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REVIEW

A systematic review of functional outcome and quality of life following reconstruction of maxillofacial defects using vascularized free fibula flaps and dental rehabilitation reveals poor data quality

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Head and neck
cancer;
Vascularized free
fibula flap;
Oral rehabilitation;
Functional outcome;
Quality of life

Summary *Background:* Reconstruction and oral rehabilitation of segmental maxillofacial defects resulting from ablative surgery is commonly achieved by osteocutaneous vascularized free fibula (VFFF) transplantation combined with implant-supported dental prostheses. We systematically reviewed the literature regarding impact of oral rehabilitation with or without dental implants on functional outcome and quality of life (QoL) following reconstruction of such segmental maxillofacial defects with VFFF.

Methods: This systematic review was performed according to the PRISMA guidelines. A literature search was conducted using the databases of Cochrane, MEDLINE and EMBASE. Relevant search terms for maxilla or mandible, reconstruction with VFFF, and oral rehabilitation were used. Two reviewers independently assessed the publications using eligibility and research quality criteria (MINORS).

Results: In total, 554 unique publications were found. After scrutinization, 2 prospective studies and 8 retrospective case-series without comparison were left for ultimate analysis. Quality ranged from 44% to 88% of the maximum score. Overall survival rate of the VFFF was

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99% and the survival rate of dental implants was 95%. Speech intelligibility and overall aesthetic outcome were 'good' to 'excellent'. No statistically significant changes in QoL were found. Methods to measure functional outcome varied strongly, making pooling impossible.

Conclusions: Oral rehabilitation with implant-supported dental prostheses after reconstruction of segmental maxillofacial defects with VFFF results in good to excellent speech intelligibility and aesthetics. Results are probably positively biased by the retrospective nature of the studies. In future prospective research, functional outcome measures should be addressed using standardized questionnaires and validated objective tests with adequate follow-up.

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Introduction

Segmental resection of the maxilla and/or the mandible for the treatment of neoplasms often results in complex maxillofacial defects, involving soft tissue, bone and dentition. These defects can be debilitating since they impair oral functions and disturb aesthetic contours, and may lead to social isolation and poor quality of life (QoL).^{1–4} Since its introduction, the transplantation of a vascularized free fibula flap (VFFF) has evolved into the standard procedure for reconstruction of complex segmental maxillofacial defects.^{5–13} The VFFF can be reliably harvested and transferred, with a flap survival rate up to 95%, and low donor site morbidity.^{6,14–19}

Restoration of oral functions requires not only reconstruction of the maxillofacial defect, but also dental rehabilitation.^{20–22} Due to the surgical ablation

and reconstruction, the options to obtain sufficient prosthesis retention and stability are reduced. When radiotherapy has been applied and/or the mobility of the tongue and overlying soft tissues is reduced, chances of successful dental rehabilitation decrease further due to the changed anatomical conditions and the intolerance of the denture-bearing mucosa to mechanical loading.^{1–4,23–25}

The bicortical fibular bone of the VFFF has an excellent ability to accept dental implants to support dental prostheses, and implant survival rates are reported to be high (93–99%).^{26–32} Implant-supported prostheses contribute significantly to oral functions such as speech, swallowing and mastication, and there seems to be a tendency to use implants as a part of the standard rehabilitation plan.^{1,2,5–8,10–13,20–22,25,30,32–47}

Systematic evaluation of the literature regarding functional outcomes related to prosthetic treatment

after maxillofacial reconstruction in patients treated for head and neck cancer has been performed previously, but did not focus specifically on reconstruction with VFFF, and QoL assessment was not performed.⁴⁸ The aim of this study was to systematically review the literature regarding the impact of oral rehabilitation with or without dental implants on functional outcome and quality of life following reconstruction of a segmental maxillofacial defect with VFFF.

