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Scuola di Specializzazione in Chirurgia Odontostomatologica
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TESI DI SPECIALIZZAZIONE

SEVERI RIASSORBIMENTI ORIZZONTALI.
UTILIZZO DEGLI IMPIANTI A LAMA
SECONDO I DETTAMI AUTORIZZATIVI DELLA F.D.A.

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Anno Accademico 2013/2014

Sommario

IMPIANTO PLAT FORM (A LAMA)

L'ideazione e l'applicazione clinica dell'*Impianto a Lama* (etimo: *lamina*, *struttura sottile*) per l'implantoprotesi odontoiatrica, si attribuiscono al Prof. Leonard Linkow (USA), che lo presentò nel 1966 e lo diffuse in tutto il mondo.

L' implantologia odontoiatrica moderna, scientificamente, qualitativamente e eticamente sostenibile, considerata la disponibilità sul mercato internazionale di varie morfologie di mezzi impianti endossei e di protocolli applicativo-metodologici diversificati, impone al Clinico un approccio critico ed individualizzato al caso e quindi la scelta del tipo di impianto non dovrebbe essere condizionato da una "filosofia soggettiva" operatore-dipendente, indipendentemente dalle affinità individuali, ma dettata invece da esigenze anatomiche e funzionali.
Ecco allora che le Lame Implantari trovano appunto una particolare indicazione anatomica elettiva nelle situazioni di cresta ossea sottile ed anche un'indicazione funzionale nelle sedi in cui il carico masticatorio trasmesso alla lama stessa è biomeccanicamente più compatibile con la loro forma rispetto a quella di altri impianti.

Data l'esiguità dello spessore, la lama può essere utilizzata sia in creste ampie che in creste sottili e proprio questa la versatilità ha erroneamente convinto molti Clinici che si tratti di un "impianto universale", da poter inserire in qualsiasi cresta ossea, senza discriminazioni.
Ma l'analisi degli insuccessi ottenuti con questo impianto ha portato alla conclusione che la loro causa sia da imputarsi all'utilizzo in sedi ossee inidonee (iperspongiose), all'uso improprio della tecnica, al mancato rispetto del protocollo chirurgico e all'applicazione indiscriminata ai "casi-limite" che di per se stessi ovviamente ottengono percentuali inferiori di successo clinico.
Attuando una corretta selezione dei pazienti, seguendo i dettami del protocollo chirurgico, che inderogabilmente prevede un affondamento dell'impianto al di sotto della cresta di osso corticale con un posizionamento che ottenga un

appoggio basale su osso corticale (bicorticalismo) nelle zone in cui la lama va soggetta a carico assiale, nonché gestendo con la dovuta perizia il periodo post-operatorio e la protesizzazione, l’impianto a lama dà risultati di estrema soddisfazione funzionale ed estetica e affidabilità nel tempo.

Tipologie di lame per l’implantologia odontoiatrica

La lama originale di Linkow era un impianto monolitico a moncone fisso, che aveva forma diverse in dipendenza delle sedi anatomiche cui era destinata. In un periodo successivo Linkow apportò numerose modifiche alla superficie ed alla forma dell’impianto e ne realizzò anche una versione “sommersa” per applicazione bifasica. All’inizio degli anni ’70 Ugo Pasqualini presentò una lama “polimorfa” semi-emergente che poteva essere modellata in modo da essere adattata alle più frequenti conformazioni anatomiche. Sia le lame di Linkow che quelle di Pasqualini sono tuttora commercializzate ed utilizzate. Numerosi altri Autori hanno presentato variazioni e modifiche, che consentono di poter scegliere la forma di impianto che più si avvicina alla conformazione ossea in esame, sviluppando forme emergenti e sommerse (Fig.1-4).

Figure 1 - 4
Alcuni tipi di lama emergente e sommersa in commercio

Oggi le forme di impianto a lama presenti sul mercato soddisfano le esigenze di ogni conformazione anatomica e sono dotate di evolute componentistiche protesiche.
Le forme sommerse posseggono un calice utile all’inserimento del moncone protesico dopo l’osteo-inclusione dell’impianto.

Potenzialità degli impianti a lama

a. Possibilità di utilizzo in siti ossei sottili in spessore;
b. Adattabilità alla maggior parte delle conformazioni anatomiche;
c. Valorizzazione dei tessuti esistenti evitando procedure di rigenerazione quando non indispensabili;
d. Correzione meccanica in sede di intervento dei problemi di parallelismo;
e. Adattamento alle strutture anatomiche profonde modificando l’impianto (fig. 6);

f. Possibilità di far scivolare una parte dell'impianto in sedi ossee poste sotto elementi dentari inclinati (fig.18);
g. Maggiore facilità, data l'estensione della lama, a raggiungere con l'impianto punti di contatto con l'osso corticale in profondità;
h. Possibilità di sfruttare sedi distali della cresta ossea per conferire stabilità all'impianto-protesi;
i. Gestione della gengiva aderente già in sede di intervento;
j. Minore quantità di componenti protesiche rispetto ad un impianto sommerso;
k. Semplicità della tecnica chirurgica, attuabile con strumentario standard;
l. Affidabilità.

Limiti clinici degli impianti a lama

a. Con lame estese in senso mesio-distale, invasione delle sedi ossee adiacenti (quindi carico distribuito su di un minor numero di pilastri);
b. Scarsa adattabilità all'inserzione in alveoli post-estrattivi.

Aspetti Biomeccanici:

La possibilità, prevista dalla tecnica chirurgica, di modificare l'impianto a lama per adattarlo alla sede anatomica cui è destinato, presuppone da parte dell'operatore la capacità di valutare l'idoneità biomeccanica dell'impianto. Questo aspetto è apparentemente in contrasto con l'impostazione attuale dell'implantologia orale, la quale è basata su prodotti le cui caratteristiche sono standardizzate, in quanto in implatoproteseologia, il momento dell'inserimento radicolo-protesico è solo funzionale alla finalizzazione corono-protesica che è sempre individualizzata con un dispositivo su misura in adattamento anatomico. Tuttavia, con ogni sistema implantare, la scelta della lunghezza dell'impianto, della sua collocazione in tessuti di diversa densità a contatto o meno della corticale ossea, della protesi che all'impianto verrà ancorata, della funzione più o meno fisiologica cui la sovrastruttura protesica verrà sottoposta, nonché di numerosi altri aspetti da cui dipende il successo della terapia, è condizionata dalle scelte metodologiche dell'operatore. L'impianto a lama responsabilizza l'implantologo sottraendolo a "condizionamenti culturali" involontariamente ma inevitabilmente secondari ai "condizionamenti dell'industria" che rischiano di trasformarlo in mero esecutore di tecniche chirurgiche codificate.
La regola protocollare accettata è che l'impianto a lama abbia almeno un rapporto radice corona pari ad 1/1 in profondità o, se la profondità è esigua, superiore ad 1/1 in estensione (figura 5). In figura 6 l'implantoprotesi ha un rapporto radice/corona ideale (2/1). Figure 7 e 8 documentano il posizionamento di un mono-impianto a lama in una cresta sottilissima in zona 24 e il controllo Rx dopo 4 anni.

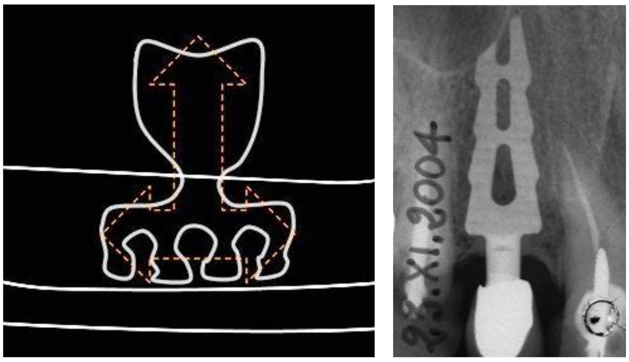


Figure 5 - 6

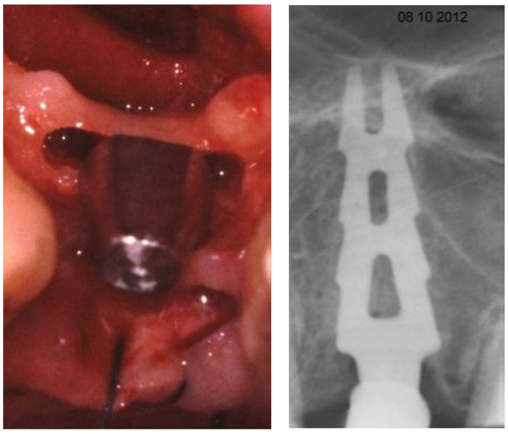


Figure 7 - 8

Scelta dell’impianto

Come per ogni altro impianto, la scelta di inserire un impianto a lama deve essere effettuata sulla base dell’idoneità a risolvere la particolare situazione anatomica in esame.

Le creste ossee contratte nella dimensione linguo-vestibolare sono particolarmente adatte ad essere trattate con questo tipo di impianto, che viene collocato tra due corticali strettamente addossate che gli conferiscono stabilità immediata, aumentata ancor di più se corroborata anche dal contatto con una terza corticale in profondità (fig.9-11).

