014	2	Mean preop 86, mean postop 34, mean improvement 52
Estrella and Montales, 2016	38	Mean postop 43.09 (SD=14.9) (no preop)
Yang et al., 2016	42	Mean postop 51.14 (SD=20.97) (No preop)
Satbhal et al., 2016	16	Mean preop 53.8, mean improvement 19.7
Potter and Ferris, 2017	16	Mean postop 47.3 (no preop)

Pain using a pain scale: 4 studies (132 patients)

	Number of patients	Mean VAS score for pain
Dodakundi et al., 2013	36	47
Satbhal et al., 2016	16	49
Yang et al., 2016	42	severe pain: 19% moderate pain: 31% mild pain: 29% no pain: 21%
Estrella and Montales, 2016	38	3.6

Return to work or school and satisfaction: 4 studies (88 patients)

			(I)	
	Number of patients	Return to work/school	Using the reconstructed limb for activities of daily living	Satisfaction with the surgery
Dodakundi et al., 2013	36	75%	25%	50%
Satbhal et al., 2016	16	83%	96%	74%
Kay et al., 2010	26	80%	-	73%
Coulet et al., 2011	10	-	-	91%

Yang et al. (2016) found 43% of 42 patients reported anxiety, with 2% experiencing severe anxiety after the procedure. Forty-five per cent of patients reported depression, with 10% experiencing severe depression.

Abbreviations used: DASH, disabilities of the arm, shoulder and hand; FFMT, free-functioning muscle transfer; MRC, Medical Research Council; SD, standard deviation; VAS, visual analogue scale.

Study 2 Hoang D (2018)

Details

Study type	Systematic review
Country	Not reported for individual studies
Recruitment period	Search date: June 2016
	Publication years for included studies: 1982 to 2015
Study population and number	n=33 studies (103 patients, 50 free functional muscle transfers [12 studies] compared with 53 nerve reconstruction [22 studies])
	Patients with late (≥12 months) presentation of traumatic brachial plexus injuries
Age and sex	FFMT: median 28.9 years (range 18 to 56 years); gender was not reported
	Nerve reconstruction: median 27 years (range 18 to 54 years); gender was not reported
Patient selection criteria	Inclusion criteria: studies in the English language, published between 1940 and 2016, and concerning brachial plexus injuries treated by nerve graft, nerve transfer, or free functional muscle transfer.
	Exclusion criteria: non-traumatic brachial plexus injuries, patients younger than 18 years, studies without any data on duration from injury to surgery, patients who had surgical intervention less than 12 months from their injury, patients who had follow up less than 12 months after their operation, and studies without any functional data for elbow flexion.
Technique	FFMT: muscles of FFMT were gracilis (7 studies, 40 patients), medial gastrocnemius (1 study, 4 patients), rectus femoris (1 study, 1 patient), latissimus dorsi (2 studies, 3 patients), and a combination of gracilis latissimus dorsi (1 study, 2 patients). Transferred nerves were spinal accessory, intercostal and ulnar nerves.
Follow-up	FFMT: median 35.5 months
	Nerve reconstruction: median 24 months
Conflict of interest/source of funding	No financial interest and no specific grant from any funding agency.

Analysis

Follow-up issues: There was a statistically significant different in the median length of follow up between patients who had free-functioning muscle transfer (FFMT; 35.5 months, range 12 to 260 months) and patients who had nerve reconstruction (24 months, range 10 to 120 months, p=0.02). Losses to follow up were not reported for individual studies.

Study design issues: This systematic review evaluated recovery of elbow flexion after nerve reconstruction compared with FFMT for late, traumatic brachial plexus palsy. This review was conducted in accordance with the PRISMA guidelines. Three databases were searched by 2 authors independently. These 2 authors independently screened titles and abstracts, and then reviewed the full text of the articles. When there was disagreement, a consensus decision was determined with the assistance of the senior author.

To evaluate study quality and reporting bias, the methodological index for non-randomised studies criteria was applied. Each study was evaluated by 2 authors with a score of 0, 1 or 2 points for each of the applicable methodological index for non-randomised studies criteria items. The scores were added and reported in percentages (of a possible 16 points for non-comparative studies and 24 points for comparative studies) to allow for a review of individual study quality. One hundred percent indicates a perfectly conducted study and 0% indicates the worst possible study design.

Postoperatively, clinically useful strength for elbow flexion was defined as grade M3 or greater. Postoperative management was not described.

Study population issues: The methodological quality of included studies ranged from 50% to 92%, with a mean methodological index for non-randomised studies criteria score of 59% (95% CI 51% to 67%) for FFMT studies and 62%

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(95% CI 56% to 67%) for nerve reconstruction studies (p=0.72). There were no differences across groups regarding surgical age (time from injury) and preoperative elbow flexion. FFMT patients demonstrated a significantly longer interval from injury to surgery (p<0.01) and length of follow up (p=0.02) than nerve reconstruction patients.

For FFMT, 20% involved upper trunk injuries and 80% were for total brachial plexus injuries. For nerve reconstruction, 64% involved upper trunk injuries and 36% were for total brachial plexus injuries.

Key efficacy and safety findings

	Upper tr	unk		Total BP	P		Overall		
	FFMT	Nerve reconstruction	р	FFMT	Nerve reconstruction	р	FFMT	Nerve reconstruction	р
Overall sample size	10	34		40	19		50	53	
Preoperative MRC grade ≤1, % (n)	100% (5/5)	100% (25/25)	1	100% (20/20)	100 (2/2)	1	100% (25/25)	100% (27/27)	0.92
Postoperative MRC grade ≥3, % [95% CI], (n)	100% [72 to 100] (10/10)	53% [36 to 70] (16/30)	<0.01	78% [63 to 89] (29/37)	37% [19 to 59] (7/19)	<0.01	82% [70 to 91] (39/47)	47% [34 to 61] (23/49)	<0.0
Postoperative MRC grade ≥4, % [95% CI], (n)	70% [40 to 89] (7/10)	43% [27 to 61] (13/30)	0.17	46% [31 to 62] (17/37)	16% [6 to 38] (3/19)	<0.04	51% [37 to 65] (24/47)	33% [21 to 47] (16/49)	<0.0

Preoperative MRC grade for elbow flexion was available for 50% (25 of 50) of FFMT patients and 51% (27 of 53) of nerve reconstruction patients.

Comparison of FFMT and nerve transfers stratified by upper and total brachial plexus injuries

	Upper trunk			Total BPP			Overall		
	FFMT	Nerve transfer	р	FFMT	Nerve transfer	р	FFMT	Nerve transfer	р
Overall sample size	10	26		40	5		50	31	
Preoperative MRC grade ≤1, % (n)	100% (5/5)	100% (21/21)	1	100% (20/20)	100% (2/2)	1	100% (26/26)	100% (23/23)	1
Postoperative MRC grade ≥3, % [95% Cl], (n)	100% [72 to 100] (10/10)	59% [39 to 76] (13/22)	<0.03	78% [63 to 89] (29/37)	20% [3.6 to 62] (1/5)	<0.02	82% [70 to 91] (39/47)	52% [34 to 69] (14/27)	<0.01
Postoperative MRC grade ≥4, % [95% CI], (n)	70% [40 to 89] (7/10)	50% [31 to 69] (11/22)	0.44	46% [31 to 62] (17/37)	20% [4 to 62] (1/5)	0.37	51% [37 to 65] (24/47)	44% [27 to 63] (12/27)	0.58

Active range of motion for elbow flexion:

- FFMT: mean postoperative active range of motion was 97.1⁰±33.9⁰, which improved from a preoperative baseline of 5⁰±5⁰ (p<0.01).
 - Preoperative range of motion was reported in 8% (4/50) of FFMT patients, whereas postoperative active range of motion was reported in 65% (43/50) of FFMT patients.

IP overview: Free-functioning gracilis transfer to restore upper limb function in brachial plexus injury

Safety data were not reported.

Abbreviations used: BPP, brachial plexus palsy; CI, confidence interval; FFMT, free-functioning muscle transfer; MRC, Medical Research Council.

IP overview: Free-functioning gracilis transfer to restore upper limb function in brachial plexus injury

Study 3 Satbhai NG (2016)

Details

Study type	Non-randomised comparative study						
Country	Japan (single centre)						
Recruitment period	2002 to 2011						
Study population and	n=81 (47 double FFMT [gracilis], 16 single FFMT [gracilis] and 18 nerve transfer)						
number	Patients with a traumatic total brachial plexus injury						
Age and sex	Double FFMT (gracilis): mean 27.3 years (range 16 to 54 years); 94% (44/47) male						
	Single FFMT (gracilis): mean 27.2 years (range 18 to 51 years); 100% (16/16) male						
	Nerve transfer: mean 27.8 years (range 16 to 60 years); 83% (15/18) male						
Patient selection	Inclusion criteria: all patients with a traumatic total brachial plexus injury.						
criteria	Exclusion criteria: age between 5 and 60 years; willing to undergo long-term rehabilitation and follow up; age>60 years; pre-school children; follow up<24 months; associated spinal cord injury; associated cerebral vascular accident; non-compliance with the treatment; and lost to follow up.						
Technique	Nerve transfers: i) single stage nerve transfers for shoulder, elbow and hand reconstruction; and ii) secondary procedures.						
	Single FFMT (gracilis): i) nerve transfers for shoulder function, ii) free-functioning gracilis transfer for elbow flexion and finger flexion/extension; iii) secondary procedures.						
	Double FFMT (gracilis): i) nerve transfers for shoulder function and elbow extension; ii) free-functioning gracilis transfer for elbow flexion and finger extension; iii) free-functioning gracilis transfer for finger flexion; and iv) secondary procedures (wrist fusion, MPJ capsulodosis, shoulder fusion)						
Follow-up	Double FFMT (gracilis): mean 33 months						
	Single FFMF (gracilis): mean 55 months						
	<u>Nerve transfer</u> : mean 45 months						
Conflict of interest/source of funding	No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.						

Analysis

Follow-up issues: Twenty-four patients were excluded from the final analysis, including 2 patients in the double FFMT (gracilis) group and 1 in the single FFMT (gracilis) group who had flaps which failed because of vascular compromise; 3 patients with an associated thoracic cord injury and 1 patient with post-operative cerebral vascular disease in SMT; 14 patients who were lost to follow up and 3 international patients who did not reply to the Disability of Arm, Shoulder and Hand questionnaire (DASH) and quality of life questionnaire.

Study design issues: This comparative study evaluated functional outcomes and quality of life of patients with a traumatic total brachial plexus injury before and after 3 different procedures. Arm function was assessed in terms of the active range of movement (ROM) of shoulder abduction, flexion, external rotation, rotation arc, elbow flexion and extension, and total active movement (TAM) of fingers. The power of elbow flexion and extension were graded using the system described by the Medical Research Council (MRC). Quantitative isokinetic measurement of elbow flexion was assessed using a computerised dynamometer (KIN-COM). Hook grip strength was measured using digital hanging scale. All measurements were carried out on 3 separate occasions by different hand therapists. DASH scores were measured by qualified nurses at regular intervals (about 3 months) for a minimum of 2 years after the patient's last operation. All surgical procedures (nerve transfer, single FFMT [gracilis] and double FFMT [gracilis]) were performed by 1 senior surgeon.

After each muscle transfer, the upper limb was immobilised in an air bag arm brace and above-elbow backslab for 8 weeks. Early passive movements were started 1 week after surgery to prevent adhesion of the transferred muscle and

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tendon and continued until active finger movement was seen. Subsequently, a sling was used to prevent subluxation of the glenohumeral joint until the shoulder girdle or transferred muscles had recovered. A progressive muscle strengthening programme was started when electromyography showed that the transferred muscles or repaired nerves had been re-innervated.

Study population issues: In terms of demographic profile, the mean age, gender distribution, time after injury of operation and follow up period of the 3 groups (double FFMT [gracilis], single FFMT [gracilis] and nerve transfer) showed no significant differences. There was no significant difference between the 3 groups in the incidence of associated injuries which could have an impact on the outcome for nerve repairs for shoulder reconstruction. There was no significant difference in the injury pattern of the C5 root between the 3 groups. The mean length of time since injury was 16.7 months in the double FFMT (gracilis) group, 6.5 months in the single FFMT (gracilis) group and 3.2 months in the nerve transfer group (p=0.328).

