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Elaborazione di un algoritmo di pianificazione di ricostruzioni del cavo orale, dell'orofaringe, della mandibola.

Presentata da: **Dott.ssa Rossella Sgarzani**

Coordinatore Dottorato **Relatore**

Prof.A. Stella **Prof. C. Marchetti**

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"Elaborazione di un algoritmo di pianificazione di ricostruzioni del cavo orale, dell'orofaringe, della mandibola."

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1. Elaborazione di un algoritmo di pianificazione di ricostruzioni della mandibola.

1a Introduzione

La chirurgia ricostruttiva di ossa e tessuti molli della faccia è una specifica specialità chirurgica che ha come obiettivo il ripristino delle normali strutture anatomiche e funzionali in seguito ad una resezione oncologica, un trauma o una malformazione facciale. Quando una ricostruzione è indicata per qualsiasi di questi motivi, l'obiettivo della procedura è di ripristinare la normale anatomia nel modo più preciso possibile. Il trasferimento di tessuti autologhi prelevati da un altro distretto corporeo e rivascolarizzati con tecnica microchirurgica permette di ottenere in questo campo risultati esteticamente e funzionalmente soddisfacenti. I lembi microchirurgici sono tuttavia interventi complessi, richiedono specifiche competenze tecniche che si ottengono con una formazione lunga e difficile, implicano tempi operatori prolungati, possono comportare specifiche complicanze microchirurgiche e richiedono un follow-up intensivo nell'immediato post-operatorio. Si tratta in sostanza di interventi impegnativi sia per l'equipe medica che per il paziente e con un importante costo biologico in termini di tempo di recupero ed economico in termini di risorse impiegate.

E'naturale che affrontando questo tipo di costi ci si debba proporre il migliore risultato possibile. Negli ultimi 20 anni la pianificazione delle ricostruzioni tridimensionali con lembi microchirurgici venivano fatte basandosi sulla sola esperienza dei chirurghi. Attualmente le nuove tecniche di immaging ci permettono una programmazione puntuale ed oggettiva dei margini di resezione e delle dimensioni tridimensionali dei tessuti da ricostruire.

Le ricostruzione dei tessuti ossei mancanti veniva eseguita modellando, in base al difetto, manualmente intraoperatoriamente in modo artigianale placche di osteosintesi in titanio, ed eseguendo osteotomie sull'osso trapiantato in modo da adeguarlo alla placca così confezionata.

Tra gli strumenti oggi a nostra disposizione vi è la possibilità di avere nella fase di studio preoperatoria e durante l'intervento chirurgico dei modelli ottenuti con la metodica di proto tipizzazione rapida.

La proto tipizzazione rapida è una tecnologia che consente la produzione di oggetti di geometria complessa in tempi molto ridotti a partire dalla definizione matematica dell'oggetto stesso realizzata su un modello CAD (Computer Aided Design) bidimensionale progettato al computer. Si basa sulla considerazione che ogni oggetto è costituito da tante sezioni di spessore infinitesimo: il prototipo viene realizzato sezione dopo sezione, trasformando il problema da tridimensionale a bidimensionale. Gli oggetti sono ottenuti con progressiva aggiunta di materia mediante apposite stampanti e per questo motivo la tecnologia di proto tipizzazione rapida è anche definita tecnica di produzione per strati o per piani (layer manufacturing).

In ambito medico il prototipo derivante dalla stampa 3D normalmente impiegato è un modello riproducente fedelmente e nei minimi particolari l'anatomia del paziente e che consente al medico di ottenere velocemente le migliori informazioni sul caso clinico in esame, pianificandone al meglio l'intervento chirugico. In chirurgia Maxillo- Facciale questi modelli possono essere utilizzati per il modellamento della placca ricostruttiva che rimane comunque seppur più preciso un modellamento a mano, operatore dipendente.

Con il nostro studio noi vorremmo creare algoritmo di pianificazione di ricostruzioni della mandibola attraverso progettazione virtuale direttamente al Computer (evitando la necessita di ricorrere al passaggio intermedio dei modelli anatomici) di:

- placche di osteosintesi di precisione premodellate su misura per il paziente,
- guide di taglio per la resezione mandibolare,
- guide di taglio per il modellamento del perone.

Le placche ricostruttive sono state utilizzate assieme a guide di taglio per il modellamento del perone in 7 dei 10 pazienti che hanno preso parte al Progetto di Ricerca PL01 "Ricostruzioni ossee maxillo-facciali con lembi liberi microchirurgici modellati su placche di osteosintesi di precisione stampate con tecnologia DMLS - direct metal laser sintering-" permettendo di ottenere una riproducibilità del progetto virtuale superiore all' 80%.

Obiettivi della ricostruzione mandibolare

Gli obiettivi della ricostruzione mandibolare sono due:

1- *Ripristino funzionale* per la fonazione, deglutizione e masticazione,
2- *Ripristino estetico* della simmetria del volto, della proiezione anteriore del mento e del volume dei tessuti molli intraorali e/o cutanei della regione sottomandibolare e geniena.

Per raggiungere questi obiettivi è necessario ricostruire al meglio non solo l'architettura e la forma dell'osso mandibolare, ma anche contemporaneamente ripristinare il volume dei tessuti molli asportati siano essi cutanei e/o mucosi. Particolare importanza riveste la ricostruzione dell'arco anteriore perché previene il collasso postero-inferiore del mento. In tutti i casi una mancata ricostruzione dell'osso crea notevoli problemi sia di natura estetica che funzionale; anche una ricostruzione con tessuti molli non adeguata al gap siano essi in eccesso che in difetto crea altrettanti problemi (se è poco si può verificare l'esposizione dell'osso e quindi la sua infezione o riassorbimento o mancata saldatura dei segmenti, l'esposizione dei vasi e fistole oro cutanee; se è troppo vi è una riduzione della mobilità della lingua, difficoltà nella fonazione e deglutizione, nonché una aumentata difficoltà a posizionare in futuro le protesi dentarie; infine una buona guarigione dei tessuti molli consente di avviare entro i tempi adeguati (6-8 sett)) la radioterapia postoperatoria.

Importante concetto per ottenere una corretta ricostruzione è anche il momento della ricostruzione: la ricostruzione andrebbe eseguita nello stesso intervento demolitivo e non differita, perché con il tempo i tessuti molli senza un sostegno vanno incontro a retrazione ed atrofia difficilmente correggibili con interventi successivi.

Tecniche di ricostruzione mandibolare

Storicamente la ricostruzione della mandibola è sempre stata una sfida di difficile risoluzione per il chirurgo.

Prima dell'avvento della microchirurgia sono state proposte svariate tecniche che hanno portato successi limitati e parziali; esse comunque venivano riservate a pazienti in buone condizioni generali e con prognosi non troppo severe. Nelle altre situazioni viste le lunghe procedure chirurgiche ed ospedalizzazioni si preferiva non eseguire la ricostruzione con tessuti bensì affidarsi a placche protesiche. In entrambi i casi comunque la qualità di vita residua era molto scadente.

Tra le tecniche proposte ricordiamo:

1. i trapianti di osso non vascolarizzato (Lexer nel 1911) fissati con placche (fig.3) per aumentare la stabilità e le possibilità di saldatura ed integrazione dell'innesto.
2. I lembi peduncolati osteomuscolari(sternocleidomastoideo+clavicola, il m. temporale+osso parietale, m. trapezio+spina della scapola (anche 10-14cm) e il m.pettorale+5° o 6° costa)
3. L'utilizzo di placche protesiche, che sono risultate spesso inefficaci per problemi di estrusione e riassorbimento.

Attualmente le ricostruzioni microchirurgiche vengono considerate la prima scelta:

1. lembo libero di fibula,
2. cresta iliaca,
3. lembo radiale,
4. lembo di scapola.

Lembo libero di fibula

Il lembo di fibula è stato usato per la prima volta da Taylor nel 1975 per la ricostruzione post-traumatica della tibia controlaterale. Da allora il suo uso è cresciuto e diventato popolare per la ricostruzione di ulna, omero, femore e radio (anche come double barrel), ma solo nel 1989 Hidalgo ha utilizzato tale lembo per la ricostruzione della mandibola dimostrando che l'osso poteva essere più volte segmentato con osteotomie.

Il lembo di fibula può essere lungo fino a 25 cm. La fibula è contenuta nel compartimento posteriore della gamba ed è contornata dal m. peroneo lateralmente, dal m. estensore lungo delle dita anteriormente, dal m. tibiale posteriore medialmente e dal m. flessore lungo dell'alluce posteriormente.

La fibula ha una robusta vascolarizzazione segmentale che è data dall'a. peronea uno dei tre rami terminali dell'a.poplitea assieme all'a. tibiale anteriore e all'a. tibiale posteriore. Ci sono situazioni rare in cui l'a. peronea è il vaso dominante per la gamba; in questi casi è possibile che l'arto non sia sufficientemente nutrito dai vasi tibiali anteriori e posteriori; in questi casi andrebbe eseguita un'arteriografia preoperatoria ed in caso si presentasse questa alterazione il lembo non andrebbe utilizzato (clinicamente si può sospettare questa anomalia quando è presente una riduzione del polso dell'a. pedidea o sono presenti segni di atrofia cutanea).

L'a. peronea con le sue due vene comitanti si stacca assieme all'a. tibiale posteriore dall'a. poplitea circa 7cm sotto il ginocchio e decorre parallela lungo tutto l'asse mediale della fibula e lascia numerosi vasi periostali segmentali che sono alla base del nutrimento dell'osso.

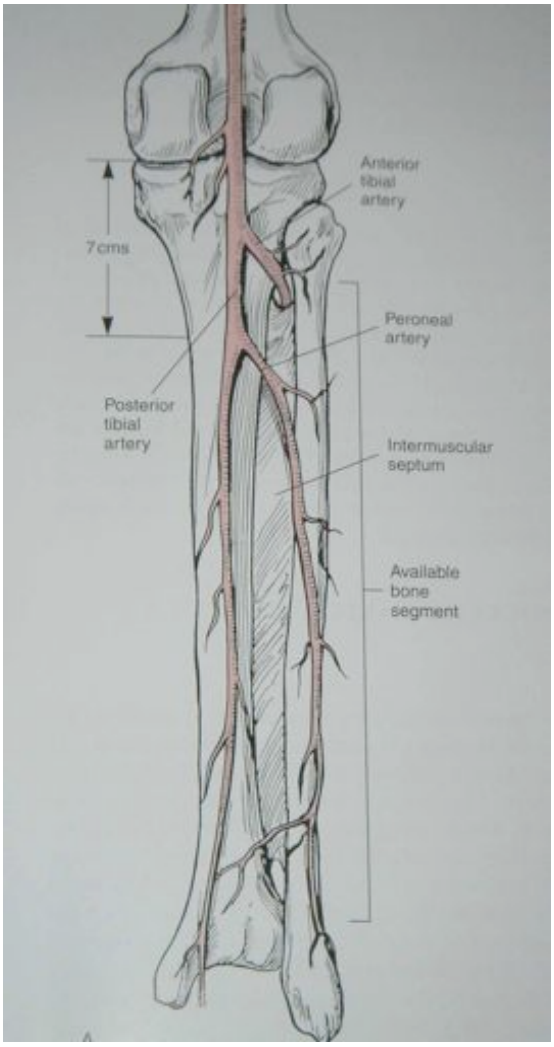


fig.1

In realtà è presente anche un ramo nutritizio centromidollare che penetra l'osso nel forame nutritizio localizzato nella metà craniale del terzo medio; una volta penetrato nel canale midollare si divide in un ramo ascendente ed in uno discendente. (Pertanto una volta eseguite le osteotomie il nutrimento del segmento osseo che contiene il forame nutritizio è assicurato da entrambi i sistemi mentre per i segmenti distali e prossimali la vascolarizzazione è assicurata solo dal sistema dei vasi segmentali al periostio).

Grazie alla presenza di perforanti sottocutanee (presenti almeno nel 90 % dei casi) che percorrono il setto intermuscolare posteriore (compreso fra il m. peroneo ed il m. soleo) il lembo può essere sollevato con un'isola di cute.

La cute viene disegnata parallela alla gamba nella porzione distale della metà della gamba perché qui sono presenti il più alto numero di vasi perforanti. Se il lembo di cute viene disegnato troppo in alto o se realmente mancano le a. settocutanee (10% dei casi) è possibile comunque il prelievo purché sia inclusa una cuffia di m. flessore lungo dell'alluce e m. soleo che contengono i vasi muscolocutanei. Ancora l'isola di cute non deve superare i 6 cm in larghezza altrimenti è necessario chiudere l'area donatrice con un innesto.

Il lembo può inoltre essere prelevato anche con il m. flessore lungo dell'alluce senza precludere più di tanto la funzione del piede, anche parte del m. soleo può essere prelevata se necessario (entrambi i muscoli sono posizionati nella porzione sottomentale per colmare il deficit di tessuti molli o nella porzione mucosa per coprire l'osso; in quest'ultimo caso entrambi si mucosizzano spontaneamente nel giro di qualche settimana).

Superiormente al m. peroneo e prossimalmente passa il n. peroneo superficiale che non va danneggiato.

La fibula riveste un ruolo importante nella funzione di stabilità della caviglia e pertanto gli ultimi 6 cm di fibula inferiormente vanno mantenuti. Si consiglia di lasciare gli stessi centimetri di fibula anche superiormente.

L'isola di cute può essere anche reinnervata grazie alla presenza nel lembo del n. cutaneo surale laterale.

Il paziente posizionato supino ha la gamba flessa a 45° sulla coscia. Si disegnano sulla faccia laterale della gamba la testa della fibula sul ginocchio, il nervo peroneo subito sotto la testa della fibula e il malleolo laterale sulla caviglia. Si disegna quindi una fibula sulla gamba e l'isola di cute che deve trovarsi centrata sul bordo posteriore della fibula e compresa fra i 15 ed i 25 cm dalla testa della fibula stessa. L'incisione viene eseguita prima sul bordo anteriore del disegno dell'isola di cute e si prosegue superiormente ed inferiormente centrandola sul disegno dell'osso;

ci si approfondisce quindi fino al piano fasciale del m. peroneo includendo la fascia nel lembo. Già da subito bisogna stare attenti al n. peroneo superficiale che a questo livello decorre sottofasciale nel bordo anteriore del m. peroneo. La dissezione continua posteriormente sul piano sopramuscolare e sottofasciale esponendo tutto il m. peroneo e raggiungendo il setto intermuscolare posterolaterale compreso fra m. peroneo anteriormente e m. soleo posteriormente. In questo setto sono comprese le perforanti sottocutanee per la cute.

Trazionando il m. peroneo in avanti si prosegue in profondità lungo il setto posterolaterale fino a raggiungere il bordo laterale della fibula. Si incide la porzione più profonda del m.peroneo sulla fibula lungo tutta la sua lunghezza lasciandone qualche millimetro attaccato all'osso (il n. peroneo è superficiale e anteriore alm.peroneo a livello della metà della gamba e via via prossimamente si approfondisce per passare sotto il ventre del m.peroneo; a circa 5 cm dalla testa della fibula il n. si trova proprio in corrispondenza del ventre profondo del muscolo); sezionando in avanti tutto il m.

peroneo si raggiunge il setto intermuscolare anterolaterale che divide il compartimento laterale da quello anteriore ed è compreso fra i mm. peroneo posteriormente e estensore lungo delle dita anteriormente. Si incide il setto intermuscolare anterolaterale e si penetra nel compartimento anteriore dove rimanendo a qualche millimetro sopra il periostio si incidono i mm estensore lungo delle dita per primo ed a seguire estensore lungo dell'alluce; attenzione a non danneggiare i vasi tibiali anteriori ed il nervo tibiale anteriore. Sezionati i muscoli del compartimento anteriore ed evitato il peduncolo neurovascolare si raggiunge e si incide la membrana interossea, molto resistente che separa il compartimento anteriore da quello posteriore e che separa i mm. estensore lungo dell'alluce anteriormente dal m. tibiale posteriore posteriormente.

Incisa la membrana interossea si esegue una dissezione sottoperiostea dell'osso nei punti in cui si eseguiranno le osteotomie (la dissezione sottoperiostea circolare dell'osso mette al riparo da possibili danni all'arteria peronea); si praticano quindi le osteotomie della fibula distale prima e prossimale poi con sega oscillante (devono essere lasciati in sede 6 cm almeno di osso sia distale che prossimale per evitare problemi di instabilità alla gamba; conviene sempre prendere tutto l'osso disponibile poiché lasciarne di più non migliora la ripresa funzionale della gamba e a livello prossimale soprattutto non consente di raggiungere l'origine dell'a.peronea facilmente; prendere tutto l'osso inoltre permette di allungare il peduncolo vascolare quando si elimina la porzione in eccesso prossimale).

L'incisione della membrana interossea e le osteotomie della fibula distale e prossimale consentono il trazionamento dell'osso sezionato verso l'esterno; ciò facilita la ricerca, la legatura e la sezione del peduncolo peroneale distale; inoltre espone il m. tibiale posteriore che viene successivamente inciso interamente in senso distale-prossimale nella sua porzione centrale (il centro del m. tibiale posteriore è ben visibile perché corrisponde al rafe a spina di pesce; rimanendo nella porzione centrale del muscolo tibiale posteriore si evitano i vasi tibiali posteriori che sono più profondi ed il peduncolo dell'osso).

Completata l'incisione del m. tibiale posteriore si incontra il m. flessore lungo dell'alluce. A questo punto si passa all'incisione posteriore dell'isola di cute spingendosi in profondità fino al m. soleo e conservando la fascia nel lembo; si continua la dissezione sul piano sopramuscolare sottofasciale fino al bordo anteriore del m. soleo e cioè fino ad incontrare il setto intermuscolare posteriore che contiene i vasi settocutanei per la cute; a questo livello sono presenti i rami per il m.soleo che possono essere sezionati oppure inclusi nel lembo con parte del soleo stesso (alcuni sezionano il m.soleo per alcuni cm fino ad incontrare il m.flessore lungo dell'alluce; ciò aiuta ad evitare danni ai vasi perforanti settocutanei ed eventualmente a prelevare anche i vasi muscolocutanei che perforano il soleo e vanno alla cute)

A questo punto si deve decidere se prelevare con il lembo anche il m.flessore lungo dell'alluce oppure no. Se il muscolo è necessario esso può essere prelevato per tutta la sua lunghezza o quanto necessario. Il lembo ora è tenuto unito solo dal peduncolo vascolare che viene isolato fino all'origine e sezionato.

Se il lembo è solo osseo l'incisione è centrata sul disegno dell'osso; la dissezione prosegue circondando l'osso allo stesso modo come descritto in precedenza. L'unica variante è che il m.soleo viene lasciato completamente integro se non è necessario prelevarlo.

Tecnica "Double barrel": il limite più importante della fibula risiede nel fatto che è un osso non molto alto e nei pazienti che hanno una mandibola non edentula o non atrofica il successivo alloggiamento degli impianti può creare dei problemi per la notevole differenza fra l'altezza della neo-mandibola e quella dell'osso mandibolare residuo. La mancanza di una adeguata cresta alveolare può creare dei problemi nella successiva implantologia. Infatti la piccola altezza della fibula crea una grande distanza dal piano occlusale ed una dimensione verticale degli impianti notevole che sforza notevolmente gli impianti stessi e ne determina un usura notevole riducendone il tempo di permanenza. Per ovviare a questo problema si è pensato di allestire un lungo lembo di fibula e di ripiegarlo su sé stesso nella porzione laterale (opposta al peduncolo) raddoppiandone l'altezza. Per fare questo un segmento di circa 1cm di osso centrale viene ad essere perduto ed il periostio deve essere mantenuto. Fra i due segmenti di osso non può esserci consolidamento per la presenza di periostio e muscoli.

Vantaggi:

1) possibilità di prelevare osso e segmentarlo in sicurezza
2) area donatrice che si chiude per prima intenzione se solo osso viene prelevato o se la cute e esigua (< 6cm)
3) Cute sottile molto buona per il pavimento della cavità orale
4) Possibilità di prelevare senza grossi danni il m. flessore lungo delle dita (per la porzione submentale) e/o di m. soleo (per la cavità orale)
5) Possibilità a due equipes di lavorare in contemporanea e distanti gli uni dagli altri
6) osso che consente bene gli impianti osteintegrati
7) peduncolo di buon calibro e sicuro

Svantaggi:

1) peduncolo vascolare corto
2) difficoltà di allestimento
3) morbilità nell'area donatrice vista la grande quantità di strutture pascolo-nervose importanti (problemi alla deambulazione, riduzione della flesso-estensione della caviglia nel 29% dei casi, eversione-inversione della cavigliariduzione della forza nella gamba, edema del piede ipoestesia nella zona di distribuzione del n. peroneo superficiale, perdita della flessione dell'alluce, possibilità di innesto ci cute se prelevata un'isola di cute ampia)
4) osso poco alto se non usato come double barrel per gli impianti in mandibole normali e con denti

Indicazioni:

1) deficit laterali soprattutto come double barrel
2) deficit anteriori soprattutto perché la cute può essere ruotata al di sopra per ricostruire il pavimento della bocca.

1b Protocollo di ricerca PL01"Ricostruzioni ossee maxillo-facciali con lembi liberi microchirurgici modellati su placche di osteosintesi di precisione stampate con tecnologia DMLS - direct metal laser sintering-"

Il protocollo di ricerca PL01 è uno studio monocentrico, indipendente, prospettico, pilota, promosso da Sintac s.r.l e condotto presso il Reparto di Chirurgia Orale e Maxillo-Facciale del Policlinico Sant' Orsola Malpighi. Sono stati arruolati nello studio 10 pazienti che dovevano essere sottoposti a chirurgia ricostruttiva per difetti ossei dei mascellari mediante metodica mocrochirurgica microvascolare con lembo libero di perone o ALT nel biennio 2011-2012.

Lo studio ha avuto l'obiettivo di creare e testare una procedura di progettazione virtuale al Computer (CAD, computer aided design) e produzione (CAM, computer aided manufacturing) di un dispositivo medico innovativo, una placca di osteosintesi di precisione su misura per ogni paziente in caso di:

- Ricostruzione mandibolare,
- Ricostruzione del mascellare superiore.

Il dispositivo medico testato è impiantato a lungo termine nel paziente durante l'intervento chirurgico ricostruttivo.

Classicamente nelle ricostruzioni dei mascellari venivano utilizzate placche di osteosintesi preformate, modellate manualmente dal chirurgo durante l'intervento per adattarsi al difetto da ricostruire.

Più recentemente l'utilizzo di tecnologia CAD CAD ha permesso di elaborare immagini TC ed utilizzarle per stampare modelli anatomici stereolittografici tridimensionali, su cui le placche di osteosintesi potevano essere modellate manualmente pre-operatoriamente (fig. 2, 3).

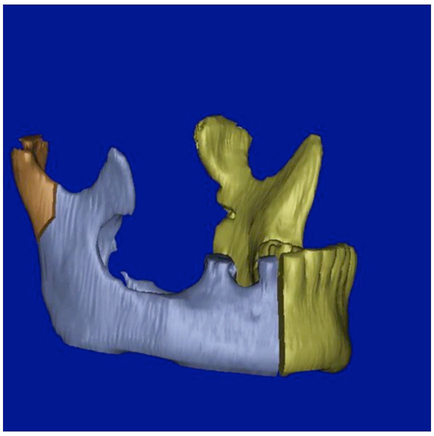
2.

3.

La metodica oggetto dello studio è un evoluzione innovativa che permette di evitare il modellamento manuale della placca di osteosintesi pre-formata.

La metodica può essere definita come una metodica CAD CAM diretta (considerando “indiretta” quella che permette la stampa di modelli stereolittografici”) ed comprende 3 fasi:

1. pianificazione virtuale dell’intervento (fig. 4, 5);



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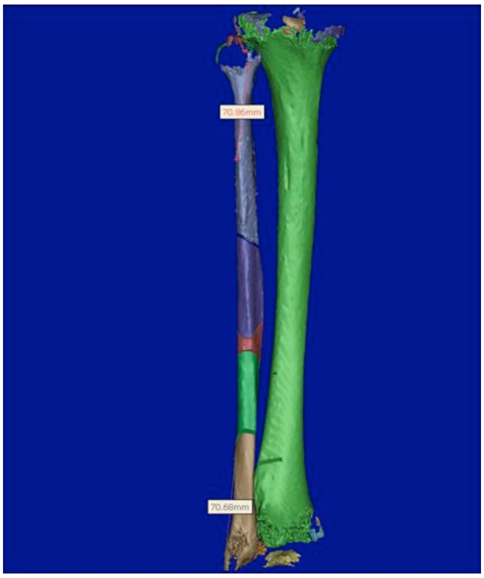
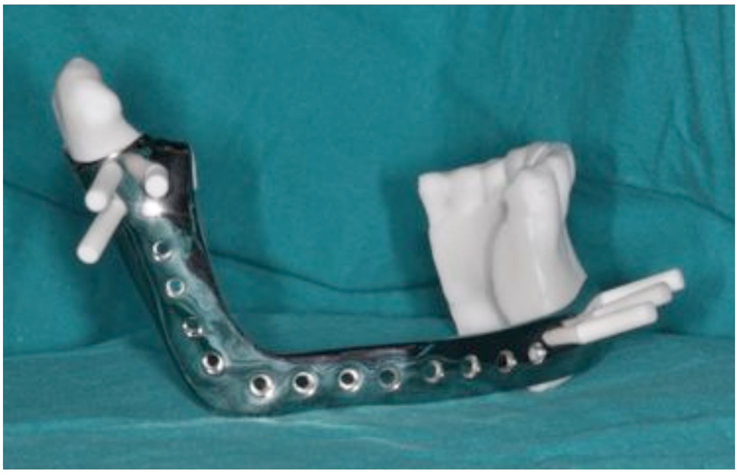


5.