Material and methods

Protocol

This systematic review was designed a priori, according to the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines.⁴⁹

Information sources and search strategy

An initial literature search was conducted on May 31, 2013 and updated until April 10, 2015 using the electronic databases of Cochrane Library, MEDLINE by means of PubMed, and the search was adapted for EMBASE. Relevant search terms for the head and neck area involving the maxilla or mandible, reconstruction with VFFF, and oral rehabilitation were used. These search terms were matched to relevant MeSH (MEDLINE, Cochrane) and Emtree terms (EMBASE) and exploded or searched as keywords (Table 1). (Systematic) reviews were not included in the study but were used to identify potentially relevant studies missed in the search.

Selection and assessment of relevant studies

Results of the search were imported into a RefWorks® (ProQuest LLC, Bethesda, MD, USA) database. Duplicate publications were removed. Publications were assessed for inclusion in two selection rounds according to inclusion criteria (Table 2). Publications were excluded if they were published in a language other than English, German, or Dutch. In case of overlapping study populations in publications from the same authors, these publications were considered as one study, or the most recent publication with the longest follow-up was used.

In the first selection round, two reviewers (JW, RS) independently assessed titles and abstracts for inclusion and exclusion criteria. If an abstract was not available, the full text of the article was assessed in the second round. Both reviewers allocated titles and abstracts as 'included', 'excluded', or 'indecisive'. In the second round, full text assessment of the 'included' and 'indecisive' publications was performed according to the same criteria. After each selection round, discrepancies between the two reviewers were resolved in a consensus meeting. If no consensus could be reached, a third reviewer (PD) gave a binding verdict. Inter-reviewer agreement was determined by Cohen's κ .^{50,51} Reference lists of the included studies were searched for relevant studies missed in the database searches. Potential publication bias was assessed using funnel plots and 'trim and fill' method.⁵²

Quality assessment of included studies

The Methodological Index of Nonrandomized Studies (MINORS), a valid and reliable instrument to assess methodological quality and potential bias in nonrandomized studies,

Table 1 Search strategy.

Pubmed and Cochrane search		EMBASE search	
#1	"Face"[MeSH] OR "Jaw"[MeSH] OR "Mouth"[MeSH] OR Head and Neck OR Jaw OR Mouth OR Oral OR Mandib* OR Maxill* OR Palat* OR Midfac* OR Alveolar bone* OR Alveolar process* OR Dental OR Dentition OR Tooth OR Teeth OR Periodont* OR Lip OR Lips OR Gingiv* OR Tongue* OR (Mouth AND Floor) OR (Mouth AND Mucos*) OR (Oral mucosa) OR Chin OR Cheek* OR Salivary gland* OR Parotid gland* OR Sublingual gland* OR Submandibular gland* OR Oropharyn* OR Hypopharyn*	#1	'Face'/exp OR 'Skull'/exp OR 'Mouth and Teeth'/exp OR 'Head and Neck' OR Jaw OR Mouth OR Oral OR Mandib* OR Maxill* OR Palat* OR Midfac* OR 'Alveolar bone' OR 'Alveolar bones' OR 'Alveolar process' OR 'Alveolar processes' OR Dental OR Dentition OR Tooth OR Teeth OR Periodont* OR Lip OR Lips OR Gingiv* OR Tongue* OR (Mouth AND Floor) OR (Mouth AND Mucos*) OR 'Oral mucosa' OR Chin OR Cheek* OR 'Salivary gland' OR 'Salivary glands' OR 'Parotid gland' OR 'Parotid glands' OR 'Sublingual gland' OR 'Sublingual glands' OR 'Submandibular gland' OR 'Submandibular glands' OR Oropharyn* OR Hypopharyn* AND [embase]/lim
#2	"Fibula"[MeSH] OR Fibul*	#2	'Fibula'/exp OR Fibul* AND [embase]/lim
#3	"Dentistry"[MeSH] OR "Prosthodontics"[MeSH] OR "Dental Prosthesis"[MeSH] OR "Dental Implants"[MeSH] OR ((Mouth OR Oral OR Dental) AND (Rehabilitation OR Implant OR Implants OR Prosthes*)) OR Prosthodontic* OR Denture	#3	'Reparative dentistry'/exp OR ((Mouth OR Oral OR Dental) AND (Rehabilitation OR Implant OR Implants OR Prosthes*)) OR Prosthodontic* OR Denture AND [embase]/lim
#4	((#1 AND#2) AND#3) NOT Review	#4	#1 AND#2 AND#3