Secondary procedures for each treatment group were:

- Double FFMT (gracilis): 2 shoulder fusions, 32 wrist fusions, 8 metacarpophalangeal joint capsulodesis and 6 tenolysis.
- Single FFMT (gracilis): 2 shoulder fusions, 3 wrist fusions and 2 tenolysis.
- Nerve transfer: 1 wrist fusion.

At a mean of 21.6 months after these procedure, tenolysis, capsulodesis, transient stabilisation of the proximal interphalangeal and distal interphalangeal joints and wrist fusion were performed. A total of 4 patients had shoulder fusion. Functional assessment was undertaken before the shoulder was fused.

Key efficacy and safety findings

unctional outcome:					
		Double FFMT (gracilis)	Single FFMT (gracilis)	Nerve transfer	P
Follow up (months)	Mean	33.2	55.2	45.1	0.323
	Range	24 to 79	24 to 180	24 to 120	
Shoulder ROM (⁰)			1	J	
Abduction	Mean	34.6	28.1	32.8	0.632
	Range	0 to 90	0 to 80	10 to 80	
Flexion	Mean	26.4	25.4	14.2	0.188
	Range	0 to 90	0 to 80	0 to 80	
External rotation	Mean	-14.5	-20.7	-40.0	0.004
	Range	-70 to 30	-80 to 20	-80 to 10	
Arc of rotation	Mean	65.1	47.3	32.6	0.002
	Range	0 to 120	0 to 100	0 to 70	
Elbow function (⁰)			1		1
Flexion	Mean	119.7	106.9	113.6	0.018
	Range	85 to 155	85 to 155 85 to 135		
		P	P=0.005562		
Flexion (MMT)	Mean	3.9	3.3	3.5	0.015
	Range	3 to 5	2 to 4	3 to 4	

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Flexion (KIN- COM)	n=	37	11	11	
Concentric	Mean, %	20.4	11.8	12.1	0.012
	Range, %	5 to 56	5 to 28	3 to 26	
Eccentric	Mean, %	20.9	14.4	14.5	0.022
	Range, %	3 to 44	6 to 36	5 to 32	
Extension	Mean	-33.2	-30.0	-31.7	0.514
	Range	-60 to -15	-50 to -20	-50 to -20	
Extension (MMT)	Mean	1.3	0.4	0.5	0.0106
	Range	0 to 5	0 to 3	0 to 3	
Finger function (°)					
ТАМ	Mean	46.8	13.5	0.0	
	Range	0 to 142	10 to 24	0.0	
ROM - MCPJ	Mean	30			
	Range	0 to 70			
	Mean Extension to Flexion arc	-11 to 40			
ROM - PIPJ	Mean	16			
	Range	0 to 54			
	Mean Extension to Flexion arc	-61 to 77			
Hook grip (kg)	Mean	3.8	3.7	0.0	
	Range	0 to 19.6	3 to 4.1	0.0	

There was significant correlation between MMT of elbow extension and TAM in the double FFMT (gracilis) group (Pearson's correlation coefficient, 0.396).

DASH and pain

		Double FFMT (gracilis)	Single FFMT (gracilis)	Nerve transfer	Р
DASH score					•
Pre-operative score	Mean	64.5	53.8	7.7	0.239
	Range	35 to 90	33 to 82	40 to 93	
Improvement	Mean	31.2	19.7	18.3	0.0096
	Range	4 to 65	-24 to 53	-32 to 79	
Pain score (Q24, 25	, 26, 29)				•
Pre-operative score	Mean	3.2	3.0	3.9	0.0601
	Range	1 to 5	1 to 5	1 to 5	
Improvement	Mean	0.7	0.5	1.2	0.0261
	Range	-2 to 4	-4 to 4	-3 to 4	

The MCID of DASH for all upper extremity disorders is 17 points, and this implies genuine clinical improvement in patients' activities of daily living.

No significant correlation was found between improvement in DASH score and factors such as age, follow up period, shoulder ROM, elbow ROM, elbow power and finger TAM.

DASH score – 21 items relating to motor function:

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- An improvement of >1.5 points: 9 patients in the double FFMT (gracilis) group;
- A mean improvement of 1 or more points: 13 items in the double FFMT (gracilis) group, 12 in the single FFMT (gracilis) group and 4 in the nerve transfer group.

DASH score – 9 items relating to social and psychosomatic attributes:

• A mean improvement of 1.0 points: 4 items in the double FFMT (gracilis) group, 1 in the single FFMT (gracilis) group and 6 in the nerve transfer group.

In the double FFMT (gracilis) group, most improvement was noted for carrying a heavy object over 5 kg (Q11), washing or blow drying hair (Q13) and putting on a pullover sweater (Q15) (mean improvement score>2). The double FFMT (gracilis) patients showed an overall improvement in function of the arm, particularly for activities which required the use of both hands.

Return to work:

- Double FFMT (gracilis): 83% (39/47)
- Single FFMT (gracilis): 75% (12/16)
- Nerve transfer: 75% (13/18)

Use of the reconstructed limb:

- Double FFMT (gracilis): 43% (20/47)
- Ssingle FFMT (gracilis): 25% (4/16)
- Nerve transfer: 25% (5/18)

Overall satisfaction with the treatment:

- Double FFMT (gracilis): 71% (33/47)
- Single FFMT (gracilis): 50% (8/16)
- Nerve transfer: 50% (9/18)

P values >0.05

Shoulder fusion: n=4, after fusion, the mean improvement in shoulder abduction and flexion was 36° (25° to 60°) and 38° (30° to 60°), respectively, in external rotation. The improvement in elbow flexion was 14° (10° to 20°). Mean DASH improvement was 4.3 points (3.8 to 5.1).

Pain using VAS, mean (range)

- Double FFMT (gracilis): 51 (range 0 to 100)
- Single FFMT (gracilis): 49 (range 0 to 80)
- Nerve transfer: 49 (range 0 to 80) p=0.953

Taking analgesics:

	Double FFMT (gracilis)	Single FFMT (gracilis)	Nerve transfer
Always	5	2	2
Sometimes	7	1	1
Rarely	4	0	0
Almost never	12	0	0
Never	13	9	9

p=0.004

Safety data were not reported.

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Abbreviations used: DASH, disabilities of the arm, shoulder and hand; FFMT, free-functioning muscle transfer; KIN-COM, quantitative analysis of elbow flexion by KIN-COM machine; MCID, minimum clinically important difference; MCPJ, metacarpophalangeal joint; MMT, manual muscle testing; PIPJ, proximal interphalangeal joint; ROM, range of movement; TAM, total active finger movement; VAS, visual analogue scale.

IP overview: Free-functioning gracilis transfer to restore upper limb function in brachial plexus injury

Study 4 Maldonado AA (2017)

Details

Study type	Non-randomised comparative study
Country	USA (single centre)
Recruitment period	2000 to 2013
Study population and number	n=65 (32 FFMT [gracilis] compared with 33 FFMT [gracilis] with neurotisation [ICN to MCN transfer])
	Patients with traumatic brachial pan-plexus injuries
Age and sex	FFMT (gracilis): mean 30.7 years (SD=14.7); 72% (23/32) male
	FFMT (gracilis) with neurotisation (ICN to MCN transfer): mean 32.5 years (SD=14.3); 88% (29/33) male
Patient selection criteria	Inclusion criteria: patients with pan-plexus avulsive injuries who underwent an FFMT reconstruction with and without the ICN to MCN transfer for elbow flexion between January 2000 and December 2013 were included.
	Exclusion criteria: patients with follow up less than 24 months from the data analysis, and patients who had other types of reconstruction for elbow flexion.
Technique	FFMT (gracilis): After harvesting the gracilis muscle with its vessels and nerve, the proximal tendon of the gracilis muscle was secured to the acromion and lateral clavicle using suture anchors, and the thoracoacromial artery and cephalic vein were anastomosed to the gracilis pedicle. Direct coaptation of the gracilis obturator nerve and the donor nerve (SAN or 2 to 4 ICNs) was performed.
	<u>Neurotisation (ICN to MCN transfer)</u> : the biceps motor branch was dissected proximally off the MCN proper, and 2 to 3 ICNs were dissected and sutured directly without an intervening nerve graft as distally as possible. An operating microscope and 9 to 0 nylon sutures were used to coapt the nerves and all nerve coaptations were wrapped in a split collagen conduit and fibrin glued.
Follow-up	FFMT (gracilis): median 36.5 months (range 28.9 to 47.4 months)
	FFMT (gracilis) with neurotisation (ICN to MCN transfer): median 36 months (range 30.5 to 53 months)
Conflict of interest/source of funding	No benefits in any form have been received or will be received related directly or indirectly to the subject of this article.

Analysis

Follow-up issues: Patients in the FFMT (gracilis) group were followed up at a median of 36.5 months (range 28.9 to 47.4 months) and patients in the FFMT (gracilis) with neurotisation (intercostal nerve [ICN] to musculocutaneous nerve [MCN] transfer) at a median of 36 months (range 30.5 to 53 months). Losses to follow up were not reported.

Study design issues: This retrospective comparative study determined if the combination of both techniques (FFMT (gracilis) and ICN-to-MCN transfer, the MCN was used to innervate biceps) has stronger elbow flexion compared with FFMT (gracilis) alone. The 2 groups were compared with respect to postoperative elbow flexion strength, preoperative and postoperative disability of the arm, shoulder and hand (DASH) questionnaire scores, age, sex, body mass index (BMI), time from injury to operation, FFMT (gracilis) neurotisation (ICN or spinal accessory nerve [SAN]), and FFMT (gracilis) distal tendon insertion (biceps tendon or flexor digitorum profundus [FDP] and flexor pollicis longus [FPL] tendon). The primary outcome was elbow flexion strength graded using a modified British medical research council (BMRC) by the 3 senior authors. All operations were performed at a single institution by the senior authors of the study. Postoperative management was not described.

Study population issues: Demographic variables (sex, age and BMI) and follow-up average time were similar between the 2 groups. Average time from injury to surgery was statistically significantly different (p<0.05) between groups. The FFMT (gracilis) group had surgery a median of 23.4 months (range 6.3 to 47.9 months) after injury, and the FFMT

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(gracilis) and ICN to MCN transfer group had surgery a mean of 5.8 months (range 2.2 to 11.4 months) after traumatic complete brachial plexus injury.

Key efficacy and safety findings

Efficacy			Safety	
Number of pa transfer])	atients analysed: 65 (32 FFMT [gra	acilis] versus 33 FFMT [gracilis] with neurotisation [ICN to MCN	Safety data were not reported.	
BMRC grade			-	
	FFMT (gracilis)	FFMT (gracilis)+neurotisation (ICN to MCN)		
M0	6.3% (2)	0%]	
M1	0%	0%	1	
M2	25% (8)	36.4% (12)	11	
M3	25% (8)	21.2% (7)	11	
M4	43.7% (14)	42.4% (14)	1	
M<3	31.3% (10)	36.4% (12)	1	
M≥3	68.7% (22)	63.6% (21)	11	
р		>0.05	11	

DASH scores, mean±SD

	Preoperative score	Postoperative score	Change in score	р
FFMT (gracilis)	43.5±21.4	38±19	4.6±17	>0.05
FFMT (gracilis)+neurotisation (ICN to MCN)	51.7±14.6	32.8±16	18.9±15.8	<0.05

FFMT (gracilis) innervation:

- FFMT (gracilis): 23 SAN and 9 ICN
- FFMT (gracilis)+neurotisation (ICN to MCN): 6 SAN and 27 ICN

Elbow flexion grade differences between the spinal accessory nerve and intercostal nerve transfer to obturator nerve for FFMT (gracilis) neurotisation

BMRC grade	SAN transfer (n=29)	ICN transfer (n=36)
M<3	9 (31%)	13 (36.1%)
M≥3	20 (69%)	23 (63.9%)
р		>0.05

Elbow flexion grade differences in gracilis distal tendon attachment

BMRC grade	Biceps tendon attachment (n=38)	FDP/FPL tendon attachment (n=27)
M<3	47.4% (18)	14.8% (4)
M≥3	52.6% (20)	85.2% (23)
р		<0.05

Abbreviations used: BMRC, British Medical Research Council; FDP, flexor digitorum profundus; FFMT, free-functioning muscle transfer; FPL, flexor pollicis longus; ICN, intercostal nerve; MCN, musculocutaneous nerve; SD, standard deviation.