2. computer aided design di:
    a. placca di osteodintesi su misura (dispositivo medico in studio),
    b. eventualmente guide di taglio per la mandibola,
    c. eventualmente guide di taglio per il perone;
3. computer aided manifacturing dei dispositivi medici:
    a. placca di osteodintesi su misura (dispositivo medico in studio) (fig. 6),
    b. eventualmente guide di taglio per la mandibola (fig. 7),
    c. eventualmente guide di taglio per il perone (fig. 8).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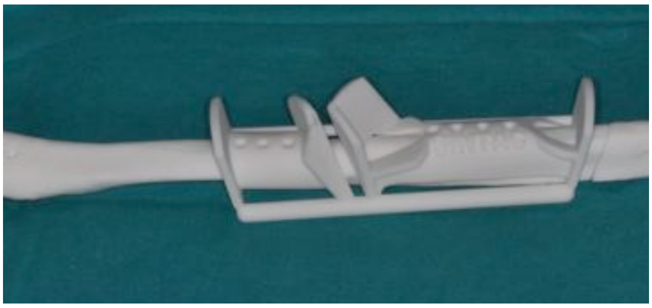
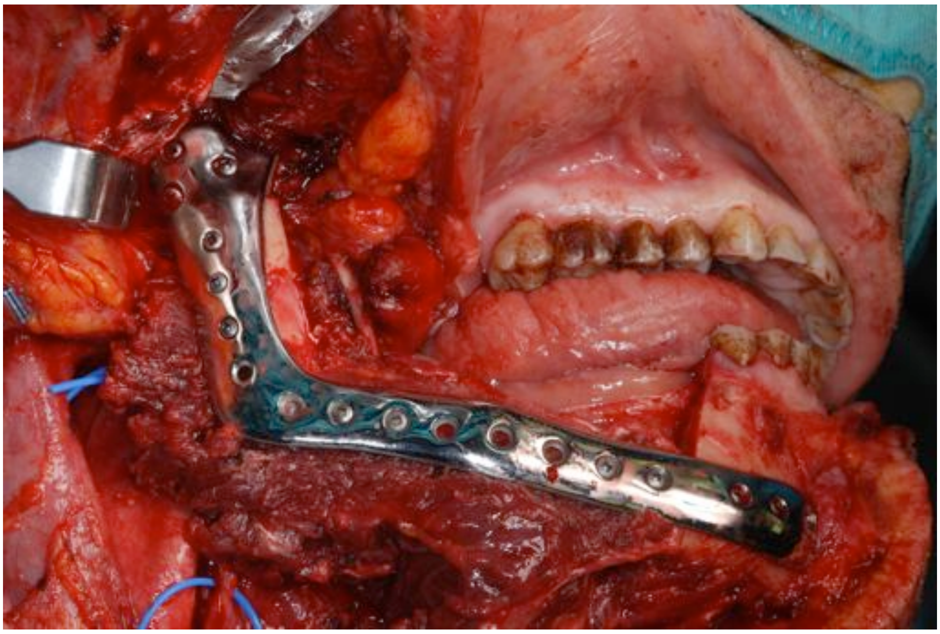

8.

Le placche sono state utilizzate durante l'intervento microchirurgico ricostruttivo (fig. 9) ottenendo una riproducibilità del progetto virtuale non inferiore al 80% nella serie in esame.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4. CARATTERISTICHE DELLO STUDIO

4.1. Promotore della Ricerca

[illegible]

4.2. Sede della sperimentazione

[illegible]

4.3. Disegno dello studio

[illegible]

[illegible]

4.5. Stima del campione

[illegible]

4.6. Durata dello Studio

[illegible]

1c Algoritmo di pianificazione di ricostruzioni mandibolari con tecnologia CAD CAM diretta

Dei 10 pazienti arruolati nello studio PL01 7 sono stati sottoposti a ricostruzione mandibolare immediata con lembo libero di perone con l'utilizzo di:

- placche di osteosintesi di precisione prodotte su misura per il paziente con tecnologia CAD CAM,
- guide di taglio per la resezione mandibolare,
- guide di taglio per il modellamento del perone.

I restanti 3 pazienti sono esclusi dalla nostra valutazione in quanto un paziente è stato ricostruito con placca custom made e lembo di tessuti molli (ALT) e per gli altri due (i primi della serie) non è stata elaborata e prodotta la guida di taglio per il perone.

Classificazione dei difetti mandibolari

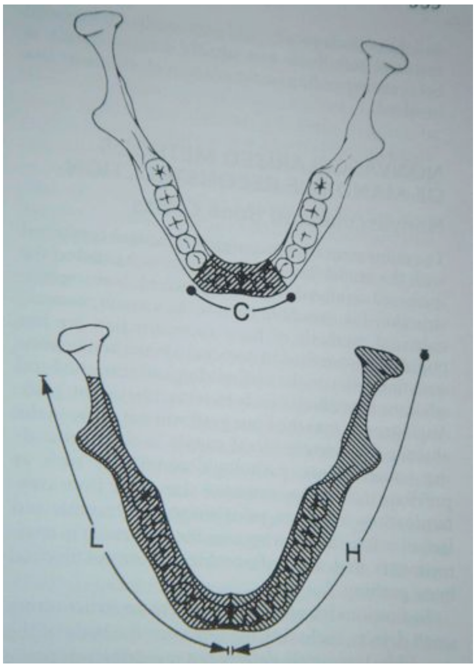
Così come per il cavo orale, molte sono le classificazioni proposte per i difetti mandibolari alcune che tengono in considerazione la componente ossea insieme e quella dei tessuti molli coinvolti, altre che considerano solo il difetto osseo (David 1988 e Jewer 1989). Le prime risultano indaginose poiché oltre che classificare il difetto osseo dividono in sottocategorie i tessuti molli coinvolti (pavimento, lingua, cute esterna, ecc) creando così una notevole difficoltà pratica per la omogenicità delle varie esperienze scientifiche. Le altre, escludendo il difetto dei tessuti molli, semplificano molto la schema e pertanto risultano molto più semplici da applicare nella pratica clinica.

Un semplice sistema pratico classificativo è quello proposto do Boyd nel 1994 (fig. 10) che semplifica il problema definendo:

-L	Laterali	segmenti laterali (corpo, angolo, ramo)
-H	Emimandibola	segmenti laterali + condilo
-C	Centrali	segmenti centrali del corpo compresi fra canino e canino

Naturalmente i difetti coinvolgono spesso segmenti diversi configurandosi situazioni LC,LCL, HC.

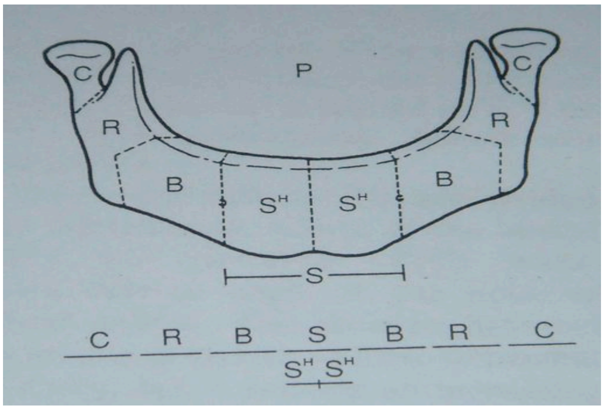
(David 1988 e Jewer 1989)



10.

La classificazione che abbiamo tuttavia trovato più utile nella pianificazione delle ricostruzioni è quella proposta da Urken nel 1991 per i tessuti ossei. Egli ha esposto tre classificazioni separate fra loro: una per il deficit della componente ossea, una per quelli dei tessuti molli ed una per quelli neurologici. Per quel che riguarda l'osso l'Autore divide in segmenti la mandibola poiché ritiene che ogni distretto abbia singolarmente una sua importanza nel ripristino della funzionalità ed dell'estetica (fig 11) :

- C condilo
- R ramo (con l'angolo mandibolare)
- B corpo
- S sinfisi
  - S^H emi-sinfisi (fino alla linea mediana)
  - S sinfisi completa (da canino a canino)



11.

Sui dati raccolti sui 7 casi eseguiti è stata elaborata una prososta di classificazione dei difetti mandibolari guidata dalla pianificazione ricostruttiva (numero di vagoni di perone necessari per ricostruire un difetto laterale o centrale).

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
lat	1dx								
	1sin								
lat	1							2	2
	2dx								
	2sin								
lat	2							3	1
	3dx								
	3sin								
lat	3							4	1
cent	1								
cent	1							1	0
	2dx								
	2sin								
cent	2							2 o 3	2
	3		1/2			1/2			
cent	3							3	0
	4								
cent	4							4	1

Nella classificazione dei difetti sono stati esclusi i difetti condilari, in quanto nella serie di pazienti arruolati nel protocollo PL01 nessuno richiedeva una resezione del condilo.

Il condilo vista la sua funzione importante viene di solito mantenuto e non asportato con il corpo mandibolare (raramente infatti il tumore interessa il condilo); si distacca dalla fossetta glenoidea temporaneamente e si fissa al lembo ricostruttivo: l'innesto di condilo in genere garantisce un risultato funzionale soddisfacente nel tempo. Se il condilo deve essere asportato ci sono diverse tecniche: a) il condilo non viene ricostruito ed il ramo viene lasciato più corto lasciando un gap, b) il ramo viene portato sino alla fossetta glenoidea ed arrotondato come un neo-condilo, c) il condilo viene sostituito con una protesi di condilo.

Non escludiamo tuttavia che la placca ricostruttiva su misura sperimentata nel protocollo PL01 possa essere dotata di u condilo protesico, se si dovesse rendere necessaria l'asportazione del condilo, come vediamo in questo modello sperimentale non ancora utilizzato nella pratica clinica (fig. 12).

12.

Nella serie studiata i difetti LATERALI hanno richiesto una ricostruzione con:

- 2 vagoni per difetti di ramo e corpo (classe 1, destra o sinistra)
- 3 vagoni per ramo, corpo e sinfisi fino alla linea mediana (classe 2, destra o sinistra)
- 4 vagoni per ramo, corpo sinfisi con superamento della linea mediana (classe 3, destra o sinistra)

I difetti CENTRALI richiedono una ricosruzione con:

- 1 vagone se interessano solo la sinfisi (classe 1)
- 2/3 vagoni se comprendevano l'intera sinfisi e si estendevano nel corpo a dx o sin (classe 2, destra o sinistra)
- 3 vagoni se si estendevano su entrambi i corpi senza interessarli completamente (classe 3)
- 4 vagoni se si estendevano su entrambi i corpi fino a entrambi gli angoli (classe 4).

Dettagli tecnici di pianificazione

La pianificazione virtuale della ricostruzione mandibolare inizia da alcuni elementi basilari:

- numero e lunghezza dei vagoni necessari (al massimo 4 vagoni, vagoni almeno di 2,5 cm),
- necessità di prelevare del muscolo,
- -necessità di prelevare un'isola cutanea.

1. Pianificazione della placca ricostruttiva

La placca di osteosintesi custom made puo'essere prodotta con qualsiasi curvatura fino a riprodurre fedelmente il profilo del segmento di mandibola mancante, tuttavia il limite è che la placca deve essere a contatto con il perone utilizzato per la ricostruzione ed il perone puo'essere segmentato in vagoni rettilinei la cui lunghezza non sia inferiore ai 2,5-3 cm per essere certi della vascolarizzazione.

La pianificazione al computer deve tener conto di questi due fattori, ottenendo così la miglior riproduzione del profilo mandibolare possibile in sicurezza.

La placca ricostruttiva quindi:

- potrebbe mimare precisamente il profilo mandibolare mancante, ma con lo svantaggio di non avere sufficiente contatto coi segmenti ossei ricostruttivi,
- deve essere attentamente progettata per essere il più simile possinìbile al profilo mandibolare ma permettendo il massimo contatto.

2. Pianificazione del prelievo di fibula:

L'entità del difetto ed il numero di osteotomie programmate (numero di vagoni) determina la lunghezza di perone necessario.

La fibula riveste un ruolo importante nella funzione di stabilità della caviglia e pertanto gli ultimi 6 cm di fibula inferiormente vanno mantenuti, in genere anche superiormente si lasciano in sede 6 cm di fibula.

L'angio TC eseguita sulla gamba preoperatoriamente permette:

- di visualizzare i 3 tronchi arteriosi della gamba e verificarne la pervietà,
- di calcolare qual'è la lunghezza del peduncolo vascolare dall'emergenza della peronea all'osteotomia distale, e valutare se nelle ricostruzioni multi-vagoni tale lunghezza permetta di eseguire anastomosi in sicurezza,

- di valutare l'emergenza dall'arteria peronea di vasi perforanti su cui poter centrale una padella cutanea, pianigìficando così su quale dei vagoni ricostruttivi si staccherà,
- di eseguire una ricostruzione 3D su cui vengono progettate le osteotomie del perone
    - calcolo preciso degli angoli e delle lunghezze,
    - calcolo della superficie di contatto fra i vari segmenti.

Non tutta la fibula prelevata puo'essere utilizzata per la ricostruzione, in quanto è necessario liberare un tratto di peduncolo sufficiente a raggiungere i vasi laterocervicali per le anastomosi vascolari.

Il peduncolo benché di ottimo calibro sia come arteria che come vene, non essendo particolarmente lungo deve essere posizionato in modo da ottenere la massima vicinanza ai vasi del collo, per tanto in tutti i casi abbiamo:

- prelevato il perone controlaterale,
- programmato di utilizzare la porzione distale del perone per la ricostruzione,
- fatto uscire il peduncolo nella porzione terminale del corpo/ramo lateralmente dalla parte della anastomosi,
- per i difetti laterali eseguito le anastomosi omolateralmente al difetto.

3. Pianificazione delle osteotomie della fibula

Il modellamento del lembo può essere effettuato prima o dopo aver sezionato il peduncolo. L'unico vantaggio legato al prima è che si riducono i tempi di ischemia del lembo. Questo puo'essere un vantaggio se si usa il manipolo piezoelettrico per le osteotomie, che permette una precisione elevata ed un minor danno tissutale ma richiede più tempo.

Le ostetomie della fibula sono disposte a cuneo con la base del cuneo esterna non interrompendo il periostio fra i segmenti.

Gli angoli delle osteotomie vengono progettati al computer per:

- ottimizzare la superficie di contatto fra i segmenti,
- ottimizzare la riproduzione del profilo mandibolare originario.

Molte osteotomie inoltre richiedono un'angolazione su più di un piano per ottenere una somiglianza di forma con la mandibola asportata, il progetto virtuale viene riprodotto grazie all'utilizzo di guide di taglio che vengono utilizzate intraoperatoriamente. Il perone ha una sezione triangolare per gran parte della sua lunghezza, la faccia laerale è quella con meno inserzioni muscolari sulla quale va appoggiata la guida di taglio.

La dima di taglio per il perone:

- rende più precisa la ricostruzione (aumentà la riproducibilità del progetto),
- utilizzando il manipolo piezoelettrico per le osteeotomie ci ha permesso di utilizzare in sicurezza vagoncini di meno di 3 cm di lunghezza (2,5 cm),

Durante il modellamento è importante eliminare il periostio dal peduncolo liberato dall'osso per la possibilità di ossificazione del peduncolo stesso.

4. Pianificazione dell'isola cutanea

Nel caso sia necessaria un'isola di cute la sua vascolarizzazione e posizione (a quale vagone di perone è connessa) può essere decisa nel programma virtuale in base ai perforanti visualizzati nella TC pre-operatoria sulla gamba. Prima di iniziare l'inetervento l'utilizzo di un doppler con sonda lineare permetterà di riportare il progetto sulla cute.

5. Vantaggi e svantaggi della metodica

La metodica permette di aumentare la precisione, il contatto fra le linee osteotomiche e la riproducibilità del progetto pre-operatorio, tuttavia ha anche alcuni svantaggi quali: il costo, il tempo ncessario per la progettazione, la curva di apprendimento nella progettazione che causa alcuni errori nei primi casi ed il fatto di rendere impossibili modifiche di programma intraoperatorie.

Casi clinici, esempi divisi per classe di difetto

LAT 1

Difetto laterale di tipo 1, destro: ramo e corpo, 2 vagoni

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
lat	1dx							2	2

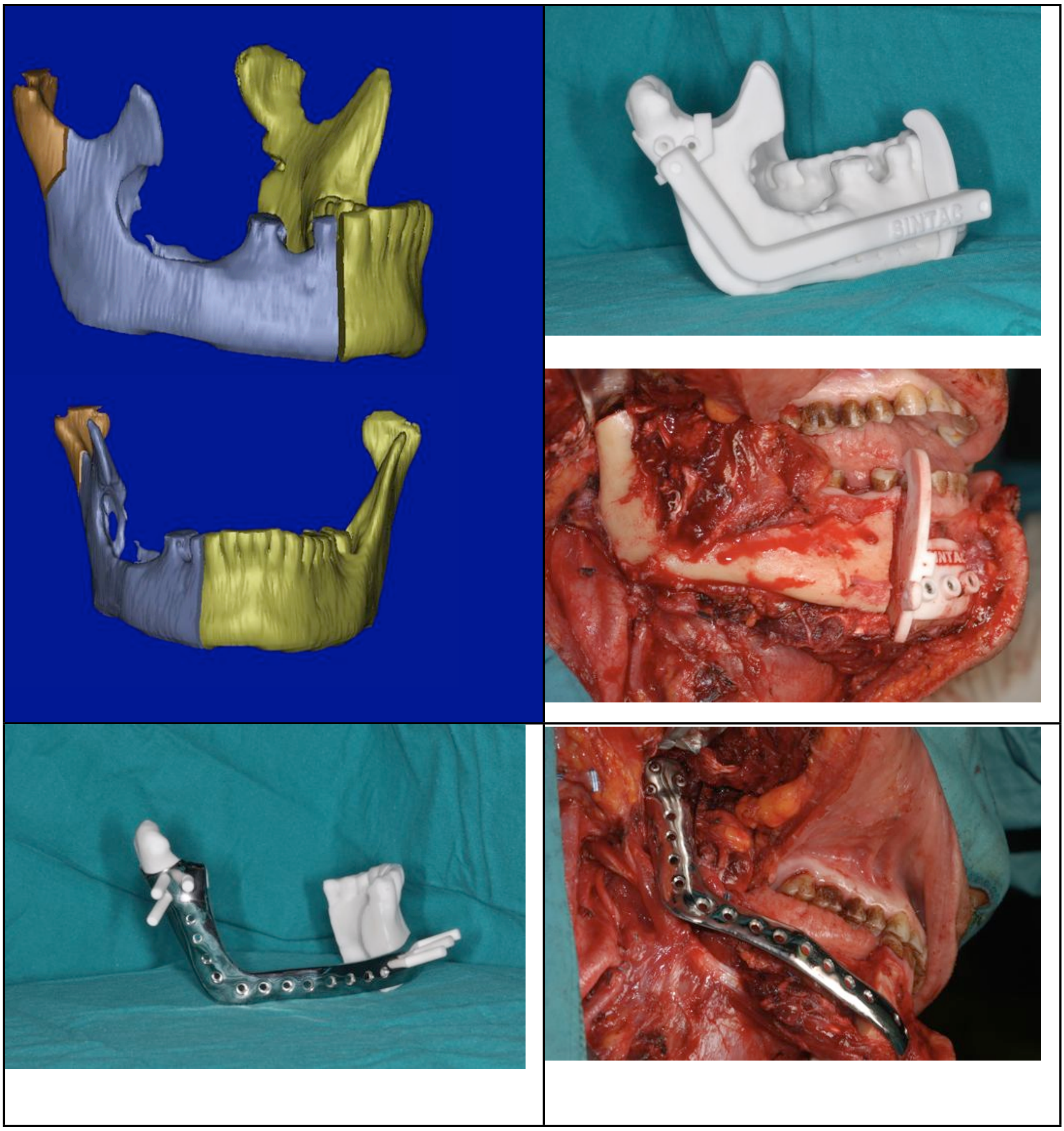
Paziente affetto da carcinoma squamocellulare, si programma resezione di corpo e ramo destro (da sottocondilare ad elemento dentale 44).

Ricostruzione mandibolare con lembo osteo-muscolare libero di perone sinistro (controlaterale), anastomosi omolaterali al difetto.

Modellamento del perone con dima di taglio in 2 vagoni.

Osteosintesi mediante placca custom made su misura.

Il paziente è stato sottoposto a radioterapia pot-operatoria senza effetti collaterali.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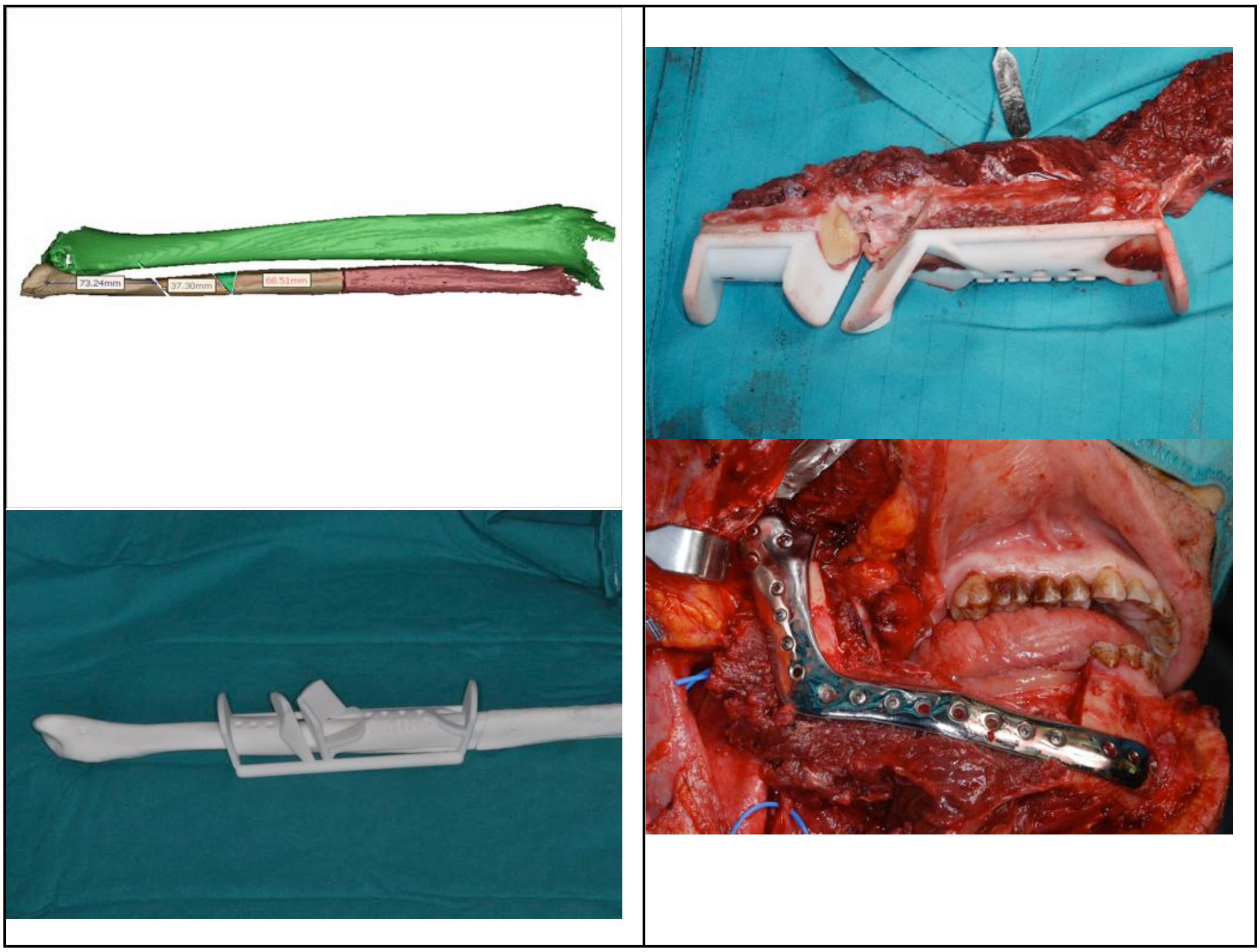

73.24mm
37.30mm
68.51mm

LAT 2

Difetto laterale di tipo 2, destro: ramo, corpo e sinfisi fino alla linea mediana, 3 vagoni

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
	2dx							3	1

Paziente affetto da recidiva di carcinoma squamocellulare, si programma resezione mucosaa e cutanea della guancia destra, corpo, ramo destro e sinfisi (da sottocondilare a linea mediana).

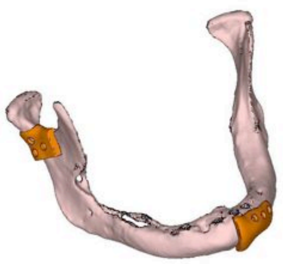
Ricostruzione mandibolare con lembo osteo-mio-cutaneo libero di perone sinistro (controlaterale), anastomosi controlaterali al difetto.

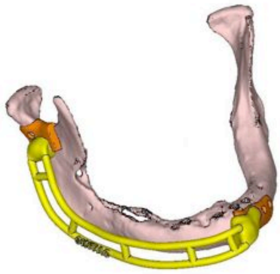
L'anastomosi è stata eseguita controlateralmente per collocare nella guancia destra l'isola cutanea.

Modellamento del perone con dima di taglio in 3 vagoni.

Osteosintesi mediante placca custom made su misura.

Il paziente è stato sottoposto a radioterapia pot-operatoria senza effetti collaterali.