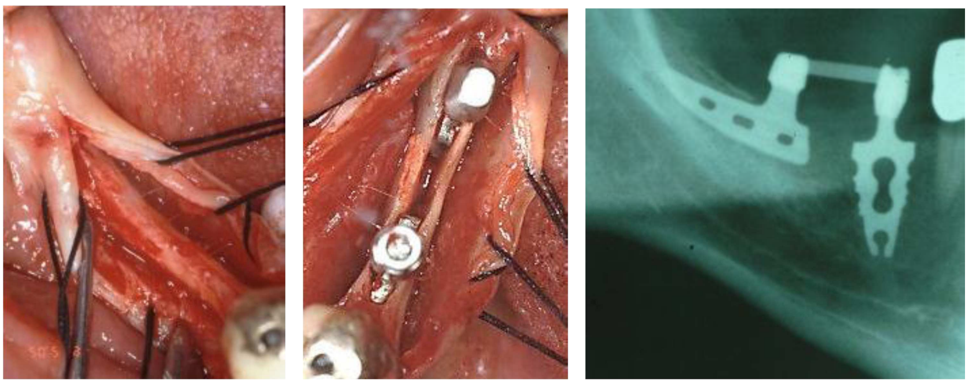


Figure 9 - 11

Lo studio del caso va fatto con attenzione. Infatti, nel caso in cui si possa prevedere che il moncone non abbia la possibilità di cadere al di sotto della cuspide di centrica, è consigliabile intraprendere la strada della rigenerazione ossea, in modo da modificare l'anatomia per rendere più fisiologico il rapporto con l'antagonista. Nei settori distali, la presenza di un contatto occlusale al di fuori dall'asse dell'impianto determina una torsione che può causare la frattura del moncone, che non va imputata all'impianto, ma all'errata pianificazione terapeutica (fig. 12).

Figura 12

L'impianto a lama può essere la prima scelta anche in situazioni in cui la cresta sia trattabile anche con impianti a vite. Ad esempio, nel settore anteriore superiore è l'impianto che più di ogni altro può essere posizionato in prossimità della corticale vestibolare, ottenendo di ridurre al minimo lo stress indotto dall'azione degli incisivi inferiori durante il movimento protrusivo (fig.13). A questo movimento si oppone in modo particolarmente efficace in ragione della sua conformazione piatta.

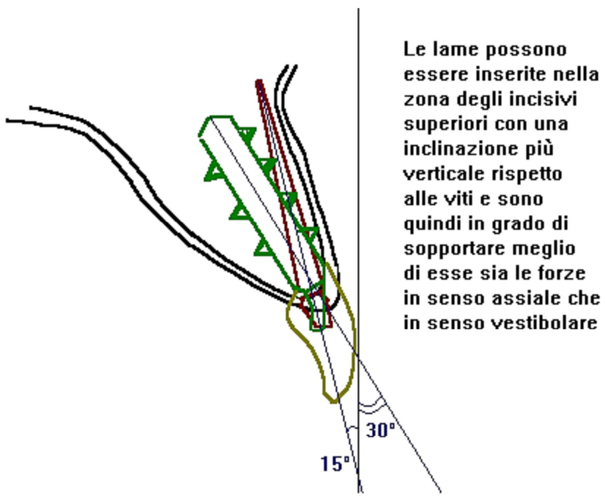


Figura 13

Tecnica Chirurgica

Le fasi preliminari della pianificazione del programma terapeutico prevedono in sintesi gli esami diagnostici e la valutazione di fattibilità del lavoro eseguita basandosi sulle valutazioni anamnestiche, gli esami ematologici, sull'esame

obiettivo e sulla visione delle radiografie e/o tomografie. Il paziente deve essere ampiamente informato sulle possibilità terapeutiche attuabili nel suo caso, in modo che possa coglierne vantaggi e svantaggi. In questo modo lo si rende maggiormente conscio del fatto che l'opzione di utilizzare un impianto a lama viene selezionata non per scelta preconcetta di un particolare tipo di impianto, ma per l'idoneità terapeutica di un presidio terapeutico adatto alla situazione in esame.
L'anestesia consigliata è la locale, eseguita utilizzando, se non vi sono contro-indicazioni, anestetico con vasocostrittore. L'incisione va fatta, come per ogni impianto emergente o semi-emergente, a centro cresta, preoccupandosi già in questa fase di rispettare le adeguate dimensioni di gengiva aderente che dovranno circondare il punto di sbocco del moncone protesico. Per decidere con precisione la posizione del moncone, che dovrà cadere al di sotto del punto di scarico delle forze originanti dalla funzione (es.: cuspide di centrica in un molare inferiore), può essere utile aiutarsi con una dima chirurgica (fig. 14).
Eseguita l'incisione, si procede a scollare il mucoperiostio con uno scollaperiostio. Nel caso in cui la cresta sia molto sottile, è conveniente scollare il minimo indispensabile, in modo da non sottrarre irrorazione all'osso.
Utilizzando una fresa in metallo multilame del calibro di 0,9 mm. montata su turbotrapano (fig.15), si procede ora ad eseguire dei forellini sulla superficie della cresta (fig. 16), che serviranno da guida per eseguire la breccia chirurgica. Sotto adeguato raffreddamento non vi è pericolo di surriscaldare dell'osso né lavorando in superficie, né in profondità. Frese analoghe montate sugli stessi trapani sono usate dai chirurghi maxillo-facciali per lavorare sull'osso dei mascellari. In alternativa al turbo-trapano, si può usare il manipolo contrangolo ad alta velocità (anello rosso), sempre sotto adeguato raffreddamento. È anche possibile l'uso del bisturi piezo-elettrico.
Le dimensioni della breccia devono essere calcolate in senso mesio-distale in base alle dimensioni della lama che, analizzando l'anatomia e le radiografie, si è deciso di inserire. E' di norma consigliabile eseguire una breccia ossea leggermente sotto-dimensionata, in modo che, dopo l'inserimento a percussione (press-fit), l'impianto abbia maggior stabilità immediata. La breccia deve essere disegnata con un lento movimento di rotazione del polso, seguendo in senso longitudinale l'andamento della cresta. La profondità tenuta nella prima fresatura deve essere tale da mantenersi ad una distanza di sicurezza dalle strutture anatomiche profonde.
In alternativa alla tecnica di fresatura sopra descritta, si può utilizzare una ruota apposita montata su manipolo contrangolo.
Eseguita la breccia in senso mesio-distale, si possono adottare diverse metodiche per stabilire la profondità a cui dovrà essere inserito l'impianto, aspetto che va attentamente calcolato prima della sua collocazione definitiva, in modo da attuare le eventuali modifiche utili ad adattarlo all'osso compatto presente in profondità.
La spalla dell'impianto a lama dovrà infatti essere almeno di 2 mm. più profonda della corticale superficiale (cfr. caso clinico di figure 16-18).

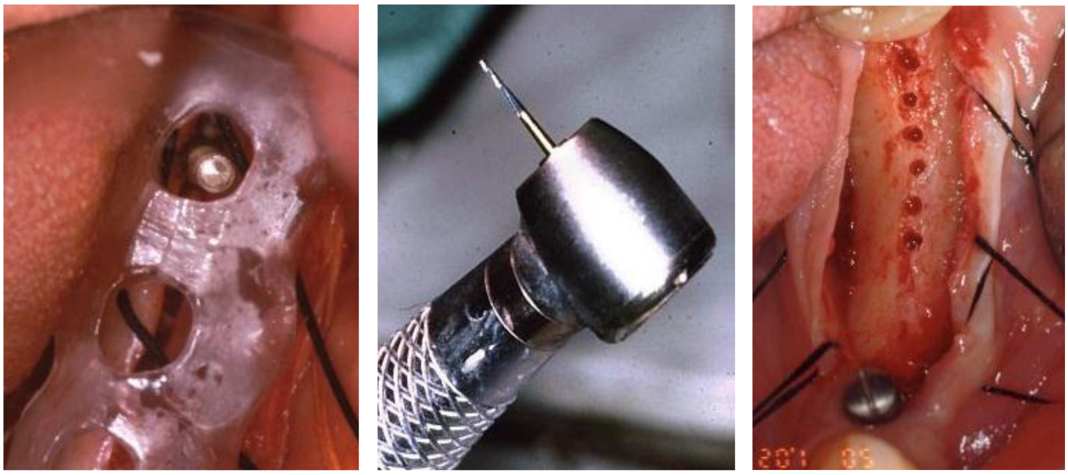


Figure 14 - 16

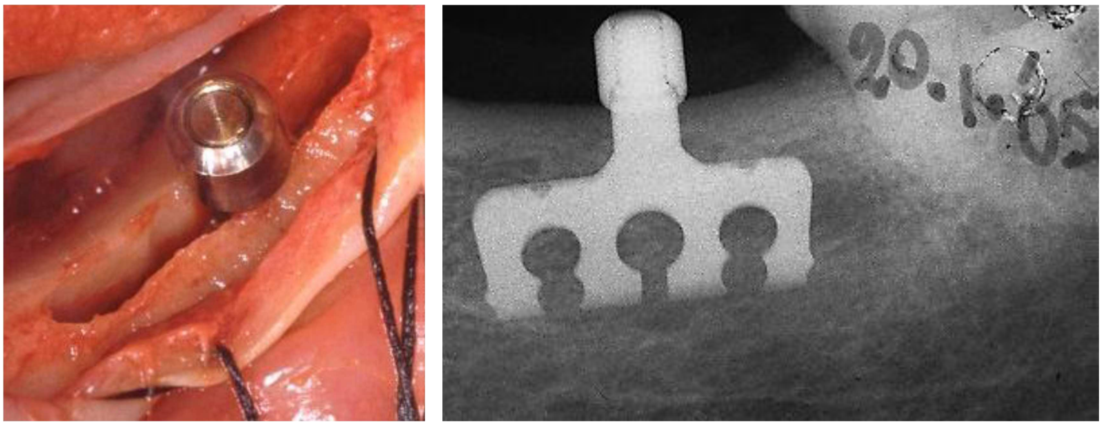


Figure 17 - 18

Un metodo utile a prendere la misura consiste nell'inserire parzialmente l'impianto nella breccia ed eseguire una radiografia per calcolare quanto manca alla sua collocazione definitiva. Figura 19 è la radiografia endorale eseguita durante l'intervento di inserzione di un impianto a lama in zona 36, prima di attuare le modifiche di forma necessarie, assestare l'impianto con alcuni colpetti di martello e constatarne il corretto posizionamento (figure 20-21).