IP overview: Free-functioning gracilis transfer to restore upper limb function in brachial plexus injury

Study 5 Maldonado AA (2016)

Details

Study type	Non-randomised comparative study		
Country	USA (single centre)		
Recruitment period	2000 to 2012		
Study population and	n=62 (31 FFMT (gracilis) compared with 31 neurotisation [ICN-to-MCN transfer])		
number	Patients with traumatic brachial pan-plexus injuries		
Age and sex	FFMT (gracilis): mean 34 years (SD=13.3); 74% (23/31) male		
	Neurotisation (ICN-to-MCN transfer): mean 30.1 years (SD=11.9); 81% (25/31) male		
Patient selection criteria	Inclusion criteria: patients after pan-plexus injuries who had free functional muscle transfer reconstruction or intercostal nerve-to-musculocutaneous nerve transfer for elbow flexion from 2000 to 2012.		
	Exclusion criteria: patients with follow up less than 18 months and patients who had simultaneous free- functioning muscle transfer and nerve transfer/nerve graft to the musculocutaneous nerve.		
Technique	<u>FFMT (gracilis)</u> : gracilis was used in the free-functioning muscle transfer group, and donor nerves for muscle reinnervation were either the intercostal nerve (n=10) or the spinal accessory nerve (n=21). The proximal tendon of the gracilis muscle was secured to the acromion and lateral clavicle using suture anchors, and the thoracoacromial artery and cephalic vein were anastomosed to the gracilis pedicle. Direct coaptation of the gracilis obturator nerve and the donor nerve was performed without tension, with the arm abducted 90 ⁰ and externally rotated 90 ⁰ .		
	<u>Neurotisation (ICN-to-MCN transfer)</u> : 2 to 4 intercostal nerves were dissected and sutured directly without an intervening nerve graft to the musculocutaneous nerve as distally as possible.		
Follow-up	18 months		
Conflict of interest/source of funding	No financial interest		

Analysis

Follow-up issues: Of the 72 patients identified who had FFMT (gracilis) or neurotisation (intercostal nerve-tomusculocutaneous nerve [ICN-to-MCN] transfer) for elbow flexion, 10 had less than 18 months follow up; so, 62 patients were included in this article.

Study design issues: The retrospective comparative study determined the outcomes of FFMT (gracilis) versus neurotisation (ICN-to-MCN transfers) for the restoration of elbow flexion. The key outcomes included elbow flexion strength and DASH score. Elbow flexion was measured using a modified BMRC grade by 3 senior authors and a mean of these authors' measurements was used. To obtain a BMRC grade of 3, patients had to have active motion equivalent to passive motion against gravity. All operations were performed at a single institution by 3 senior authors. Postoperative management was not described.

This study was included in Yi Lee et al. (2019).

Study population issues: The DASH scores were obtained preoperatively and postoperatively in 69% (43/62) of patients. There were no statistically significant differences in demographic variables (sex, age, injured side and body mass index) and average follow-up time between the 2 groups. Mean time from injury to surgery was statistically significantly different (mean 68.7 months in the FFMT [gracilis] group compared with mean 5.4 months in the neurotisation [ICN-to-MCN transfer] group, p<0.01).

Key efficacy and safety findings

	f nationte analyz	od 62 (34 EEMT	(gracilic)	compared with 31 per	rotisation [ICN-to-MCN t	ranefor1)	Safety Safety data were
	r patients analys	ieu. 02 (31 Frivi i	(gracins)	compared with 51 neu		ransierj)	not reported.
BMRC gr	ade, % (n)						
	FFMT (grac	ilis)	neuroti	sation (ICN-to-MCN tra	nsfer)		
M0	6% (2)		6% (2)				
M1	0		16% (5)				
M2	26% (8)		36% (11)			
M3	29% (9)		16% (5)				
M4	39% (12)		26% (8)				
M<3	32.3% (10)		58.1% (18)			
M≥3	67.7% (21)		41.9% (13)			
р			0.04				
DASH sc	ores						
		Mean preope score±SD	rative	Mean postoperative score±SD	Mean change in score±SD	P	
FFMT (g	racilis)	43.2±21		37±20.1	5.5±15.6	0.09	
Neurotis MCN tra	ation (ICN-to- nsfer)	53±20.6		46.8±17.1	6.3±14.5	0.08	
р		0.13		0.10	0.77		
BMRC g	Irade		N transfer				
M<3		29%	6 (6)	6) 40% (4)			
M≥3		71%	% (15)	6	60% (6)		
р				C	.99		
BMRC g	5	CN transfer) gro	up: differe	ences between the num			
	Iraue			2.7±0.6	M313D		
M<3				2.8±0.8			
M≥3				0.54			
M≥3 p				10.04			1

Study 6 Cho AB (2018)

Details

Study type	Non-randomised comparative study
Country	Brazil (single centre)
Recruitment period	2003 to 2014
Study population and number	n=38 (18 FFMT [gracilis] neurotised by SAN compared with 20 FFMT [gracilis] neurotised by ulnar nerve)
	Patients with traumatic brachial plexus injuries
Age and sex	Mean 28.3 years (range 17 to 49 years); 97.4% (37/38) male
Patient selection criteria	Inclusion criteria: patients with traumatic brachial plexus injuries had FFMT (gracilis) to restore elbow flexion using either the SAN or the ulnar nerve as the source of donor nerve.
Technique	Gracilis was harvested, with its nerve and vascular pedicle; and the muscle was then transferred and joined in the recipient site and neurotised by donor nerves (SAN or ulnar nerves).
	Ulnar nerve fascicles were used on partial brachial plexus injuries every time intraoperatively nerve stimulation showed normal flexor carpi ulnaris contraction. The thoracoacromial artery and veins were the most utilised vessels with end-to-end anastomosis to the gracilis pedicle.
	The gracilis flap was attached to 2 to 3 anchors placed at the acromion and lateral portion of the clavicle and microvascular anastomosis followed by nerve transfer were performed. The tendon of the gracilis muscle was sutured to the insertion of the biceps tendon at a tension sufficient to keep the elbow flexed at about 20 ^o to 30 ^o .
	Patients were allowed to ambulate unassisted on the first postoperative day and the upper limb was placed in a sling for 4 weeks.
Follow-up	Mean 25 months (range 12 to 98 months)
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Of the 44 patients with traumatic brachial plexus injuries, 6 were excluded: 4 of the FFMT (gracilis) neurotised by spinal accessory nerve (SAN) group as a result of nerve graft interposition and 2 of the FFMT (gracilis) neurotised by ulnar nerve group, 1 as a result of vascular failure of the flap and 1 with follow up shorter than 12 months. Patients were evaluated at weeks 1 and 2, and then months 1, 3, 6, 9, 12 and 18, and yearly after that.

Study design issues: The retrospective study compared the results of elbow flexion recovery in traumatic brachial plexus injury in adults, using the SAN and ulnar nerves as the source of donor nerve. The British Medical Research Council (BMRC) scale was used to evaluate elbow flexion strength, with M≥3 being a good result. Four authors (surgeons) assessed for elbow flexion strength. Postoperative management was not described.

Study population issues: Of the 38 patients, the non-dominant side was affected in 58.6% of patients, complete injuries were seen in 36.8% (14/38) of patients, C5 to C6 injuries in 39.4% (15/38), and C5 to C7 injuries in 23.7% (9/38). Traumas were caused by motorcycle accidents (86.8%), being run over (7.8%), bicycle accidents (2.6%) and a physical assault (2.6%). Average interval between trauma and surgery was 37.7 months (range 5 to 159 months). Seven patients who had FFMT (gracilis) had been previously submitted to brachial plexus reconstruction without success: 2 reconstructions with sural nerve grafts and 5 nerve transfers.

Efficacy					Safety
vith 20 FF	MT (gracilis)	ysed: 38 (18 FFMT (graci neurotised by ulnar ner transferred, % (n)	lis) neurotised by SAN cor ve)	npared	Complications: n=4 (10.5%, early surgical reintervention was performed) • Vascular impairment of the
	Total, n=38	FFMT (gracilis) neurotised by SAN	FFMT (gracilis) neurotised by ulnar	р	skin monitor : n=2 (both patients received skin grafts)
			nerve		Postoperative infection: n=2
Good result (≥M3)	68.4% (26)	83.3% (15)	55.0% (11)	0.086	(1 at the upper limb and 1 at the donor thigh. They were solved with simple superficial
M0	0%	0%	0%	0.32	debridement without harming the flap.
M1	10.5% (4)	0%	20.0% (4)		
M2	21.1% (8)	16.7% (3)	25.0% (5)		
M3	23.7% (9)	38.9% (7)	10.0% (2)		
M4	44.7% (17)	44.4% (8)	45.0% (9)		
ravity (≥M Analysis re and time be	je time elapse 3) was 11 mc vealed that ag etween accide	onths when SAN was used ge, gender, trauma mecha	I e first record of elbow flexion I and 14 months with ULNAF Inism, lesion laterality, level Iuence elbow flexion strengt	R.	

Abbreviations used: BMRC, British Medical Research Council; FFMT, free-functioning muscle transfer; SAN, spinal accessory nerve; ULNAR, ulnar nerve.

Study 7 Adams JE (2009)

Details

Study type	Case series
Country	USA (single centre)
Recruitment period	1989 to 2007
Study population and	n= 130
number	Patients with acute or chronic brachial plexus injuries
Age and sex	Not reported
Patient selection criteria	Inclusion criteria: all patients with brachial plexus injuries (adult and paediatric) who had FFMT (gracilis) to restore elbow flexion or finger flexion in either the acute or chronic setting.
	A major change in the surgical technique occurred in 2005 so patients were divided into 2 groups: patients who had surgery before the technique change (before 27 August 2005) and patients who had surgery after the technique change (27 August 2005 to 1 December 2007).
Technique	The gracilis was harvested together with its innervating branch of the obturator nerve and its vascular supply, a branch of the profunda femoris artery. A skin paddle was typically harvested to facilitate postoperative flap monitoring. The muscle was transferred and joined in the recipient site and reinnervated by donor nerves (intercostal motor nerves, the spinal accessory nerve or the musculocutaneous nerve).
	In 2005, the surgical technique of placement of the gracilis on the clavicle was modified. The gracilis was no longer wrapped around the clavicle but placed on the anterior surface of the acromion and distal clavicle and shifted laterally compared with the previous technique.
Follow-up	Not reported
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: Losses to follow up were not reported.

Study design issues: This retrospective study evaluated the outcomes and complications following FFMT (gracilis) for the restoration of elbow flexion and/or finger flexion in patients with acute or chronic brachial plexus injuries. The outcomes included the overall survival rate of the gracilis muscle, complications which included post-surgical clavicle fractures, non-functioning or inadequately functioning muscles (those with BMRC grade 2 or less) and need for additional surgery related to the free-functioning muscle. Postoperative management was not described.