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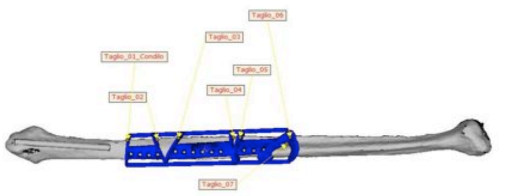
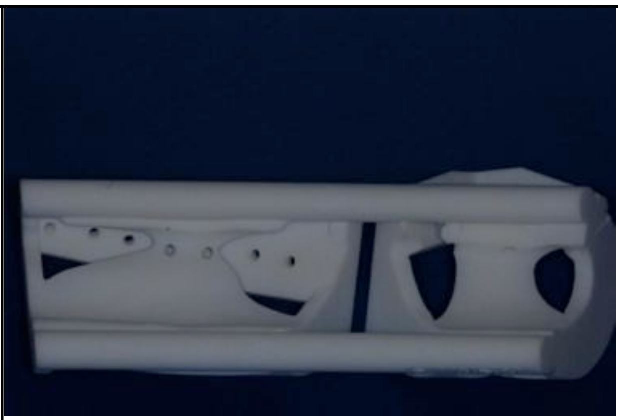

Taglio_06
Taglio_03
Taglio_01_Condilo
Taglio_05
Taglio_04
Taglio_02
Taglio_07



LAT 3

Difetto laterale di tipo 3, sinistro: ramo, corpo ed intera sinfisi, 4 vagoni

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
	3sin							4	1

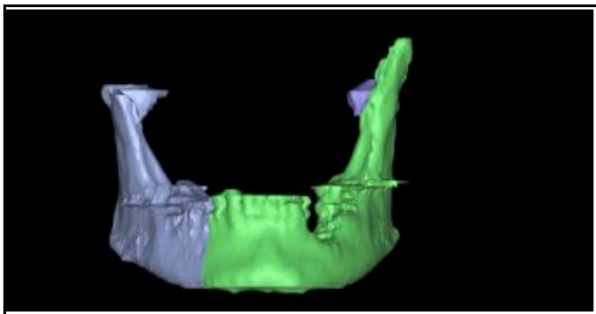
Paziente affetto da osteosarcoma condroblastico. Si programma resezione dalla regione parasinfisaria destra (dall'elemento dentale 44) al collo del condilo di sinistra (intera sinfisi, corpo e ramo sinistro).

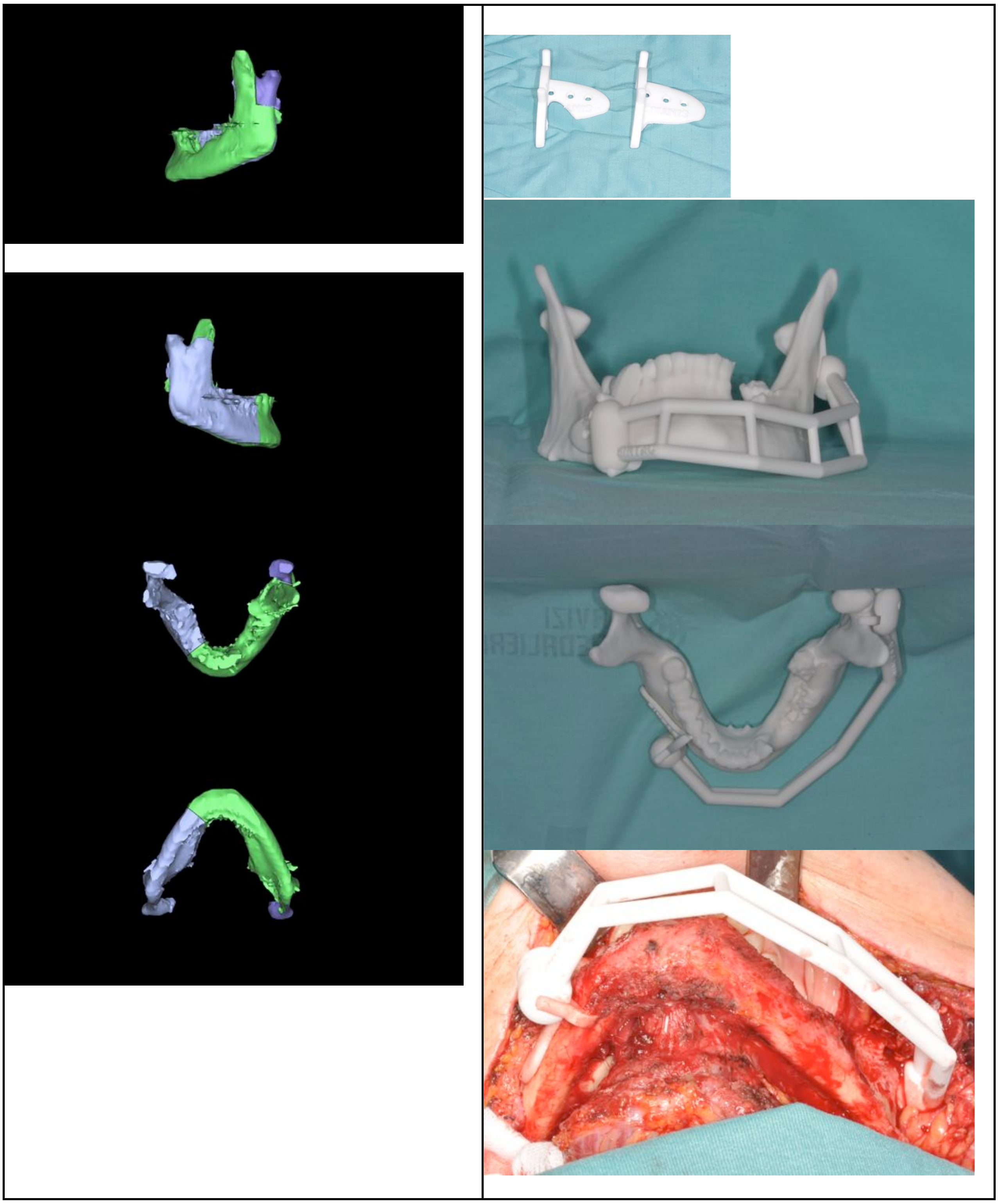
Ricostruzione mandibolare con lembo osteo-mio-cutaneo libero di perone destro (controlaterale), anastomosi controlaterali al difetto (a destra).

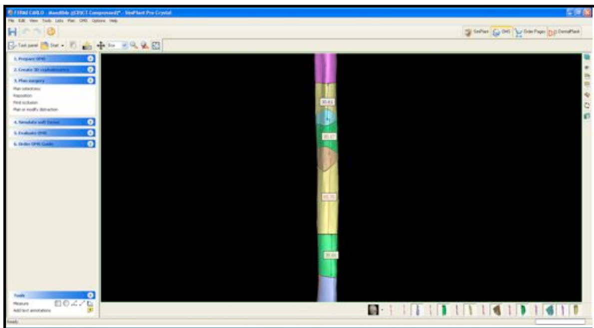
L'anastomosi è stata eseguita controlateralmente per collocare dove richiesto l'isola cutanea.

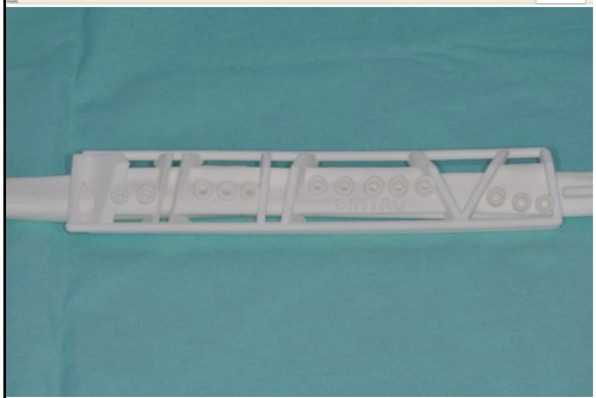
Modellamento del perone con dima di taglio in 4 vagoni.

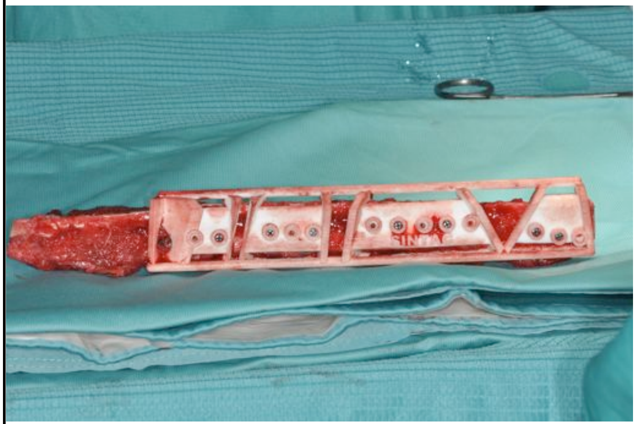
Osteosintesi mediante placca custom made su misura.

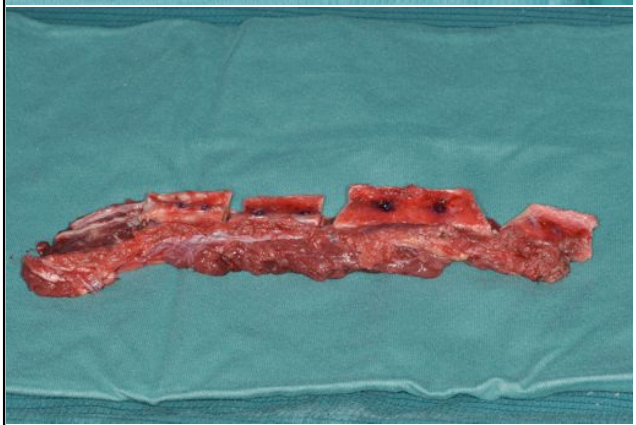










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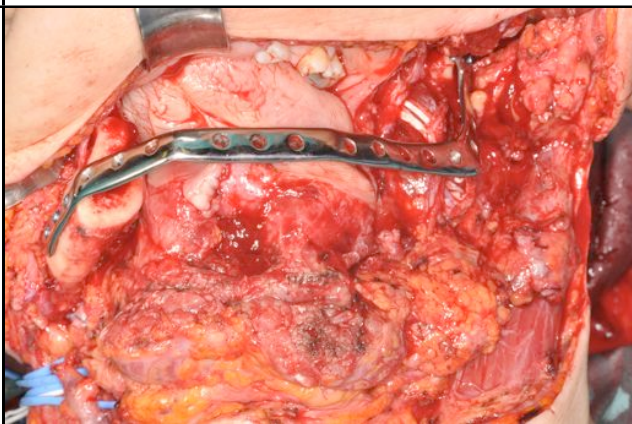
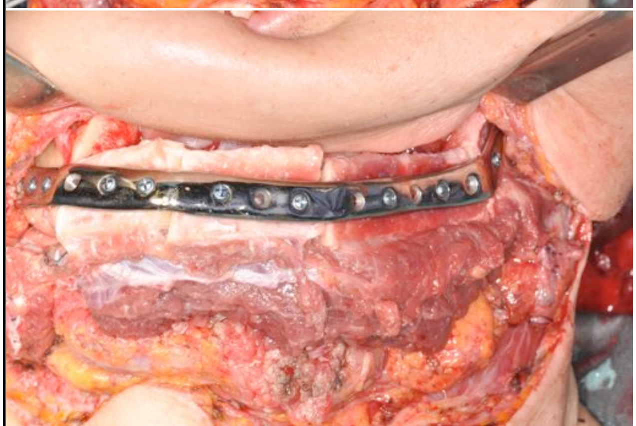




CENTRALE 1

Difetto centrale di tipo 1, intera sinfisi, 1 vagone

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
cent	1							1	0

Nessun paziente della serie aveva un difetto di questo tipo, le placche di osteosintesi con pianificazione CAD CAM vengono riservate per difetti tridimensionalmente più complessi.

CENTRALE 2

Difetto centrale di tipo 2, destro: intera sinfisi e parte del corpo di destra, 3 vagoni

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
	2dx							3	2

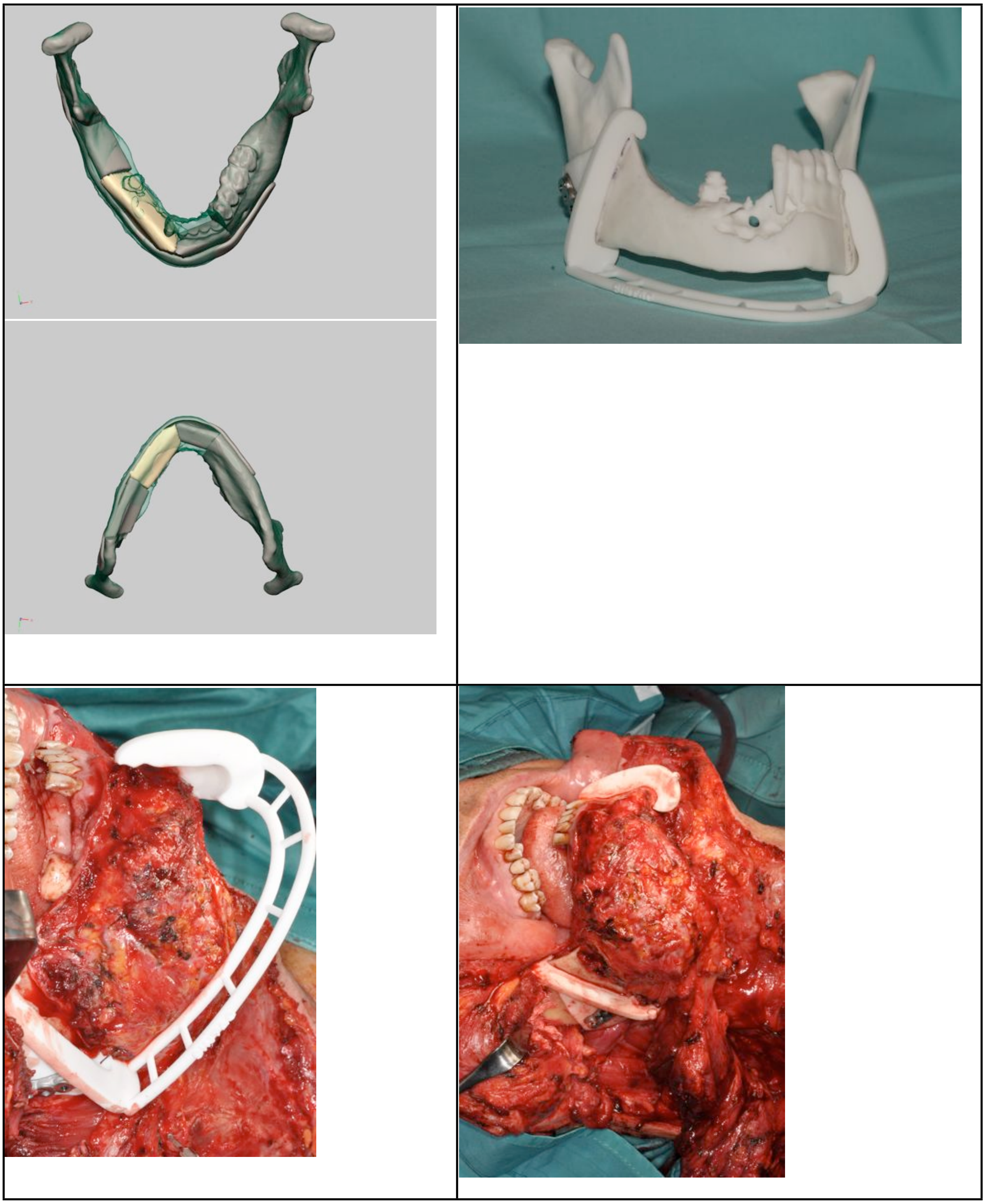
Paziente affetto da carcinoma squamocellulare. Si programma resezione dall'angolo destro all'elemento dentale 33 (corpo destro, sinfisi destra, sinfisi sinistra).

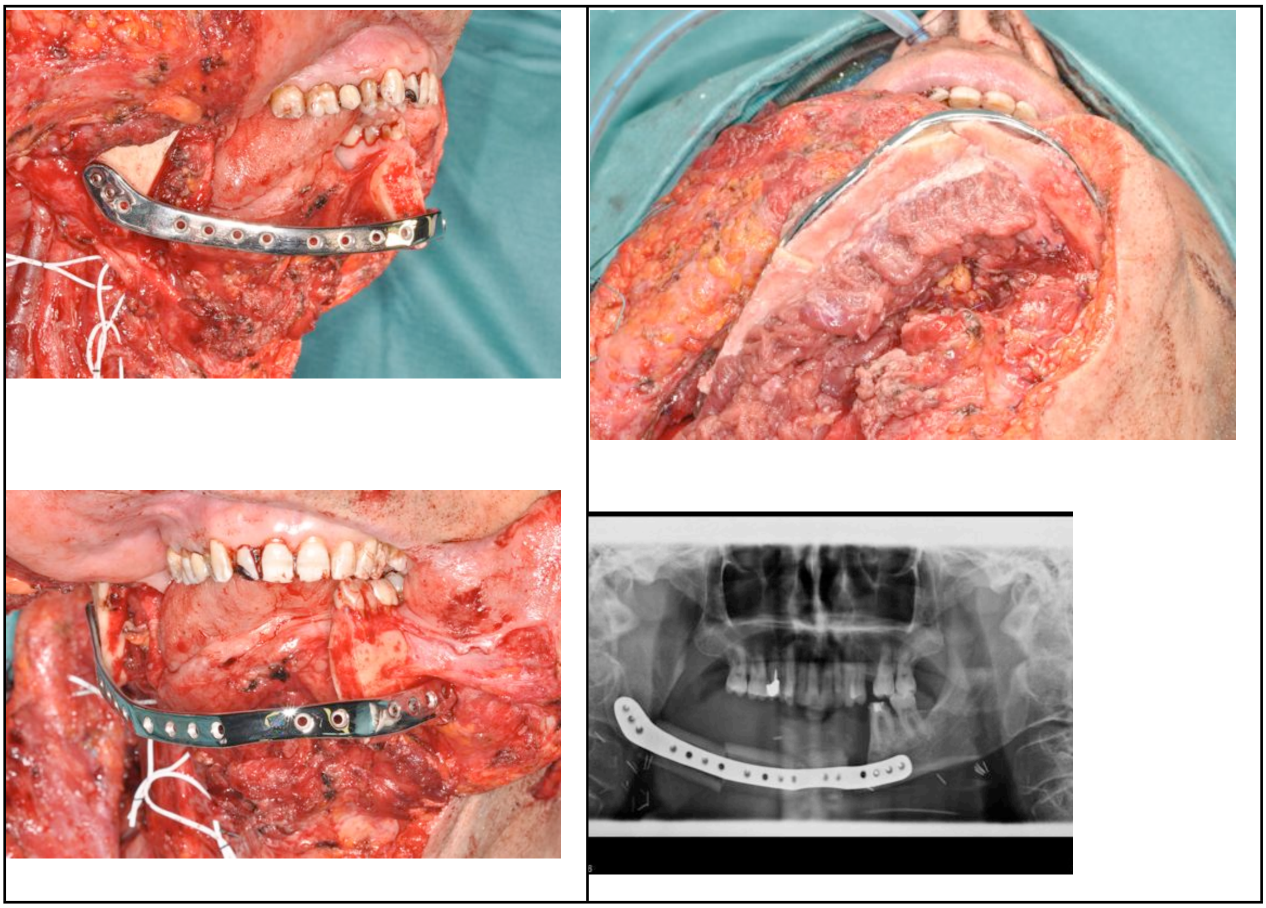
Ricostruzione mandibolare con lembo osteo-mio-cutaneo libero di perone sinistro (controlaterale), anastomosi omolaterale al difetto (a sinistra).

Modellamento del perone con dima di taglio in 3 vagoni.

Osteosintesi mediante placca custom made su misura.

42





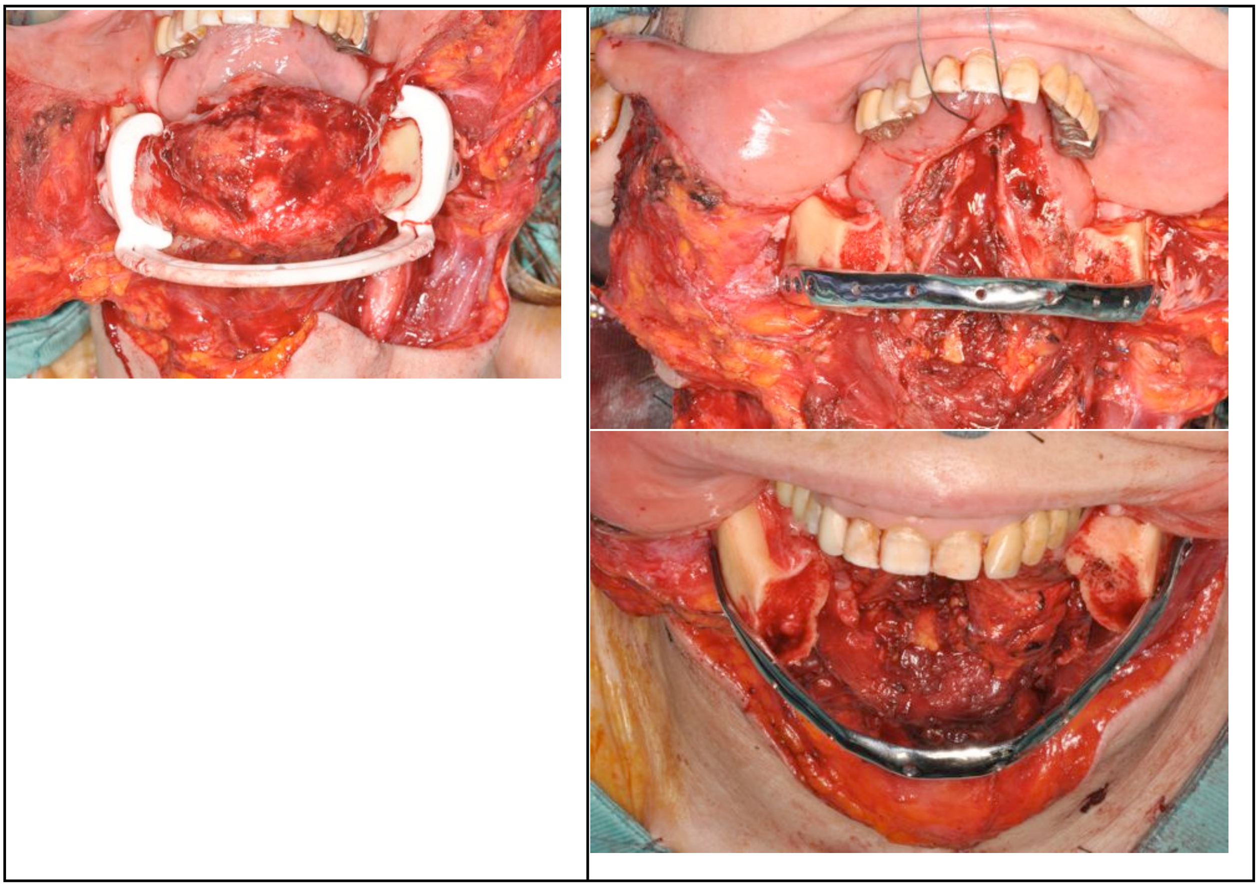
CENTRALE 3

Difetto centrale di tipo 3: intera sinfisi e parte del corpo bilateralmente, 3 vagoni

difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
	3		1/2			1/2		3	0

Nessun paziente della serie ricostruita con lembo di perone ha un difetto di questa categoria.

Una paziente arruolata nello studio PL01 affetta da questo difetto (per resezione simmetrica dall'elemento 36 all'elemento 46 di carcinoma squamocellulare) è stata ricostruita con placca custom made e lembo libero di tessuti molli. Se si fosse pianificata ricostruzione con lembo di perone sarebbero stati necessari 3 vagoni.



CENTRALE 4

Difetto centrale di tipo 4: intera sinfisi, corpo di destra, e corpo di sinistra da ramo a ramo, 4 vagoni

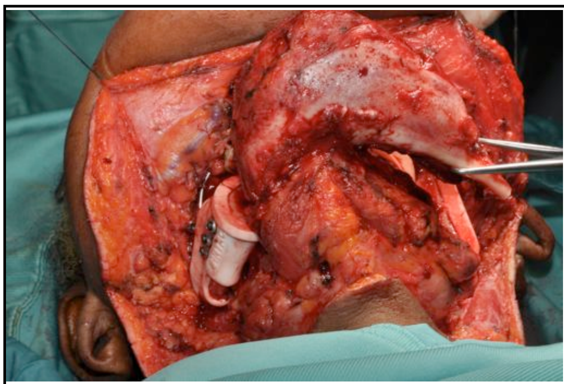
difetto	classe	RAMO DX	CORPO DX	SINFISI DX	SINFISI SIN	CORPO SIN	RAMO SIN	n° vagoni	n° pazienti
	4							4	1

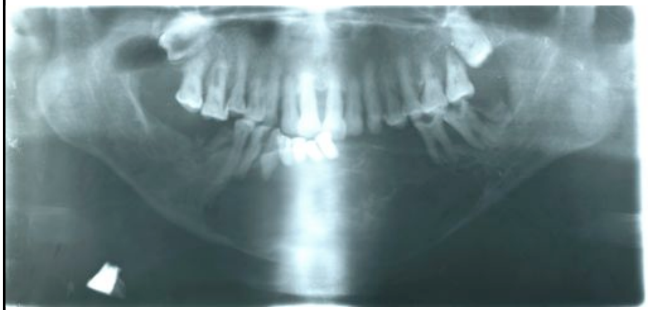
Paziente affetta da ameloblastoma. Si programma resezione da angolo ad angolo.