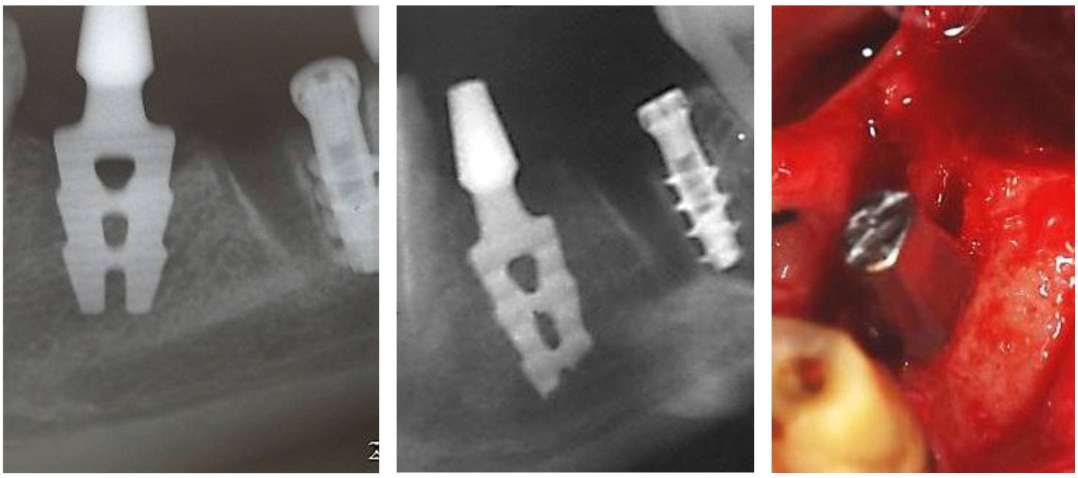


Figure 19 – 21

Un secondo metodo per prendere la misura di profondità, molto preciso, è quello di inserire uno o più impianti ad ago (figure 22 e 23) o dei “Torpan” (fig. 24, cfr. tecnica di figg. 46-49), od uno scalpello (fig. 25-26), fare una radiografia e misurare la profondità di immersione di questi strumenti nel tessuto osseo. Lo scalpello di figure 25-26 è stato inserito tra la corticale del seno mascellare e quella del palato, secondo lo schema di figura 27. In figura 28 è visibile la radiografia della lama rimodellata ed inserita in questo contesto anatomico dopo 10 anni di funzione.

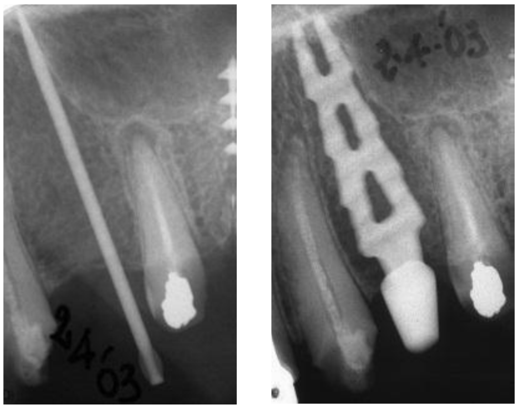


Figure 22 - 23

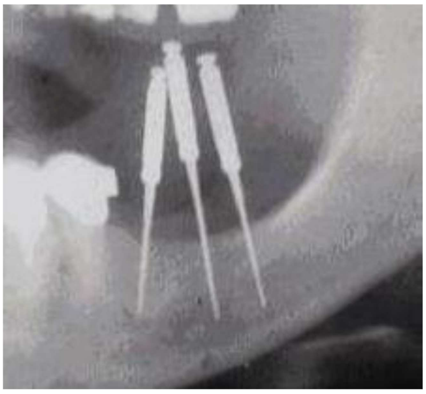


Figura 24

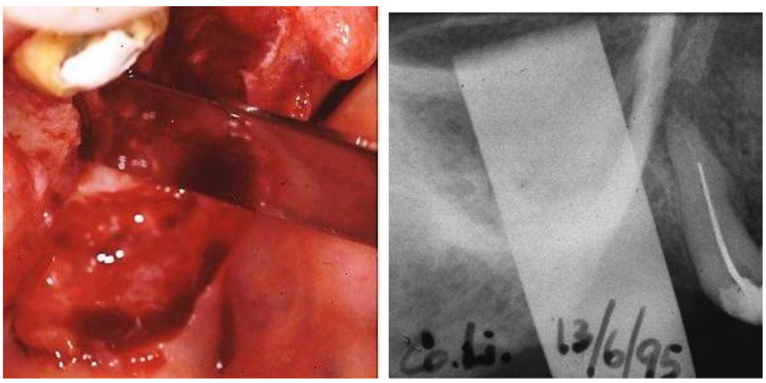


Figure 25 – 26

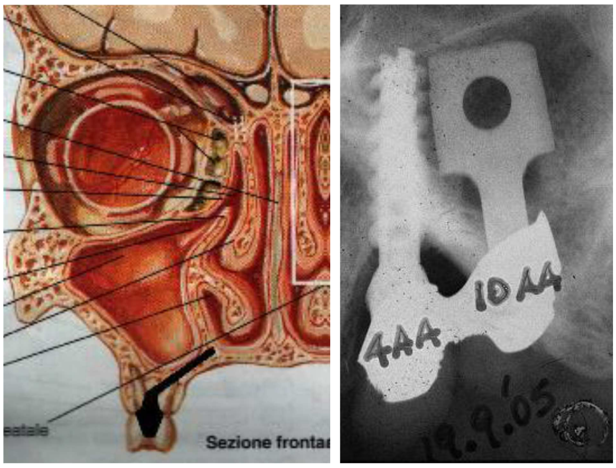


Figure 27 – 28

La misurazione corretta dell’area di immersione nel tessuto osseo è la principale condizione utile a posizionare l’impianto a lama in modo congruo. Alla profondità ossea desunta con precisione analizzando le radiografie sopra descritte, devono essere sottratti almeno due millimetri, in modo che la spalla dell’impianto sia collocata al di sotto della corticale ossea. E’ meglio eccedere che peccare in difetto, perché è possibile che l’impianto a lama si arresti ad una profondità leggermente inferiore rispetto agli strumenti di misurazione.

La breccia ossea deve essere disegnata in modo da avere la certezza che l’impianto possa ripetere la medesima strada tracciata con le frese. Questo è particolarmente importante in quelle situazioni in cui vi siano addensamenti ossei in profondità che impediscono all’impianto di progredire con l’ausilio della sola percussione. Se il tessuto osseo è particolarmente rarefatto, può essere sufficiente tracciare la sola breccia superficiale ed assestare l’impianto in profondità rompendo le trabecole ossee con la sola percussione. A questo punto si confrontano con l’impianto a lama le dimensioni della breccia e si eseguono le eventuali modifiche utili ad adattarlo alla perfezione all’anatomia ossea profonda. In figure 29-31 si può osservare come l’impianto a lama sia stato modificato seguendo le indicazioni tratte dalla radiografia riducendo la profondità della parte distale e le indicazioni derivate dall’esame dell’anatomia ossea visibile curvandolo in modo da adattarlo al decorso curvilineo della cresta ossea.

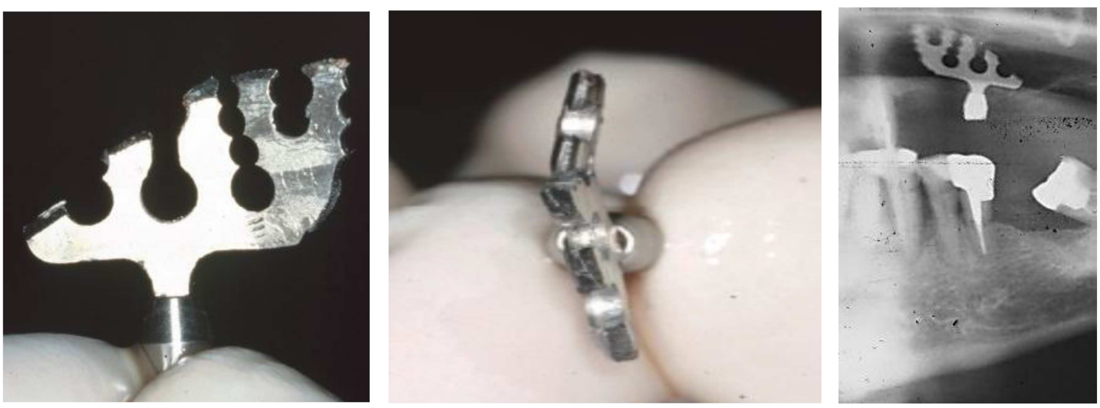


Figure 29 - 31

Nel caso in cui il moncone dell’impianto non sia parallelo, è possibile adattarlo meccanicamente prima del posizionamento in sede dell’impianto, risolvendo subito i problemi protesici che ne deriverebbero. In figure 32-34 è visibile un impianto a lama “parallelizzato” ed inserito in zona 35.