Table 2 Inclusion and exclusion criteria.**Studies were included in case of:***Population*

1. ≥ 10 human subjects
2. Segmental maxillary or mandibular defect
3. Reconstruction with vascularized free fibula flap

Intervention

4. Oral rehabilitation with conventional or implant-supported prosthesis

Outcome measures

- A. Survival of the free fibula flap
- B. Success rate of dental implants
- C. Mastication
- D. Mouth opening/trismus
- E. Speech
- F. Swallowing
- G. Oral diet
- H. Quality of life
- I. Aesthetic outcome
- J. Donor site morbidity
- K. Complications

Studies were excluded in case of:

- Follow-up < 4 months or mean follow-up < 1 year
- Language other than English, Dutch or German
- (Systematic) reviews
- Cadaveric studies
- Animal studies

was applied.⁵³ The MINORS scoring list consists of 12 items, eight apply to non-comparative studies and the remaining four items apply to comparative studies. Items are scored as 0 (not reported), 1 (reported but inadequate) and 2 (reported and adequate). JW and RS independently assessed the quality of the included studies. Disagreement was resolved in a consensus meeting.

Data extraction and analysis

JW and RS independently performed data extraction using a pre-designed electronic database form (Microsoft Excel; Microsoft Corp., Redmond, WA, USA). Agreement on data collection was reached by consensus. Data was collected and analyzed regarding study characteristics, patient characteristics, information on the treatment modality (VFFF with conventional or implant-supported prosthesis), and outcome measures regarding functional outcome and QoL (speech, mastication, deglutition, dietary intake, oral continence, mouth opening/trismus, QoL, aesthetic outcome, and donor site morbidity).

Results

Study selection

The data base search and updated searches (629 articles) together with the reference check (105 publications)

yielded 734 publications (Figure 1). Removing duplicate publications (177) yielded a total of 554 unique publications. Assessment of the titles and abstracts resulted in 180 unique publications that were eligible for further assessment. In the second selection round, a further 168 publications were excluded. Three publications were excluded because they revealed extensive overlap of data (same study population) with a more recent paper.^{54–56} One study was excluded because no full text was available.⁵⁷ Of the 12 remaining studies, three studies addressed the same population using the same study design and were considered as one study.^{58–60} Thus, ten unique studies were included in this systematic review.^{27,58–68} During the selection process, the inter-reviewer agreement (Cohen's κ and percentage of agreement) for the first round, the second round, and quality assessment was 0.76 (87%), 0.55 (82%), and 0.53 (60%), respectively. A reference list of excluded studies is provided (online only).

Characteristics and quality of included studies

Of the ten included studies, two were non-randomized prospective,^{58–60,63} the others were retrospective case series.^{27,61,62,64–68} One prospective case series was used in three publications, each described different functional outcomes of conventional and implant supported dental prosthesis in patients requiring segmental mandibulectomy and reconstruction with VFFF.^{58–60} The other prospective study assessed treatment outcomes and impact on QoL in

Figure 1 Flowchart of study selection procedure.

patients rehabilitated with implant-retained prosthesis after segmental resection and reconstruction.⁶³ None of the retrospective studies were comparative.

In the ten included studies, 260 patients were described who underwent reconstruction using 261 VFFF's following segmental resection of the maxilla (55 VFFF's) or mandible (206 VFFF's). The number of patients per study ranged from 12⁶³ to 74 patients⁶⁸ (mean: 26 patients), in the age range of 14–83 years (weighted mean, 50.9 years). Preoperative dental status was reported in four studies.^{27,58–60,62,63} The time interval between reconstruction with VFFF and placement of dental implants ranged from 0 to 75 months. The follow-up period after dental rehabilitation ranged from 6 to 267 months (weighted mean, 58.3 months) (Table 3).