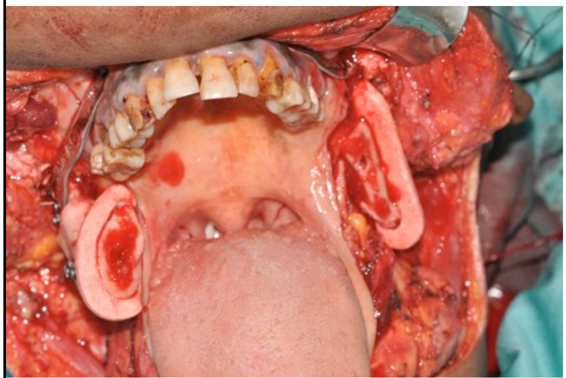
Ricostruzione mandibolare con lembo osteo-muscolare libero di perone destro, anastomosi a destra.

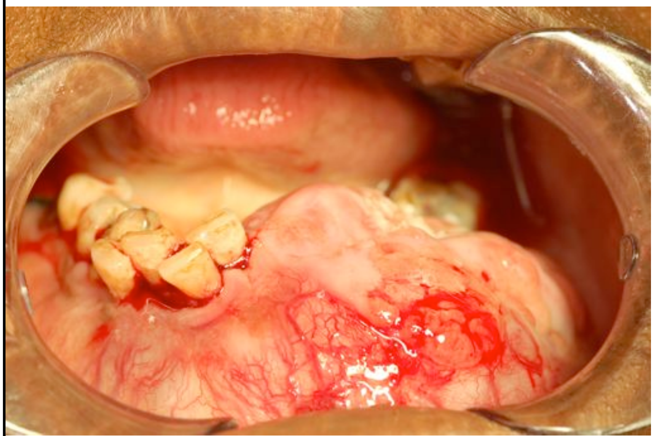
Modellamento del perone con dima di taglio in 4 vagoni.

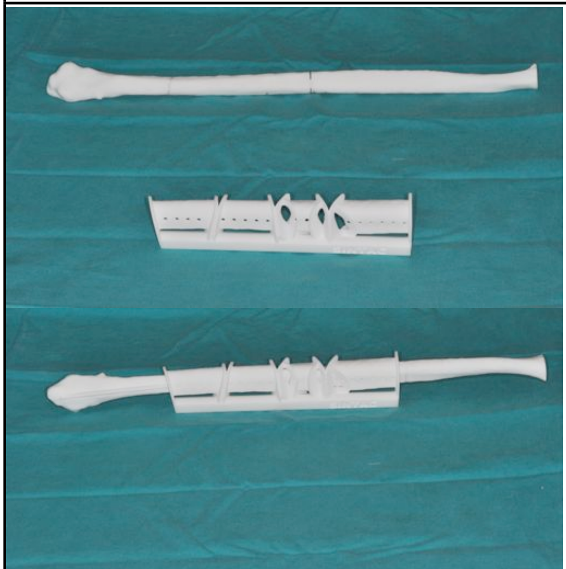
Osteosintesi mediante placca custom made su misura.

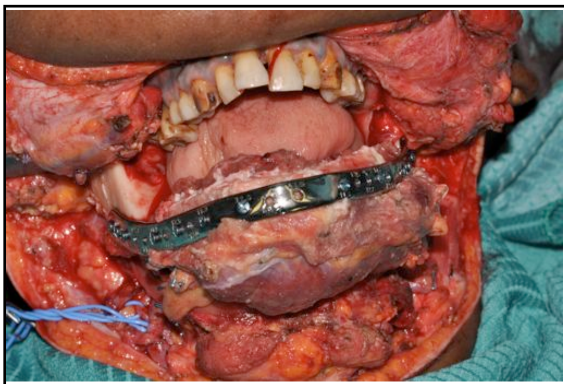


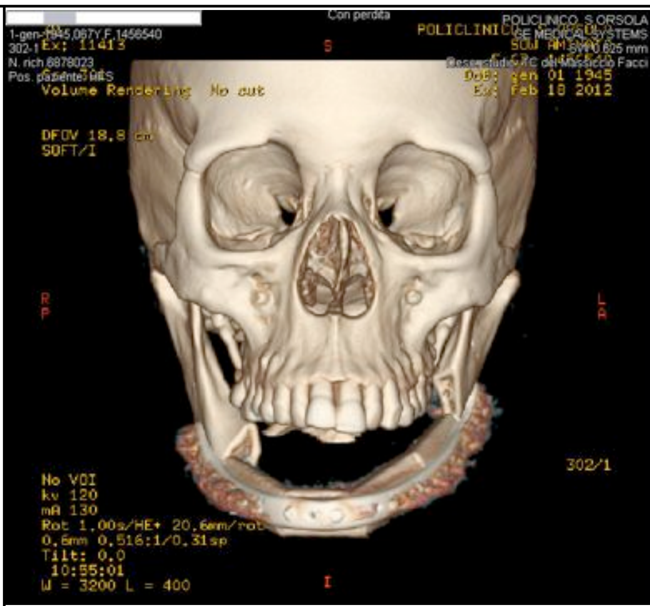












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1d Confronto dei risultati ottenuti con la metodica descritta nel protocollo di ricerca PL01 (CAD CAM diretta) e la metodica di pre-plating su modello stereolittografico (CAD CAM indiretta)

Classicamente nelle ricostruzioni dei mascellari venivano utilizzate placche di osteosintesi preformate, modellate manualmente dal chirurgo durante l'intervento per adattarsi al difetto da ricostruire.

Più recentemente l'utilizzo di tecnologia CAD CAD ha permesso di elaborare immagini TC ed utilizzarle per stampare modelli anatomici stereolittografici tridimensionali, su cui le placche di osteosintesi potevano essere modellate manualmente pre-operatoriamente.

La metodica oggetto dello studio PL01 è un evoluzione innovativa che permette di evitare il modellamento manuale della placca di osteosintesi pre-formata.

La metodica può essere definita come una metodica CAD CAM diretta (considerando "indiretta" quella che permette la stampa di modelli stereolittografici") ed comprende 3 fasi:

1. pianificazione virtuale dell'intervento;
2. computer aided design di:
   a. placca di osteodintesi su misura (dispositivo medico in studio),
   b. eventualmente guide di taglio per la mandibola,
   c. eventualmente guide di taglio per il perone;
3. computer aided manifacturing dei suddetti dispositivi medici.

I risultati ottenuti in 7 pazienti ricostruiti con tecnica CAD CAM diretta sono stati confrontati con i risultati con i risultati ottenuti in 5 pazienti ricostruiti con tecnica CAD CAM indiretta.

L'articolo accettato per la pubblicazione su Plastic and Reconstructive Surgery viene riportato in seguito.

Plastic and Reconstructive Surgery

Prosthetically guided maxillofacial surgery: Evaluation of the accuracy of a surgical guide and custom-made bone plate in oncology patients after mandibular reconstruction

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Corresponding Author:	Leonardo Ciocca, DDS, PhD University of Bologna Bologna, ITALY
Corresponding Author Secondary Information:	
Corresponding Author's Institution:	University of Bologna
Corresponding Author's Secondary Institution:	
First Author:	Simona Mazzoni, PhD Student
First Author Secondary Information:	
Order of Authors:	Simona Mazzoni, PhD Student
	Claudio Marchetti, Professor of Maxillofacial Surgery
	Rossella Sgarzani, PhD Student
	Riccardo Cipriani, Professor of Plastic Surgery
	Roberto Scotti, Full professor and dean of Prosthodontics
	Leonardo Ciocca, DDS, PhD
Order of Authors Secondary Information:	
Abstract:	Abstract Background: The aim of the present study was to evaluate the accuracy of prosthetically guided maxillofacial surgery (PGMS) in reconstructing the mandible with a free vascularized flap using custom-made bone plates and a surgical guide to cut the mandible and fibula. Methods: The surgical protocol was applied in a study group of seven consecutive mandibular-reconstructed patients who were compared with a control group treated using the standard pre-plating technique on stereolithographic models (indirect CAD-CAM method). The precision of both surgical techniques (PGMS and indirect CAD-CAM procedure) was evaluated by comparing pre-operative and post-operative CT data and assessment of specific landmarks. Results: Midline deviation: No significant difference was documented between the test and control groups. Mandibular angle shift: Only one left angle shift on the lateral plane showed a statistically significant difference between the groups. Angular deviation of the body axis: The data showed a significant difference in the arch deviation. All patients in the control group registered >6° of deviation, determining a facial contracture of the external profile at the lower margin of the mandible. Condylar position: The postoperative condylar position was better in the test group than in the control group, although no significant difference was detected. Conclusion: The new protocol for mandibular reconstruction using CAD-CAM PGMS to construct custom-made guides and plates may represent a viable method of reproducing the patient's anatomical contour, giving the surgeon better procedural control and reducing procedure time.

Abstract

Background: The aim of the present study was to evaluate the accuracy of prosthetically guided maxillofacial surgery (PGMS) in reconstructing the mandible with a free vascularized flap using custom-made bone plates and a surgical guide to cut the mandible and fibula.

Methods: The surgical protocol was applied in a study group of seven consecutive mandibular-reconstructed patients who were compared with a control group treated using the standard pre-plating technique on stereolithographic models (indirect CAD-CAM method). The precision of both surgical techniques (PGMS and indirect CAD-CAM procedure) was evaluated by comparing pre-operative and post-operative CT data and assessment of specific landmarks.

Results: *Midline deviation*: No significant difference was documented between the test and control groups. *Mandibular angle shift*: Only one left angle shift on the lateral plane showed a statistically significant difference between the groups. *Angular deviation of the body axis*: The data showed a significant difference in the arch deviation. All patients in the control group registered >8° of deviation, determining a facial contracture of the external profile at the lower margin of the mandible. *Condylar position*: The postoperative condylar position was better in the test group than in the control group, although no significant difference was detected.

Conclusion: The new protocol for mandibular reconstruction using CAD-CAM PGMS to construct custom-made guides and plates may represent a viable method of reproducing the patient's anatomical contour, giving the surgeon better procedural control and reducing procedure time.

INTRODUCTION

Reconstruction of mandibular defects represents a challenge in head and neck reconstructive surgery after oncological resection. Currently, microvascular free-flap reconstruction is the first choice. The fibula free flap, introduced by Hidalgo in 1989, is used routinely. It must be shaped by multiple osteotomies to reproduce preoperative mandibular contours. The bone can be fixed to a reconstructive titanium plate that is usually manually bent by the surgeon intraoperatively, eventually using the native mandible as a template (preplating). A previous presented four different methods of preshaping the reconstructive mandibular plate.[1] Computer-aided design/computer-aided manufacturing (CAD/CAM) and rapid prototyping (RP), introduced in the last decade, have facilitated improvement of the precision of mandibular reconstruction. Using the indirect CAD-CAM method, it is possible to print CT scan data to produce a 3D stereolithographic model of the mandible (biomodel), on which a reconstructive plate can be manually bent preoperatively Although this method is currently used widely and reduces procedure time, shaping precision is limited by at least three factors: 1) bone deformities are printed together with healthy bone, 2) the elastic properties of the manually bent titanium plate cause positioning bias, and 3) positioning of the manually bent plate is not guided during the operative procedure.

To address these issues, the use of a direct CAD-CAM procedure with the manufacture of a custom-made reconstructive mandibular plate through direct metal laser sintering (DMSL) was introduced; this protocol is named prosthetically guided maxillofacial surgery (PGMS).

Several articles have been published to evaluate the application of CAD-CAM systems to the clinical demands of maxillofacial surgery. Scolozzi *et al.* (2010) evaluated the accuracy and reliability of non-preformed mesh plates (NPMPs) versus three-dimensionally (3D) preformed titanium mesh plates (PMPs) for post-traumatic orbital volume restoration.[2] Chen *et al.* (2011)[3] evaluated the accuracy of computed tomography (CT)-based osteotomy templates on cadaver mandibles and the outcome after intraoral vertical ramus osteotomy (IVRO) for correction of mandibular prognathism. They concluded that the system is rather convenient for vertical osteotomy in IVRO, increasing the intraoperative accuracy and efficiency. Ibrahim *et al.* (2009) evaluated the ability of three methods to reproduce the mandibular anatomy and the dimensional error associated with each. They concluded that the selective laser sintering (SLS) prototype exhibited greater dimensional accuracy than did the PolyJet® or 3DP® models.[4] Weitz *et al.* (2010) evaluated the accuracy of a surgical template-aided implant placement produced by rapid prototyping using a DICOM dataset from cone-beam CT. They concluded that the accuracy of the low-dose Sirona Galileos® DICOM dataset showed a high deviation that was not suitable for accurate transfer in implant surgery.[5] Ciocca *et al.* published some articles focused on prosthetically guided maxillofacial surgery (PGMS). They described examples of the utilization of custom-made surgical guides for mandibular sectioning and the laser printing of custom-made titanium bone plates to support the free fibula flap according to aesthetic and functional requirements.[6 7 8]

The aim of the present study was to evaluate the accuracy of CAD-CAM custom-made surgical guides and bone plates in reconstructing the mandible with free vascularized flaps, comparing the PGMS and indirect CAD-CAM technologies.

MATERIALS AND METHODS

The PGMS CAD-CAM surgical protocol was applied to seven consecutive mandibular reconstructed patients between September, 2011 and March, 2012. All patients were affected by tumor lesions that required mandibular resection and reconstruction using a microvascular free flap; all were treated at the Maxillofacial Unit of S. Orsola-Malpighi engagement of the device on the mandible. Four holes (2.4-mm diameter) were created for fixation of the guides to the mandible with titanium screws, as described by Leiginner *et al.*[9]

A fibular osteotomy guide was used. This allows the free flap to fit the defect perfectly, as planned preoperatively.

The third component of the device was the customized reconstructive bone plate that supported the fibula/iliac free flap. The bone plate was designed by thickening the outer surface of the healthy side of the mandible to obtain an ideal aesthetic contour and avoid bone deformities on the side affected by the tumor.

Positioning of the reconstructive plate could be guided using this method; the holes created to fix the guide were also used to position the reconstructive plates ("transferring principle").

CAM and RP procedures

The solid-to-layer files of the guide and plate were then manufactured by direct metal laser sintering (DMLS) using an EOSINT M270 system (Electro-Optical Systems, GmbH, Munich, Germany). DMLS was used to fuse the metal powder into a solid form and then melt it locally with a focused laser beam. As with other additive manufacturing technologies, the components were built up additively in layers. The cutting guide, created using EOS Cobalt-Chrome MP1 (Electro-Optical Systems), was a multipurpose cobalt–chrome–molybdenum-based superalloy powder optimized for DMLS on EOSINT M systems. The bone plate was produced using EOS Titanium Ti64 (Electro-Optical Systems), a pre-alloyed Ti6Al/V4 alloy in fine-powder form with excellent mechanical properties and corrosion resistance, low specific weight, and good biocompatibility, which makes it particularly suitable for the production of biomedical implants.

To provide the surgeons "biomodels" of the mandible in the preoperative condition and after the planned osteotomy, the biomodels were manufactured directly using a 3D soluble support technology RP machine (Stratasys, Eden Prairie, MN, USA) (Fig. 2).

Surgery

The mandibles were accessed through a sub-transmandibular/cervicolateral incision, and the tumors were delineated. The cutting guide was introduced into the field and fixed to the mandibular bone, leaving the proposed surgical margins within safe tissues. The cutting guides were fixed with titanium screws (Fig. 3a), and a sagittal saw was then used to perform the osteotomy. The cutting guides were removed after resection of the mandible. The reconstructive bone plates were positioned and used to support the fibula/iliac free flaps to restore the original mandibular contour.

The bone plate was introduced and fixed to the mandible using the same holes with which the cutting guide had been fixed to assure correct mutual positioning of the two components (Fig. 3b).

Study design

The study included patients affected by mandibular tumors that required mandibular resection and reconstruction using a free fibula flap.

All patients were evaluated by preoperative and a postoperative CT scans 1 month after surgery, performed using the same machine and identical parameters.

The patients were divided into test and control groups (Table 1a, b).

The test group included seven consecutive patients who underwent mandibular reconstruction with the described PGMS method between September, 2011 and March, 2012. To evaluate the accuracy of the PGMS method, the virtual plan was compared with the post-operative CT.

The control group included five patients reconstructed by indirect pre-plating: the standard osteosynthesis plates were manually bent preoperatively on a stereolithographic model of the mandible.

A number of factors (see below) indicative of the precision/accuracy of the reconstruction were evaluated on the postoperative CT scan of each patient. The results achieved in the test group were compared with those of the control group.

Accuracy evaluation

The factors indicative of the precision/accuracy of the reconstruction were: 1) the midline deviation on the vertical and horizontal plane, 2) the variation on the horizontal and sagittal planes of the mandibular angle (angle shift), 3) the angular deviation of the mandibular arch as a contracture toward the median axis or as a lateral expansion, and 4) the condyle position (Table 2).

The first parameter was calculated at the median line of the inferior border of the mandible; this point was detected on the horizontal and vertical planes to determine its lateral deviation and retrusion, respectively. The second parameter (the mandibular angle shift) was measured on the horizontal and vertical (sagittal) planes for the left and right ramus. The third parameter, the angular deviation of the mandibular arch, was a measure of the contracture–reduction of the arch and was intended to measure the preservation of the native mandibular occlusal arch position. The condylar position (fourth parameter) was assessed taking into account the external pole of each condyle, as shown in the image; this was also calculated on the horizontal and vertical planes.

RESULTS

No significant difference in midline deviation between the control and test groups was identified (Table 3a, b). The mean deviation on the vertical (frontal) plane was 1.713 mm in the test group and 1.061 mm in the control group; on the horizontal plane, the mean deviation was 0.728 mm in the test group and 3.436 mm in the control group. However, on the horizontal plane, three patients showed a 0-mm deviation in the test group (60% of patients), compared with four cases in the control group (57.1%).

The mean values of the right mandibular angle shift (Table 4a, b) in the test group were as follows: in the right angle, 1.899 mm on the frontal (X) plane and 2.006 mm on the lateral (Y) plane; in the left angle, 1.539 mm on the frontal plane and 1.400 mm on the lateral plane. In the control group, the mean values were 2.451 mm on the frontal (X) plane and 1.613 mm on the lateral (Y) plane; the shift of the left mandibular angle was 1.652 mm on the frontal plane and 5.042 mm on the lateral plane. The differences between groups were not statistically significant with the exception of that between the left angle shift on the lateral (Y) plane ($p = 0.006$).

The mean angular deviations of the mandibular body (mandible arch contracture or expansion) (Table 5a, b) in the test group were 0.941° in the right body and 2.240° in the left body; in the control group, they were 8.941° in the right body and 8.198° in the left body. The difference between groups in terms of the facial contracture of the external profile at the lower margin of the mandible was significant ($p = 0.05$) for the right, but not for the left ($p = 0.085$). The mean values of the condyle position (Table 6a, b) in the test group were 0.789 in the left condyle and 1.297 in the right. In the control group, the mean values of the left and right condyles were 2.457 and 4.458, respectively. The difference between groups was significant for the right ($p = 0.035$), but not for the left ($p = 0.068$).

DISCUSSION

CAD/CAM and RP technologies have been introduced in the field of maxillofacial bone reconstruction to increase precision and reduce morbidity and procedure time.

The accuracy evaluation of the precision of both surgical techniques, PGMS and the indirect CAD-CAM procedure, was carried out by comparing preoperative and postoperative CT data using specific anatomical landmarks. These were positioned at the extreme lateral point of the condyles and at the median mental position to evaluate the eventual malposition of the condyle after surgery and the eventual deviation of the mandibular arch (frontal plane rotation). Moreover, an angular measurement of the mandibular arch was taken to assess the contracture or expansion of the mandible. Linear measurement of the mandibular angle shift (toward front or back) was also performed. These parameters were particularly important for prosthetic rehabilitation because maintenance of the occlusal arch and the position of the mandibular angle are fundamental for generation of appropriate intermaxillary postoperative relationships. Results showed that a highly accurate reproduction was obtained using the PGMS CAD-CAM procedure, which was in some instances statistically different from the conventional reconstructive technique (indirect CAD-CAM).

Midline deviation: No significant difference between the test and control groups was documented, including when the difference in the mean value on the y-plane (horizontal) was greater. This was due to the possibility of precise shaping of the reconstructive plate using the pre-plating technique on the rapidly prototyped resin biomodel. The stereolithographic models facilitated more accurate contouring of the bone plate without eventual alteration of the anatomy due to the cancer.

Mandibular angle shift: Only one left angle shift on the lateral plane showed a statistically significant difference between the groups. This may be due to the precision of the indirect and PGMS CAD-CAM techniques in terms of mandibular body length.

Angular deviation of the body axis: The data showed a significant difference in the arch deviation. All patients in the control group exhibited higher degrees of deviation than those in the test group, determining a facial contracture of the external profile at the lower margin of the mandible. This causes evident aesthetic alteration and variation of the occlusal arch that increases the difficulty associated with oral rehabilitation: the position of the reconstructed bone is either too lateral (molateral defect) or too retruded (anterior defect) with respect to the occlusal plane of the upper jaw, causing transversal arch incoordination. This problem has a marked effect on maxillofacial prosthetic rehabilitation in terms of patient satisfaction and home hygienic care and maintenance.

Condylar position: The postoperative condylar position yielded better control in the test group versus the control group. The difference was statistically significant for only the left condyle, likely because six of seven patients in the test group and four of five in the control group underwent surgical procedures on the left side. These data confirm that the deviation is more significant in condyles of the operated side when PGMS is not used. This important result influenced the functional activity of the condyle.

The surgical protocol presented in this paper offers also several clinical advantages. These were analyzed qualitatively but not quantitatively on the basis of the surgeons' experience.

The first advantage is that the virtual environment permitted ideal preoperative planning for tumor ablation: the boundaries of the resection were placed accurately in safe tissues. The cutting guide allowed the site and orientation of the planned osteotomies to be replicated accurately during surgery.

Second, intraoperative time was not consumed by approximately and repeatedly modeling the plate to the native mandible (as in conventional procedures that do not use stereolithographic models). Finally, no complications occurred postoperatively. The reconstruction plate provided an appropriate bone–plate relationship and maintained correct occlusal centric relation. Condylar distortion and poor functional outcome were avoided. The patients regained good masticatory performance 3 weeks after surgery.

Potential drawbacks of this technique include difficulties in adapting to situations in which the surgical plane changes intraoperatively (*i.e.*, positive margins), and the cost of designing and prototyping the device. To avoid positive margins during surgery, the times between CT scan examination, the beginning of the CAD-CAM procedure, and the surgery should be minimized to not more than 2 weeks.

Further investigations are necessary to compare the tolerance and mechanical properties of custom-made titanium reconstruction plates with those of the commercially available plates that are currently used in reconstructive surgery.

CONCLUSION

Seven consecutive patients underwent mandibular reconstruction by means of a novel method involving CAD/CAM PGMS to produce a custom-made surgical guide and reconstructive plate. The virtual planning of a guide for mandibular segment repositioning/osteotomies and a reconstructive plate manufactured using DMLS technology facilitated restoration of mandibular function and native mandibular contour when using microvascular free flaps. This method also provides the surgeon better procedural control and reduces procedure time, and the prosthodontist is provided with an anatomy suitable for restoration using implant-supported oral prostheses.

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2. Elaborazione di un algoritmo di pianificazione di ricostruzioni del cavo orale, dell'orofaringe.

Questa seconda parte della tesi di dottorato contiene una raccolta di alcuni studi retrospettivi svolti durante il triennio del dottorato di ricerca con l'obiettivo di migliorare pianificazione e linee guida ricostruttive.

2a "Surgical strategies based on standard templates for microsurgical reconstruction of oral cavity and oropharynx soft tissue: A 20 years' experience."

Un'analisi retrospettiva condotta sui pazienti sottoposti a ricostruzione del cavo orale e dell'orofaringe nel ventennio 1992-2012 presso il Policlinico S.Orsola Malpighi ha permesso di elaborare un algoritmo di pianificazione delle ricostruzioni del cavo orale e dell'orofaringe basato su templates. I risultati sono stati pubblicati su Microsurgery nell'articolo di seguito riportato.

SURGICAL STRATEGIES BASED ON STANDARD TEMPLATES FOR MICROSURGICAL RECONSTRUCTION OF ORAL CAVITY AND OROPHARYNX SOFT TISSUE: A 20 YEARS' EXPERIENCE

UMBERTO CALICETI, M.D.,[1] OTTAVIO PICCIN, M.D.,[1] ROSSELLA SGARZANI, M.D.,[2] LUCA NEGOSANTI, M.D.,[2*]
IGNACIO JAVIER FERNANDEZ, M.D.,[1] AUREL NEBIAJ, M.D.,[1] FEDERICO CONTEDINI, M.D.,[2]
RICCARDO CIPRIANI, M.D.,[2] and ALBERTO RINALDI CERONI, M.D.[1]

Background Microsurgical reconstruction has become the worldwide gold standard for repairing surgical defects in head and neck cancer. The aim of this article is to describe a standardized reconstructive approach to the oral cavity and oropharynx soft tissue defects. *Patients and methods* Since 1992, the authors have treated 163 patients affected by oral cavity and oropharynx cancer, performing a total of 175 flaps. A systematic postoperative functional study prompted a surgical strategy, in terms of flap choice, shape, and insetting. A two-dimensional template was used to obtain a three-dimensional reconstruction for the best functional and aesthetic outcome. To simplify preoperative planning, surgical resections were divided into a set number of classes. The templates, flap choice, and insetting are described for each region. *Results* Complications consisted of seven partial necroses of the flap which easily resolved with a local toilette and 12 complete necroses of the flap due to vascular thrombosis, these patients required a secondary reconstruction with another free flap. Functional results were systematically evaluated in the first 60 patients of our series with particular attention to the swallowing function, which was analyzed by both videofluoroscopy and functional endoscopic evaluation of swallowing. Results showed a good functional recovery with the described reconstructive techniques. *Conclusion* A standardized surgical strategy based on reproducible templates might facilitate less experienced surgeons in analyzing the problem, choosing the best technical solution and foreseeing the functional outcomes. © 2012 Wiley Periodicals, Inc. Microsurgery 00:000–*000, 2012.*

Microsurgical reconstruction has become the worldwide gold standard in head and neck oncology, because it enhances both the healing process and the patient's quality of life.