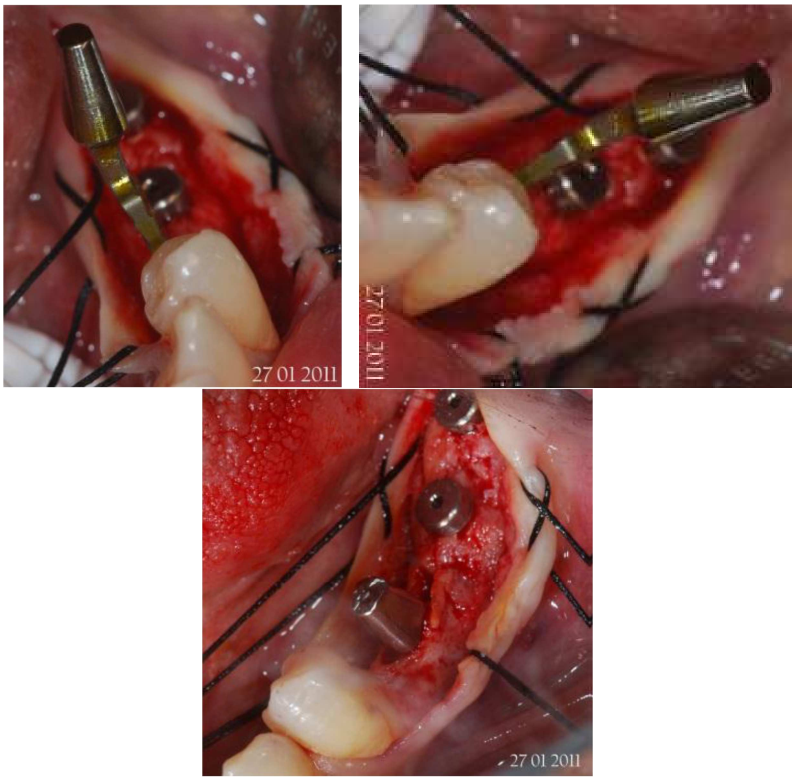


Figure 32 - 34

Le figure 34-35 illustrano l’aspetto delle mucose attorno al moncone dell’impianto e la protesi fissa definitiva.

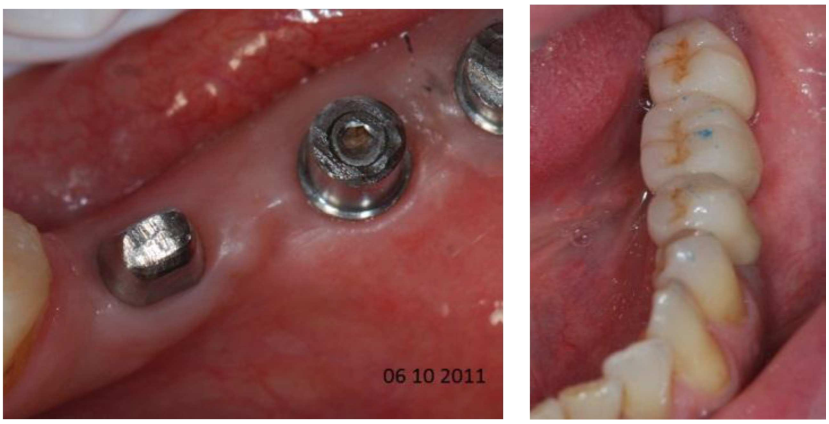


Figure 35 - 36

Il collocamento in sede dell’impianto viene effettuato utilizzando una pinza per inserirlo nella breccia chirurgica, per poi proseguire nell'assestarlo martellando con delicatezza su di un percussore posizionato sulla spalla dell’impianto (Fig. 37).

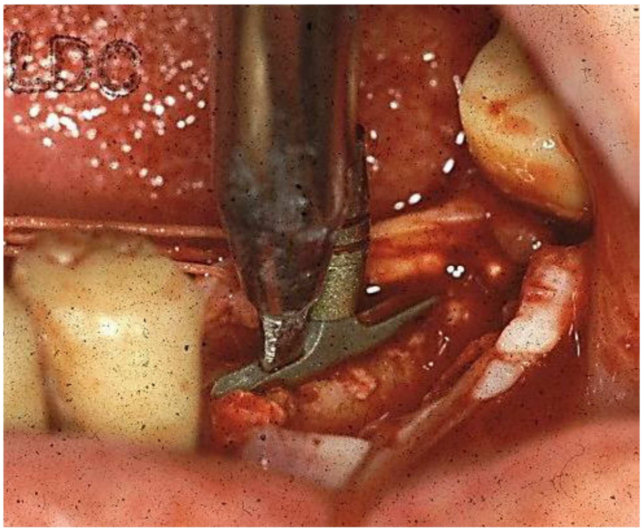


Figura 37

Le suture devono contornare il moncone uscente e rispettare l'anatomia delle papille eventualmente presenti. Accertatosi che il moncone non vada soggetto a traumi da parte di denti, strutture protesiche o tessuti molli, l'operatore può ora congedare il paziente prescrivendogli una adeguata copertura antibiotica.
Riassumendo, si riconoscono quindi 9 fasi chirurgiche:

a. Incisione
b. Scollamento
c. Micro-osteotomie (fori seriali corticali)
d. Breccia
e. Misura
f. Modifiche (se necessarie)
g. Parallelizzazione (se necessaria)
h. Posizionamento
i. Sutura

Decorso post-operatorio

Nonostante la tecnica di inserzione in "press-fit" di questi impianti possa lasciar presumere che vi siano particolari sequele post-chirurgiche, il decorso post-operatorio è di norma tranquillo, accompagnato talora da gonfiore, con normale sintomatologia post-operatoria. La prescrizione di cinque giorni di terapia antibiotica è una misura prudenziale che protegge il paziente dagli effetti dell'infezione batterica legata all'insulto chirurgico.

Protesi

L'impianto a lama ha uno spessore di circa 1,5 mm. La condizione ideale si ottiene quando la base del moncone penetra la cresta ossea, andando a chiuderne l'accesso. In questo modo l'ampiezza biologica va a collocarsi attorno al moncone e non al di sotto di esso, creando i presupposti per un profilo di emergenza dai tessuti molli adatto alle dimensioni del dente di protesi (figure 33 e 34).
Se invece l'impianto non scende alla profondità ideale e quindi il collo del moncone si trova visibile sopra la cresta ossea, l'ampiezza biologica andrà a

circondarlo e la base del moncone sarà “seduta”, con andamento obliquo, sui tessuti molli, creando un sovra-contorno.
È comunque preferibile il sovra-contorno del moncone, che è in titanio, liscio e privo di soluzioni di continuità, rispetto al sovra-contorno protesico (fig. 38).

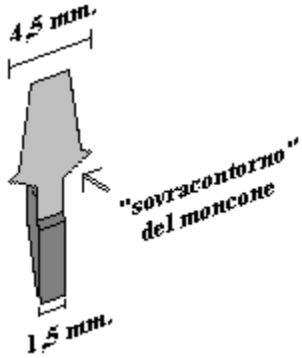


Figura 38

Nonostante queste considerazioni legate all’esiguo spessore dell’impianto, non c’è una differenza apprezzabile tra il risultato protesico ottenibile con un impianto a lama e quello ottenibile con un impianto a vite (fig.39: aspetto dei monconi di un impianto a vite sommersa, a sinistra, e di un impianto a lama, a destra).

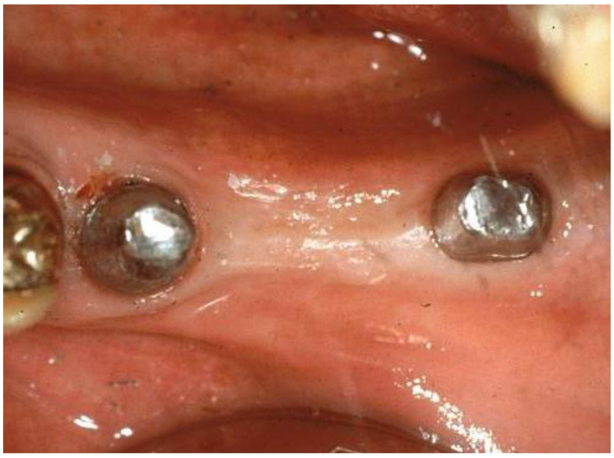


Figura 39

Nel caso in cui invece il moncone abbia uno spessore sottile, il sovra-contorno protesico che ne consegue non inficia la durata dell’impianto-protesi, ma ne rende meno igienica e fisiologica l’accettazione da parte dei tessuti molli.

Carico Immediato

L’impianto a lama può essere caricato immediatamente qualora non vi siano forze che agiscono sulla protesi subito applicata che ne possano pregiudicare la stabilità. La valutazione di opportunità è dunque legata alla capacità dell’operatore di distinguere le situazioni di maggiore o minore idoneità e dalla conoscenza della funzione occlusale, dalla quale dipende il successo della terapia. Le Figure 40-45 illustrano un caso di carico immediato di un impianto a lama di Pasqualini e di un impianto a vite emergente inseriti nel settore distale inferiore 44-47. Sono visibili il provvisorio immediato (fig. 42) e le registrazioni occlusali in occlusione statica e dinamica, che devono essere meticolosamente seguite sia nella fase della protesizzazione provvisoria che in quella della protesizzazione definitiva.