The median MINORS score was 50% (inter quartile range 25; 75) (Table 3).^{58–60}

Survival of the VFFF and success rate of dental implants

In only two of the included studies, loss of the VFFF was reported,^{64,68} resulting in an overall survival rate of 99% (Table 4). Nine studies reported a total of 662 osseointegrated dental implants inserted in 210 patients, with a cumulative survival rate of 95% in a follow-up period of 0–155 months (Table 4). In five studies, the number of implants placed was specified to the implant site, being VFFF or native jaw (Table 3).^{27,61,62,64,66} All patients received dental implants secondarily after healing of the VFFF, except for five patients who received dental implants at the time of reconstruction.^{64,66} Four studies described that radiotherapy was administered before implant placement in 38 patients.^{27,61,63,68} Two of these studies reported late (>17 months) loss of seven implants in two patients who had received radiotherapy,⁶³ and a reduction in survival rate from 84% to 97%.⁶¹ Another study reported loss of one implant in an irradiated FFF (Table 4).²⁷

Mastication, deglutition, and dietary intake

Five studies reported on mastication.^{27,58–60,63,64,66} One prospective study used a standardized masticatory performance test, using peanuts as test food.^{58–60} Furthermore, three questionnaires were applied in this study, of which two regarded chewing and food preference. The outcomes of the study showed that patients with implant retained dentures performed better than patients rehabilitated without implants.^{58–60} One study found excellent or good chewing ability in 29 of 30 patients.²⁷ Another study found a reduced occlusal force of $61 \pm 10\%$ of the pre-ablative occlusal force irrespective of the dental status.⁶⁴ Two studies found no significant improvement in mastication performance (Table 4).^{63,66}

Speech

Speech outcome was assessed in nine studies, but methods to assess speech varied between studies. One study reported both objective evaluation of speech using speech software and subjective evaluation using standardized

questionnaires.⁶³ In a Chinese study a standardized speech intelligibility test was performed,⁶⁴ and in a Japanese study a standard classification was used.⁶⁵ In the other studies, speech intelligibility was assessed using a questionnaire^{66–68} or a 3-point Likert scale.^{27,61,62} Overall, speech intelligibility was excellent or good in most patients, and moderate or poor in a minority of patients (Table 4).

Quality of life

Only two studies used a Quality of Life Questionnaire (EORTC QLQ-H&N35, EORTC QLQ-C30).^{63,66} They found no statistically significant changes in quality of life after dental rehabilitation except for the social aspect. In another study, a Oral Health Impact Profile (OHIP) questionnaire showed that most of the subjects rarely reported to have had problems at one year postoperatively.⁶⁸ In one study a visual analogue scale (VAS) was used (Anchored 0: best outcome, 10: worst outcome) to assess oral functioning (mean VAS 4.2), aesthetic outcome (mean VAS 3.3), and overall satisfaction (mean VAS 3.6).⁶⁶

One study reported that social life and satisfaction were not altered grossly. However, the percentage of subjects experiencing moderate to severe limitations in food choices after the ablative and reconstructive surgery, but before oral rehabilitation increased from 61% to 78% ($P < 0.05$) (Table 4).^{58–60}

Aesthetic outcome

Seven studies reported on aesthetic outcome. None of these studies used a standardized questionnaire or objective test. In most studies, aesthetic outcome was scored either by a physician and/or through self-assessment, on a 3-point or 4-point Likert scale. The overall outcome of these rating of both patients and physicians was 'good' to 'excellent', only one study described a mean aesthetic satisfaction score of 3.3 on a 10-point VAS-score (Table 4).

Complications and donor site morbidity

Overall, complications rarely occurred. Five studies reported on complications such as flap necrosis, peri-implant soft tissue hyperplasia, fracture or exposure of osteosynthesis, abscesses, and saliva- or oronasal fistula development.^{61–65} Wound healing disturbance of the donor site was observed in just one case. Five patients complained of difficulties in foot motility⁶¹ or impaired ankle function⁶⁸ after surgery (Table 4).