Any surgical defect can be reconstructed by choosing from a number of flaps with appropriate structural features for the resected area.[1–3] However, resection patterns have not been universally codified. This makes it difficult for less experienced surgeons to decide which reconstructive technique might achieve the best functional result.

Flap harvesting techniques have been well standardized, whereas shaping and insetting methods have not, since the same flap is used for the same defect in very different ways. Flap insetting plays an important role in the functional results, especially the swallowing function.[4] An analytical and methodical approach and a few clear reconstruction reference models might also facilitate less experienced surgeons to achieve reproducible results.

The authors' experience of 288 flaps over 20 years and a systematic functional study performed post operatively have enabled a surgical strategy, in terms of flap choice, shape, and insetting, to be selected for each class of surgical defect.

The purpose of this study is to describe this standardized approach to oral cavity and oropharyngeal soft tissue defect reconstruction.

PATIENTS AND METHODS

Between November 1992 and March 2012, 288 flaps in 270 patients affected by head and neck cancer were performed in the ear nose and throat (ENT) department of the University Hospital of Bologna, Italy. One hundred sixty-three of these patients underwent reconstruction of the soft tissues of the oral cavity or oropharynx. The mean age of the patients was 57.8 years (range 26–84 years) with a male:female ratio of 3.5:1. None of the patients had distant metastasis at the time of the presentation. Tumor size was T2 in 23 patients (14.11%), T3 in 84 patients (51.53%), and T4 in 56 patients (34.36%). Pathological findings reported squamocellular carcinoma in 160 cases and adenoid cystic carcinoma in three cases. Fifteen patients (9.20%) received preoperative chemotherapy and 43 (26.38%) received preoperative radiotherapy. Fifteen patients (9.20%) received postoperative chemotherapy and 96 (58.90%) received postoperative radiotherapy. To simplify preoperative planning, surgical resections were divided into a set number of classes; which for the oral cavity were: hemiglossectomy with or without corresponding floor of mouth resection, anterior 2/3 glossectomy, anterior 2/3 glossectomy plus corresponding floor of mouth resection, subtotal and total glossectomy

[1]ENT Department, S.Orsola-Malpighi Hospital, University of Bologna, Bologna, Italy
[2]Plastic Surgery Department, S.Orsola-Malpighi Hospital, University of Bologna, Bologna, Italy
*Correspondence to: Luca Negosanti, M.D., Plastic Surgery Department, S.Orsola-Malpighi Hospital, Via Massarenti 9, 40138, Bologna, Italy.
E-mail: luca.negosanti81@gmail.com
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Table 1. Classification Based on Type of Resection and Reconstruction

Site	Number of cases	Reconstruction		Complications: Partial necrosis	Complications: Complete necrosis
Hemiglossectomy with or without corresponding floor of mouth resection	29	ALT	13	2	2
		C	6		
		LB	2		
		LD	5		
		RA	3		
Anterior 2/3 glossectomy	5	ALT	3		
		C	1		
		LD	1		
Anterior 2/3 glossectomy plus corresponding floor of mouth resection	16	ALT	3	1	
		C	6		
		RA	4		
		LD	3		
		LB	2		
Subtotal and total glossectomy plus corresponding floor of mouth resection	16	ALT	10	2	2
		C	3		
		LD	4		
		RA	1		
Posterior glossectomy (partial or total)	18	ALT	9		
		C	7		
		RA	2		
Partial resection of the soft palate and tonsillar fossa and partial tongue base	30	ALT	3		
		C	17	2	2
		LB	2		
		LD	2		
		RA	6		1
Half soft palate resection	21	ALT	2		
		C	12		3
		LD	5		
		RA	2		
Total soft palate resection	12	ALT	6		
		C	9		1
		LD	3		
Half oropharyngectomy	16	ALT	6		
		C	10		1
		LD	2		
Total	163		175	7	12

ALT, anterolateral thigh flap; F, forearm flap; LA, lateral arm flap; LD, latissimus dorsi flap; RA, rectus abdominis flap.

plus corresponding floor of mouth resection; and for the oropharynx: posterior glossectomy (partial or total), partial resection of the soft palate and tonsillar fossa and partial tongue base, half soft palate resection, total soft palate resection, and half oropharyngectomy. The authors' patients consisted of 29 cases of hemiglossectomy with or without corresponding floor of mouth resection, 5 anterior 2/3 glossectomy, 16 anterior 2/3 glossectomy plus corresponding floor of mouth resection, 16 subtotal and total glossectomy plus corresponding floor of mouth resection, 18 posterior glossectomy, 30 partial resection of the soft palate and tonsillar fossa and partial tongue resection, 21 half soft palate resection, 12 total soft palate resection, and 16 half oropharyngectomy. we performed 55 anterolateral thigh (ALT) flaps, 71 forearm flaps, 6 lateral arm flaps, 25 latissimus dorsi flaps, and 18 rectus abdominis flaps. The type of resection and reconstruction performed is reported in Table 1.

To quantify the surgical defect accurately, the classification shown in Figure 1 was used. For each patient, three anatomical drawings were considered: an axial view of the oral cavity and the tongue, an axial view of the oral cavity and floor of mouth, and a coronal view of the tongue and floor of mouth. Each drawing was divided by a grid into segments that we call blocks. Based on the corresponding computer tomography (CT) or magnetic resonance imaging (MRI) images for each patient, each block involved by the tumor was filled in to quantify the defect.

The ENT surgeon prepared a template according to the quantified defect corresponding to the size and the shape of the area to be resected. The template was two-

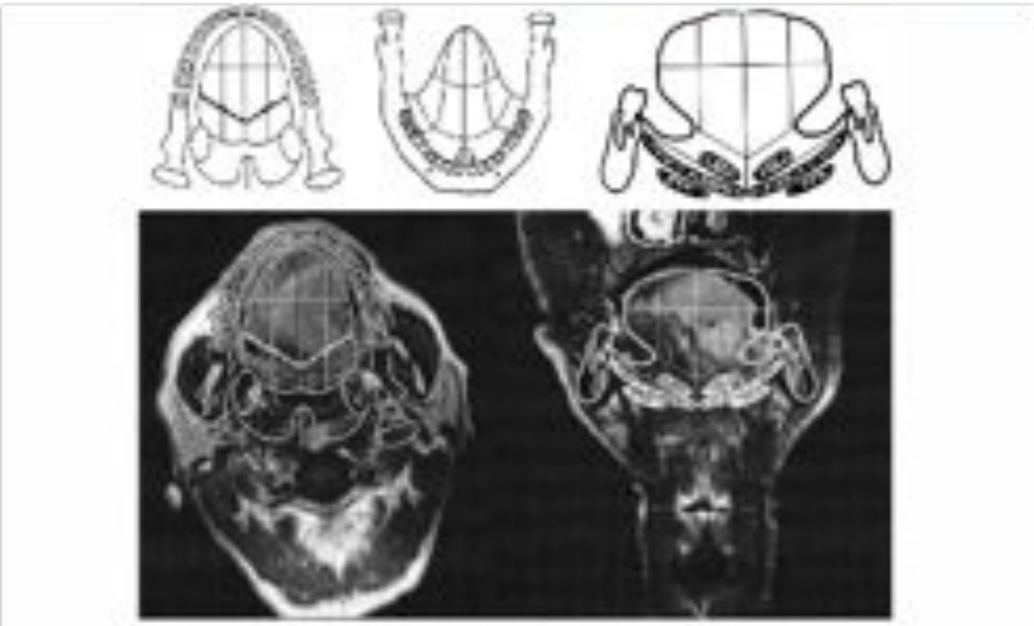

Figure 1. Classification of surgical defects: three anatomical drawings were considered: an axial view of the oral cavity and the tongue, an axial view of the oral cavity and floor of mouth, and a coronal view of the tongue and floor of mouth. Each drawing was divided into segments by a grid. Based on the corresponding CT or MR images, each segment involved by the tumor was filled in to quantify the defect.

Figure 2. Scheme of reconstruction following hemiglossectomy with corresponding floor of mouth resection. ***A****: The template was made of three wings.* ***B****: Temporary skin-to-skin stitches were placed between the margin of the new tongue and the new floor of mouth to recreate a sublingual fold.* ***C****: Flap modeled before insetting. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

dimensional (2D). However, its shape took into consideration the need to be folded to obtain a three-dimensional (3D) structure, and the overall area of the template corresponded to the actual extent of the mucosal resection. This method enabled a reconstruction that was as similar as possible to the original anatomical condition. The flap choice was based on the pliability and volume required and a second option was always planned in case the first one failed.

This template was then transferred to photographic tape that could be easily sterilized and used during the operation. The following template models, in the authors' experience, have shown to produce a satisfactory anatomical and functional reconstructive result. For clarity, each class of defect is discussed separately.

SURGICAL TECHNIQUES

Hemiglossectomy With or Without Corresponding Floor of Mouth Resection

The template (Fig. 2) used for hemiglossectomy with or without corresponding floor of mouth resection was based on that described by Urken in 1994.[7] The posterior

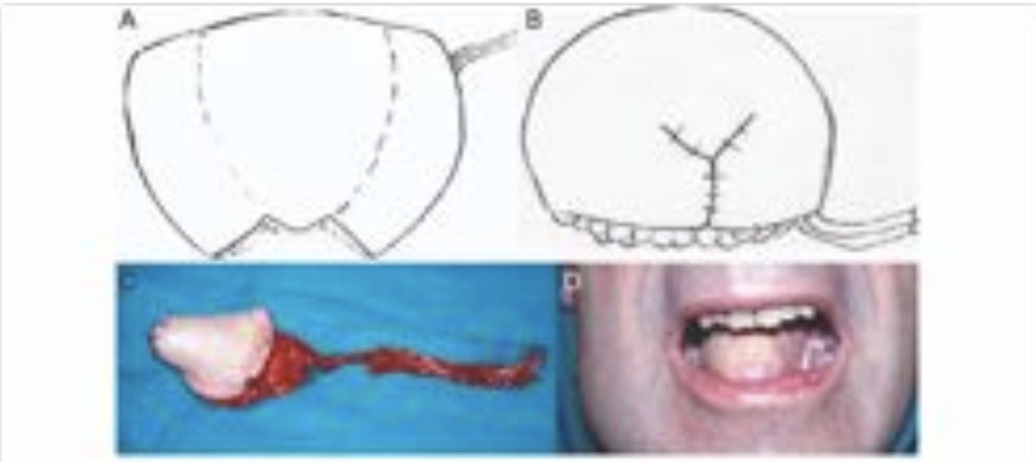

*Figure 3. Scheme of reconstruction following anterior 2/3 glossectomy. **A**: The template was made of one central larger petal to recreate the superior surface of the tongue and two lateral petals. **B**: Lateral petals were sutured, before inserting, to recreate the inferior surface of the tongue tip. **C**: Flap modeled before insetting. **D**: Final result. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

part of the flap was semicircular and bulky to reconstruct the posterior part of the tongue. The flap was bench tailored before insetting as follows: the anterior part of the flap was made of three thin wings (Fig. 2A), sutured to each other to recreate the tip of the tongue (Fig. 2B). Temporary skin-to-skin stitches were placed between the margin of the new tongue and the new floor of mouth to recreate a sublingual fold. After tailoring, the flap was inset (Fig. 2C). The pedicle exited the flap posteriorly, to reduce the distance to the neck vessels. The side of the flap opposite to the pedicle was sutured to the remaining tongue. In case of hemiglossectomy, the drawing was similar, but made of two wings only. Depending on the volume required and the thickness of the patient's thigh, the surgeon could decide to use an ALTflap[2–4] or a radial forearm flap.[10–14]

Anterior 2/3 Glossectomy

The template used for anterior 2/3 glossectomy is shown in Figure 3. The posterior part of the flap was semicircular and possibly bulky and was sutured to the posterior residual part of the tongue; the anterior part of the flap, possibly thinned, was made of one central larger petal to recreate the superior surface of the tongue and two lateral petals (Fig. 3A) that were sutured, before inserting, to recreate the inferior surface of the tongue tip (Figs. 3B–3D). The pedicle exited the flap posteriorly. The flap of choice was usually the ALT flap,[6–8] but sometimes it needed to be thinned.[15] The deep inferior epigastric perforator flap (DIEP)[16–18] could be considered, whereas the radial flap was not the best alternative, because it was often too thin.

Anterior 2/3 Glossectomy Plus Corresponding Floor of Mouth Resection

The template used for glossectomy plus corresponding floor of mouth resection was described by the first author in 1998[14] and is shown in Figure 4. The posterior part was made of two large petals sutured together to recreate a convex and bulky superior surface of the new tongue. The semicircular anterior part of the flap recreated the anterior floor of mouth. Two deepithelialized triangles at the mid point of the lateral borders provided a flap plication to recreate the inferior surface of the tongue tip, the anterior floor of mouth and the fold between them (Fig. 4A). During bench tailoring some temporary skin-to-skin stitches were placed to maintain the optimal position of this fold (Figs. 4B and 4C). Depending on the volume required and the thickness of the patient's thigh and abdomen, the surgeon could decide to use an ALT flap[4–7] or a DIEP flap.[16–18] The radial forearm flap[10–14] was not the best alternative.

Subtotal and Total Glossectomy Plus Corresponding Floor of Mouth Resection

The template used for total floor of mouth resection and glossectomy is shown in Figure 5. The basic shape of the flap was oval. Three deepithelialized triangles (one anterior and one lateral on each side) transformed an oval 2D surface (Fig. 5A) into a 3D structure (Fig. 5B) to

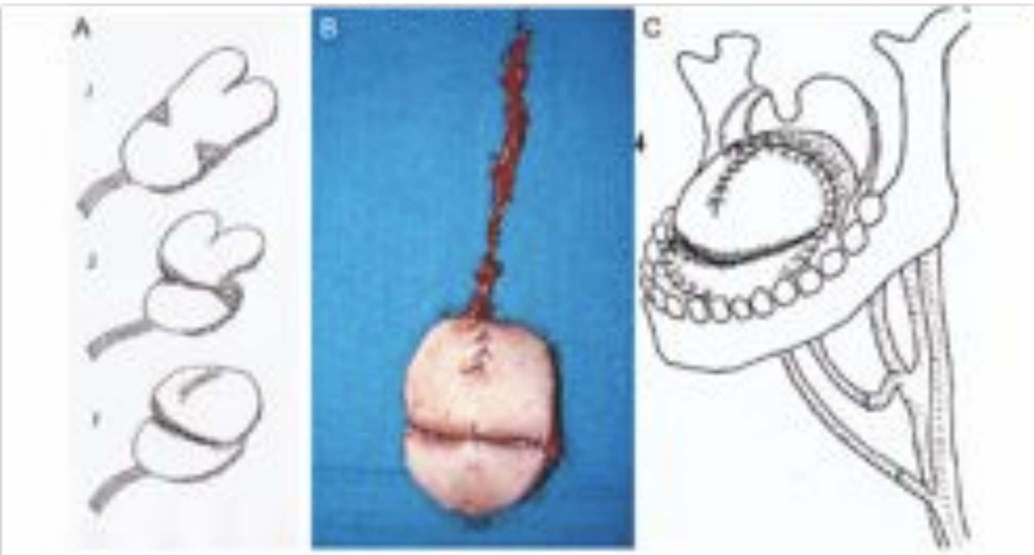

*Figure 4. Scheme of reconstruction following anterior 2/3 glossectomy plus corresponding floor of mouth resection. **A**: The template was made of two deepithelialized triangles at the mid point of the lateral borders that provided a flap plication to recreate the inferior surface of the tongue tip, the anterior floor of mouth and the fold between them, during bench tailoring some temporary skin-to-skin stitches were placed to maintain the optimal position of this fold. **B**: Flap modeled before inseting. **C**: Scheme of flap inseting. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

create a new tongue (Fig. 5C). The preferred flap was the ALT flap;[4–7] alternatively, a rectus abdominis flap[23] or DIEP flap[16–19] could be used.

Posterior Glossectomy (Partial or Total)

The template used for partial or total posterior glossectomy is shown in Figure 6. The flap shape was quite simple with a planned lateral plication to create the fold between the tongue and the tonsillar fossa (Fig. 6A); temporary sutures were not always necessary. The pedicle exited laterally, whereas the opposite side was deepithelialized and sutured to the remaining muscular part of the tongue (Fig. 6B). The edges of the skin paddle were sutured to the residual part of tongue and oral cavity mucosa (Fig. 6C). In total posterior glossectomy, the template shape was similar, with an increased length. The flap of choice was usually the ALT flap[4–7]; other options were, the lateral arm[21–23] and the radial forearm flap.[10–14]

Partial Resection of the Soft Palate and Tonsillar Fossa and Partial Tongue Base

The template used is shown in Figure 7. The flap was three-petal shaped (Fig. 7A): one petal replaced the tongue base and the other two reconstructed the tonsillar fossa and the mucosal layers of soft palate (Figs. 7B and 7C). Depending on the volume required and the thickness of the patient's thigh and abdomen, the surgeon could decide to use an ALT flap,[4–8] a DIEP flap[16–19] or a radial forearm flap.[10–14]

Half Soft Palate Resection

The template, shown in Figure 8, was heart shaped with two petals (Fig. 8B) recreating the front and rear sides of the hemipalate.

Inseting started by suturing the posterior wall (Fig. 8C). The first stitches between rhinopharynx mucosa and the rear surface of the new palate could be challenging. Having completed this suture, the flap was then folded back onto itself and sutured to the mucosa of the anterior face of the palate (Fig. 8D). The flap needed to be very thin so the radial forearm flap[10–14] was preferred.

Total Soft Palate Resection

The template is shown in Figure 9, as described by the first author in 2000.[14] The template was made by two petals separated by a deep notch (Fig. 9B) to recreate a new palatal arch (Fig. 9C) very similar in size and appearance to the original. Inseting the flap was similar to that described for partial soft palate reconstruction; the posterior wall had to be sutured first (Figs. 9D–9E). The

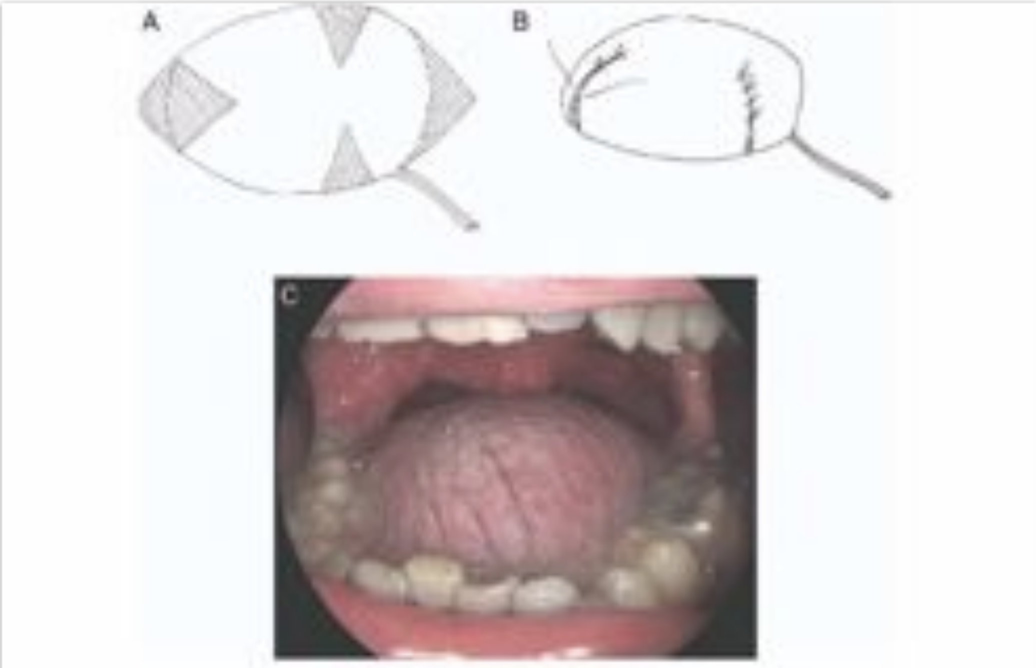

Figure 5. Scheme of reconstruction following subtotal and total glossectomy plus corresponding floor of mouth resection. ***A****: The basic shape of the template was oval.* ***B****: Three deepithelialized triangles (one anterior and one lateral on each side) transformed an oval 2D surface into a 3D structure to create a new tongue.* ***C****: Final result. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

Figure 6. Scheme of reconstruction following posterior glossectomy. ***A****: The shape of the template was oval.* ***B****: A planned lateral plication created the fold between the tongue and the tonsillar fossa.* ***C****: Flap modeled before inserting. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

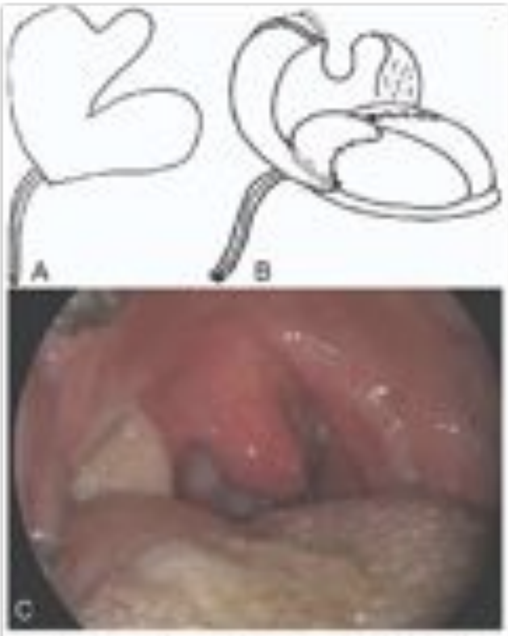

*Figure 7. Scheme of reconstruction following resection of tonsillar fossa and partial resection of soft palate and tongue base. **A**: The template was three-petal shaped. **B**: Scheme of flap insetting (one petal replaced the tongue base and the other two reconstructed the tonsillar fossa and the mucosal layers of soft palate). **C**: Final result. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

flap needed to be very thin, so the radial forearm flap[10-14,20] was imperative.

Half Oropharyngectomy

The template, shown in Figure 10, was heart shaped with an adjacent rectangle (Fig. 10B): the two petals recreated the mucosal layers of hemipalate as described above (Fig. 10C), whereas the rectangular surface of the skin paddle recreated the posterior aspect of the oropharynx (Fig. 10D). Depending on the volume required and the thickness of the patient's thigh, the surgeon could use an ALT flap.[6,7] The radial forearm flap[10,11] might be an alternative, although it was sometimes too small. Also the latissimus dorsi flap[26,27] might be a valid alternative even if not optimal requiring the change of patient's position and affected by a high donor site morbidity.

Flap Shaping

Flap shaping must avoid damaging vascularization, so it was mandatory to thin and tailor each petal of the flap step by step, while continuously checking the blood supply.

When using perforator flaps, such as ALT and DIEP, it was important to consider that for each petal of the flap the base-height ratio should be the same as common random flaps (maximum 1:2) and, if the flap was thinned, the Kimata rules were applied.[7] Plication of the flap did not compromise its vascularization, even if a small part was deepithelialized. When the petals of the flap were arranged on different planes (as in amigdalo-glosso-palatine reconstructions) the 1:2 base-height ratio could be maintained if the perforator was positioned in the center of the flap. In that case, it was mandatory not to exceed a 90° angle between the petals so as not to interfere with the blood supply.

In soft palate reconstructions with radial flap, the flap was made of two long petals, whose base-height ratio could reach 1:3 (but not exceed it). These petals were sutured together along the two edges of the notch without problems to the vascular supply, thus obtaining the arched free border of the new soft palate. Obviously, the pedicle ran along one of the two petals and was inset as the anterior face of the new palate (oral side) to facilitate postoperative monitoring.

RESULTS

The average overall survival at 5 years in patients affected by oral cavity cancer was 45.9% and the disease-specific survival was 49.6%; in patients affected by oropharyngeal cancer the overall survival was 59.1% and the disease-specific survival was 61.3%.

Seven patients (2.43%) displayed partial necrosis of the flap, of which five were ALT to reconstruct oral cavity defects and two were radial forearm flaps to reconstruct oropharynx defects. All these complications were easily resolved with a local toilette. Twelve patients (4.17%) displayed complete necrosis of the flap due to vascular thrombosis, of which one was a rectus abdominis flap to reconstruct oropharynx defect, four were ALT flaps to reconstruct oral cavity defects, and seven were radial forearm flaps to reconstruct oropharynx defects. All required a secondary reconstruction with another free flap.