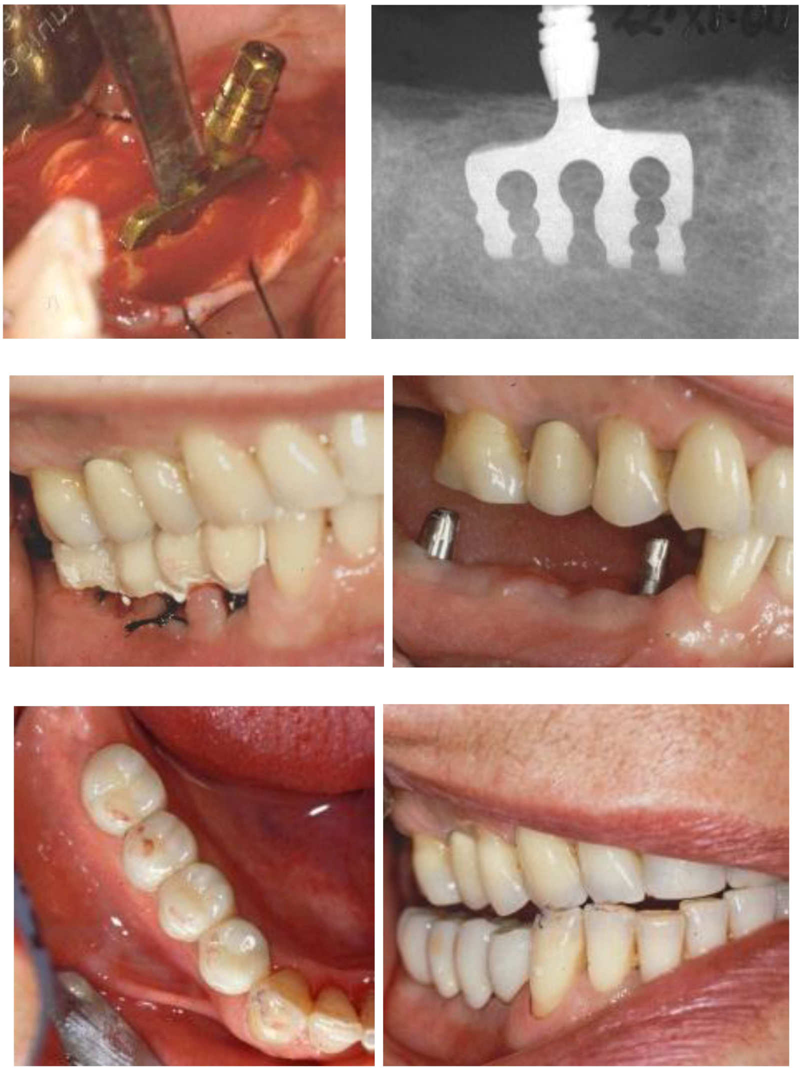


Figure 40 - 45

Nuove impostazioni chirurgiche

La validità della tecnica di inserzione dell'impianto a lama proposta da Linkow è universalmente accettata e confermata da inequivocabili risultati a distanza di tempo. Nel corso degli anni sono state proposte da alcuni autori delle varianti della tecnica originale le quali risultano particolarmente utili in alcune situazioni specifiche. Le modalità sotto descritte sono volte a migliorare il trattamento del settore distale inferiore, particolarmente delicato con qualsiasi tipo di impianto.

a. Lama Bicorticale Distale

Presentata più volte in ambito congressuale da oltre 15 anni e pubblicata dal suo ideatore(177), la tecnica prevede una particolare modalità di attuazione della breccia ossea, la quale viene tracciata utilizzando alcuni "allarga-canali" da contrangolo, i quali vengono inseriti in profondità fino a raggiungere la corticale ossea profonda a livello della linea milo-ioidea (fig.24 e 46). Misurata con precisione la profondità di lavoro e riprodotta sull'impianto, la lama viene fatta penetrare a percussione rompendo i setti ossei presenti tra un foro e l'altro fino a quando non giunge alla profondità prevista. Si ottiene così un impianto estremamente stabile già subito dopo il suo posizionamento, in grado di sostenere carichi importanti anche in condizioni di sfavorevole rapporto radice/corona (figg.46-49).

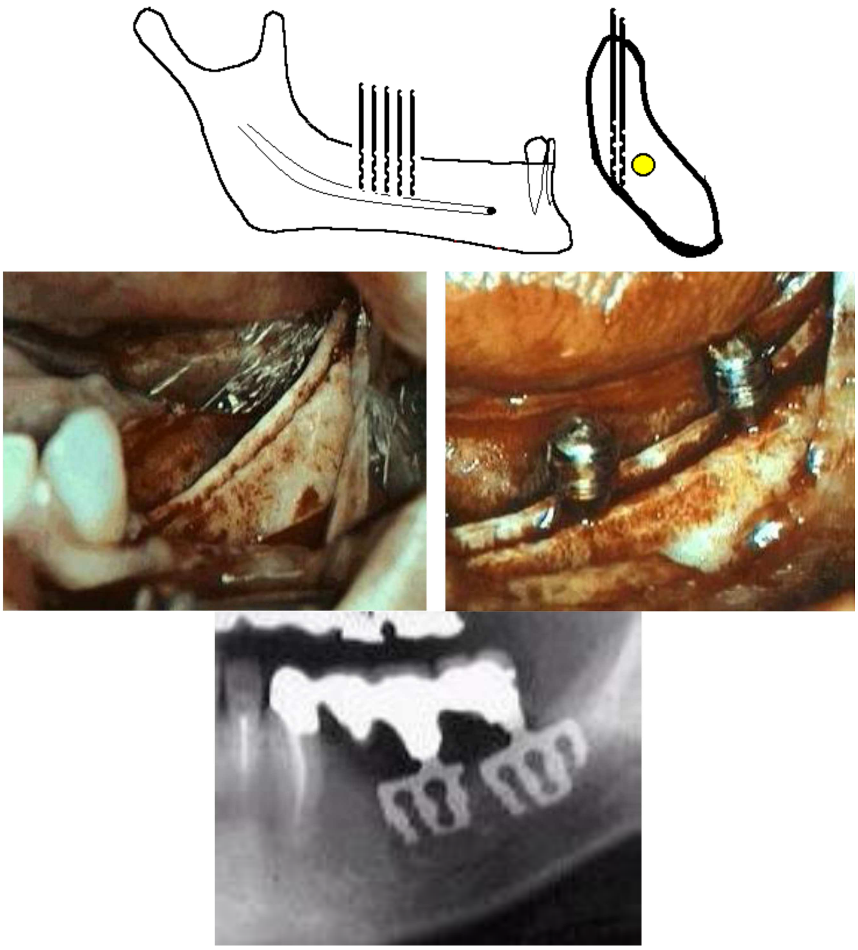


Figure 46 - 49

b. . *Estensione Distale Endossea (E.D.E.)*

E' stata pubblicata dal suo ideatore nel 2001 dopo 8 anni di esperienza clinica(176,180). La tecnica prevede che si tracci la breccia ossea mesialmente rispetto alla sede di collocazione definitiva della lama, imponendo all'impianto una rotazione ed una progressione in senso distale, fino a quando il moncone non raggiunge il bordo distale della breccia (fig.50).

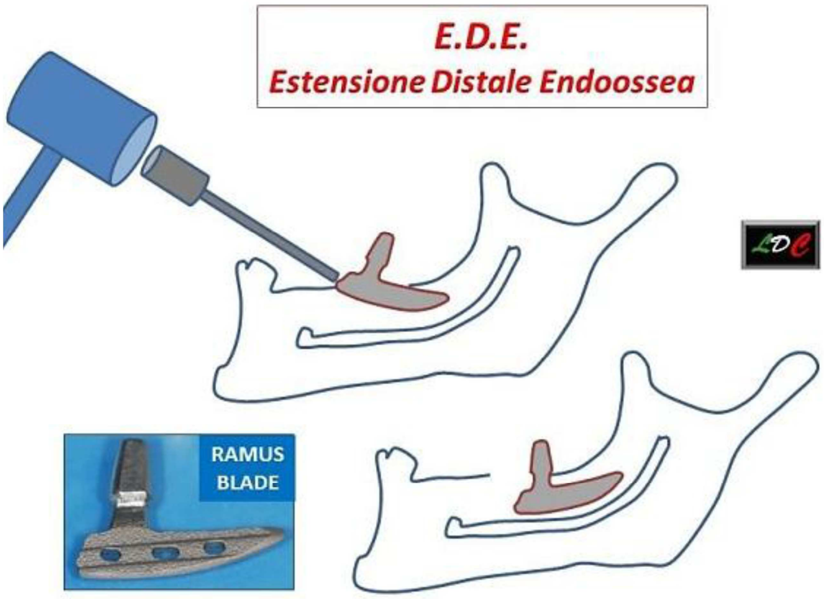


Figura 50

In questo modo quasi tutto l'impianto viene ad essere collocato al di sotto di tessuto osseo e tessuti molli intatti. La presenza della corticale ossea superficiale si può apprezzare all'esame radiografico (fig.51).

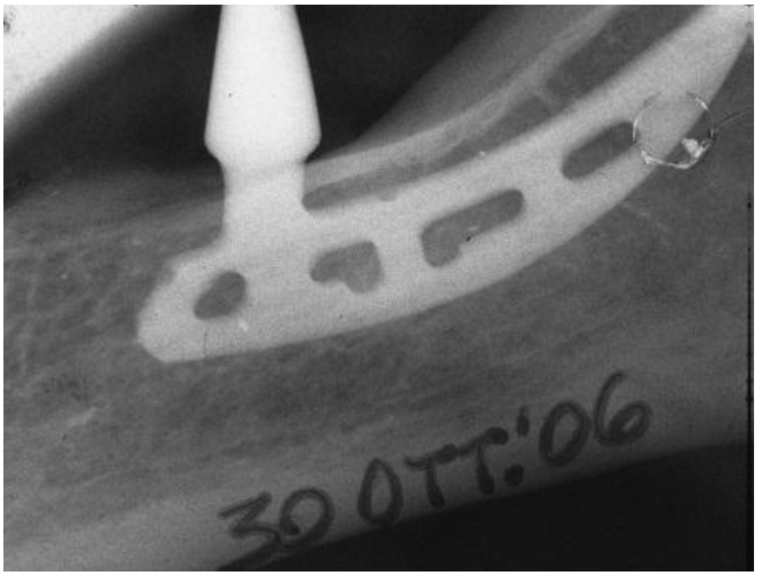


Figura 51

Questa soluzione tecnica può essere utilizzata per realizzare i pilastri posteriori inferiori di una protesi fissa completa inferiore. In figure 52-54 è documentato il caso di una protesi fissa “circolare” inferiore con due impianti a lama E.D.E. alle estremità. Figura 52 documenta l’impianto a lama posizionato in zona 47 nel 1999, figura 53 l’aspetto dei tessuti molli attorno all’impianto a lama e alla vite adiacente alcuni mesi dopo, figura 54 è l’ortopantomografia eseguita 9 anni dopo.