Assessment of publication bias

The funnel plots based on data regarding survival of VFFF (Figure 2) and survival of dental implants (Figure 3) suggested asymmetry (blank circles in Figures 2 and 3). This finding was confirmed by the 'trim and fill' analysis, which showed that the number of missing studies was 4 (black circles in Figure 2) and 3 (black circles in Figure 3), respectively.

Table 3 MINORS score and summary of study characteristics.

Reference	MINORS score	Study design	Subjects with VFFF (n)	Defect Maxilla/ Mandible (n)	Mean age (range, years)	Gender (Male/ Female)	Mean follow-up (range, months)	Pre-operative dental status	Radiotherapy pre-implant or post-implant	Number of subjects with implants	Number of implants (in VFFF/ in native jaw)	Type of prosthesis (n)
*Garrett et al., 2006 ⁵⁸ *Roumanas et al., 2006 ⁵⁹ *Fueki et al., 2014 ⁶⁰	88% (14/16)	P	46	—/46	60.0 (19–83)	22/24	19.7 (15–31)	7 E, 39 PD	NR	17	58 (NR)	13 NP, 18 CP, 15 IP
Ferrari et al., 2013 ⁶¹	75% (12/16)	R	14	—/14	50.8 (15–65)	8/6	110.4 (12–120)	NR	7 pre-implant	14	62 (57/5)	14 IP
Wang et al., 2013 ⁶²	75% (12/16)	R	12	—/12	42.9 (28–55)	7/5	42.1 (36–47)	3 E, 9 PD	0	12	37 (35/2)	12 IP
Dholam et al., 2011 ⁶³	75% (12/16)	P	12	10/2	NR	NR	18.0 (18–18)	5 E, 7 PD	8 pre-implant	12	35 (NR)	12 IP
Sun et al., 2011 ⁶⁴	63% (10/16)	R	20	20/—	42.6 ^{23–63}	14/6	34.7 (9–83)	NR	15, pre or post not specified	1	3/—	9 CP, 1 IP
Katsuragi et al., 2011 ⁶⁵	63% (10/16)	R	12	—/12	56.3 (14–80)	8/9	15.8 (6–33)	NR	2 post-VFFF (no implants)	1	NR	107 CP, 1 IP
Raoul et al., 2009 ²⁷	63% (10/16)	R	30	25/6	46.0 (19–72)	18/12	74.9 (7–155)	2 E, 28 PD	14 pre-implant	30	105/0	31 IP
Hundepool et al., 2008 ⁶⁶	56% (9/16)	R	14	—/14	58.0 (19–77)	8/6	39.5 (6–89)	NR	NR for this subgroup	24	90 (69/21)	18 IP
Bodard et al., 2015 ⁶⁷	56% (9/16)	R	26	—/26	54.1 (19–72)	17/9	75.3 (9–156)	NR	NR	26	80 (NR)	26 IP
Fang et al., 2015 ⁶⁸	44% (7/16)	R	74	—/74	47.0 (19–75)	61/13	153.0 (41–267)	NR	9 pre-implant	74	192 (NR)	74 IP

MINORS, Methodological Index of Nonrandomized Studies; VFFF, vascularized free fibula flap; n, number; *, three articles describing different outcome measurements in the same study population; P, prospective study; R, retrospective study; E, edentulous; PD, partially dentate; NR, not reported; NP, no prosthesis; CP, conventional prosthesis; IP, implant-supported prosthesis.

Table 4 Functional outcome measures.