Key efficacy and safety findings

Efficacy	Safety				
Number of patients analysed: 130	Recipient site complications				
Group 1 (patients had surgery before	Clavicle fractures:				
the technique change, before 27 August 2005): n=89	• Group 1 : 7.9% (7/89, 95% CI 3% to 16%) happened at a mean of 56.6 weeks after gracilis transfer (range 12 to 156 weeks). Three patients had non-surgical				
Doi procedure for restoration	treatment and 4 had surgery using plate and screw constructs.				
of elbow flexion/extension and	Mechanism of injury:				
 prehension using bilateral gracilis muscle: n=15 Gracilis transfer for elbow flexion alone: n=47 	- Fall from ground level height: n=3				
	- Pathological fractures: n=4				
	Initial non-surgical treatment was done in 6 patients. The fracture went on to radiographic but clinically asymptomatic non-union in 1 patient, healing in 1, it				

 1 stage procedure to obtain elbow flexion/extension and 	healed in 1 after use of a bone stimulator, and 3 required open reduction and internal fixation for non-union after failed non-operative therapy.			
prehension: n=27	• Group 2: 0% (95% CI 0% to 8.6%)			
Group 2 (patients had surgery after the technique change, 27 August 2005 to 1 December 2007): n=41	• p=0 .097 (before and after the procedure was modified)			
	Gracilis graft failure:			
Non-functioning muscles (BMRC grade 2 or less) at final follow up	• Group 1 : 7.9% (7/89, 95% CI 3.2% to 15.5%) - All 7 patients were male, with average age 33.4 years (range 17 to 65 years).			
• Group 1: 12.4% (11/89)	Failure mechanism:			
• Group 2 : 2.4% (1/41, Cl 0% to	- Arterial thromboses n=2			
12.9%)	 Arterial and venous thromboses: n=1 			
• P =0.102 (before and after the	- Venous thrombosis: n=1			
procedure was modified)	- Haematoma: n=1			
	- Infection: n=1			
	- Vascular insufficiency with apparently patent vessels at exploration: n=1			
	Exploration and removal of the muscle occurred at a mean of 6.8 days post index procedure (range 1 to 34 days).			
	• Group 2: 2.4% (1/41, 95% CI 0% to 12.9%)			
	A 26-year-old female developed an infection in the 12 days after surgery. Her transferred gracilis was explored, was initially viable, but succumbed to infection and with vessel thrombosis. The muscle was subsequently removed 15 days postoperatively.			
	• p =0.434 (before and after the procedure was modified)			
	Bowstringing:			
	• Group 1: 13.5% (12/89, 95% CI 7.2% to 22.4%).			
	• Group 2: 0			
	• p=0.018			
	Overall complication rate before and after the technique change: p<0.001			
Abbreviations used: BMRC, British Medic	cal Research Council; CI, confidence interval.			

Study 8 Estrella (2016)

Study type	Case series				
Country	Philippines (single centre)				
Recruitment period	2005 to 2014				
Study population and	n= 42				
number	Patients with traumatic brachial plexus injuries				
Age and sex	Mean 28.6 years (SD=5.8); 93% (39/42) male				
Patient selection criteria	Inclusion criteria: patients had traumatic brachial plexus injuries where a functioning free muscle was used for elbow flexion with at least 12 months follow up.				
	Exclusion criteria: patients had a combination of nerve reconstruction or local muscle transfer with free muscle transfer procedures for the restoration of elbow flexion and brachial plexus injuries with concomitant spinal cord injuries; and bilateral plexus injuries.				
Technique	Standard harvest for the gracilis muscle with its vessels and nerve was done. The gracilis muscle was sutured to the recipient site and reinnervated by the spinal accessory nerve or the 3rd to 5th intercostal nerve because of trapezius paralysis.				
	A single-stage, double muscle transfer technique was also used, with the gracilis-adductor longus muscles as donor muscles to restore elbow flexion (adductor longus) and finger flexion (gracilis) combined with wrist fusion for patients with total brachial plexus injuries.				
	No postoperative antithrombosis was given except for aspirin 325 mg once a day for 2 weeks. In all patients, no reconstruction for elbow extension was done.				
Follow-up	Mean 30 months				
Conflict of interest/source of funding	Not reported				

Analysis

Follow-up issues: After the operation, all patients were followed up weekly for the first 4 weeks for wound monitoring and then every 2 to 3 months until they had grade 1 muscle contraction.

Study design issues: This retrospective study presented the clinical outcomes and complications of using FFMT (gracilis) for the restoration of elbow flexion in patients with traumatic brachial plexus injuries. The outcome measures were elbow flexion in terms of range of motion in degrees, muscle strength using the modified British Medical Research Council staging (BMRC), postoperative Disability of Arm, Shoulder and Hand (DASH) scores, VAS (Visual Analogue Scale) for pain, postoperative complications, including major and minor complications. A major complication was defined as having a failed flap, whether acute or delayed or any disability that might result from the surgical procedure, such as an additional nerve injury.

Two teams did the surgery simultaneously: 1 team explored the brachial plexus, isolated the donor vessels, isolated the spinal accessory nerve and prepared the proximal and distal attachments of the transferred gracilis. The other team harvested the gracilis muscle.

After the surgery, patients were immobilised in an arm sling with elbows at 100^o flexion and in slight forward flexion. The patient was positioned with a moderately high back rest of 45^o. Flap monitoring was done every hour for the first 48 hours using flap colour evaluation and temperature changes using an infrared temperature monitor as parameters. Any changes within the hour unresponsive to wound dressing loosening would necessitate bringing the patient back to the operating room for exploration. Patients were formally referred to the physiotherapy department once they had grade 1 motor grade of the transferred gracilis.

This study was included in Yi Lee et al. (2019).

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Study population issues: Of the 42 patients, 36 had a single gracilis muscle transfer and 6 had a single-stage, double free muscle transfer (gracilis-adductor muscle). In terms of the types of injury, 39 patients were of the total type (C5 to T1) and 3 were of the upper (C5 to C6) or extended upper type injuries (C5 to C7). The spinal accessory nerve was the donor nerve in all cases (except in 1 case where the 3rd to 5th intercostal nerves were used as donor nerves). Average delay from injury to FFMT (gracilis) was 16 months (SD=14.3).

Key efficacy and safety findings

Efficacy			Safety					
Number of patients analysed: 42			Complications, n=15					
 Single gracilis muscle transfer: n=36 Single-stage, double free muscle transfer (gracilis-adductor muscle): n=6 					Additional surgery	Outcome of elbow flexion	Follow up (months)	
				Major (n=5)				
DASH sco	70 .			Failed flap*	Flap removal done	All 4 patients	N/A	
Mean postoperative DASH score=43.09 (SD=14.9)			(n=4)	within 1 week	refused further treatment			
Flap success rate for viability: 90.5% (38/42)			Transient	None (resolved after 3	Patient 1: M4 (30 ⁰ to 130 ⁰)	23		
38 patients with viable muscle transfers:			peroneal palsy	months)				
	bow flexion str		MRC	(n=1)				
•	ade=3.7 (SD=0			Minor (n=10)			10	
 Elbow flexion range: mean range of motion=107⁰ (SD=20.4⁰) Mean FIL DASH score=43.09 (SD=14.9) Success rate based on MRC staging:			Wound dehiscence	Dehiscence near skin flap closure	Patient 1: M4 (20 ⁰ to 130 ⁰)	13		
			(n=3)		Patient 2: M4 (20 ⁰ to 90 ⁰)	17		
				Local debridement and closure were done	Patient 3: M4 (30 ⁰ to 115 ⁰)	32		
	Number	%, n=38	%, n=42	Skin flap	Inspection of anastomosis within 24	Patient 1: M3 (20 ⁰ to 100 ⁰)	22	
M2/5	1	3%	2%	necrosis (n=2)				
M3/5	9	24%	21%		hours after surgery, no revision of anastomosis			
M4/5	28	74%	67%		done			
 ≥M3/5 37 97% 88% Pain: of the 38 patients with viable muscle transfers, the mean postoperative VAS for pain was 3.6 (SD=3.0). Single-stage double free muscle transfer: Success rate: 67% (4/6) 				Skin flap excised with small window for muscle monitoring. Delayed closure within 1 week.	Patient 2: M3 (20 ⁰ to 90 ⁰)	36		
			Re-tensioning of tendon repair (n=3)	Re-tensioning of gracilis tendon to biceps tendon stump	Patient 1: M3 (30 ⁰ to 100 ⁰)	36		
					Patient 2: M4 (20 ⁰ to 120 ⁰)	31		
4 patients with viable double muscle transfers:					Patient 3: M4 (20 ⁰ to 120 ⁰)	40		
 Mean follow up: 20 months (SD=9 months) Mean MRC grade=3.75 (SD=0.5) 			Transient sensory	None	Patient 1: M4 (20 ⁰ to 115 ⁰)	12		
• Mean range of motion=112.5 ^o (SD=24.9 ^o)			disturbance (knee, n=2)	Resolved after 3 and 5	Patient 2: M4	12		
from 60° to	acarpo-phalang 90 ⁰ and on the 80 ⁰ to 100 ⁰ .			*Two were secondary to arterial thrombosis and the other 2 were secondar				
All wrist fusions had radiographic signs of union at final follow-up.			to no-reflow phenomena. Two of these acute flap failures had a single-stage double free muscle transfer which were attributed to no-reflow phenomena. These 2 transfers had prolonged ischaemia with difficulties in anastomosis					

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	due to a short pedicle. The failed flaps were removed within 1 week from the initial transfer. All 4 patients did not consent to an additional muscle transfer.
Abbreviations used: DASH, disabilities of the arm, sho	oulder and hand; FIL, Filipino version; MRC, Medical Research Council; SD,
standard deviation; VAS, visual analogue scale.	

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Study 9 Yavari M (2018)

Details

Study type	Case series
Country	Iran (single centre)
Recruitment period	2003 to 2015
Study population and	n= 61
number	Patients with brachial plexus injuries
Age and sex	Mean 22.95 years (SD=5.35); 94.1% (64/68) male
Patient selection criteria	Inclusion criteria: patients with brachial injury more than 2 years ago who had received no treatment or had undergone an ineffective nerve transfer surgery at least 1.5 years ago.
Technique	All patients had contralateral pectoral nerve transfer and, if successful, free gracilis muscle transfer was performed after 12 to 15 months.
	Stage 1: contralateral medial pectoral nerve from the intact side was transferred to the damaged side as a recipient nerve.
	<u>Stage 2</u> : the gracilis muscle was removed in a classic method with appropriate nerve and vascular pedicle length. The gracilis muscle was then transferred and joined in the recipient site, and its motor nerve (a branch of the obturator nerve) was sutured to the end of the sural nerve.
Follow-up	1 year
Conflict of interest/source of funding	The authors reported no proprietary or commercial interest in any product mentioned or concept discussed in this article.

Analysis

Follow-up issues: Of the 68 patients recruited, 2 had free flap failure. This was probably due to technical problems, but arterial thrombosis was seen in 1 patient and atherosclerotic arteries in the other. Five patients withdrew from the second phase of the surgery. After 12 months, 61 patients completely participated in the study. Patients were regularly visited, and their muscle power was measured and recorded within 1 year after the surgery.

Study design issues: This retrospective case series evaluated the efficacy of contralateral pectoral nerve transfer followed by free muscle transplantation for patients with total brachial plexus palsy more than 2 years ago.

All operations were performed by a team of surgeons. The donor site was repaired by the assistant, whereas the senior surgeon worked at the recipient site. During follow up, patients were visited in the clinic by hand therapists. They were under regular supervision by a permanent team of physiotherapy and occupational therapy. After 3 weeks, passive mobilisation with stretching was started.

Study population issues: The brachial plexus was involved on the right and left sides in 36.8% (25/68) and 63.2% (43/68) of patients, respectively. The mean length of the sural nerve grafts was 44.4 cm (SD=2.2).

Key efficacy and safety findings

Efficacy						Safety	
Number o	f patients a	nalysed: 61					Free flap failure: n=2
Postoperative gain of function results based on BMRC scale and chuang modification						ion This was probably due to technica problems, but arterial thrombosis was seen in 1 patient and	
	MO	M1	M2	M3	M4	Total	atherosclerotic arteries in 1
Male	3.3% (2)	11.5% (7)	4.9% (3)	39.3 (24)	34.4% (21)	93.4% (57)	patient.
Female	0% (0)	0% (0)	3.3% (2)	3.3% (2)	0% (0)	6.6% (4)	
Total	3.3% (2)	11.5% (7)	8.2% (5)	42.6% (26)	34.4% (21)	100% (61)	
	f ollow up: inger flexio		5 ⁰ and 60 ⁰ :	68.8% (42/61)		
Validity and generalisability of the studies

- Where reported, 3 studies were done in the US^{4, 5, 7}, 1 in Japan³, 1 in Brazil⁶, 1 in the Philippines⁸ and 1 in Iran⁹.
- There were a few publications including the same population; there was likely to be some patient overlap between them.
- There was variation in the samples relating to the type and severity of the injury, and the length of time since the injury (range 0.5 to 276 months).
- Where reported, the mean age ranged from 23 to 34 years and the follow-up periods ranged from 12 to 89 months.
- A total of 47 patients were excluded from the analysis in 4 studies (range 10% to 23%)^{3, 5, 6, 9}, including losses to follow up.
- Although the procedure focused on free-functioning gracilis transfer, other muscles were used^{1, 2, 8}, such as latissimus dorsi, rectus femoris and a combination of gracilis and adductor longus/latissimus dorsi.
- In addition to free-functioning gracilis transfer (single and/or double muscle transfer), some studies reported additional procedures performed, such as nerve transfers.
- There was no specific device for this procedure, but surgical technique has been modified over the years and the improved technique has resulted in a decrease in overall complications, as described in study 7 and Hou et al. (2015) in the appendix.
- Postoperative muscle strengthening exercise played an important role in functional recovery and relearning neurological muscle control; only 3 studies^{3,}
 ^{8,9} reported postoperative management.
- Most studies^{1, 2, 4-8} assessed the outcomes of free-functioning gracilis transfer for the restoration of elbow flexion while only 2 studies^{3, 9} reported the functional outcomes for finger and/or shoulder.