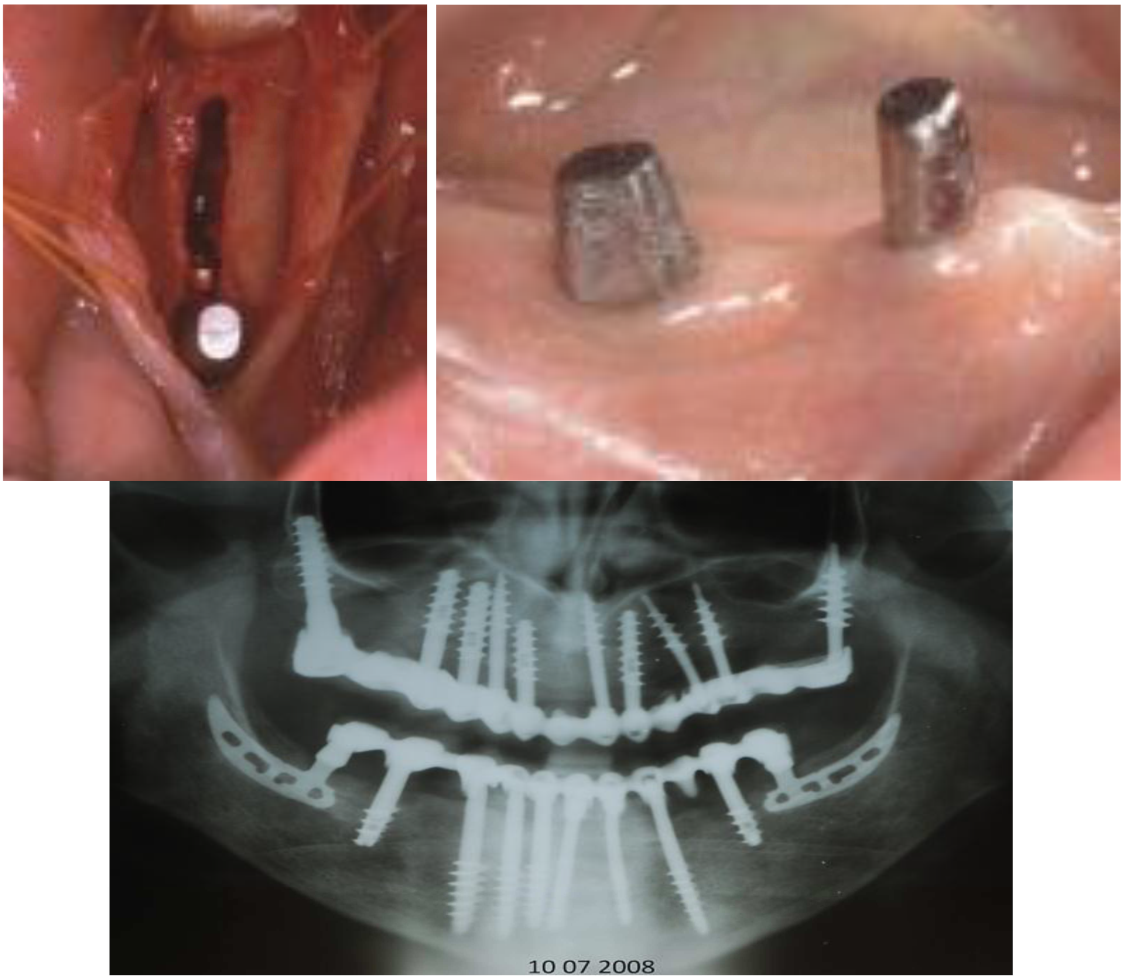
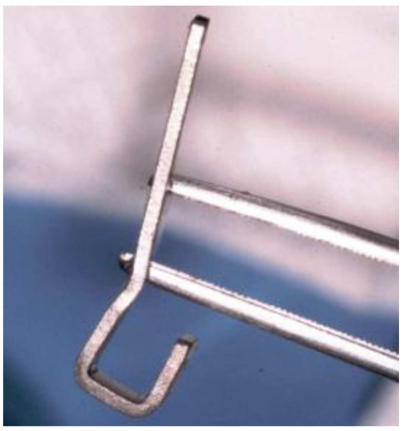
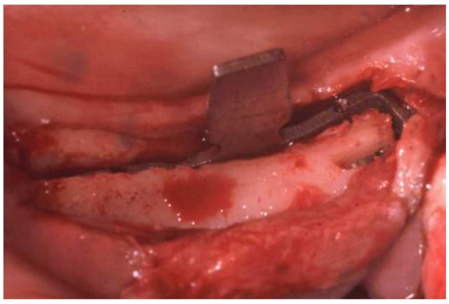


Figure 52-54

Gli impianti di Oleg Surov

Il dott. Oleg Surov ha proposto attorno agli anni 2000 una forma d’impianto particolare, con altezza di soli 4 mm. e forma a L, utile a trattare le atrofie marcate dei mascellari posteriori. È proprio la parte curva dell’impianto a conferirgli particolare stabilità. Il corpo dell’impianto può essere modificato con una pinza tipo “tre becchi” per assecondare la forma della cresta ossea (figure 55-60).





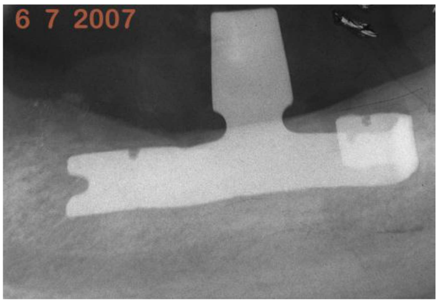


Figure 55-59

Predicibilità dell'efficacia clinica degli impianti a lama

Numerose sono le pubblicazioni che attestano la possibilità di questi impianti di durare funzionalmente e fisiologicamente nel tempo (vedi ad esempio voci bibliografiche 49, 87, 97, 125, 130, 153, 170, 182, 183, 186, 188, 189, 192 e 193) e le conferme istologiche della loro osteo-inclusione senza interposizione di tessuto connettivo tra osso ed impianto (es. istologia di fig.60).

Figura 60

Se seguite con scrupolo anche nel periodo che segue la protesizzazione, con visite di controllo "on demand" e semestrali volte a tenere sempre sotto controllo l'equilibrio occlusale e l'igiene orale del paziente, le lame non temono confronti con gli altri impianti. Di un impianto a lama di Pasqualini posizionato in zona 21 è stata pubblicata nel 2010 l'eccezionale documentazione fotografica e radiografica del momento dell'inserzione dell'impianto, avvenuta nel 1972, e del controllo eseguito nel 2010, 38 anni dopo (186). Figure 61 e 62 documentano il controllo clinico e radiografico a 40 anni.

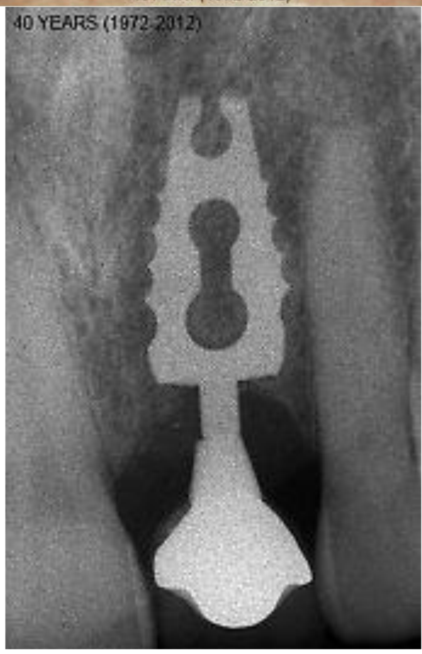


Figure 61 e 62

In particolare si evidenzia che recentemente (192-193) la FDI, Organismo americano super-odontoiatrico che protegge e promuove la salute pubblica, riaffermano la validità clinica degli impianti a lama, ricollocandoli in Classe di rischio assicurativo pari a tutti gli altri.