Functional results were systematically evaluated in a group of 60 patients that is formed by the first patients treated for each class of resection. The swallowing function was analyzed by both videofluoroscopy (VFS) and functional endoscopic evaluation of swallowing (FEES).[28-31] Given the fact that 58 out of the 60 patients (97%) underwent preoperative or postoperative radiotherapy, the effect of radiotherapy on the final functional result could not be assessed independently of the postsurgical effects. Testing was performed after an adequate

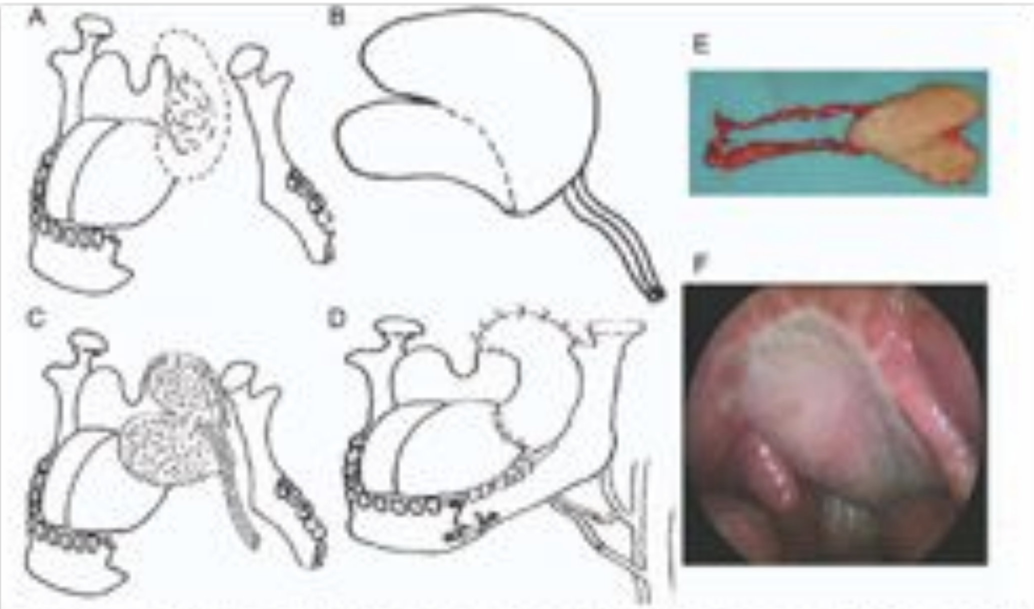

*Figure 8. Scheme of reconstruction following half soft palate resection. **A**: Scheme of half soft palate defect. **B**: Template was heart shaped with two petals. **C**: Insetting started by suturing the posterior wall. **D**: Flap was then folded back onto itself and sutured to the mucosa of the anterior face of the palate. **E**: Flap modeled before insetting. **F**: Final result. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

swallowing rehabilitation program and at least 3 months after the end of the radiotherapy for all patients. The results obtained in the 60 patients studied allowed us to consider the functional recovery achieved with the presented reconstructive techniques for each class of defect satisfactory, and so further swallowing studies were no longer performed routinely for obvious reasons of simplification and reduction of costs in patient management.

VFS, as previously reported,[17] was performed using high density (250% W/V) barium meal diluted with 100 ml of water, with the administration of at least 2 boluses of 5–7 ml. In cases with suspected inhalation, examination began with boluses of 2–3 ml. A semisolid paste (biscuits mixed with barium meal) was administered to those patients not showing signs of inhalation. Parameters recorded for each examination were: barium residue at oropharyngeal level (pharyngeal pooling), laryngeal penetration and inhalation, reduction of pharyngeal contraction (pharyngeal weakness), and rhinopharyngeal reflux.

FEES was performed using a 4-mm fiber optic flexible laryngoscope. During FEES, patients were given both semisolid and liquid material mixed with methylene blue. Pharyngeal and laryngeal sensitivity was assessed qualitatively by the contact between the mucosa and the endoscope tip. The parameters recorded were: degree of laryngopharyngeal sensitivity loss, pharyngeal phase onset latency, preswallowing spillage, degree of pharyngeal residue, laryngeal penetration and inhalation, and pooling of saliva.

The results of swallowing in the 60 patients analyzed by VFS and FEES are reported in Tables 2 and 3.

VFS showed the presence of oral pooling in 40 patients (66.67%), pharyngeal pooling in 59 (98.3%), laryngeal inhalation in 38 (63.33%), reduction of pharyngeal contraction in 28 (46.67%), and rhinopharyngeal reflux in 23 (38.33%). It should be underlined that there was an absence of oral pooling in all cases of posterior glossectomy and in three out of four patients treated by half oropharyngectomy. Laryngeal inhalation was present in every intervention of tongue reconstruction (90.91% of hemiglossectomy, 100% of subtotal or total glossectomy and posterior glossectomy) and 75% of half oropharyngectomy patients, but it was nearly always "mild" without causing coughing to protect the airway. It appeared moderate only in some patients with variable degrees of tongue base resection. Reduction of pharyngeal contraction was present in all cases of partial resection of soft palate, tonsillar fossa and partial tongue base resection

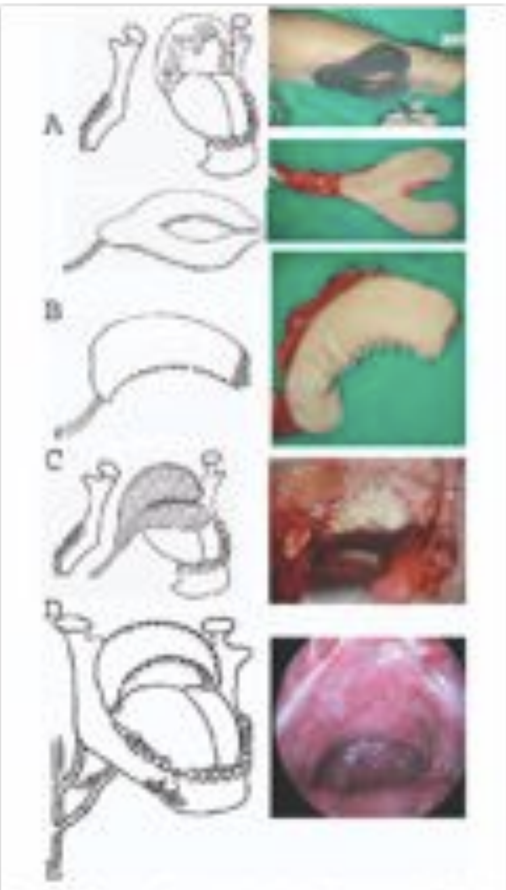

Figure 8. Scheme of reconstruction following total soft-palate resection. A: Scheme of total soft-palate defect with planned reconstruction with template. B: The template was made by two petals separated by a deep notch. C: The two petals were sutured together to recreate a new palatal arch. D: The posterior wall needed to be sutured first. E: Flap insetting after anterior wall suture and final result. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

and half oropharyngectomy. A certain amount of rhinopharyngeal reflux was noted in most of the cases of soft palate resection.

FEES revealed a mild sensitivity reduction in 17 cases (28.33%), moderate in 41 (68.33%), and severe in only two patients (3.33%) treated by half oropharyngectomy. Latency was increased in 47 (78.33%) patients, unchanged in seven (11.67%), and reduced in six cases (10%). The latter patients were treated by anterior 2/3 glossectomy without (three cases) or with corresponding oral floor resection (three cases). Preswallowing spillage was present in 50 (83.33%) patients; it should be noted that it was absent in six out of eight patients (75%) treated by half soft palate resection. Pharyngeal residue was present in 40 (66.67%) cases, pharyngeal pool of saliva in 35 (58.33%), laryngeal penetration in 38 (63.33%), and rhinopharyngeal reflux in 20 (3.33%). Pharyngeal pooling of saliva was present in all cases of half oropharyngectomy, posterior glossectomy, and hemi glossectomy. Rhinopharyngeal reflux was obviously present in patients treated by reconstruction involving soft palate. Concerning laryngeal penetration, it was considered severe in only one patient (1.67%) treated by half oropharyngectomy, moderate in 10 (16.67%), and mild in 27 (45%).

Only one patient of the present series (1.6%) required percutaneous endoscopic gastrostomy (PEG). This patient, with a right hemiglossectomy and a left transient hypoglossal nerve injury, required PEG for 7 months, until nerve function recovered. None of the patients required maintenance of the tracheostomy at discharge.

DISCUSSION

Reconstruction with free flaps is a keystone procedure in head and neck cancer surgery: not only does it allow resection size limits to be increased, but it also improves the remaining quality of life of the patient.

The standard method of reconstruction proposed is the result of an 20-year evolution of the technique and the templates were not all designed at the same time, but it was a progressive extension of the method from its initial application in reconstruction after hemi glossectomy to the most recent reconstruction after half oropharyngectomy.

Initially, having no terms of reference, it was difficult to predict the functional outcomes, especially concerning the swallowing function. Nowadays, experience allows us to predict the patient's functional recovery with good reliability.

Functional assessment of postoperative swallowing is a very difficult issue to address due to the numerous variables that influence this aspect. This is still one of the drawbacks of the literature. The authors' approach was to study all the patients that first underwent a specific type of resection and consequent reconstruction based on specific templates and to see what the main problems were (laryngeal penetration, oral and pharyngeal pooling ...) to try and, as far as possible, detect the corresponding compensatory manoeuvres. Naturally, part of the alterations observed (Tables 2 and 3) are unavoidable in any treatment, either by surgery or radiotherapy, and the combination of both these treatments obviously adds together their negative effects. It is, however, worth remembering

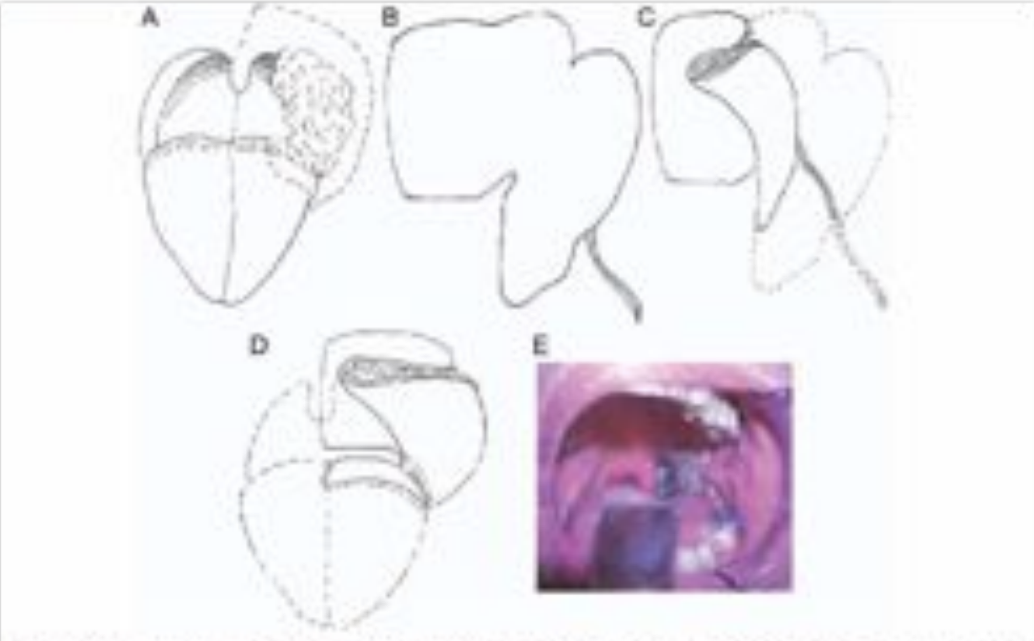

*Figure 10. Scheme of reconstruction following half oropharyngectomy. **A**: Scheme of half oropharynx defect. **B**: The template was heart shaped with an adjacent rectangle. **C**: The two petals recreated the mucosal layers of hemipalate. **D**: The rectangular surface of the skin paddle recreated the posterior aspect of the oropharynx. **E**: Final result. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]*

that the more widespread the area resected in terms of both loss of sensitive mucosal surface and organized contractile force, the more marked the functional alterations will be, independently of the type of flap and insetting used. Together the latter aspects can contribute to making the act of swallowing possible and acceptable again, despite being unavoidably altered in its oral and oropharyngeal phases. These alterations can be compensated for by the aforementioned manoeuvres and facilitating postures. In every case, a pool of specialists formed by the surgeon, the radiologist and the speech therapist should evaluate the functional outcome and decide on therapy, based on the most effective remedial systems.

In our experience, all patients presented at least one or more marked functional alterations but the objective result was that none of them on discharge needed enteral nutrition and the maintenance of the tracheostomy, except one case where a temporary paralysis of the residual half-tongue occurred. We would also like to underline that the most commonly observed alterations, such as oral and pharyngeal pooling and laryngeal penetration, are common to several types of defect because they are partially induced by the complementary radiotherapy. Surgery changes and amplifies alterations correlated to radiotherapy and vice versa. VFS and FEES data show how laryngeal penetration is nearly always "mild." This aspect, which is mentioned out of a need to be objective and thorough, is not significant if not accompanied by coughing and is very often compensated for by the patient by acquiring and developing a compensatory pattern. Conversely, severe inhalation represents an actual serious problem that excludes feeding by the natural pathway and obliges to consider the possibility of a laryngectomy.

Unfortunately, the literature does not yet provide a view of the problem with clear guidelines to judge beforehand when restoration of swallowing can be certain, probable or certainly unlikely.

As aforementioned, several factors[17] contribute to functional recovery and the features of the selected flap and its insetting technique are important, but only one aspect of the problem; some other factors to consider are staging, site and extension of resection, maintenance of innervation, complementary radio and chemotherapy, age and general conditions of the patient and it is actually difficult to state the value of each factor.

Table 2. Videofluoroscopy Results in First 60 Patients

Site	Number of patients	Oral pooling		Pharyngeal pooling		Laryngeal penetration/ inhalation		Reduction of pharyngeal contraction		Rhino-pharyngeal reflux	
Hemiglossectomy with or without	11	Yes	11	Yes	11	Yes	10 (mild)	Yes	5	Yes	0
corresponding floor of mouth resection		No	0	No	0	No	1	No	6	No	11
Anterior 2/3 glossectomy	4	Yes	4 (Mild)	Yes	3 (Mild)	Yes	0	Yes	0	Yes	0
		No	0	No	1	No	4	No	4	No	4
Anterior 2/3 glossectomy plus	5	Yes	5 (Moderate)	Yes	5 (Mild)	Yes	0	Yes	0	Yes	0
corresponding floor of mouth resection		No	0	No	0	No	5	No	5	No	5
Subtotal and total glossectomy plus	7	Yes	7	Yes	7	Yes	7 (Mild)	Yes	5	Yes	1 (Mild)
corresponding floor of mouth resection		No	0	No	0	No	0	No	2	No	6
Posterior glossectomy (partial or total)	6	Yes	0	Yes	6	Yes	5 (Moderate) 1 (inhalation)	Yes	0	Yes	0
		No	6	No	0	No	0	No	6	No	6
Partial resection of the soft palate and	10	Yes	7 (Moderate)	Yes	10 (Moderate)	Yes	7 (Mild)	Yes	10	Yes	9 (Mild)
tonsillar fossa and partial tongue base		No	3	No	0	No	3	No	0	No	1
Half soft palate resection	8	Yes	0	Yes	8 (Mild)	Yes	0	Yes	1	Yes	8 (Mild)
		No	8	No	0	No	8	No	7	No	0
Total soft palate resection	5	Yes	5 (Mild)	Yes	5 (Mild)	Yes	5 (Mild)	Yes	3	Yes	4 (Mild) 1 (Moderate)
		No	0	No	0	No	0	No	2	No	0
Half oropharyngectomy	4	Yes	1 (Mild)	Yes	4 (Moderate)	Yes	3 (Mild)	Yes	4	Yes	0
	No	3	No	0	No	1	No	0	No	6	

The idea of developing templates to plan 3D reconstructions in the oral cavity came from the model described by Urken in 1994 to reconstruct patients undergoing significant glossectomy.[7]

Prompted by this concept new models were designed to reconstruct the defects resulting from different soft tissue resections of the oral cavity and oropharynx.

The authors decided to exclude all composite reconstructions from the present series. On one hand, mandibular and maxillary bone defects share concepts in terms of flap choice (fibula flap, iliac crest flap, radial flap, and scapular flap) and flap inserting, but on the other hand, composite reconstructions cannot always be performed following the preoperative planning because it is difficult to predict the reliable amount of soft tissue accompanying bone flaps. Moreover, the shaping possibilities of the soft tissue component of the flap are limited by connections to the bone; therefore, composite reconstructions often require two simultaneous flaps.

Another major challenge is the objective classification of the resection defects. Although many classification systems have been proposed,[27–29] the authors adopted a personal classification criterion based on a grid subdivision of the different anatomical sites (Fig. 1). The aim of the classification is an easy visualization of the defect: dividing the grid into blocks allows the defect to be quantified, group similar cases by creating a data base, and compare reconstructions and outcomes.

The difficulty in choosing the best reconstruction technique in terms of flap choice and insetting can be seen in the example of Haghey's method for tongue body and base reconstruction[30]; the author proposed the use of a radial flap, modeled with the "fold and roll" technique that to our knowledge has not been adopted anywhere in Italy. It is clear that the spiral folding of the flap onto itself is not considered easy and safe; therefore, another type of insetting of the flap is generally preferred.

Flap choice has changed greatly over the years since the latissimus dorsi or the rectus abdominis flaps have been abandoned in favor of perforator flaps. The latter have subsequently entered into the authors' practice and have advantages over the previous ones of a lower morbidity of the donor site compared to muscle flaps and a longer pedicle than lateral arm flap. Currently, the first choices are the ALT and the Chinese flaps and other mentioned flaps are taken into account as an alternative.

Concerning tongue reconstruction some points, which can also be found in the literature, might be worth underlining. The goal is to rebuild the resected tongue volume[31,32]; this newly reconstructed portion of tongue will act as a passive mass moved by the remaining active muscles. This might be true not only for resections smaller than a hemiglossectomy but also for subtotal glossectomies where at least half a tongue base can be

Table 3. FEES Results in First 60 Patients

Site	Number of Patients	Sensitivity reduction		Alteration of latency		Preswallowing spillage		Pharyngeal residue		Pharyngeal pooling of saliva		Laryngeal penetration		Rhino-pharyngeal reflux	
Hemiglossectomy with or	11	Mild	1	Increased	11	Yes	11	Yes	11	Yes	11	Mild	8	Yes	0
without corresponding floor		Moderate	10	Unchanged	0	No	0	No	0	No	0	Moderate	2	No	11
of mouth resection		Severe	0	Reduced	0							Severe	0		
												No	1		
Anterior 2/3 glossectomy	4	Mild	0	Increased	0	Yes	3	Yes	0	Yes	0	Mild	0	Yes	0
		Moderate	4	Unchanged	1	No	1	No	4	No	4	Moderate	0	No	4
		Severe	0	Reduced	3							Severe	0		
												No	4		
Anterior 2/3 glossectomy	5	Mild	0	Increased	1	Yes	5	Yes	0	Yes	0	Mild	0	Yes	0
plus corresponding floor		Moderate	5	Unchanged	1	No	0	No	5	No	5	Moderate	0	No	5
of mouth resection		Severe	0	Reduced	3							Severe	0		
												No	5		
Subtotal and total	7	Mild	4	Increased	7							Mild	4		
glossectomy plus						Yes	7	Yes	5	Yes	3	Moderate	0	Yes	0
corresponding floor of		Moderate	3	Unchanged	0							Severe	0		
mouth resection						No	0	No	2	No	4			No	7
		Severe	0	Reduced	0							No	3		
Posterior glossectomy	6	Mild	5	Increased	2	Yes	6	Yes	6	Yes	6	Mild	5	Yes	0
(partial or total)		Moderate	1	Unchanged	4	No	0	No	0	No	0	Moderate	1	No	6
		Severe	0	Reduced	0							Severe	0		
												No	0		
Partial resection	10	Mild	0	Increased	10	Yes	9	Yes	9	Yes	7	Mild	5	Yes	9
of the soft palate and		Moderate	10	Unchanged	0	No	1	No	1	No	3	Moderate	3	No	1
tonsillar fossa and		Severe	0	Reduced	0							Severe	0		
partial tongue base												No	2		
Half soft palate resection	8	Mild	7	Increased	7	Yes	2	Yes	2	Yes	0	Mild	1	Yes	4
		Moderate	1	Unchanged	1	No	6	No	6	No	8	Moderate	0	No	4
		Severe	0	Reduced	0							Severe	0		
												No	7		
Total soft palate resection	5	Mild	0	Increased	5	Yes	3	Yes	3	Yes	4	Mild	4	Yes	5
		Moderate	5	Unchanged	0	No	2	No	2	No	1	Moderate	1	No	0
		Severe	0	Reduced	0							Severe	0		
												No	0		
Half oropharyngectomy	4	Mild	0	Increased	4	Yes	4	Yes	4	Yes	4	Mild	0	Yes	2
		Moderate	2	Unchanged	0	No	0	No	0	No	0	Moderate	3	No	2
		Severe	2	Reduced	0							Severe	1		
												No	0		

assumed to be still functioning. In this case, the new tongue must have *the widest possible range of motion*: the reconstruction of a sublingual fold with skin-to-skin temporary sutures (as described in Figs. 2 and 4) was extremely useful and relevant.

All these considerations about passive movement of the new tongue obviously depend on the possibility to preserve the innervation of the remaining muscles.

According to the concepts well expressed by Kimata,[43,47] in total glossectomy with or without floor of mouth resection, the flap placed between the inner surface of the mandible and the hyoid bone should provide a similar reconstructed volume to that of the original volume of the tongue at rest.

The rigidity of the skin of the flap modeled according to a scheme described in Figure 5 might be enough to counteract the lowering of the hyoid-larynx complex, and the hyoid suspension proposed by some authors might not be mandatory.[44]

In our oral cavity group, the degree of swallowing impairment was related to the extent of tongue resection, particularly toward the tongue base. The swallowing alterations noted after hemi-tongue base resection (hemiglossectomy with or without corresponding oral floor resection, subtotal glossectomy) was pharyngeal and oral pooling, a mild decrease of pharyngeal contractility, a reduction of sensitivity with increase of the latency of pharyngeal phase triggering, and finally a mild laryngeal penetration (Tables 2 and 3).

It should be highlighted that reconstruction after total glossectomy plus corresponding floor of mouth resection with laryngeal sparing did not always guarantee an acceptable functional outcome. This was due to important variables, such as the patient's ability to understand and perform the postural manoeuvres necessary to compensate for the deficit in the oral and oropharyngeal phase of swallowing. The patient must be informed about the possible need for a further surgical procedure to remove the larynx.[36,47,48]

If the defect involves the tongue body only (two anterior thirds), a fully satisfactory result could generally be obtained using the template shown in Figure 3. The reconstruction of a new tongue, very similar in shape to the original one, permitted a satisfactory functional outcome in terms of phonetics, even allowing telephone conversations.

Some standard situations can also be found concerning the oropharynx. In more-than-half or total tongue base resection reconstruction with a free flap did not seem to be indispensable because, in the authors' experience,[42] if the resection did not exceed the lingual V, it was possible to suture the residual anterior tongue directly to the hyoid bone given the sparing of at least one hypoglossal nerve.

This solution, however, increased the distance between the tongue tip and the anterior teeth leading to a marked worsening of the speech articulation. The interposition of a free flap (Fig. 6) reduces the aforementioned lingual-teeth distance, therefore, allowing a better phonetic function. In this group, the swallowing impairment was related to the extent of the resection. Patients showed pharyngeal pooling, reduction of sensitivity, and increased latency of pharyngeal phase triggering, preswallowing spillage and mild to moderate laryngeal penetration. A less predictable outcome was observed by patients undergoing total posterior glossectomy, since they were affected by a moderate laryngeal penetration requiring an active training assessed by the speech therapist on the basis of VFS and FEES results.

Resection of the tonsillar fossa and partial resection of soft palate and tongue base (Fig. 7) possibly required a 3D reconstruction by a three-petal-shaped flap: one petal replaced the resected portion of tongue base, whereas the other two reconstructed the soft palate at the front and rear. This conformation enabled a very precise anatomical reconstruction even with the creation of a new glossotonsillar fold for a better flow of the bolus from the floor of mouth to the oropharynx.

Functional outcome of patients undergoing partial resection of the soft palate and tonsillar fossa and partial tongue base, as expected, resulted in an overlap of the impairment observed in the different single structure reconstruction: a reduction in pharyngeal contractility, pharyngeal pooling, reduced sensitivity and increased swallowing latency, a possible mild rhinopharyngeal reflux and preswallowing spillage. The final swallowing objective result was however satisfactory.

When it was necessary to reconstruct a full thickness hemipalate, it was often convenient to use the radial flap that was most appropriate in terms of thinness and pliability, although in some cases the ALT flap may also be thin or can be thinned sufficiently.[38] Figures 8 and 9 show the reconstruction technique in half or whole soft-palatectomies. The shape of the template with two petals separated by a deep notch made it possible to recreate a new palatal arch very similar in size and appearance to the original soft palate. The static accuracy of this reconstruction could be seen on radiological images obtained with the volume rendering technique that showed the new palatal diaphragm in the sagittal view, which was anatomically similar to the original one (Fig. 11). The above described inserting method allowed both the anterior and the rear side of palate to be reconstructed avoiding the presence of unepithelized areas, as described by other authors.[47]

The lack of movement in the new palate was compensated for by increased contractility of the posterior wall (upper pharyngeal constrictor muscle) with a result-

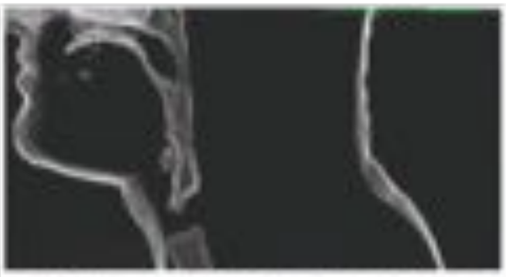

Figure 11. Anatomical result after total soft-palate reconstruction: volume rendering technique showed the static accuracy of this reconstruction with a new palatal diaphragm in the sagittal view, which was anatomically similar to the original one. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

ing absent or mild rhinopharyngeal reflux of the bolus. Even the verbal nasalization appeared minimal or absent. This functional result excluded the need to perform a velopharyngoplasty between the flap and posterior wall of the pharynx, as proposed by other authors.[33,36]

The final technical consideration concerns the extension of resection in the pharynx. In the authors' experience, the resection of the pharyngeal contracting wall could be pushed up to the midline but not over it (Fig. 10). The principle underlying this was that if a whole hemipharynx, which will obviously be adynamic, was reconstructed, the propulsion of the bolus could be performed by the contralateral contracting system. If the contralateral wall was also compromised, the bolus would not be able to progress, resulting in inevitable stagnation and consequent inhalation into the airways. In the authors' experience, the resection of the posterior wall or the subtotal resection of the oropharynx and hypopharynx was incompatible with the possibility to preserve the larynx.[37]

Finally, it should be underlined that microsurgical reconstruction based on a template was possible only with a totally viable flap: partial necrosis must be avoided. Partial flap necrosis in oral reconstruction was, however, not frequent: in fact, in the authors' experience this occurred in only 2.5% of cases, whereas marginal dehiscence occurred in about 8%. However, marginal dehiscence did not compromise reconstructive outcomes, but took a longer healing time.