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Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure.

Interventional procedures

- Nerve transfer to partially restore upper limb function in tetraplegia. NICE interventional procedures guidance 610 (2018). Available from <u>https://www.nice.org.uk/guidance/ipg610</u>
- Phrenic nerve transfer in brachial plexus injury. NICE interventional procedure guidance 468 (2013). Available from <u>https://www.nice.org.uk/guidance/ipg468</u>

NICE guidelines

Spinal injury: assessment and initial management. NICE guideline 41 (2016).
Available from https://www.nice.org.uk/guidance/ng41

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. One professional expert questionnaire for free-functioning gracilis transfer to restore upper limb function in brachial plexus injury was submitted and can be found on the <u>NICE website</u>.

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Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

There is no specific device used for this procedure. Therefore, no structured information requests were sent to companies.

Issues for consideration by IPAC

Ongoing trial

• <u>A retrospective investigation for the functioning free gracilis transplantation</u> <u>in the brachial plexus injury patients.</u> ChiCTR1900020769. Case series. Recruitment completed: 55 patients. China.

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References

- 1. Yi Lee TM, Sechachalam S and Satkunanantham M (2019) Systematic review on outcome of free functioning muscle transfers for elbow flexion in brachial plexus injuries. The journal of hand surgery, 44: 620-627
- Hoang D, Chen VW and Seruya M (2018) Recovery of elbow flexion after nerve reconstruction versus free functional muscle transfer for late, traumatic brachial plexus palsy: A systematic review. Plastic and reconstructive surgery, 141(4): 949-959
- 3. Satbhai NG, Doi K, Hattori Y et al. (2016) Functional outcome and quality of life after traumatic total brachial plexus injury treated by nerve transfer or single/double free muscle transfers. The bone & joint journal, 98b: 20-217
- Maldonado AA, Kircher MF, Spinner RJ et al. (2017) Free functioning gracilis muscle transfer with and without simultaneous intercostal nerve transfer to musculocutaneous nerve for restoration of elbow flexion after traumatic adult brachial pan-plexus injury. The journal of hand surgery, 42(4): 293.e1-e7
- Maldonado AA, Kircher MF, Spinner RJ et al. (2016) Free functioning gracilis muscle transfer versus intercostal nerve transfer to musculocutaneous nerve for restoration of elbow flexion after traumatic adult brachial pan-plexus injury. Plastic and reconstructive surgery, 138: 483e
- 6. Cho AB, Silva GB, Pisani MJ et al. (2018) Comparison between donor nerves to motorise the free functional gracilis muscle transfer for elbow flexion: retrospective study of 38 consecutive cases in traumatic adult brachial plexus injuries. Microsurgery, 39(%): 400-404
- 7. Adams JE, Kircher MF, Spinner RJ et al. (2009) Complications and outcomes of functional free gracilis transfer in brachial plexus palsy. Acta orthopaedica belgica, 75(1): 8-13
- Estrella EP and Montales TD (2016) Functioning free muscle transfer for the restoration of elbow flexion in brachial plexus injury patients. Injury, 47(11): 2525-2533
- 9. Yavari M, Mahmoudvand H, Nadri S et al. (2018) Contralateral medial pectoral nerve transfer with free gracilis muscle transfer in old brachial plexus palsy. Journal of surgical research, 231: 94-98

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Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	24/10/2019	Issue 10 of 12, October 2019
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	24/10/2019	Issue 10 of 12, October 2019
HTA database (CRD website)	24/10/2019	n/a
MEDLINE (Ovid)	24/10/2019	1946 to October 21, 2019
MEDLINE In-Process (Ovid)	24/10/2019	1946 to October 22, 2019
MEDLINE ePubs ahead of print (Ovid)	24/10/2019	October 22, 2019
EMBASE (Ovid)	24/10/2019	1974 to 2019 October 23
BLIC	24/10/2019	n/a

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

- 1 Brachial Plexus/ (8397)
- 2 Brachial Plexus Neuropathies/ (2169)
- 3 Paralysis/ (20676)
- 4 (brachi* adj4 plex*).tw. (9342)
- 5 Radiculopathy/ (4910)

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- 6 (radiculit* or radiculitide* or radiculopath*).tw. (5613)
- 7 (nerve* adj4 root* adj4 (avuls* or disord* or inflam* or compress*)).tw. (1984)
- 8 Peripheral Nerve Injuries/ (6386)
- 9 (peripher* adj4 nerv* adj4 (injur* or damag* or paraly* or pals* or traum* or incapacitat* freez* or frozen* or weaken* or impair* or avuls*)).tw. (8362)
- 10 (upper* adj4 extremit* adj4 reanimat*).tw. (7)
- 11 or/1-10 (52398)
- 12 Gracilis Muscle/ (134)
- 13 (gracil* adj4 (muscl* or flap*)).tw. (1923)
- 14 (free* adj4 (gracil* or muscl*) adj4 (transfer* or transplant* or graft*)).tw. (1031)
- 15 FFGMT.tw. (1)
- 16 ((gracil* or muscl*) adj4 reinnervat*).tw. (1722)
- 17 or/12-16 (4402)
- 18 11 and 17 (414)
- 19 animals/ not humans/ (4602086)
- 20 18 not 19 (274)
- 21 limit 20 to english language (249)

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non- inclusion in table 2
Hattori Y, Doi K, Sakamoto S et al. (2009) Elbow joint position sense following brachial plexus palsy treated with double free muscle transfer. The journal of hand surgery, 34: 1667-1673	Non-randomised comparative study n=23 (DFMT 13 [mean 24.7 years; 92% male] versus control 10 [mean 22.7 years; 100% male]) Follow up: 3.2 years	In control patients, mean AE measured $4^0 \pm 1^0$ at the target angle of 60^0 and $4^0 \pm 2^0$ at 80^0 . After DFMT, patients' mean AE measured $5^0 \pm 2^0$ at the target angle of 60^0 and $5^0 \pm 3^0$ at 80^0 . There was no statistical difference between the control and DFMT groups at target angles of 60^0 and 80^0 .	This article was included in Hoang (2018)
Hou Y, Yang J, Yang Y et al. (2015) Flow- through anastomosis using a T-shaped vascular pedicle for gracilis functioning free muscle transplantation in brachial plexus injury. Clinics, 70(8): 544-549	Non-randomised comparative study n=71 (46 flow- through anastomosis versus 25 end-to- end anastomosis)	The diameter of the arterial anastomosis in the flow-through group was significantly larger than that in the end-to-end group (3.87 mm compared with 2.06 mm, p<0.001), and there were significantly fewer cases of vascular compromise in the flow-through group (2 [4.35%] compared with 6 [24%] p=0.019). All flaps in the flow- through group survived, whereas 2 in the end-to-end group failed. Minimal donor-site morbidity was noted in groups.	This study compared flow- through anastomosis with conventional end- to-end anastomosis.
Kimura LK, do Nascimento AT, Capocio R et al. (2010) Microsurgical transfer of the gracilis muscle for elbow flexion in brachial plexus injury in adults: retrospective study of eight cases. Rev Bras Ortop, 46(5): 534-39	Non-randomised comparative study n=8 (Group 1, neurorrhaphy of the muscle flap with sural nerve grafting and anastomosis more distally; Group 2, direct neurorrhaphy in the spinal accessory nerve)	A significant difference between the groups was found. A greater number of satisfactory results (75% M4) were found among patients who underwent direct neurorrhaphy, whereas the procedure using grafts for neurorrhaphy was less successful (25% M4).	The sample size was small.
Potter SM and Ferris SI (2017) Reliability of functioning free muscle transfer and vascularised ulnar nerve grafting for elbow flexion in complete brachial plexus palsy.	Non-randomised comparative study n=24 (mean 32 years; 100% male) 8 patients with vascularised ulnar nerve grafts, 13	At 45 months, 3 of 8 primary vascularized ulnar nerve graft patients regained grade 4 elbow flexion, while 1regained grade 3. All 13 primary gracilis transfer patients regained grade 4 elbow flexion. Four patients with vascularized ulnar nerve grafts	This article was included in Yi Lee (2019) in table 2.

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The journal of hand surgery, 42E(7): 693- 699	with gracilis transfers and 3 with salvage functioning free muscle transfers	failed and subsequently had salvage functioning free muscle transfer procedures resulting in delayed recovery. Although vascularized ulnar nerve graft- based primary reconstructions can provide useful elbow flexion, this was achieved in less than half the cases. We consider primary gracilis functioning free muscle transfer neurotised by the distal spinal accessory nerve as the most reliable reconstruction for the restoration of elbow flexion in complete brachial plexus injury.	
Terzis JK and Kostopoulos VK (2009) Free muscle transfer in posttraumatic plexopathies part II: the elbow. Hand, 5: 160- 170	Non-randomised comparative study n=73 free muscle transfers (37 latissimus dorsi, 28 gracilis, 7 rectus femoris and 1 vastus lateralis)	Selection of powerful muscle units was more important than the effect of neurotization which was not as strong as it was in muscle transfers for facial or hand reanimation.	The sample size for free functioning gracilis transfer was small
Akasaka Y, Hara T and Takahashi M (1990) Restoration of elbow flexion and wrist extension in brachial plexus paralyses by means of free muscle transplantation innervated by intercostal nerve. Ann Hand Surg, 9(%): 341- 350	Case series n=29 (range 11 to 38 years) Follow up: over 1 year	All except 2 patients had procedures to restore wrist flexion and wrist extension. Two patients failed following venous thrombosis and all other transfers took well. Seventeen patients have been followed for over 1 year. Recovery of muscle strength was delayed for approximately 3 months longer than the corresponding recovery for the elbow procedure. Nine of the 17 patients have regained muscle strength of at least M3.	The sample size was small.
Bahm J and Ocampo- Pavez C (2008) Free functional gracilis muscle transfer in children with severe sequelae from obstetric brachial plexus palsy (2008) Journal of brachial plexus and peripheral nerve injury, 3(23)	Case series n=4 (6 to 13 years)	Patients had successfully reanimated long finger flexion using a free functional gracilis muscle transfer.	The sample size was small.
Barries KA, Steinmann SP, Shin AY et al. (2004) Gracilis free muscle transfer for restoration of function after complete brachial plexus avulsion.	Case series n=23 patients (mean 25 years; 87% male; 29 gracilis FFMT)	At a minimum follow-up of 1 year, 5 muscles achieved less than or equal to Grade M2, 8 Grade M3, 4 Grade M4, and 12 Grade M5. Transfer for combined elbow flexion and wrist extension compared with	This article was included in Hoang (2018)