Reference	VFFF survival rate	Implant survival rate	Mastication (n)	Deglutition (n)	Dietary intake (n)	Speech (n)	Quality of Life	Aesthetic outcome (n)	Complications (n)	Donor site morbidity (n)
*Garrett et al., 2006 ⁵⁸ *Roumanas et al., 2006 ⁵⁹ *Fueki et al., 2014 ⁶⁰	100%	98%	Masticatory performance similar to presurgical levels may be achieved with both CP and IP	SwT performance with the IP was similar to that of an average denture wearer	NR	NR	Moderate to severe limitations in food choices increased from 61% to 78%	NR	NR	NR
Ferrari et al., 2013 ⁶¹	100%	92%	NR	NR	12 normal 1 soft 1 tube	11 intelligible 2 intelligible with effort 1 unintelligible	NR	10 good 2 moderate 2 poor	1 flap necrosis, 1 plate loss, 1 implant loss	1 difficult wound healing, 2 impaired foot motility
Wang et al., 2013 ⁶²	100%	100%	NR	NR	NR	7 fully satisfied 5 partially satisfied	NR	10 fully satisfied 2 partially satisfied 0 unsatisfied	2 granulation around implants	NR
Dholam et al., 2011 ⁶³	100%	80%	No improvement	No improvement	6 normal 3 soft 3 NR	Speech intelligibility was improved in 80%	Scores remained unchanged after 18 months	NR	2 food pocketing, 4 xerostomia, 4 hypersensitive to food temperature	NR
Sun et al., 2011 ⁶⁴	95%	100%	Post-operative occlusal force 61 of preoperative	NR	All patients regular or soft	Mean speech intelligibility score of 97% at 6 months postoperative	NR	15 excellent 4 good 1 fair	1 partial fibular ORN, 1 necrotic VFFF, 3 fistulas	NR
Katsuragi et al., 2011 ⁶⁵	100%	100%	NR	NR	12 normal 5 soft diet 0 tube feeding	All patients exhibited excellent speech patterns	NR	12 excellent 2 good 2 fair 1 poor	2 salivary fistulae, 1 abscess, 1 partial necrosis of skin flap, 1 late fracture	1 hammer toe
Raoul et al., 2009 ²⁷	100%	96%	22 excellent 7 good 1 bad	NR	NR	21 excellent 9 good 0 bad	NR	25 excellent 4 good 1 bad	NR	NR
Hundepool et al., 2008 ⁶⁶	100%	97%	Improvement after prosthetic rehabilitation	Improvement after prosthetic	NR	Improvement after prosthetic rehabilitation	No improvement except for	Aesthetic satisfaction score of 3.3 on a 10-point	NR	NR

(continued on next page)

Table 4 (continued)

Reference	VFFF survival rate	Implant survival rate (n)	Mastication (n)	Deglutition (n)	Dietary intake (n)	Speech (n)	Quality of Life	Aesthetic outcome (n)	Complications (n)	Donor site morbidity (n)
Bodard et al., 2015 ⁶⁷	100%	98%	NR	rehabilitation (p > 0.01) NR	20 regular, 6 soft; Dietary improvement in 9/20 (35%)	Improvement in speech in 6/26 (23%)	social aspect	VAS-score	NR	NR
Fang et al., 2015 ⁶⁸	98%	90% (5 y) [†] 83% (10 y) 69% (20 y)	NR	NR	Diet unsatisfactory: N: 26%, HE: 33%, OC: 21%, FO: 9%, VO: 11% [‡]	Trouble pronouncing: N: 32%, HE: 23%, OC: 21%, FO: 16%, VO: 9% [‡]	Life less satisfying: N: 11%, HE: 33%, OC: 28%, FO: 15%, VO: 13% [‡]	Aesthetic improvement in 20/26 (77%)	6 recipient site problems	3 impaired ankle function

VFFF, vascularized free fibula flap; n, number; *, three articles describing different outcome measurements in the same study population; CP, conventional prosthesis; IP, implant-supported prosthesis; SwT, swallowing threshold; NR, not reported; ORN, osteoradionecrosis; y, years; †, 5-year survival used for cumulative survival rate of implants; ‡, OHIP questionnaire outcome: N: normal, HE: hardly ever, OC: occasionally, FO: fairly often, VO: very often.