NUOVE MORFOLOGIE e TRATTAMENTI DI SUPERFICIE

DEGLI IMPIANTI A LAMA

Bibliografia di Riferimento

1. Linkow L.I.: Clinical Evaluation of the Various Designed Endosseous Implants - J.Oral Implant Transplant Surg. Vol.12, pp.35-46, 1966
2. Linkow L.I.: The Endosseous Blade: a new Dimension in Oral Implantology - Swiss Journal of Oral Impl. Vol. V, pagg.2-11, 1968
3. Linkow L.I.: The Blade Vent - A New Dimension in Endoddeous Implants - Dent.Concepts Vol.11, p.13-18, 1968
4. Linkow L.I.: Mouth Reconstruction for the Edentulous Maxilla Using Endosseous Blades - Dent.Concepts Vol.12 (1), pp.3-21, 1969
5. Viscido AJ.: The blade vents-endosseous implants - J Dist Columbia Dent Soc. 44(4):107-9. 1969 Jul.
6. Baumhammers A, Baumhammers I: Blade-vent implants - Pa Dent J (Harrisb). 37(8):273-82, 1970 Nov.
7. Linkow L.I.: Endosseous Blade-Vent Implants: A Two Years Report - J.Prosth.Dent.Vol.23, pp.441-449,1970
8. Grafelmann Hans L., Brandt Hans H.: Erfahrungen mit enossalen Extensions-Implantaten nach Linkow - Die Quintessenz 11/21, 1970
9. Avigdor AB: Implants with the vent-blade - ADM.;28(4):299-306, 1971
10. Trudeau PJ.: Endosseous blade implants - J Dent Que. ;8(6):7-9, Jun.1971
11. Morphree FA.: Why blade implants? - J Miss Dent Assoc. 27(2):10-2. 1971
12. Beck PM.: Versatility of endosseous blade implants - J Ont Dent Assoc. 48(4):110-2, 1971 Apr
13. Ricciardi A.: Fixed prosthesis employing endosseous blade implants - Dent Dig. ;77(4):198-205, 1971 Apr
14. Linkow L.I.: Latest Developments in Blade Implantology - Greater St.Louis Dental Society Vol.42, N°11,pp.261-264, 1971
15. Linkow L.I.: The Ideal Implant Support: The Clet-Blade Implant. Report after 3 Years - Promot.Dent. 34-39, 1971
16. Halpert LF.: A clinical discussion for successful endosseous blade vent implants. - J Baltimore Coll Dent Surg. 1971 Dec;26(2):72-80. 1971
17. Varn MH 3rd.: Endosseous blade implants.- S C Dent J. 1971 Oct;29(10):16-20. 1971
18. Cranin AN, Dennison TA.: Construction techniques for blade and anchor implants. - J Am Dent Assoc. 1971 Oct;83(4):833-9. 1971
19. Glazebrook P.: An approach to blade implants. - Probe (Lond). 1971 Sep;13(3):77-80. 1971
20. Allenby RW.: A G.P. observes blade-vent implants. - J Conn State Dent Assoc. 1971 Jul;45(3):172-8. 1971
21. Muratori G.: L'impianto a "lama su misura" - Dental Cadmos, Giugno 1971
22. Pasqualini U.: Corso di implantologia a lama - Clinica Odontoiatrica Università di Zurigo, 7-9 Novembre 1971
23. Smithloff M, Fritz ME.: The use of blade implants in a selected population of partially edentulous patients; a preliminary report. - J Periodontol. 1972 Dec;43(12):723-36. 1972
24. Linkow LI.: An honest evaluation of blade type implants. - Bull. Hudson Cty Dent Soc. 1972 Mar;41(6):22-4. 1972
25. Babbush CA.: Endosseous blade-vent implants: a research review. - J Oral Surg. 1972 Mar;30(3):168-75. 1972
26. Viscido AJ.: Endosseous blade implants: technique for abutments in fixed prosthodontics. - Dent Dig. 1972 Feb;78(2):64-75. 1972
27. Muratori G.: Importance of conservative therapy in implantology. Multitype and blade implants "to measure" - Promot Dent. 1972;(16):8 passimc. French. 1972 11
28. Grafelmann Hans L.: Enossale Blattimplantate - Vortraege Bayerischer Zahnaerztetag - Carl Hanser Verlag, 1972
29. Linkow L.I.: An Honest Evaluation of Blade Type Implant - The Bullettin of The Hudson County Dental Society Vol.41 (6), pp.22-24, 1972

30. Pasqualini U.: Reperti istoanatomopatologici di sette impianti a lama post-mortem - Assoc.Ital.Imp.All., gennaio 1972
31. Pasqualini U.: Impianti Endoossei: La protezione dell'osteogenesi riparativa con la metodica del "moncone avvitato". Tecnica personale - Dental Cadmos N°8, 1972
32. Pasqualini U., Imperiali G.M.: Corso teorico-pratico sugli impianti di lame - Bari 23-25 giugno 1972
33. Babbush C.: Endosseous Blade-Vent Implants: A Research Review - Journal of Oral Implantology 3:261, 1973
34. Babbush CA.: Endosseous "blade vent" implants - Med Hyg (Geneve). 1973 Oct 10;31(73):1499-1502. 1973
35. Gershkoff A.: Subperiosteal and endosteal blade implants - J Prosthet Dent. 1973 Oct;30(4):611. 1973
36. Pileggi GF.: Endosseous blade implants for the G.P.: case report. - Dent Surv. 1973 Jul;49(7):24-6. 1973
37. Weiss CM, Judy KW, Chiarenza AR.: Precompacted, coined titanium endosteal blade implants. - Oral Implantol. 1973 Spring;3(4):237-60. 1973
38. Linkow L.I.: Macroscopic and Microscopic Studies of Endosteal Bladevent Implants (Six Months Dog Study) - Oral Implantology Vol.3 (4), Spring 1973
39. Ackermann R., Bader J., Bernkopf A., Ceffa G., Colognato G., Del Monaco F., Ferreol P., Guastamacchia C., Imperiali G., Morra Greco A., Muratori G., Pasqualini U., Piras E., Toffenetti F., Tramonte S.M.: Implantologia Oggi – Edizioni CADMOS 1974
40. Linkow Leonard I., Glassman Paul E., Asnis Saul T.: Makroskopische und Mikroskopische Untersuchungen enossale Blattimplantaten (sechsmonatige Tierexperimente) - Orale Implantologie DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 1/1974
41. Guaccio R.: Endosteal blade implants--abutments for routine as well as complicated restorations. - Oral Implantol. 5(1):110-9. 1974 Summer
42. Spatz S, Krongold S.: A technique for parallel insertion of multiple intraosseous blade implants - J Oral Surg. 1974 Jan;32(1):62-4. 1974
43. Caldwell CB.: "Almost parallel" blade implants. - Oral Implantol. 1974 Autumn;5(2):191-4. 1974
44. Giro CM.: Precautions in utilizing blade implants - Oral Implantol. 1974 Summer;5(1):104-9. 1974
45. Doms P.: The tissue response to endosteal blade implants--microradiographic and tetracycline marking. - I.Oral Implantol. 1974 Spring;4(4):470-4. 1974
46. Myska W.: Linkow-blade-vents in the office. Experience report of endosseous blade implants - Orale Implantol. 1974 Nov;1(2):53-92., 1974
47. Rosenthal RI.: A technique for using endosteal blade implants. - J Prosthet Dent. 1974 Jul;32(1):96-100. 1974
48. Meenagham M.A., Natiella J.R., Armitage J.E., Greene G.W., Lipani C.S.: The crypt surface of blade-vent implants in clinical failure: an electron microscopic study. - J Prosthet Dent. 1974 Jun;31(6):681-90. 1974
49. Koch WL.: Statistical evaluation of success and reasons for failure in 700 endosseous blade implants done in the office - Orale Implantol. 1974 Apr;1(1):105-38., 1974
50. Bobbio A, Nardini AD, Roccella AL.: Philosophy and advantages of blade vent endosseous implants - Rev Assoc Paul Cir Dent. 1974 Mar-Apr;28(2):69-72, 74, 77 passim. 1974
51. Viscido AJ.: Submerged functional predictive endosteal blade implants. - Oral Implantol. 1974 Autumn;5(2):195-209. 1974 12
52. Nixon JJ.: A secondary wedging technique for stabilized reimplantation of endosteal blade implants. - Oral Implantol. 1974 Summer;5(1):93-103.
53. Ricciardi A.: Fixed prostheses and blade implants - J N J Dent Assoc. 1974 Winter;45(2):24-7. 1974
54. Weiss Charles M., Judy Kenneth W.M., Chiarenza Angelo R.: Enossale Blattimplantate aus Forgeformten, gepraegtem Titan - DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 1/1974
55. Jacobs Hans G.: Knochenreaktionen im Tierversuch nach Eingliederung von enossalen Blattimplantaten - Orale Implantologie DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 1/1974
56. Brandt Hans H.: Die Blattimplantation - fuenf Jahre nach ihrer Einfuehrung in Deutschland - Orale Implantologie DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 2/1974