The modeling phase is a key point: the flap was usually shaped, if necessary, tailored and inset before revascularization, always with the utmost care to preserve the blood supply and try to keep ischemia time under 1 hour. One of the limitations of this study is that the number from each class and type of flaps were small so that no statistical analysis could be performed and no comparison between classes and types of flaps used could be made.

CONCLUSION

It is difficult for those approaching the field of oncological surgery based on free flaps to have objective information on the best techniques to use with regards to the procedure (flap choice, insetting, morbidity, complications) and functional outcome. The literature lacks a systematic and critical review about insetting and it is, therefore, difficult to compare functional results and to identify the best reconstructive technique. The proposed standardized surgical strategy based on reproducible templates might make it easier for less experienced surgeons to analyze the problem, to choose the best technical solution, and to foresee the functional outcomes.

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2b “Evolution in Microsurgical correction in facial contour deformities: remarks on 22 consecutive flaps”

Un’analisi retrospettiva su 20 pazienti sottoposti ad intervento microchirurgico per correzione delle deformità di contorno facciale ha evidenziato un’evoluzione della tecnica ricostruttiva. I risultati dello studio sono stati pubblicati sull’Italian Journal of Maxillofacial Surgery nell’articolo riportato in seguito.

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Evolution of microsurgical correction in facial contour deformities: remarks on 22 consecutive flaps

R. SGARZANI [1], L. NEGOSANTI [1], F. CONTEDINI [1], A. BIANCHI [2], C. MARCHETTI [2], R. CIPRIANI [1]

[1]Department of Plastic Surgery, S. Orsola Malpighi Hospital, Bologna, Italy
[2]Department of Maxillofacial Surgery, S. Orsola Malpighi Hospital, Bologna, Italy

Aim. **Facial contour deformities with hemifacial or bilateral tissue atrophy can have many different etiologies, both congenital and acquired. Microsurgical reconstruction is currently the treatment of choice for facial soft tissue integration, to obtain satisfactory and long-lasting contour restoration.**
Methods. **Our experience includes 20 patients with facial contour deformity, treated with the transfer of 22 microsurgical flaps, from 1990 to 2007. We have experienced an evolution in flap selection: we used the scapular flap in our first four patients, and then adopted the perforator flaps (ALT, DIEP, SGAP, with a total of 14 perforator flaps in 13 patients). Our current standard approach in these cases is the adiposal DIEP flap.**
Results. **There were no flap losses in this series of 22 flaps, two patients developed postoperative hematoma and flap revision was performed in eight patients (liposuction, fat graft, scar revision). Unlike our previous experience with the scapular flaps, using the perforator flaps we have been able to reduce donor site morbidity, and obtain better contour restoration, as perforator flaps are more easily modelled. The introduction of adiposal DIEP flaps has led to further reduction of donor site morbidity, with minor residual scarring in the supra-pubic region, and a softer and more natural reconstruction, thanks to the lack of a dermal component.**
Conclusion. **Based on our experience, the adiposal DIEP flaps can currently be considered the gold standard in the treatment of facial contour deformities.**

Key words: Congenital abnormalities - Facial asymmetry - Free tissue flaps.

Facial soft and hard tissue atrophy, with facial contour deformity of different grades of severity, can be determined by many different etiologies. Atrophy distribution can be hemifacial or bilateral.

Causes can be congenital or acquired. Congenital malformations frequently affect skin, subcutaneous tissue, fat, muscle and the underlying bone structures, as in the cases of Goldenhar's Syndrome and Hemifacial Microsomia. Acquired causes are heterogeneous and include Romberg's disease, scleroderma, postradiation sequelae, cancer surgery and trauma.

A variety of techniques have been described both for the correction of bone deformities (osteotomy, distraction) and for contour augmentation.

In the past, non vascularized fat or dermis grafts [1-9] were used to obtain soft tissue integration, but long-term results were unpredictable due to progressive resorption. Consequently, vascularized flaps have been adopted with more satisfactory long-term results.

At the present time, some authors use the fat grafts according to Coleman technique,[10-12] both for mild and severe atrophy, with multiple surgical procedures.

In our experience, this technique plays a minor role, as it is used only for refinements in combination with liposuction.

The first free flap used to correct hemifacial atrophy was the free deltopectoral dermal-fat flap, described by Fujino in 1975.[13] Later on, in 1977, Harashina introduced the vascularized groin dermal-fat

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Corresponding author: L. Negosanti (Plastic Surgery Unit, S. Orsola-Malpighi Hospital), via Giuseppe Dagnini 3, 40137, Bologna, Italy. E-mail: [illegible]

Figure 2.—Patient affected by scleroderma with bilateral facial contour deformity.

Five patients had a congenital asymmetry: three had hemifacial microsomia (Figure 1) and two had a Goldenhar's Syndrome.

Fifteen patients had acquired etiologies: five Romberg's disease, one scleroderma (bilateral) (Figure 2), four cancer surgery, one trauma and four postradiation sequelae (one was bilateral).

The scapular flaps were used in four patients, the dermoadiposal ALT flaps in five patients, the dermoadiposal DIEP flaps in seven patients (one bilateral, with a total of eight dermoadiposal DIEP flaps performed), the dermoadiposal SGAP flap in one patient and the adiposal DIEP flap in three patients (one bilateral, with a total of four dermoadiposal DIEP flaps performed) (Table I).

Surgical management

Two surgical teams are at work simultaneously to prepare the subcutaneous pocket in the recipient site and to harvest the DIEP or ALT perforator flaps, with considerable reduction in OR time.

On the cheek, the first step consists in the preparation of a template (generally a sterile photographic film) to reproduce the area to be filled, according to the position and length of the pedicle (Figure 3).

A facelift-type incision is then performed, fol-

TABLE I.—*Our series of 20 patients and of 22 flaps.*

	Name	Pathology	Age	Sex	Flap	Complications
1	S.S.	Postradiation sequelae	63	M	scapular	none
2	H.M.	Hemifacial microsomia	51	M	scapular	none
3	M.W.	Trauma	45	M	scapular	none
4	C.M.	Cancer surgery	56	M	scapular	none
5	A.S.	Hemifacial microsomia	30	M	DIEP	none
6	L.C.M.	Romberg's Disease	26	F	DIEP	none
7	C.M.C.	Romberg's Disease	37	F	DIEP	none
8	C.A.	Romberg's Disease	62	M	ALT	none
9	D.P.C.	Postradiation sequelae	28	F	DIEP	none
10	D.M.	Hemifacial microsomia	17	F	ALT	none
11	B.I.	Postradiation sequelae	42	F	ALT	none
12	C.A.	Goldenhar Sd.	17	F	DIEP	none
13	G.D.F.	Romberg's Disease	19	M	DIEP	hematoma
14	A.B.	Cancer surgery	40	F	ALT	none
15	M.M.	Cancer surgery	55	F	ALT	none
16	A.F.	Cancer surgery	35	M	SGAP	none
17	A.R.	Postradiation sequelae	57	M	2 DIEP	none
18	B.A.	Goldenhar Sd.	21	F	adiposal DIEP	none
19	G.D.	Romberg's Disease	37	M	adiposal DIEP	none
20	R.A.	Scleroderma	30	F	2 adiposal DIEP	hematoma

Figure 3.—Template that reproduce the defect.

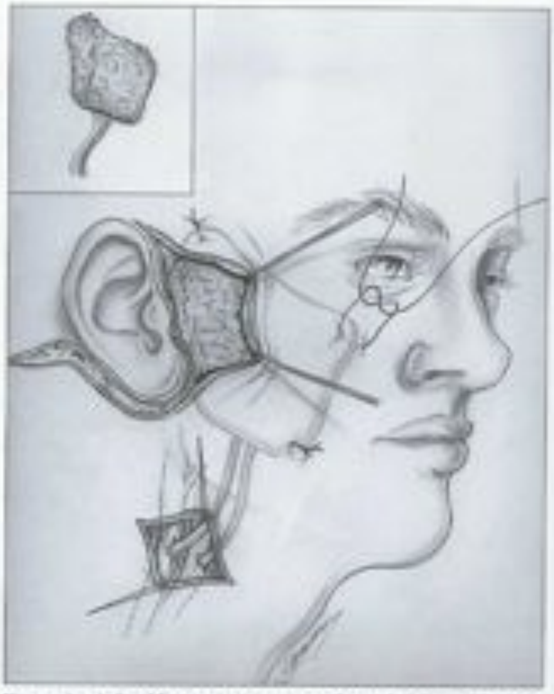

Figure 4.—A facelift-type incision is performed, followed by subcutaneous dissection to create a pocket for flap accommodation. An additional 4 cm incision inside a neck fold can then be made to identify the superior thyroid artery or the thyrolingual-facial trunk.

lowed by subcutaneous dissection to create a pocket for flap accommodation (Figure 4). The pocket must extend at least 2 cm beyond the defect.

The next step is devoted to the preparation of the recipient vessels. We generally prefer the superior thyroid artery or the thyrolingual-facial trunk because of the larger size and because they are far from the affected area, since patients with these malformations are often characterized by vessels with a reduced diameter in the affected hemiface.

An additional 4 cm incision inside a neck fold can then be made to identify the superior thyroid artery or the thyrolingual-facial trunk.

Using the template, the flap is marked on the thigh or the abdomen, so that the flap center corresponds to the point of emergence of the selected perforator (Figures 5, 6). Doppler can help to locate the right point.

The de-epitelialized DIEP and ALT flaps are prepared following the conventional procedure. Flap de-epitelialization is performed after dissection. The abdomen is eventually repaired with abdominoplasty. With the ALT flap, the donor site can always be repaired by direct suture.

Harvesting of the adiposal DIEP flap starts with an incision approx 15 cm long in the supra-pubic region (Figure 7A), followed by the superficial subcutaneous dissection of the entire flap area. A totally adiposal flap is then harvested using a closed approach (Figure 7B). After flap harvesting, the supra-pubic incision is sutured with no tension so that there is no need for additional abdominoplasty. To obtain a symmetrical correction, liposuction is performed on the contralateral abdominal quadrants (Figure 8).

The flap is then introduced into the prepared pocket. The de-epitelialized side is placed superficially in order for the pedicle to be accommodated deeper down inside the pocket.

Figure 5.—Template centred on the perforator.

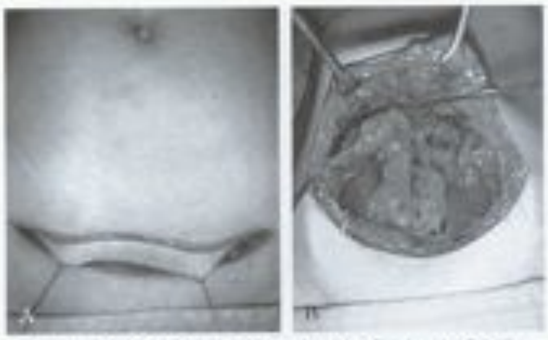

Figure 7.—A) Adiposal DIEP flaps harvested using a closed approach. Adiposal DIEP flap is harvested and then introduced into the prepared pocket, transfixion sutures are applied to keep the flap in place.

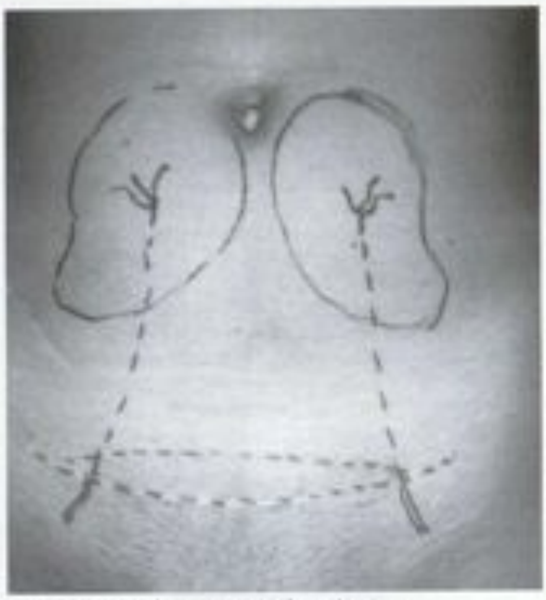

Figure 6.—Bilateral adiposal DIEP flaps planning.

Figure 8.—Donor site's scar after adiposal DIEP flap transplant.

In our experience, no flap loosening or dislocation have been observed. Transfixion sutures are applied to keep the flap in place. Revision refinements with either liposuction or fat graft can easily be performed. Liposuction promotes fibrous tissue formation which makes the area more compact and uniform (Figure 9).

Figure 9.—A, B) Long-term result after a minor revision.

Results

In our series of 22 flaps, there were no microvascular complications and no flap losses. Two patients developed postoperative hematoma, that had to be surgically removed but caused no significant delay in the healing process. Both hematomas were caused by spread bleeding.

In five patients, postoperative flap monitoring was possible thanks to a pre-auricular skin paddle that was subsequently removed during revision surgery. In six patients, flap monitoring of dermis and fat tissue was carried out through a 2 cm opening in the preauricular incision that was sutured seven days after surgery by simply tying the previously prepared stitches. In the remaining cases, post-operative flap monitoring was performed by echo-Doppler.

There were no donor-site problems, but the dorsal scars in patients submitted to reconstruction with scapular flap was not satisfactory.

Minor flap revisions under local anesthesia were performed in eight patients, using liposuction, fat graft and scar revision. Liposuction of the abdominal region to correct abdominal contour irregularities was performed during the same surgical procedure in patients submitted to reconstruction with adiposal DIEP flaps.

Discussion

These conditions, and particularly malformations, are observed in patients previously submitted to multiple surgical procedures. After undergoing bone distraction or orthognatic surgery, these patients demand that reliable results be obtained in a one stage procedure. This is the main reason why free flaps seem to provide the most effective solution.

Successful microsurgical anastomosis, reduced donor site morbidity and shorter length of surgery contribute to very predictable and reliable results.

In our experience of 22 flaps, there were no microsurgical complications with considerable patient satisfaction and long-lasting results, obtained with reasonably short and pain-free procedures.

Free flaps have been demonstrated to be substantially better than dermo-adiposal grafts and fat grafts.[33, 34]

Even though the fat graft has been incorporated in the new Coleman's technique,[30-32] we have experienced that it is only indicated in deformities of the lip, the nose, the eyes and the chin, or as a refinement of inadequate results.

There is a wide range of free flaps to choose from. Some authors have recently proposed that the omental flap be resumed,[35, 36] even though it has long been considered inadequate for these conditions, due to the unpredictable fat content and the poor long-term results. Some surgeons can probably obtain good results even with "old fashioned" flaps.

Undoubtedly, however, perforator flaps are innovative, not only for their vascular pattern, but especially because they are characterized by reduced donor site morbidity.[37, 38]

Perforator flaps offer a number of advantages compared to the scapular flaps, which were used in the first four patients of our series with stable and satisfactory long-term results. The advantages are the following: 1) shorter OR time, since two teams can work simultaneously (this applies to ALT and DIEP flaps, but not to SGAP flaps); 2) the pedicle is long enough to reach the thyroid artery and the thyro-linguo-facial venous trunk, thus avoiding the anastomosis of facial vessels that are often small in malformed patients; 3) flap fat tissue can be largely removed during harvesting, based on volume requirements; 4) the predominantly fat tissue in perforator flaps, compared to scapular flaps that have a very thick dermal component, makes the reconstruction softer and allows secondary revisions to be performed by liposuction; 5) finally, donor site morbidity is limited.

The choice of perforator flaps depends on tissue availability from the donor site, *i.e.*, on fat tissue distribution on the patient's abdomen, thighs or gluteal region.

However, whenever the patient's anatomy allows for the flap to be harvested from the abdominal region, we think that the adiposal DIEP flap can be currently considered the gold standard.

The flap is harvested through a supra-pubic skin incision, the wound is sutured with no tension so that the scar is usually very inconspicuous. Abdominoplasty is not necessary to repair the donor site. Flap thickness can be adapted immediately to the defect. The lack of a dermal component makes the reconstruction softer and more natural, and very easy to contour by revision liposuction. The only disadvantage of adiposal DIEP flap harvesting is that it may cause minor abdominal contour irregularities, which can be easily corrected by revision liposuction.

Conclusions

Based on our experience, we can conclude that the scapular flap can be considered as an "out-of-date" technique for the correction of facial contour deformities, even if it was used in the first four patients of our series with stable and satisfactory long-term results.

The results obtained with perforator flaps show that they offer a number of important advantages, including reduced donor site morbidity, and are therefore to be preferred for the correction of facial contour deformities.

When patient's anatomy is such as to allow for the flap to be harvested from the abdominal region, the adiposal DIEP flap should be considered as the treatment of choice in these conditions, for additional reduction of donor site morbidity - only minor scarring in the supra-pubic region - and for a softer and more natural reconstruction, as a consequence of the lack of a dermal component.

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2c "Deformità del contorno facciale: progettazione mediante CAD e valutazione oggettiva dei risultati ottenuti con lembo libero e successive liposculture"

Il poster che viene riportato è stato presentato a Progetti in Mostra 2011.

Rossella Sgarzani

DEFORMITA'DEL CONTORNO FACCIALE: PROGETTAZIONE MEDIANTE CAD E VALUTAZIONE OGGETTIVA DEI RISULTATI ottenuti con lembo libero e successive liposculture

Scuola di dottorato in Scienze Mediche e Chirurgiche
(Coordinatore Prof. Andrea Stella)
Progetto: Problematiche ricostruttive in Chirurgia Maxillo-Facciale: nuove linee di ricerca
(Responsabile Prof. Claudio Marchetti)
Dipartimento di Scienze Odontostomatologiche

Università di Bologna

Le deformità del contorno facciale in genere non determinano problemi funzionali, ma possono avere un importante impatto sulla vita di relazione del paziente.
La chirurgia ricostruttiva in questi casi ha finalità estetiche: l'obiettivo è **reintegrare i volumi mancanti e migliorare la forma e la simmetria facciale.**
La ricerca che stiamo conducendo ha l'obiettivo primario di **proporre una nuova metodica di pianificazione 3D dei volumi da integrare.**
Prima di qualsiasi trattamento chirurgico il paziente viene studiato mediante TC, RM e laser scan di superficie.
I dati raccolti vengono elaborati sfruttando software di **Computer Aided Design -CAD** per produrre un **progetto virtuale del risultato finale desiderato**. La metodica permette inoltre di **calcolare i volumi effettivi di tessuto da aggiungere.**

La ricerca ha inoltre l'obiettivo di introdurre un **metodo oggettivo di valutazione dei risultati** ottenuti mediante la tecnica: lembo libero e successive liposculture.
Questo procedimento chirurgico prevede:
1. un primo intervento durante il quale un lembo di tessuti molli (grasso oppure grasso e cute) viene prelevato da un'altra regione del corpo (in genere pancia o cosce), trasferito in regione facciale e collegato ad un'arteria ed una vena del collo per ricevere nutrimento. Questo intervento apporta un abbondante volume di tessuti molli che necessita modellamenti successivi: è come procurare ad uno scultore un blocco di marmo da modellare.
2. successivi piccoli interventi di liposcultura, cioè modellamento del tessuto adiposo trapiantato mediante lipoaspirazioni (aspirazione del grasso in eccesso) e lipofilling (iniezioni di grasso).

Il paziente

Il progetto

Il paziente **dopo ogni modellamento chirurgico viene nuovamente sottoposto a laser scan di superficie.**
Per la rielaborazione ed il confronto dei dati vengono utilizzati software generici di Scientific Visualization (tipo Amira) e di Reverse Engineering (tipo Rapidform): questi programmi permettono di ottenere un valore numerico che esprime la precisione e riproducibilità della metodica.
Per **riproducibilità** si intende la possibilità di realizzare chirurgicamente ciò che si è progettato virtualmente. Il file 3D postoperatorio viene confrontato con il file 3D del progetto virtuale al fine di calcolare "l'errore di sovrapposizione" ("overlap error") tra le due immagini. L'errore di sovrapposizione delle immagini ricostruito viene espressa con una immagine unica di sovrapposizione con scala colorimetrica e in numero percentuale (0-100%: 0---nessuna sovrapposizione 100%---sovrapposizione completa).

1°modellamento

2°modellamento

50% sovrapposizione

70% sovrapposizione

85% sovrapposizione

Di solito molteplici piccoli interventi di liposcultura sono necessari per ottenere un risultato soddisfacente.
Verrà considerato soddisfacente un risultato che sia sovrapponibile al 85-95% con il risultato virtuale pianificato pre-operatoriamente al computer.
Obiettivo secondario della ricerca è **stabilire il numero medio di modellamenti necessari per ottenere un risultato soddisfacente.**

2d "Lembi liberi microvascolari per la ricostruzione cervicofacciale: comparazione dei risultati oncologici e ricostruttivi fra pazienti giovani e anziani"

Un'analisi restrospettiva è stata condotta su 85 pazineti per valutare se esistano differenze, in termini di complicanze, morbidità e funzione, in due popolazioni di pazienti: giovani-adulti (< 75 anni) ed anziani (≥ 75 anni), sottoposti a trattamento chirurgico microvascolare per tumori avanzati del distretto testa-collo. Le differenze non sono risultate significative. I risultati sono stati pubblicati su Acta Otorhinolaringologica Italica nell'articolo riportato in seguito.

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HEAD AND NECK

Head and neck cancer in elderly patients: is microsurgical free-tissue transfer a safe procedure?

Tumori del distretto cervico-facciale nel paziente anziano: le ricostruzioni microchirurgiche rappresentano una procedura sicura?

A. TARSITANO[1], A. PIZZIGALLO[1], R. SGARZANI[2], C.M. ORANGES[2], R. CIPRIANI[2], C. MARCHETTI[1]

[1] Maxillofacial Surgery Unit, [2] Plastic Surgery Unit, Policlinico S.Orsola-Malpighi, "Alma Mater Studiorum", University of Bologna, Bologna Italy

SUMMARY

The safety and success of microvascular transfer have been well documented in the general population, but the good results achieved with the use of free flaps in elderly patients have received little attention. This study sought to identify differences in complications, morbidity and functional outcomes between elderly (≥ 75 years) and younger (< 75 years) patients treated surgically for advanced head and neck cancer using the Head and Neck 35 module of the European Organisation for Research and Treatment of Cancer quality of life questionnaire. Patient treatment consisted of composite resection, including excision of the primary tumour with ipsilateral or bilateral neck dissection and microvascular reconstruction. Eighty-five microvascular tissue transfers were performed to reconstruct major surgical defects. Postoperative radiation therapy was performed when indicated. Total flap loss occurred in three cases in elderly patients and two cases in younger patients. The rates of major surgical complication were 9% in young patients and 11% in elderly patients. No significant difference was observed between the two groups in the rates of major and minor flap complications, morbidity or long-term functional outcome. The results of the present analysis indicate that free-flap microvascular reconstruction can be considered a safe procedure in elderly patients with head and neck cancer.

KEY WORDS: Head and neck cancer • Elderly patient • Microvascular free flap • Complication • Functional outcome

RIASSUNTO

Sebbene la sicurezza ed il successo delle procedure ricostruttive microvascolari del distretto cervicofacciale siano state ben analizzate e documentate nella letteratura medica recente, non altrettatanto è accaduto per le procedure microchirurgiche nella popolazione anziana. Questo studio si prefigge lo scopo di valutare se esistano differenze, in termini di complicanze, morbidità e funzione, in due popolazioni di pazienti: giovani-adulti (< 75 anni) ed anziani (≥ 75 anni), sottoposti a trattamento chirurgico microvascolare per tumori avanzati del distretto testa-collo. Il trattamento è consistito nella chirurgia resettiva tumorale associata a dissezione linfonodale del collo ipsi o bilaterale e ricostruzione mediante il trasferimento microchirurgico di un lembo libero. Nella popolazione di pazienti in analisi 85 lembi liberi sono stati effettuati. La terapia radiante adiuvante è stata effettuata, quando necessaria, in funzione dello stadio di malattia. La perdita completa del lembo si è verificata in 3 casi nel gruppo di pazienti anziani ed in 2 casi nei pazienti giovani-adulti. La percentuale di complicanze maggiori è risultata essere del 9% nei pazienti giovani e del 11% nei pazienti anziani. Non sono emerse differenze statisticamente significative in termini di complicanze maggiori e minori legate al lembo, morbidità e risultati funzionali a lungo termine. In conclusione, dai nostri dati è possibile desumere che la chirurgia ricostruttiva microvascolare del distretto cervicofacciale possa essere considerata una procedura affidabile anche nel paziente anziano.