Discussion

The aim of this study was to systematically review the literature regarding effects of oral rehabilitation with or without dental implants on functional outcome and quality of life following reconstruction of a segmental maxillofacial defect with VFFF. We found that most studies report high patient satisfaction and favorable oral function after implant supported dental rehabilitation, but generally there is a great diversity in methods used to assess functional outcomes and QoL. We cannot draw firm conclusions about dental rehabilitation following VFFF because all studies presented relative small sample sizes, with a substantial heterogeneity in sample characteristics, based on inclusion and exclusion criteria for further rehabilitation with dental implants, number of implants and/or prosthesis, heterogeneity in instruments used to measure functional outcome and QoL, and time of follow-up (several months to a few years). This heterogeneity made data pooling impossible.⁶⁹

Comparing functional outcome of patients who received a VFFF for the reconstruction of a jaw defect is generally hampered by diversity in the bone and soft tissue defects patients have. Large defects requiring multisegment reconstructions cause more loss of function compared to small sized defects with single segment VFFF.^{33,42} Next to that, resection of the symphysis area has a more profound effect on function than lateral mandibular defects. In the included studies other essentials such as the size of the soft tissue defect or details of radiotherapy treatment were poorly described, hampering adequate comparison of outcomes between studies.

Ten studies met our inclusion criteria and were included in this review, and only two of these studies were prospective.^{58–60,63} It must be noted that in most of the included studies patients had already been successfully reconstructed with VFFF at the beginning of the study and had received dental implants and/or prosthesis. Due to this selection bias, the survival rate of the fibula grafts in these studies is probably overestimated as compared to the survival rate of the VFFF in the total population of patients receiving a VFFF for reconstruction of a maxillofacial defect.

Many objective methods exist to evaluate masticatory function, such as measuring color change in chewing gum or paraffin wax, measuring the degree of breakdown of a food by sieving the comminuted food, or measuring occlusal force.⁷⁰ In most studies included in this review, mastication was described in general terms, such as "satisfaction with mastication" or related to "type of diet" used. Only one study reported the outcome of standardized masticatory performance tests, which showed a favorable performance after implant supported dental rehabilitation.^{58–60} Overall mastication performance after dental rehabilitation was generally compared to the performance immediately after the jaw defect was conceived or after VFFF and not to the performance before both of these events. These relative changes were always measured in retrospect, and therefore could have been subject to recall bias.

Swallowing was reported in only a few studies using dietary intake as outcome measure. Only one study used a

Figure 2 Funnel plot of studies ($n = 10$) reporting survival of VFFF. A blank circle in the figure represents a study, while a black circle represents an unpublished study that would have to exist to negate the results. Two times in 2 studies (Dholam et al.⁶² and Katsuragi et al.,⁶⁴ and Ferrari et al.⁶⁰ and Hundepool et al.⁶⁵) the effect size and standard error are identical; hence 8 blank circles are plotted.

Figure 3 Funnel plot of studies ($n = 9$) reporting survival of dental implants. Of one study no effects size could be calculated since the number of dental implants was not reported (Katsuragi et al., 2011⁶⁵). A blank circle in the figure represents a study, while a black circle represents an unpublished study that would have to negate the results.

validated swallowing threshold test.^{58–60} In future research, prospective and objective assessment of deglutition should be performed, such as a swallowing threshold test, with baseline measurements before ablative surgery.

Furthermore, subjective problems that patients experience regarding mastication and deglutition after reconstruction with VFFF and oral rehabilitation should be assessed using validated questionnaires specifically designed for head and

neck cancer patients, for example the EORTC QLQ-H&N35 or the University of Washington Quality of Life Questionnaire for patients with head and neck cancer (UW-QOL). Unfortunately, the EORTC QLQ-H&N35 questionnaire was only used in two studies included in this review.^{63,66}

Seven studies reported on speech outcome, and in these studies the majority of patients performed well, while in some patients speech was slightly impaired but generally not unintelligible. In most of these studies, speech was rated for intelligibility using non-standardized rating systems (3-point or 4-point Likert scales), or for understandability of patients to hospital personnel or patients' relatives. It would have been better to use a standardized rating system for speech, which is observer-independent, and preferably the baseline speech outcome should be measured before surgery.