Neurosurg focus, 16(5): article 8		elbow flexion alone lowered the overall results for elbow flexion strength. Seventy-nine percent of the FFMTs for elbow flexion alone (single transfer) and 63% of similarly innervated muscles transferred for combined motion achieved at least Grade M4 elbow flexion strength.	
Bertelli JA (2019) Free reverse gracilis muscle combined with steindler flexorplasty for elbow flexion reconstruction after failed primary repair of extended upper-type paralysis of the brachial plexus. Journal of hand surgery, 44(2): 112-120	Case series n-24 (mean 34 years; 100% male)	Active elbow flexion was restored in 23 of 24 patients. Sixteen patients ultimately achieved M4 strength, among whom 5 had full range of motion and the remaining 10 recovered an average of 110° (CI 100° to 120°) of elbow flexion. Seven patients exhibited M3 elbow flexion strength recovery, which was associated with weaker hands and incomplete ROM, averaging 94° (CI 86° to 102°). There was, on average, a 10° (CI 4.4° to 15.6°) elbow flexion contracture. Among the 16 patients with M4 level recovery of elbow flexion, supination was partially restored in 12.	The sample size was small.
Chim H, Kircher MF, Spinner RJ et al. (2014) Free functioning gracilis transfer for traumatic brachial plexus injuries in children. The journal of hand surgery, 39(10): 1956-1966	Case series n=12 (13.8 years; 95% male) Follow up: 27 months	Eleven out of 12 patients achieved at least M3 elbow flexion, with 8 achieving M4 or greater elbow flexion. Eight of 12 patients had nerve transfer to the musculocutaneous nerve. Mean active elbow arc of motion was 79 ⁰ . Two patients aged 8 and 11 years with open growth plates developed elbow joint contractures, which limited range of motion, but they recovered M4 and M5 elbow flexion strength.	The sample size was small.
Chuang DCC, Carver N and Wei FC (1996) Results of functioning free muscle transplantation for elbow flexion. J Hand Surg, 21A: 1071-1077	Case series n=38 (mean 25 years) Follow up: at least 2 years	Reinnervation with the musculocutaneous nerve resulted in success (defined as a muscle strength of M4) in all cases (n=3) within 1 year. Success was obtained in 78% of patients following transfer of 3 intercostal nerves (n=23) with recovery in an average of 2 years. Using the spinal accessory nerve (n=4), strength of only M2+ was achieved, probably on account of the need	The sample size was small.

		for interposition nerve grafts in	
		those cases.	
Chuang DCC, Epstein MD, Yeh MC et al. (1993) Functional restoration of elbow flexion in brachial plexus injuries: results in 167 patients (excluding obstetric brachial plexus injury). The journal of hand surgery, 18(2): 285-291	Case series n=167 (17 functioning free muscle transfers; 16 gracilis and 1 rectus femoris)	Of 17 patients who had a free muscle transfer with intercostal nerve transfer, the outcomes included 7 good results (M4 to M5), 7 fair results (M3), and 3 poor results. The success rate in this group was 41%. The weight- lifting capacity was similar to that obtained with a latissimus dorsi transfer.	The sample size for free functioning gracilis transfer was small.
Chuang DCC, Ma HS, Borud LJ et al. (2002) Surgical strategy for improving forearm and hand function in late obstetric brachial plexus palsy. Plastic and reconstructive surgery, 109(6): 1934-1946	Case series n=54 (65% male) n=5 free gracilis transfers	Five patients had gracilis free flaps innervated by the divided proximal stump of the musculocutaneous nerve. All 5 achieved improved extensor digitorum communis function (M3 muscle strength), from inability to approach the targets to the ability to extend the finger to approach the target.	The sample size for free functioning gracilis transfer was small.
Chuang DCC and Soucacos PN (1995) Functioning free muscle transplantation for brachial plexus injury. Clinical orthopaedics and related research, 104-111	Case series n=64	The preliminary results for functioning free muscle transplantation were encouraging.	
Coulet B, Boch C, Boretto J et al. (2011) Free gracilis muscle transfer to restore elbow flexion in brachial plexus injuries. Orthopaedics & Traumatology: Surgery & Research, 97: 785- 792	Case series n=12 (mean 25.6 years; 100% male) Follow up: 112 months	There were 2 patients of acute arterial thrombosis (17%) that led to functional failure. When these 2 patients were excluded from the analysis, all the remaining patients had a useful result (BMRC≥M4) and 2.5 kg of elbow flexion strength measured on a dynamometer. The strength was 3.8 kg (2.7 to 55) for partial plexus injuries and 1.6 kg (0.3 to 1.5) for complete plexus injuries. For partial injuries, active elbow flexion was 128° and extension -38°, versus 103° and $-23°$ for complete injuries. The average DASH score was 42 for partial injuries and 32 for complete injuries.	The sample size was small.
Dodakundi C, Doi K, Hattori Y et al. (2013) Outcome of surgical reconstruction after traumatic total brachial plexus palsy. The	Case series n=26 (mean 29 years) Follow up: 36 months	Double free muscle transfer yielded satisfactory function and allowed use of the reconstructed hand in activities that required both hands. The improvement in	The sample size was small.

journal of bone and joint surgery, 95(16): 1505-		the DASH score was greater than in the SF-36 score.	
1512			
Doi K (2008) Management of total paralysis of the brachial plexus by the double free-muscle transfer technique. The journal of hand surgery, 33E(3): 240-251	Case series n=44 Follow-up: mean 40 months	The mean active should abduction and flexion was 26 ⁰ and mean arc of shoulder rotation was 57 ⁰ . The mean active elbow flexion was 114 ⁰ . The mean total active range of motion (TAM) of the fingers was 45 ⁰ . 91% of patients obtained more than 20 ⁰ of TAM. The mean power of hook grip lifting was 4.1 kg. there was no statistical correlation between finger TAM and power of hook grip lifting.	The sample size was small.
Doi K (1997) New reconstructive procedure for brachial plexus injury. Clinics in plastic surgery, 24(1): 75-86	Case series n=15 Follow up: 18 to 62 months Case report n=1 Follow up: 24 months	The double free-muscle transfer technique has restored prehension in patients following complete avulsion of the brachial plexus.	The sample size was small.
Doi K, Hattori Y, Sakamoto S et al. (2013) Current procedure of double free muscle transfer for traumatic total brachial plexus palsy. J Bone Joint Surg Am, 95(16): 1505-12	Case series N=36 (92% male) Follow up: mean 36 months.	The power of elbow flexion was M4 in 25 patients and M3 in 11 patients. Quantitative isokinetic measurements of elbow flexion, performed in 21 patients, revealed that the reconstructed limb had regained a concentric elbow flexion of 5 N-m (13% of that of the contralateral, normal limb) and eccentric elbow flexion of 8 N-m (15% of that of the contralateral, normal limb). The total active motion of the fingers was excellent (\geq 60°) in 11 patients, good (30° to 55°) in 17, fair (5° to 25°) in 7 and poor (0°) in 1.	The sample size was small.
Doi K, Hattori Y, Yamazaki H et al. (2008) Important of early passive mobilisation following double free gracilis muscle transfer. Plastic and reconstructive surgery, 121(6): 2037- 2045	Case series n=34 (mean 23 years; 82% male) Follow up: 24 months	Early passive mobilisation after double free gracilis muscle transfer, consisting of tendon compression at the elbow and assisted resistance exercises of finger and wrist joints, can prevent postoperative adhesion and improve tendon excursion and motion of the free transferred muscle.	This article evaluated the effectiveness of early postoperative passive mobilisation of the tendon to prevent its adhesion and the need for tenolysis.
Doi K, Sakai K, Abe Y, et al. (1993)	Case series	The speed and extent of reinnervation of the transplanted	The sample size was small.

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Transplantation for extremity reconstruction. Plastic and reconstructive surgery, 91 (5): 872	n=46 (mean 30 years; 85% male) Follow up: range 18 to 48 months.	muscle depended on the choice of recipient nerve, the patient's age, and the occurrence of postoperative vascular complications. Neurotisation by the spinal accessory nerve for the posterior interosseous nerve resulted in the most rapid recovery. The administration of postoperative chemotherapy did not delay recovery of function. Free muscle transplantation is consistently successful and provides a functional extremity in severely handicapped patients.	
Doi K, Sakai K, Kuwata N et al. (1995) Double free-muscle transfer to restore prehension following complete brachial plexus avulsion. The journal of hand surgery, 20(3): 408-414	Case series n=10 (mean 25 years)	After second free-muscle transfer, 7 of 10 patients recovered elbow function and finger flexion and extension. Five patients reported use of their hand in activities of daily living.	The sample size was small.
El-Gammal TA, El- Sayed A, Kotb MM et al. (2015) Free functioning gracilis transplantation for reconstruction of elbow and hand functions in late obstetric brachial plexus palsy. Microsurgey, 35: 350-355	Case series n=18 (mean 102.5 months; 33% male) Follow up: mean 66 months	Contraction of the transferred gracilis started at an average of 4.5±1.03 months. Average range of elbow flexion significantly improved from 30±55.7 to 104±31.6 degrees (p<0.001). elbow flexion power significantly increased with an average of 3.8 grades (p=0.000147). passive elbow range of motion significantly decreased from an average of 147 to 117 degrees (p=0.003). active finger flexion power significantly improved from 5±8.3 to 63±39.9 degrees (p<0.001). finger flexion power significantly increased with an average 2.7 grades (p<0.001). only 17% achieved used hand (grade 3) on Raimondi hand score. Triceps reconstruction resulted in an average of M4 power and 45 degrees elbow extension.	The sample size was small.
Elzinga K, Zuo KJ, Olson JL et al. (2014) Double free gracilis muscle transfer after complete brachial plexus injury: first	Case series n=2	Postoperatively, both patients achieved Medical Research Council grade 4 elbow flexion, functional handgrip and were able to return to gainful employment. Patient satisfaction	The sample size was small.

Canadian experience. Plast Surg, 22(1): 26-29 Gousheh J and Arasteh E (2010) Upper limb functional restoration in	Case series n=19 (mean 24 years)	was high and active range of motion improved substantially. Two of the gracilis muscle free transfers failed. In the remaining 17 patients, the overall result	The sample size was small.
old and complete brachial plexus paralysis. The journal of hand surgery, 35E (1): 16-22	Follow up: 1 to 3 years	was evaluated as satisfactory in 11 patients and good in 6.	
Friedman AL, Nunley JA, Goldner RD et al. (1990) Nerve transposition for the restoration of elbow flexion following brachial plexus avulsion injuries. J Neurosurg, 72: 59-64	Case series n=16 (mean 23 years; 95% male)	Of 16 patients who underwent intercostal to musculocutaneous nerve anastomosis, 7 obtained good elbow flexion. Four patients who no longer had a viable biceps brachialis muscle underwent an anastomosis between transposed intercostal nerves and a free vascularised gracilis muscle grafted to the position of the biceps. Two of these patients obtained good elbow flexion. Although synkinesis between the biceps brachialis and the inspiratory muscles can be demonstrated during coughing and deep inspiration, the patients learn to flex their reinnervated biceps brachialis muscle and maintain flexion independent of respiration.	The sample size was small.
Hosseinian MA and Tofigh AM (2008) Cross pectoral nerve transfer following free gracilis muscle transplantation for chronic brachial plexus palsy: A case series. International journal of surgery, 6: 125-128	Case series n=12 (mean 25 years; 92% male)	The gracilis muscle was used for both elbow and digital flexion. Success was defined as muscle strength of M4 and M3 which was observed in seven patients (58%). The motor level of the muscle in two patients was M0 and in two it was M1 to M2. The donor pectoral muscle of these 12 patients showed no deficit in motor and sensory functions.	The sample size was small.
Hattori Y, Doi K, Sakamoto S et al. (2013) Complete avulsion of brachial plexus with associated vascular trauma: feasibility of reconstruction using the double free muscle technique. Plastic and reconstructive surgery, 132(6): 1504-1512	Case series n=20 (mean 28 years; 95% male) n=6 gracilis transfers	The feasibility of double free muscle technique reconstruction in brachial plexus injury patients, without actual vascular repair for the associated subclavian or axillary artery trauma.	The sample size was small.