PAROLE CHIAVE: *Tumori della testa e del collo • Pazienti anziani • Lembi liberi microvascolari • Complicanze • Risultati funzionali*

Acta Otorhinolaryngol 2012;32:371-375

Introduction

The proportion of elderly people with head and neck cancer is rising due to an overall increase in life expectancy. The increasingly widespread application of microvascular free-flap reconstruction in the past 20 years has revolutionised the treatment of head and neck cancer. The safety and success of free-flap transfer have been well documented in the general population [1], but the good results achieved with the use of free flaps in elderly patients have received little attention.

When planning the treatment of an elderly patient with advanced head and neck cancer, the surgeon must weigh the risks and benefits of operating on the individual, who may be frail. Although head and neck surgery incurs substantially less perioperative mortality than cardiovascular or gastrointestinal tract surgery [2], other issues warrant consideration when a lengthy and complex reconstruction is planned. The surgeon must consider whether an elderly patient can tolerate the medical impact of prolonged surgery, whether the risk of surgical complication is increased and whether major surgical reconstruction should be considered for this kind of patient. These issues should be balanced against the presumed functional and aesthetic benefits achieved by the use of microvascular reconstruction. The aim of the present study was to evaluate whether differences exist in the rates of complications, morbidity and functional outcomes between elderly and younger patients treated surgically for advanced head and neck cancer using microvascular reconstruction.

Materials and methods

Between January 2007 and December 2010, 81 patients with advanced (stage III–IV) head and neck cancer were treated at the Oral and Maxillofacial Surgical Unit in collaboration with the Plastic Surgery Unit at S. Orsola-Malpighi University Hospital, Bologna, Italy.

Patient treatment consisted of composite resection, including excision of the primary tumour with ipsilateral or bilateral neck dissection and microvascular reconstruction. Eighty-five microvascular tissue transfers were performed to reconstruct major surgical defects. Postoperative radiation therapy was performed when indicated, depending on the tumour stage and surgical margins. Indications for postoperative radiotherapy were T3–T4 tumours, positive or close surgical margins, multiple positive nodes and/or extranodal spread.

Patients were divided into two groups according to age: a younger group included patients aged < 75 years ($n = 46$) and an elderly group with patients aged ≥ 75 years ($n = 35$). Patient details are listed in Table I.

The oral cavity was the most frequent site of reconstruction in both groups. Typically, patients undergoing major head and neck surgery and free-flap reconstruction were kept sedated and mechanically ventilated in a surgical intensive care unit overnight. The flap was monitored by checking paddle skin colour or Doppler signal every 3 h for the first 2 days, and every 4 h on days 3-5.

The following demographic variables were analysed for each group: patient sex and age, underlying disease, American Society of Anesthesiologists (ASA) score, smoking history, type of flap and defect site.

Complications were divided into donor-site, flap, and systemic complications using Classen and Ward's [3] classification. Donor-site complications were classified as seroma, haematoma, infection, dehiscence, congestion and skin loss. The number of patients who developed donor-site complications were compared between groups. Flap complications were classified as major (requiring surgical re-exploration) or minor (all others), and frequencies were calculated for each group. Postoperative comorbidities, pulmonary oedema, postoperative hypertension and sepsis were classified as systemic complications.

Table I. Defect site, reconstruction type, and American Society of Anaesthesiologists (ASA) classification in the elderly and younger patient groups.

Defect site	Elderly (n)	Younger (n)
Oral cavity	18	24
Oropharynx	6	9
Midface	11	13
Reconstruction		
Fibula	17	19
ALT	20	12
Forearm	5	4
Rectus	2	3
DCIA	1	0
Groin	0	1
Latissimus	0	1
ASA classification		
I	3	16
II	6	8
III	9	13
IV	16	9
V	1	0

Long-term functional outcomes were evaluated and compared between groups using the Head and Neck 35 module of the European Organisation for Research and Treatment of Cancer (EORTC H&N35) quality of life questionnaire [4]. Speech, swallowing and chewing functions were assessed 12 months after surgery.

Chi-squared analysis with Fischer's exact test was performed to determine the influence of age on complication rate, morbidity and functional outcome. In each group, complications were examined according to ASA status and reconstruction type. Statistical significance was defined as $p < 0.05$. All statistical analyses were performed using the SPSS® Advanced Statistical™ software package (ver. 13; SPSS Inc., Chicago, IL, USA).

Results

A total of 81 patients (50 men, 31 women; mean age, 59.85 years; range, 26-89 years) underwent surgery for head and neck tumours. Microvascular reconstruction was performed in all patients, with 85 free flaps used to reconstruct a variety of defects. The age distribution in both groups is shown in Figures 1 and 2. ASA status was determined as listed in Table I. Of 81 patients evaluated, 47 were ASA class III or IV. The most frequent histological diagnosis was squamous cell carcinoma (Fig. 3).

The following microvascular free flaps were used: fibula ($n = 36$), anterolateral thigh ($n = 32$), forearm ($n = 9$), rectus abdominis ($n = 5$), deep circumflex iliac artery ($n = 1$), groin ($n = 1$) and latissimus dorsi ($n = 1$). The fibula free

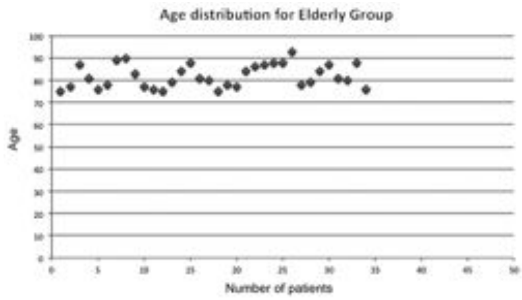

Fig. 1. Age distribution in the elderly patient group.

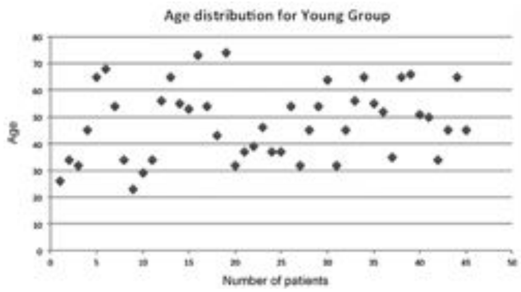

Fig. 2. Age distribution in the young patient group.

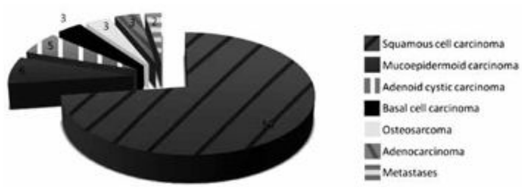

Fig. 3. Histological tumour types.

flap was used most frequently in the younger group and the anterolateral thigh free flap was used most frequently in the elderly group (Table I). One elderly patient underwent a double free-flap transfer for a complex head and neck defect. Two patients, one from the elderly group and one from the young group, received a second free-flap following flap loss. One patient underwent a second free-flap transfer for a second primary tumour.

Donor-site complications were observed in 18 cases in young patients and 20 cases in elderly patients (Table II). Seroma was the most common donor-site complication, observed in eight elderly and seven younger patients.

Minor flap complications occurred in seven cases in young patients and six cases in elderly patients (Tab. III), and consisted of infection ($n = 1$), haematoma ($n = 2$), dehiscence ($n = 1$), congestion ($n = 5$) and partial flap loss ($n = 4$). Total flap loss occurred in three elderly patients and two younger patients. Re-exploration was required in four cases in each group (Table III). The major surgical complication rate was 9% in the younger group and 11% in the elderly group.

Two younger patients and three elderly patients had systemic complications, consisting of postoperative delirium ($n = 2$) and pneumonia ($n = 1$) in the elderly group, and venous thromboembolism ($n = 1$) and myocardial ischaemia ($n = 1$) in the younger group. All but one systemic complication was resolved with medical treatment.

Perioperative mortality occurred only in one elderly patient, who suffered a heart attack during surgery for an oropharyngeal tumour. This patient had normal electrocardiogram readings before the operation and a left ventricular ejection fraction of 75%.

Swallowing, speech and chewing function domain scores at 12 months postoperatively were 64, 71 and 69 points, respectively, for younger patients and 61, 73 and 64 points, respectively, for elderly patients.

Chi-square analysis with Fisher's exact test was performed to assess the relationship between patient age and complication rates (Table IV). Age did not affect the rate of donor-site, flap, systemic complications or functional outcome (swallowing, speech or chewing). Multivariate logistic regression analysis demonstrated that age did not significantly increase the overall incidence of complications ($p = 0.31$). ASA score was the only variable show-

Table II. Donor-site complications in the elderly and younger patient groups.

Complication	Younger (n)	Elderly (n)
Seroma	7	8
Haematoma	3	3
Infection	2	4
Dehiscence	4	3
Congestion	0	0
Skin graft loss	2	2
Total	18	20

Table III. Minor and major flap complications in the elderly and younger patient groups.

Complication	Young (n)	Elderly (n)
Minor flap complications		
Skin graft loss	0	0
Infection	1	0
Haematoma	1	1
Seroma	0	0
Dehiscence	1	0
Congestion	2	3
Partial flap loss	2	2
Major flap complications		
Re-exploration	4	4
Total flap loss	2	3

Table IV. Results of chi-square analysis with Fisher's exact test.

Donor complications	Flap complications	Systemic complications	Swallowing function	Speech function	Chewing function
$p = 0.711$	$p = 0.203$	$p = 0.110$	$p = 0.671$	$p = 0.864$	$p = 0.121$

ing an association that approached statistical significance ($p = 0.04$) with the development of complication (Tab. V).

Discussion

Microvascular free-tissue transfer, a reliable technique for head and neck reconstruction, was introduced in 1959 [5]. Consistent success rates of 90-99% have been reported [6]. Complications can be divided into three main groups: general condition-related, recipient area-related and procedure-related.

Population demographics show a growing proportion of elderly people, and age has been regarded frequently as an independent risk factor for poor surgical outcome. Before the 1960s, the operative mortality rate for elderly patients undergoing elective surgery was two to six times higher than that in the general population [7]. Several well-accepted reasons explain this difference. The first factor is heart failure; an elderly patient's ageing heart has a less efficient cardiac output when placed under the stress of surgery and anaesthesia [8], and this condition is accompanied by lower renal blood flow resulting in larger water and electrolyte imbalances. The second factor is the compromise of pulmonary function with increased age due to smaller vital capacities and poorer gas exchange resulting from lung parenchyma deterioration [9]. However, the mortality rate in elderly patients has declined in the past 40 years. Today, the overall surgical mortality rate is about 0.9-2.4%, even for patients with cardiac disease [10], largely as result of safer anaesthesia techniques. In addition, the average life expectancy of a 70-year-old man is 11 years and that of a 70-year-old woman is 14 years [11].

In the literature, no exact age seems to be associated with the word ''elderly''. However, this lack of precision is not entirely relevant, as surgical indications should be based not on age, but on risk assessment. The ASA score is a commonly recommended tool for risk assessment [12].

Studies of free-flap use have been conducted in elderly patients aged 50 [13], 60 [14], 65 [3], and 70 [2] years. The flap loss rate in these studies ranged from 1% in a 92-patient series [6] to 16.7% in a 47-patient series [7]. This variation illustrates the difficulties of precisely defining the term ''elderly'' and of predicting morbidity rates in elderly patients. Many studies examining the relationship between age and free-flap complication have demonstrated that age is not an important factor influencing the success of microvascular free-flap transfer. However, surgery is often avoided in elderly patients because of the increased likelihood of various complications, regardless of the type of procedure chosen. In 1999, Pompei et al. [15] reported the results of 392 head and neck flap reconstructions, including those employing pedicled flaps; the authors found that complications in elderly patients were correlated with comorbidities, but not with age or operation length.

In 2000, Serletti et al. [3] analyzed 104 free-flap procedures in patients aged ≥ 65 years, and concluded that free-flap transfer in elderly patients achieved a success rate similar to that in the general population. They concluded that age alone should not be considered a contraindication or an independent risk factor when considering free-tissue transfer. The authors believed that ASA status was a reliable predictor of postoperative medical and surgical morbidity. They found that an operative time > 10 h was a significant factor in the development of postoperative surgical complications. Because elderly patients are also less capable of handling large fluid shifts and significant blood loss, proper fluid management and protein–calorie balance are important. Another significant factor in reconstruction failure seems to be the presence of peripheral vascular disease.

In 1994, Bridger et al. [16] found no significant difference in the rate of postoperative surgical complications between patients older (42%) and younger (37%) than 70 years, and concluded that age alone should not contraindicate head and neck microvascular procedures. Furthermore, in 2006, Classen and Ward [3] analyzed the complications of free-flap operations using the donor-site, flap and systemic complication categories. They found that age influenced only the systemic complication rate.

All of these studies evaluated factors that can lead to free-flap complication. However, precise analyses of how age influences free-flap complication have been infrequent. Moreover, some previous studies have included pedicled flaps in the analysis and have presented simple numerical complication rates without performing statistical analysis. Most of these studies have reported that age does not impact the free-flap complication rate, but the results have varied; a significant number of studies have reported that age may influence the rate of systemic complications.

In the present study, we assessed age as a variable affecting free-flap complication rate, morbidity and functional outcome.

Table V. Results of multivariate statistical analysis, including hazard ratios and 95% confidence intervals (CIs) for the variables in each model.

Model	Hazard ratio	95% CI	p
Overall complications			
Age (< 75 *vs.* ≥ 75 years)	1.12	0.83-1.52	0.31
Sex	0.92	0.65-1.31	0.65
ASA status	0.72	0.53-0.97	0.04
Tumour site	1.10	0.81-1.48	0.54

The proportion of elderly people with head and neck cancer is rising due to an overall increase in life expectancy. Our study used a 75-year cut-off value to define the elderly age group because no previously published paper has considered "elderly" patients of this age. Indeed, we believe it is valuable to assess similarly aged patients with head and neck cancer using a precisely defined cut-off value. The appropriate cut-off value for the definition of elderly patients has been a matter of much debate: Bonawitz et al. [12] defined elderly patients as those aged ≥ 60 years, Shestak and Jones [11] used a cut-off age of 50 years and Serletti [3] used 65 years.

In the present study, age was considered a continuous variable in the analysis of its association with donor-site, flap, systemic complications and major and minor surgical complication rates. Functional outcomes were also evaluated in both groups. No pedicled flap was included in this analysis. The major surgical complication rate was 9% in the young group and 11% in the elderly group.

Our results are similar to those of other published series. Shestak et al. [13] reviewed 19 patients who underwent microvascular head and neck reconstruction and found a 16% major surgical complication rate in patients aged ≥ 70 years, compared with 13% in patients aged < 70 years.

In the present study, multivariate analysis showed that ASA score was the only variable associated with an increased complication rate.

Similar to the findings of another recent report [16], the present study found a higher medical morbidity rate in elderly patients, with two complications (postoperative delirium) occurring. Chick et al. [17] found that medical complications occurred in 35% of elderly patients, compared with 10% of younger patients.

In the present study, one elderly patient died during surgery; no death occurred in the younger population. Morgan et al. [18] noted that perioperative mortality increased significantly with age, but most series have reported rates of 3–6% in elderly patients undergoing head and neck reconstruction [19]. The present study also found no significant difference between the two groups in long-term swallowing, speech and chewing functions. Peri- and postoperative complications were correlated with ASA status.

In conclusion, the present analysis indicates that free-flap microvascular reconstruction can be considered a safe procedure in elderly patients with head and neck cancer. Surgical complication rates do not appear to increase in elderly patients compared with younger patients. Only slightly more systemic complications occurred in the elderly group than in the younger group in this study.

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Address for correspondence: Achille Tarsitano, Maxillofacial Surgery Unit, S. Orsola-Malpighi Hospital, University of Bologna, via G. Massarenti 9, 40100 Bologna, Italy. Tel. +39 051 6364204. E-mail: achilletarsitano@gmail.com

2e “Vascular pedicle ossification of free fibular flap: is it a rare phenomenon? Is it possible to avoid this risk?”

Il presente studio è stato condotto su una popolazione di 61 lembi liberi di fibula utilizzati per ricostruire altrettanti difetti maxilla-mandibolari post-oncologici. La popolazione in esame è stata suddivisa in due gruppi. Il primo, costituito da 41 pazienti, è stato sottoposto ad allestimento del lembo microchirurgico secondo la tecnica classica. Il secondo gruppo, costituito da 20 pazienti, è stato sottoposto a tecnica di dissezione del periostio dal peduncolo vascolare.

La dissezione del periostio dal peduncolo è risultata fondamentale nel ridurre il rischio di ossificazione del peduncolo. I risultati sono stati accettati per la pubblicazione su Acta Otorhinolaringologica Italica nell’articolo riportato in seguito.

Vascular pedicle ossification of free fibular flap: is it a rare phenomenon? Is it possible to avoid this risk?

Running title: Vascular pedicle ossification of free fibular flap.

Abstract

Free fibula flap is the most common free tissue transfer for maxillary and mandibular reconstructions. The distal part of the harvested bone is transferred, while the proximal part is removed by sub-periosteum dissection.

The vascularised periosteum attached to the vascular pedicle has osteogenic potential.

61 patients reconstructed with free fibula flaps were divided in 2 groups: 41 flaps performed with standard technique and 20 flaps performed dissecting periosteum from the pedicle. Every patient was followed up with rx OPT and CT scan at 6, 12, 18 and 24 months after surgery. The minimum follow up time was 18 months.

With a retrospective analysis of the first group we diagnosed 7 pedicle ossifications on 41 reconstructions (17 %). In the second group no pedicle ossification was observed ($P<0.05$).

The dissection of periosteum from the vascular pedicle of free fibula flaps avoids the risk of ossification.

Riassunto

Il lembo libero di fibula è il più frequentemente utilizzato per le ricostruzioni maxilla-mandibolari. L'allestimento del suddetto lembo prevede la rimozione della porzione ossea prossimale della fibula attraverso lo scollamento sottoperiosteo dei tessuti molli entro cui è contenuto il peduncolo vascolare. Il tessuto periosteo limitrofo al peduncolo mantiene le sue caretteristiche osteogenetiche.

Il presente studio è stato condotto su una popolazione di 61 lembi liberi di fibula utilizzati per ricostruire altrettanti difetti maxilla-mandibolari post-oncologici. La popolazione in esame è stata suddivisa in due gruppi. Il primo, costituito da 41 pazienti, è stato sottoposto ad allestimento del lembo microchirurgico secondo la tecnica classica. Il secondo gruppo, costituito da 20 pazienti, è stato sottoposto a tecnica di

dissezione del periostio dal peduncolo vascolare. Ogni paziente è stato valutato mediante esecuzione di rx OPT e TC a 6, 12, 18 e 24 mesi di follow-up. 7 casi di ossificazione del peduncolo vascolare (17%) sono stati riscontrati nel primo gruppo di studio. Nessun caso è stato rilevato nel secondo gruppo sottoposto a dissezione del periostio ($P<0.05$). Il fenomeno di ossificazione del peduncolo vascolare del lembo di fibula non è risultato essere così tanto raro nella nostra casistica, come descritto da altri Autori. La dissezione del periostio dal peduncolo può essere fondamentale nel ridurre tale rischio di ossificazione

Introduction

Free flaps, combining a high success rate with low donor site morbidity, are considered the gold standard for the reconstruction of tissues lost during oncologic surgery[1].

Free fibula flap is routinely used for large jaws reconstructions[2-3]. This can be considered a safe surgical procedure also in elderly head and neck cancer patients[4].

The harvested flap transfers almost the full length of bone, while preserving the integrity of the knee and ankle joints. The harvested fibula is contoured to match the shape of the surgical defect by removing the proximal part of the bone, which permits the pedicle to be lengthened to join the neck vessels. For contouring the flap, osteotomies preserve the interconnections between the periosteum and pedicle, while retaining the surrounding muscle to preserve the blood supply to the bone.

The osteogenic potential of vascularized periosteum is well described in the literature, and many factors have been associated with an increased osteogenic activity in periosteal tissue[5].

So the vascularised periosteum attached to the vascular fibula pedicle has an osteogenic potential and some report of this uncommon phenomenon has been reported in recent literature[6-7], with a maximum of reported incidence of 9,3%[8].

This study aimed to point out the bony free flap's pedicle ossification through a 7-year retrospective study to calculate the frequency of the condition. We also discuss the management of its consequences and we propose a surgical technique, applied prospectively in our cohort of patients, to avoid this phenomenon.

Materials and Methods

We performed a restrospective-prospective study on 61 patients who have undergone maxillofacial reconstructions with free fibula flaps after oral cancer ablation at S.Orsola Malpighi Hospital in Bologna (Maxillo-Facial and Plastic Surgery Units) during the 2004 to 2011 period.

The patients were divided in two groups: in the first group we enrolled 41 flaps performed using surgical standard technique during the 2004 to 2007 period, and it was assessed retrospectively.

Due to the high percentage of pedicle ossifications in the first group, from January 2008 all flaps were harvested in our Unit according to the surgical periosteum dissection technique.

In this second group we enrolled 20 flaps performed dissecting the periosteum from the vascular pedicle from 2008 to 2011. This second group was evaluated prospectively.

Patients' follow-up included clinical examination and radiographic evaluation. All the patients were followed up systematically with rx OPT and CT scan at 6 and 12, 18 and 24 months after surgery, according to the standard oncological follow up procedure. The minimum follow-up time was 12 months.

We evaluated the descriptive statistics of bony free flaps under the two groups. The percentage of pedicle ossification was assessed. Demographic characteristics were evaluated and univariate analysis was performed. $P < 0.05$ was considered as statistically significant.

Surgical technique of periosteum dissection

The technique of fibula harvesting is well known and standardized[9]. During the harvest of the fibula free flap, approximately 20 cm of bone is harvested[10].

The proximal aspect of this bone is seldom necessary for reconstruction but is removed with the flap to facilitate vascular pedicle dissection. Subsequently, during flap contouring, the unnecessary proximal fibula is discarded. A subperiosteal dissection is performed along the area of bone to be discarded to avoid damage to the vascular pedicle. This results in up 10 to 15 cm of well-vascularized periosteum along the peroneal vascular pedicle. This tissue, usually, can be draped along native bone at the side of the reconstruction or placed over the vessels in the neck to protect the anastomoses.

To avoid the risk of pedicle ossification we performed, in our second study group of patients, the periosteum dissection technique. We removed the periosteum exceeded from the proximal peroneal vascular pedicle. This surgical procedure has been performed before vascular anastomoses. It can be done using optical loop magnification. Time consuming is 10-15 minutes more than standard surgical procedure.

Results

The flap survival rate was 100% in both groups. Microsurgery was performed to the superior thyroidian artery in 79% of the cases, to the lingual artery 21% of the cases. In all patients the recipient vein was the thyrolinguofacial trunk.

In the first group of patients 7 pedicle ossifications were diagnosed (17%). 3 were men and 4 were women. In 6 cases (85%) the fibula was used for mandible reconstruction; In 1 case (15%) the flap was performed for maxillary reconstruction.

Clinical signs were reported in 2 patients (28%). One patient had hard swelling of submandibular region; one patient had pain in cervical region associated with trismus.

Onset of vascular pedicle ossification occurred between 115 and 370 days (median 196 days).

Diagnosis was made using rx OPT [Figure 1] and CT scan [Figure 2].

In 1 patient the ossification was diagnosed at the 6 months post-operative follow-up, while in 6 patients at 12 months follow-up.

Only the 2 symptomatic patients were surgically treated. Surgical resection of ossified pedicle was performed through submandibular access [Figure 3]. It did not influence the vitality of the flap.

Asymptomatic patients were followed up.

In the second group of 20 patients, we performed dissection of the periosteum from the vascular pedicle. In this group, up to day, no pedicle ossification was observed. Univariate analysis showed a statistically significant difference ($P<0.05$) between the two study group.

No significant increase in operative time was evaluated, nor additional complications were noted.

Discussion

Only four articles in medical literature report the ossification of the vascular pedicle in free fibula flaps. Few of the reported cases were symptomatic, presenting trismus, hard swelling, severe pain during mastication and during twisting of the ipsilateral neck.

In one case report the ossification was an accidental finding during a re-intervention for recurrence[7].

The reported symptomatic cases were studied using rx OPT, CT scan and in one case biopsy for the suspect of a recurrence.

The maximum incidence reported in literature is of 9,3%[8]. Our incidence of ossification diagnosis is higher (17%) probably in relation to the systematic radiological follow-up performed in this series.

In our study 5 out 7 patients were asymptomatic. Most of the time there is no clinical expressions of the calcified pedicle. This is the reason why ossified pedicles are underestimated. Those undiagnosed ossified pedicles may potentially lead to complication as pain, trismus and swelling.

Clinically, trismus may be the result of the involvement of masticatory or buccal spaces, subsequent to the disposition of the vascular pedicle in the cheek during the reconstruction of maxillary defects. Swelling of the submandibular region is the typical sign of ossification of pedicle in the reconstruction of mandibular defects. Usually, this sign can be interpreted as a local relapse.

Gonzalez Garcia reports an histological study showing that the bone seems to be mature along the entire pedicle with no gradation, and that the bone formation is invasive towards the vascular pedicle[7].

The factors influencing the osteogenic potential of vascularised periosteum have been described[7]: contact with vascularised bone, mechanical stimuli, growth factors, systemic steroids and hormones. In all cases presenting vascular pedicle ossification the contact and the continuity between the reconstructed bone and periosteum was preserved, which is fundamental for osteogenesis. In a periosteal free flap in which no contact with bone occurs, the level of ossification is inferior[5]. This contact may play a role because the progenitor cells and bone morphogenetic proteins (BMPs), factors participating in osteoprogenitor recruitment, proliferation, and differentiation into chondrocytes and osteoblasts, have been detected in the site of bone fracture[7]. During free flap surgery, osteotomy can be considered a fracture.

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