In general, the aesthetic outcome was rated by the surgeon and the patient and was reported to be satisfactory. Observer bias was likely because observers who were involved in the treatment of these patients rated the aesthetic outcome. Future research would benefit if independent observers would rate esthetic outcome at pre-ablative and post reconstructive intervals using standardized patient (stereo) photographs or video. A validated scoring system for aesthetic outcome after head and neck reconstructive surgery is lacking. However, a more comprehensive patient-reporting outcome instrument for patients with head and neck cancer including assessment of facial appearance is under development, the FACE-Q Oncology.⁷¹

This review shows the current state of knowledge in this field and its gaps in knowledge and it shows the lack of good quality research in this field. In an era where there is increasing emphasis on functional outcome and quality of life, in the studies included in this review the most reported outcomes still are survival of the VFFF and success rate of dental implants. Additionally, the studies in this systematic review used a large variety in instruments assessing functional outcome and QoL and mostly, these instruments have soft end points. This heterogeneity in studies is based on the large number of objective and subjective measures available and on the lack of consensus about which standardized, objective instruments have to be used to measure the different functional outcome measures and QoL. Therefore, for future studies, consensus on appropriate measurement of functional outcome and QoL should be reached. This would make results and conclusions of these studies more valid, and comparisons across institutions can be readily achieved.

Since we found no randomized studies, the validated MINORS tool was used to assess methodological quality and potential bias in the nonrandomized studies included in our review. Use of this tool made it clear that most of the current studies on functional outcome and quality of life after reconstruction of maxillofacial defects with VFFF and oral rehabilitation are lacking methodological quality (median score of 50%). In none of the included studies 'unbiased assessment of the study endpoint' was performed, scoring no points on this item of the MINORS tool. All but two studies^{58–60,63} did not score points on 'prospective collection of data', and only one study performed prospective calculation of study size.^{58,59,61}

Our search strategy was performed in the databases of the Cochrane Library, MEDLINE by means of PubMed, and EMBASE. By limiting our search to these three databases, additional publications not indexed for these databases may have been missed. We therefore searched the references of included studies for additional studies missed in the search. Furthermore, publications were excluded if they were published in a language other than English, German, or Dutch. Due to this limitation, publications in other languages were not included, despite the fact that these publications might have met all the other inclusion criteria.

Case studies and case series with less than 10 subjects were not included in this review because these studies are susceptible to sample variation, and lack power. Kappa values for inter-reviewer agreement for the first selection round were 'substantial', and 'moderate' for the second selection round and quality assessment.⁵¹ This result illustrates the need of the consensus meetings.

As can be seen in Table 4, a total of 10 studies, 2 prospective and 8 retrospective, reporting on 10 outcome variables, could be included in this review. Not all studies reported on the same outcome variables and only implant survival and VFFF survival were reported in all studies. Additionally, the funnel plots regarding survival of VFFF and survival of dental implants show that publication bias is probably present (Figures 2 and 3). We believe that the results of this review are probably positively biased by the retrospective nature of the studies and the likelihood of publication bias.

Conclusions

At present, based on the limitations of the reviewed literature, it is not possible to draw firm conclusions on the effect of oral rehabilitation with implant-supported dental prostheses after reconstruction of segmental maxillofacial defects with VFFF. It is not clear on what criteria patients can be selected for oral rehabilitation with implant-retained prostheses and what the overall benefit of implant-retained prostheses for patients can be. Future studies should be prospectively designed describing in more detail the inclusion and exclusion criteria for post reconstructive oral rehabilitation. Furthermore, future studies should emphasize more on assessing functional outcome and QoL. Consensus should be obtained on standardization of measurements of functional outcome and QoL, using validated questionnaires and validated objective tests, before and after oral rehabilitation, with adequate follow-up.

Conflict of interest

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.bjps.2016.05.003>.

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