Hattori Y, Doi K, Ohi R	Case series	After free functioning gracilis	The sample size
et al. (2001) Clinical application of intraoperative measurement of choline acetyltrasferase activity during functioning free muscle transfer. The journal of hand surgery, 26: 645-648	n=12 (mean 25.7 years; 92% male) Follow up: mean 28 months	muscle transfer, all muscles had reinnervation by 3.2 months (range 2 to 5 months) and obtained useful recovery.	was small.
Ikuta Y, Yoshioka K and Tsuge K (1980) Free muscle transfer. Australisn and New Zealand journal of surgery, 50: 401-405	Case series n=8 (mean 13 years; 75% male)	Free muscle graft was used for restoration of active mobility in the upper extremity. The main factors which influenced the functional recovery of the grafted muscle were circulation, tension, and reinnervation of the motor nerve.	The sample size was small.
Kay S, Pinder R, Wiper J et al. (2010) Microvascular free functioning gracilis transfer with nerve transfer to establish elbow flexion. Journal of plastic, reconstructive & aesthetic surgery, 63: 1142-1149	Case series n=33 (median 4.8 years in children and median 34 years in adults; 79% [26/33] male)	After surgery, 70% of patients had a successful outcome. Power comparable to the other side (M5) was recorded in 2 patients, 19 patients scored M4, and 3 scored M3. FFGMT in the OBP group alone (n=13) was the most successful; all had a pre-operative score of M2 or less and post-operatively 12 (92%) achieved a score of M4 or greater. A greater increase in MRC grade for elbow flexion was achieved when intercostal nerves were transferred to innervate the gracilis flat 9mean gain 3 points, SD=1.3), than ulnar fascicles (mean gain 1.75 points, SD=2.3), p=0.05.	The sample size was small.
Kazamel M and Sorenson EJ (2016) Electromyographic findings in gracilis muscle grafts used to augment elbow flexion in traumatic brachial plexopathy (2016). Journal of clinical neurophysiology, 33(6): 549-553	Case series n=34 (median 30 years)	During a mean follow up of 22 months, 94% (32/34) of patients achieved reinnervation.	The sample size was small.
Li GY, Xue MQ, Wang JW et al. (2019) Traumatic brachial plexus injury: a study of 510 surgical cases from multicentre services in Guangxi, China. Acta	Case series n=510 Free functioning gracilis transfer, n=22	Free functioning gracilis graft as a complex procedure had a success rate of 68.18% (15/22) of patients.	The sample size for free functioning gracilis transfer was small.

neurochirurgica, 161:			
899-906			
Madura T, Doi K, Hattori Y et al. (2018) Free functioning gracilis transfer for reanimation of elbow and hand in total traumatic brachial plexopathy in children. Journal of hand surgery, 43(6): 596-608	Case series n=17 (mean 13.4 years) Follow up: 6 years	The transferred gracilis delivered a stable elbow flexion with a useful power, as well as reconstructed active finger motion. In 3-11-year-old patients there was a tendency towards developing a progressive flexion contracture of the elbow. The limb length discrepancy observed in patients was not different from the brachial plexus palsy patients treated without the free functioning gracilis transfer.	The sample size was small.
Maldonado AA, Romero-Brufau S, Kircher MF et al. (2017) Free functioning gracilis muscle transfer for elbow flexion reconstruction after traumatic adult brachial pan-plexus injury: where is the optimal distal tendon attachment for elbow flexion? Plastic and reconstructive surgery, 139: 128-139	Case series n=39 (74% male)	Distal tendon attachment was associated with M3 or M4 elbow flexion and greater range of motion compared with the biceps tendon attachment (p<0.05). there were no statistically significant improvements in disabilities of the arm, shoulder and hand questionnaire scores.	Limited data available relating to free functioning gracilis muscle transfer
Nath RK, Boutros SG and Somasundaram C (2017) Restoration of elbow flexion in patients with complete traumatic and obstetric brachial plexus injury after functional free gracilis muscle transfer: our experience and management. Plasty, 17	Case series n=24 (13 obstetric and 11 traumatic)	Ninety-two percent of all patients showed recovery and improvement. Successful free gracilis muscle transfer is defined as antigravity biceps muscle strength of M3-4/5 and higher, which was observed in 16 (8 obstetric and 8 traumatic) of 24 patients (67%) at least 1 year after functional free gracilis muscle transfer. This is statistically significant (p<0.000001) in comparison with their mean preoperative score (M0-1/5). There was no improvement in motor level of the biceps muscle (M0/5) in 2 patients (1 from each group). The donor site of 24 patients showed no deficit in motor and sensory functions.	The sample size was small.
Nicoson MC, Franco MJ and Tung TH (2016) Donor nerve sources in free functional gracilis	Case series n=13 (mean 34 years; 85% male)	Ther nerve donors utilised for free functional gracilis muscle transfer included the distal accessory nerve, intercostal with	The sample size was small.

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muscle transfer for elbow flexion in adult brachial plexus injury. Microsurgery, 37: 377- 382	Follow up: mean 31.8 months	or without rectus abdominis nerves, medial pectoral nerves, thoracodorsal nerve and flexor carpi ulnaris fascicle of ulnar nerve. Functional recovery of elbow flexion was measured using the MRC grading system which showed 1 M5/5, 5 M4, 4 M3 and 3 M2 outcomes.	
O'Brien BMcC, Morrison WA, Macleod AM et al. (1982) Free miscroneruovascular muscle transfer in limbs to provide motor power. Annals of plastic surgery, 9(5): 381-391	Case series n=7 (mean 24 years; 86% male) Follow up: mean 37.5 months (range 5 to 113 months)	Free gracilis microneurovascular flaps can be safely transferred and can aid restoration of movement following severe injuries of the limbs, including post-replantation cases; inclusion of a cutaneous island with the muscle is safe, improves cover, and simplifies closure following muscle transfer; tendon adhesions and joint stiffness are the greatest obstacles to transferred muscle function, and early passive extension is recommended; additional procedures are usually required after muscle transfer, to improve the level of function; and additional experimental work is required to determine methods of establishing the correct resting tension in transferred muscles.	The sample size was small.
Songcharoen P (1995) Brachial plexus injury in Thailand: a report of 520 cases. Microsurgery, 16(1): 35-	Case series n=530 (16 with free gracilis muscle transfers)	Of 16 free gracilis muscle transfers combined with spinal accessory or intercostal neurotisation procedures performed, 10 patients had a grade 3 recovery and 2 had a grade 2 recovery.	The sample size for free functioning gracilis transfer was small.
Sechachalam S, O'Byrne A and MacQuillan A (2017) Free functional muscle transfer tendon insertion secondary advancement procedure to improve elbow flexion. Techniques in hand & upper extremity surgery, 21: 8-12	Case series N=5 (mean 36 years)	After free functional muscle transfer most patients achieved good outcome, resulting in improved usefulness of the affected lim. However, a minority had successful reinnervation of the transferred muscle but with a suboptimal strength and range of motion of elbow flexion. A secondary procedure of FFMT tendon insertion to improve the moment arm of the muscle on the elbow joint.	This article mainly focused on FFMT tendon insertion
Soldado F and Bertelli J (2013) Free gracilis transfer reinnervated by the nerve to the	Case series n=3 (mean 24 years; 67% male)	All patients had recovery of active thumb and finger extension, soring M3 and M4 ON THE Medical Research	The sample size was small.

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supinator for the	Follow up: 12	Council scale, respectively, at a	[]
reconstruction of finger and thumb extension in longstanding C7-C1 brachial plexus root avulsion. The journal of hand surgery, 38(5): 941-946	months	mean of 12 months after surgery.	
Sungpet A, Suphachatwong C and Kawinwonggowit V (2003) Transfer of one fascicle of ulnar nerve to functioning free gracilis muscle transplantation for elbow flexion. ANZ journal of surgery, 73(3): 133-135	Case series n=3 (mean 28.7 years; 67% male) Follow up: mean 33.3 months	The average reinnervation time of gracilis muscle was 3.7 months. At the final examination, the mean strength of elbow flexion was 4.3 kgf. The grip strength, moving two-point discrimination and the strength of the wrist volar flexion on the affected side was not worse than before surgery in any patient at the last follow-up examination.	The sample size was small.
Takka S, Doi K, Hattori Y et al. (2005) Selection of grip function in double free gracilis transfer procedures after complete paralysis of the brachial plexus. Annals of plastic surgery, 54(6): 610-614	Case series n=30 (mean 23 years; 90% [27/30] male)	Only 11 patients (36%) had very light pulp-to-pulp pinch, 11 (36%) had power grip, and 25 (83%) had hook grip. The mean weight that could be carried by hook grip was 1.3 kg. the mean TAM was 43 ⁰ . Pain sensation was the only encouraging sensation recovery, radiating to the chest.	The sample size was small.
Terzis JK and Barmpitsioti A (2009) Wrist fusion in posttraumatic brachial plexus palsy. Plastic and reconstructive surgery, 124(6): 2027- 2117	Case series n=31 free muscle transfers	Patients with free-muscle transfer for finger flexion and extension achieved superior muscle grading compared with patients without wrist fusion, but this was not significant.	No exact data on the number of patients having free gracilis transfer and associated outcomes.
Terzis JK and Barmpitsioti A (2011) Secondary shoulder reconstruction in patients with brachial plexus injuries. Journal of plastic, reconstructive & aesthetic surgery, 64(7): 843-853	Case series n=55 Double free muscle transfers (gracilis and adductor longus), n=18	Secondary procedures including double free muscle transfer can provide shoulder stabilisation and improved function when results after primary reconstruction were inadequate or in late cases with long denervation time.	The sample size for double free muscle transfer using gracilis was small.
Terzis JK and Kokkalis ZT (2008) Outcomes of hand reconstruction in obstetric brachial plexus palsy. Plastic and reconstructive surgery, 122(2): 516-526	Case series n=59 (53% male)	Grade 4 or better functional recovery was observed 100% (6/6) of the patients who had primary reconstruction within the first 3 months of life. These patients did not require any secondary procedures. Multiple secondary procedures were necessitated to maximise the	The sample size was small.

		functional outcome in late cases	
		or in in patients with incomplete recovery following primary reconstruction. Overall, 75.4% (46/61) of patient achieved grade 4 or greater. The long- term results were better: 88% (23/26) with a follow up of more than 8 years achieved grade 4 or greater.	
Terzis JK and Kostopoulos VK (2009) Free muscle transfer in posttraumatic plexopathies: Part III. The hand. Plastic and reconstructive surgery, 124(4): 1225-1236	Case series n=71	Preoperative and postoperative muscle grading and range of motion were found to be significantly different. The strongest motor donor for finger extension was the distal spinal accessory. The medial antebrachial cutaneous nerve as a conduit nerve carrying motor axons yielded worse results than other motor donors. Intercostals were useful for finger flexion and the contralateral C7 root was useful for finger extension. Scar formation in the volar wrist area was frequently a problem.	This study focuses on the reinnervation technique using a sensory nerve as a motor nerve.
Terzis JK and Kokkalis ZT (2008) Outcomes of secondary shoulder reconstruction in obstetrical brachial plexus palsy. Plastic and reconstructive surgery, 122(6): 1812- 1822	Case series n=67 (mean 6.4 years, 40% male) n=4 free functioning gracilis transfers)	The concurrent transfer of the trapezius with other pedicle muscles, such as the latissimus dorsi or pectoralis major, has given significantly better results than the transfer of the trapezius alone and/or free muscle transfers for the treatment of paralytic should sequelae.	The sample size for free functioning gracilis transfer was small.
Terzis JK and Kokkalis ZT (2009) Secondary procedures for elbow flexion restoration in late obstetric brachial plexus palsy. Hand, 5: 125-134	Case series n=15 (mean 5.4 years; 40% male) Follow up: mean 8.4 years	A retrospective review of 15 patients (16 elbows) who underwent 16 pedicled and 8 free muscle transfers for elbow flexion restoration was conducted. There was significant improvement in biceps muscle power from an average grading of 2.49 ± 0.80 preoperatively to 3.64 ± 0.46 postoperatively (p<0.001). Thirteen of 16 elbows (81%) achieved good and excellent results (\geq M3+); and 3 elbows (19%) fair results (M3- or M3). The average arc of motion was significantly improved from $36^{\circ}\pm25^{\circ}$ preoperatively to $94^{\circ}\pm26^{\circ}$ postoperatively (p<0.001). The preoperative and postoperative average elbow	The sample size was small.

		flandar a santar at a	,
		flexion contracture was 10.9°±8.9° and 20°±12.2°, respectively.	
Terzis JK and Kostopoulos VK (2010) Free muscle transfer in posttraumatic plexopathies. Annals of plastic surgery, 65(3): 312-317	Case series n=22 Double muscle transfer (adductor longus and gracilis), n=18	For the double muscle transfer, the mean range of motion of shoulder abduction was found postoperatively to be 30±0.76 (p<0.001). all patients achieved a stable should, 53% yielded should abduction against gravity and 9% achieved abduction to the horizontal level.	The sample size for double muscle transfer using gracilis was small.
Yang Y, Yang JT, Fu G et al. (2016) Functioning free gracilis transfer to reconstruct elbow flexion and quality of life in global brachial plexus injured patients. Scientific reports, 6:22479	Case series n=49 (mean 26.36 years) Follow up: mean 54.5 months.	The average ROM of the elbow flexion was 106.5° (range 0 ⁰ to 142°) and was 17.00° (range 0 ⁰ to 72°) for wrist extension. The average DASH score was 51.14 (range 17.5 to 90.8). The prevalence of anxiety and depression were 42.86% and 45.24%. Thrombosis and bowstringing were the most common short and long-term complications.	The sample size was small.
Baliarsing AS, Doi K and Hattori Y (2002) Bilateral elbow flexion reconstruction with functioning free muscle transfer for obstetric brachial plexus palsy. The journal of hand surgery: journal of the British Society for Surgery of the Hand, 27(5): 484-486	Case report n=1 (1 year; male) Follow up: 10 months	The child had full range of passive elbow movement, without any flexion contracture, and achieved full active elbow flexion on both sides. He was able to use both arms effectively after 10 months.	This was a single case report.
Carlsen BT, Wendt MC, Spinner RJ et al. (2011) Use of a free- functioning muscle transfer from a paralysed lower extremity to restore upper extremity elbow flexion. Journal of surgical orthopaedic advances, 20(4): 247- 251	Case report n=1 (43 years; male) Follow up: 24 months	The free-functioning gracilis muscle transfer was performed 9 months later injury and resulted in functional elbow flexion. Clinical examination and EMG analysis document function of the transferred muscle with grade 4 muscle strength. The resultant effect on the skeletal muscle is different after upper motor neuron injury versus lower motor neuron injury.	This was a single case report.
Chwei-Chin Chuang D, Wei FC and Noordhoff MS (1993) Cross-chest C7 nerve grafting followed by free muscle transplantations for the treatment of total	Case report n=1 (34 years; male)	At 2 years after muscle transplantation, both transferred gracilis muscles attained motion to the M4 level. The patient could hold a light object with the help of a thumb splint. His elbow flexion power came from 2	This was a single case report.

avulsed brachial plexus injuries: A preliminary		sources: the ipsilateral phrenic nerve and the contralateral C7	
report. Plastic and reconstructive surgery, 92(4): 717-725		nerve.	
Doi K, Sakai K, Fuchigami Y et al. (1996) Reconstruciton of irreparable brachial plexus injurite swith reinnervated free- muscle transfer. J Neurosurg, 85: 174-177	Case report n=1 (32 years: female) Follow up: 31 months after the second muscle transfer	This microsurgical reconstruction provided the patient with an opportunity to regain a high level of functioning that otherwise would be impossible after a complete avulsion of the brachial plexus.	This was a single case report.
Doi K, Kuwata N, Muramatsu K et al. (1999) Double muscle transfer for upper extremity reconstruction following complete avulsion of the brachial plexus. Hand clinics, 15 (4): 757-768	Review and case report n=1 (24 years: male) Follow up: 20 months after the second muscle transfer	The double free muscle transfer has provided prehension for patients with complete avulsion of the brachial plexus.	This was a single case report.
Gangurde BA, Doi K, Hattori Y et al. (2014) Free functioning muscle transfer in radiation- induced brachial plexopathy: case report. The journal of hand surgery, 39(10): 1967- 1970	Case report n=1 (56 years; female) Follow up: 2 years	By 2 years after the surgery the patient regained elbow range of motion of 40° to 110° and improved in hand function. She was able to perform activities of daily living. Disabilities of the arm, shoulder, and hand score improved from 56 to 20.	This was a single case report.
Hattori Y, Doi K, Saeki Y et al. (2004) Obturator nerve injury associated with femur fracture fixation detected during gracilis muscle harvesting for functioning free muscle transfer. Journal of reconstructive microsurgery, 20(1): 21- 24	Case report n=1 (31 years; male)	A rare case was reported in which injury of the motor nerve of the gracilis (obturator nerve) was detected during its harvesting for functioning free muscle transfer. The probable cause of this rare injury was considered to be accidental penetration while drilling for a proximal locking screw in intramedullary nailing during previous femur fracture surgery.	This was a single case report.
Kakinoki R, Ikeguchi R, Nakayama K et al. (2007) Functioning transferred free muscle innervated by part of the vascularised ulnar nerve connecting the contralateral cervical seventh root to the median nerve: case report	Case report n=1 (21 years; male)	The patient received transplantation of a free vascularized gracilis muscle, innervated by a part of the transplanted vascularized ulnar nerve connecting the contralateral healthy cervical seventh nerve root (CC7) to the median nerve, and recovered wrist motion and sensation in the palm. At the final examination, the affected wrist could be flexed dorsally by the	This was a single case report.

Vekris MD, Ovrenovits M, Dova L et al. (2007)	Case report	transplanted muscle, and touch sensation had recovered up to the base of each finger. When his left index and middle fingers were touched or scrubbed, he felt just a mild tingling pain in his right middle fingertip. The patient who had 2 free functional muscle transfers for	This was a single case report.
Free functional muscle transfer failure and thrombophilic gene mutations as a potential risk factor: A case report. Microsurgery, 27: 88-90	n=1 (18 years; male)	brachial plexus reconstruction in the same forearm within an interval of 6 months. The free functional muscle transfer was failed in both cases because of vein thrombosis and subsequent arterial clot.	
Yang Y, Zou XJ, Fu G et al. (2016) Neurotisation of free gracilis transfer with the brachialis branch of the musculocutaneous nerve to restore finger and thumb flexion in lower trunk brachial plexus injury: an anatomical study and case report. Clinics, 71(4): 193-198	Case report n=1 (18 years, male)	The mean length and diameter of the brachialis muscle branch of the musculocutaneous nerve were 52.66±6.45 and 1.39±0.09 mm, respectively, and 3 branching types were observed. For the patient, the first gracilis contraction occurred during the 4th month. A noticeable improvement was observed in digit flexion 1 year later; the muscle power was M4, and the total active motion of the fingers was 209°.	This was a single case report.
Berger A, Schaller E and Mailänder P (1991) Brachial plexus injuries: An integrated treatment concept. Ann Plast Surg, 26: 70-76	Review	The combination of nerve repair with both conventional and new methods of muscle and tendon transfer, including the free muscle transplant innervated by vascularised nerve grafts, can give the patient functional use of the paralysed arm.	Review article
Bishop AT (2005) Functioning free-muscle transfer for brachial plexus injury. Hand Clin, 21: 91-102	Review	Single free-muscle transfer showed excellent results for restoration of elbow flexion. Double free-muscle transfer provided the possibility of simple grasp function when combined with nerve transfers or grafts for restoration of should motion, hand sensation and triceps function.	Review article
Carlsen B, Bishop AT and Shin AY (2009) Late reconstruction for brachial plexus injury. Neurosurgery clinics of North America, 20(1): 51-64	Review	Evidence reported good to excellent results from transfer of a single gracilis muscle for elbow flexion. The double free- functioning muscle transfer also showed favourable outcomes.	Review article

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Dafydd H and Lin CH (2014) Hand reanimation. Curr Rev Musculoskelet Med, 7: 76-82	Review	Free functioning gracilis transfer can be used as an option for hand reanimation.	Review article
Fischer JP, Elliott RM, Kozin SH et al. (2013) Free function muscle transfers for upper extremity reconstruction: A review of indications, techniques, and outcomes. J Hand Surg Am, 38(12): 2485-2490	Review	Significant advances in FFMT has been made as a direct result of improved techniques in muscle harvest, a critical assessment of efficacy of monitoring techniques, the use of adjunctive secondary procedures to optimise hand function, and a strong focus on reporting of patient outcomes.	Review article
Garcia, RM and Ruch DS (2016) Free flap functional muscle transfers. Hand clinics, 32(3): 397-405	Review	Free functional muscle transfers should be considered in patients who have either failed or are not deemed to be candidates for local muscle/tendon transfers or neurotization procedures. Free functional muscle transfer for complete brachial plexus injuries remain a powerful reconstructive tool to restore lost upper extremity function.	Review article
Gutowski KA and Orenstein HH (2000) Restoration of elbow flexion after brachial plexus injury: the role of nerve and muscle transfers. Plastic and reconstructive surgery, 106(6): 1348-1358	Review	In cases of delayed nerve reconstruction with target muscle atrophy and motor endplate degeneration, a free gracilis, rectus femoris, or contralateral latissimus dorsi muscle transfer is useful. Free muscle transfer can also combine with nerve transfers, nerve graft and neurolysis procedures.	Review article
Krauss EM, Tung TH and Moore AM (2016) Free functional muscle transfers to restore upper extremity function. Hand clinics, 32: 243-256	Review	Free functional muscle transfer provides a viable option to restore function to the upper extremity after a devastating brachial plexus injury. The identification of donor nerves, tensioning of the muscle at inset, and postoperative splinting and therapy influence the outcome of the free functional muscle transfer. Adjunctive procedures are also important in the reconstructive algorithms for patients with complex brachial plexus injuries.	Review article
Maldonado AA, Bishop AT, Spinner RJ et al. (2017) Five operations that give the best	Review	Five operations (including free functional muscle transfer) have given consistently good	Review article

results after brachial		outcomes in patients who	
plexus injury. Plastic and reconstructive surgery, 140(3): 545- 556		require surgical reconstruction.	
Songcharoen P (2008) Management of brachial plexus injury in adults. Scandinavian journal of surgery, 97: 317-323	Review	Functioning free muscle transfer, e.g. gracilis, in combination with selective nerve transfer is a reasonable surgical procedure to restore elbow and hand function for adults with brachial plexus injury.	Review article
Spinner RJ, Shin AY and Bishop AT (2005) Update on brachial plexus surgery in adults. Techniques in hand and upper extremity surgery, 9(4): 220-232	Review	Improved diagnostic modalities along with advances in surgical techniques have allowed reliable restoration of shoulder stability and elbow flexion. Use of novel extraplexal donor nerves in addition to free functioning gracilis muscle transfers now give hope for the restoration of hand function.	Review article
Stevanovic M and Sharpe F (2014) Functional free muscle transfer for upper extremity reconstruction. Plastic and reconstructive surgery, 134(2): 257e- 274e.	Review	Functional free muscle transfer is a powerful tool in upper extremity reconstruction when other options are not available. appropriate patient selection, a skilled surgical reconstructive team, and a dedicated postoperative rehabilitation programme are essential for restoration of lost function and patient satisfaction.	Review article
Wade SM, Nesti LJ, Wind GG et al. (2019) The inverted free functioning gracilis muscle transfer for restoration of elbow flexion following delayed presentation or failed primary nerve reconstruction of upper trunk injuries. Techniques in hand & upper extremity surgery.	Review	Functional restoration of elbow flexion with a free gracilis flap is a complex operation with the potential for developing multiple complications at both donor and recipient sites. Recipient site: acute complications include flap loss, rupture of the nerve coaptation, infection or hematoma. Long-term complications cover adhesion formation, joint contracture development, or loss of tension in the transferred gracilis. Donor site: acute complications include hematoma or seroma formation, wound infection, and transient sciatic nerve palsy. Long-term complications consist of chronic donor site pain, delayed wound healing, unsightly scar formation and modestly decreased	Review article

		adduction strength of the lower extremity.	
Wehrli L, Bonnard C and Anastakis DJ (2011) Current status of brachial plexus reconstruction: restoration of hand function, 38(4): 661-682	Review	Double and single free functional muscle transfers can provide reliable and useful hand function in cases of complete brachial plexus avulsion. The reported results following free functional muscle transfer vary from centre to centre. This variability may be due to patient factors or inconsistencies in the grading system.	Review article