57. Myska Wenzel: Linkow-Blade-Vents in der Praxis - ein Erfahrungsbericht ueber enossale Blattimplantationen - Orale Implantologie DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 2/1974
58. Babbush Charles A., Staikoff Lawrence S.: Das Rasterelektronenmikroskop und das enossale Blattimplantat - Orale Implantologie DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 2/1974
59. Linkow L.I.: Bladevent Design Rationale - The Rhodesian J.of Dentistry N°3, July 1975
60. Muelemann H.R.: Zur Mikrostruktur der Implantatoberflaechen - Schweiz.Mschr.Zahneilkunde 85/97, 1975
61. Linkow L.I.: Blattimplantologie - Zahnarztliche Praxis Heft. Vol.16 (26), pp.356-359, 1975
62. Picton DC, Wills DJ.: The mobility of horizontally pinned teeth in monkeys and of endosseous blade implants.- Br Dent J. 1975 Dec 16;139(12):469-71. 1975
63. Jahn E, Censi C, Dahler C, Rahn BA. onnective tissue suspension in blade implantations. Preliminary report - SSO Schweiz Monatsschr Zahnheilkd. 1975 Nov;85(11):1143-5. 1975
64. Babbush CA.: Enossal blade implants - Zahnarztl Prax. 1975 Oct 17;26(20):456-9. 1975
65. Brinkmann E.: Management of the edentulous mandible with plate implants and prosthetic solution - Dtsch Zahnarztl Z. 1975 Jul;30(7):486-91. 1975
66. Svare CW, LaVelle WE, DeLong PE, Kent J, Weber D.: Coated versus non-Proplast-coated endosseous blade-vent dental implants. - Oral Surg Oral Med Oral Pathol. 1975 Jul;40(1):2-7. 1975
67. Munir ZA, Richards LW, Prado ME.: Photoelastic studies of the stress distributions on blade-type endosteal dental implants. - Oral Implantol. 1975 Winter;5(3):296-332. 1975
68. Babbush CA.: Endosteal blade-vent implants. - Quintessence Int. 1976 Jun;7(6):9-15. 1976
69. Goldstein MA.: Endosteal blade implants--a post mortem evaluation. - Oral Health. 1976 Nov;66(11):41-3. 1976
70. Fagan MJ Jr, Fagan MJ 3rd.: Endosseous blade implants support an overlay clip-bar prosthesis. - Implantologist. 1976
71. Goldstein MA, Judy KW, Weiss CM, Chiarenza A, Phillips : Tissue response to titanium endosteal blade implants. - Implantologist. 1976 Oct;1(1):43-53. 1976
72. Strassl H.: Use of blade implants of titanium in the jaws - Osterr Z Stomatol. 1976 Sep;73(9):335-6. 1976
73. Barker BC.: Anatomical considerations when using endodontic endosseous pins and blade implants.- Aust Dent J. 1976 Aug;21(4):299-307. 1976
74. Pugh J, Weiss C, Weiss F, Malkin D.: Design and biomechanical evaluation of a cementable endosteal blade implant.- J Biomed Mater Res. 1976 Jul;10(4):571-81. 1976
75. Long term observations on endosseous blade implants. A 5 year report - Osterr Dent Z. 1976 Feb;28(2):21-50., 1976
76. Smithloff M, Fritz ME.: The use of blade implants in a selected population of partially edentulous adults. A five-year report. - J Periodontol. 1976 Jan;47(1):19-24. 1976 13
77. Schroeder A., Pohler O., Sutter F.: Gewebsreaktion auf ein Titan-Hohlzylinderimplantat mit Titan-Spritzsschichtoberflaeche - Schweiz.Mschr.Zahnheilk.86:713, 1976
78. Mueller Gerold: Blattimplantate zur Stabilisierung eines parodontal insuffizienten anterioren Restgebisses im Unterkiefer - Orale Implantologie DGZI (Deutsche Gesellschaft fuer Zahnaerztliche Implantologie) 4/1976
79. Jacobs HG, Kobes L.: Endosseous blade implantations in the edentulous patient and the prosthetic superstructure - Dtsch Zahnarztl Z. 1977 Aug;32(8):606-10. 1977
80. Muratori G.: Basis for durable implants with prostheses with "Blade screws" - Dent Cadmos. 1977 Jun;45(6):17-21. 1977
81. Reed GM.: An "implant bender" for precision alteration of endosteal blade implants.- Implantologist. 1977 Mar;1(2):116-21. No abstract available. 1977
82. Yasinovsky M.: The use of blade implants as an adjunct to complete oral rehabilitation. - Implantologist. 1977 Mar;1(2):80-3. 1977
83. Chiarenza A.: Cathodic stimulation of alveolar bone around endosteal blade implants. - Implantologist. 1977 Mar;1(2):90-7. 1977
84. Bloch VP.: Five year observation of endosteal blade implants. - J N J Dent Assoc. 1977 Winter;48(2):27-31. 1977
85. Rubinoff CH, Baumhammers A, Ceravolo FJ.: An in vitro support analysis of solid, multi-vented and grooved endosseous blade implants. - J Oral Implantol. 1977;7(2):210-6. 1977

86. Schneider P, Makek M, Feigel A, Ochsenbein H, Lutz F, Muhlemann HR.: Histologic studies of endosseous blade-vent implants of a human mandible: report of an autopsy case. - J Oral Implantol. 1978;8(1):31-40. 1978
87. Cranin AN, Rabkin MF, Garfinkel L.: Statistical evaluation of 952 endosseous implants - Riv Ital Stomatol. 1978 Jan;47(1):53-61. 1978
88. Levine M, Laracuente JM.: Endosteal blade implants: an overview of current literature. - Ohio Dent J. 1978 Sep;52(9):18-22.
89. Barker BC.: Anatomical considerations when using endodontic endosseous pins and blade implants. - Implantologist. 1978 Aug;1(3):87-101.
90. Baratieri A, Sacchi A, Miani C.: Bone changes incident to blade-vent implants. - J Biol Buccale. 1978 Jun;6(2):121-8.
91. Mazzocco DM, Ceravolo FJ, Baumhammers A, Vaughn RL, Molinari JA, Verbin R, Ruskin PF.: Quantitation of retention of endosseous dental blade implants in dogs.- J Periodontol. 1978 Jan;49(1):39-42. 1978
92. Farah JW, Craig RG, Yapp RA.: Stress distribution caused by blade type dental implants. - Implantologist. 1979 Mar;1(4):82-5.
93. Sarnachiaro O, Gargantini LC.: Biological tissue reaction to immediate post-extraction blade implants. - Implantologist. 1979 Mar;1(4):44-51.
94. Vajda TT, Fung JY.: Comparative photoelastic stress analysis of four blade-type endosteal implants. - J Oral Implantol. 1979;8(2):257-69.
95. Babbush CA, Banks BA, Weigand AJ.: Endosteal blade-vent implants modified by ion beam sputtering techniques. - J Oral Implantol. 1979;8(4):509-33.
96. Porter CB Jr, Freidline CW.: Use of Stryker saw for preparation of the intraosseous channel for endosteal blade implants. - J Oral Implantol. 1980;9(2):187-9.
97. Ricciardi A.: Nine years with Pasqualini implants--a full mandibular arch. - J Oral Implantol. 1980;9(1):83-94.
98. Judy KW, Mahler MM.: Proper selection of endosteal blade implants. - N Y J Dent. 1980 Nov;50(9):328-31.
99. Zuckerman J.: Endosseous blade implants: how and why. - Dent Surv. 1980 Aug;56(8):42-4. 14
100. Babbush CA.: Endosteal blade-vent implants. - Dent Clin North Am. 1980 Jul;24(3):421-40.
101. Strassl H.: Use of endosseous blade implants in narrow anterior spaces-Zahnarztl Prax.1980 Jan 11;31(1):6-7.
102. Linkow L.I., Kohen P.A.: Benefits and Risks of the Endosteal Blade Implant (Harvard Conference, June 1978) - Oral Implantology Vol.IX N°1,pp.9-44, 1980
103. Linkow L.I., Kohen P.A.: Evaluation of 564 Implant Patients (1540) Implants - "Implantologist" The International Journal of Oral Implantology Vol.1,N°4, pp.35-37 1979-1980
104. Linkow L.I.: Les Implantes Lames: Réalisation et Progrès - Implantologie Orale N° 1 pp.12-21, 1980
105. Knofler W, Hampel H, Bethmann W.: Problems in dental implantation. First animal studies on coated titanium blade implants: light optical and scanning electron microscopic evaluation - Stomatol DDR. 1981 Oct;31(10):729-35. German. No abstract available.
106. Knofler W, Hampel H, Bethmann W.Dental implantation problems. Initial animal experiment studies of coated titanium blade implants: methodological procedure and the clinical results - Stomatol DDR. 1981 Mar;31(3):185-9.
107. Ehrl PA, Reuther J, Frenkel G.: Al2O3-ceramic as material for dental implants: experimental and clinical study for the development of screw- and extension-implants.- Int J Oral Surg. 1981;10(Suppl 1):93-8.
108. Kent JN, Cook SD, Weinstein AM, Klawitter JJ.: A clinical comparison of LTI carbon, alumina, and carbon-coated alumina blade-type implants in baboons. - J Biomed Mater Res. 1982 Nov;16(6):887-99.
109. Pasqualini M.: Uso e possibilità delle mini-lame - Atti del 1° Seminario Intern. di Clinica Implantologica ANIO, Bari 4-6 Novembre 1982 – (Dedalo Litostampa spa, Bari 1986)
110. Smithloff M, Fritz ME.: The use of blade implants in a selected population of partially edentulous adults. A ten-year report. - J Periodontol. 1982 Jul;53(7):413-8.
111. Fazili M.:Blade implants: presurgical preparation procedures and radiographical analyses.-J Biomed Eng. 1983 Apr;5(2):141-4.
112. Heidelbach G.: Blade implants and its indication limits - Zahnarztl Prax. 1982 Jan;33(1):10, 13-8.

113. Ehrl PA: Comparative experiments on single tooth implants and blade implants of ceramic - Osterr Z Stomatol. Mar;80(3):97-102, 1983
114. Dahl GS.: Mechanical analysis of Linkow blade vent implants. - J Oral Implantol. 1983;11(1):89-92.
115. Linkow L.I.: Implantation of Bladevents and Corevents into an Iliac Crest Augmented Ridge - The N.Y. Journal of Dentistry Vol.53, N°8, pp.383-386, Dec.1983
116. Vanek J, Cecara J, Freybarg L, Zeman J, Nemec A, Smekal M.: Various properties of metal dental blade implants - Prakt Zubn Lek. 1984 Jun;32(5):133-5._
117. El-Mahady AS, Amin M, Fahmy TH, Abbas NA.: Comparison between endosseous metal blade-vent and endosseous polymer-coated metal blade-vent implants when used as distal abutment for removable appliances in free-end saddle cases.- Egypt Dent J. 1984 Apr;30(2):141-54.
118. Linkow L.I.: Endosseous Bladevent Implant Insertion Guidelines - Dentistry Today Vol.III, N°6, December 1984
119. Dahler C.: Endosseous blade implants - Schweiz Monatsschr Zahnmed. 1985 Oct;95 Spec No:879-88.
120. Niikura K, Niikura K, Hasuike T, Miyake H, Sawada S, Yagiu Y, Shimada J, Yamamoto Y.: Structural analysis of bridges over blade implants - Josai Shika Daigaku Kiyo. 1985;14(2-3):355-61.
121. Sada Moreno E.: Blade implants - Rev Actual Estomatol Esp. 1986 May;46(355):29-32.
122. Muratori G.: Blade implants simplified - Attual Dent. 1986 Apr 6;2(13):44-5, 47, 49-51
123. Kniha H, Nentwig GH, Hostermann U.: Surface structural findings in endosseous blade implants from the viewpoint of bone integration - Schweiz Monatsschr Zahnmed. 1986 Nov;96(11):1250-8.
24. Hoexter DL.: Endosteal blade implants with tricalcium phosphate--a technique for a more predictable prognosis. - N Y J Dent. 1986 Nov;56(6):214-20.
125. Ferrer F, Castillo J, Rodriguez H, Guzman J, Korchin L, Cabanas R.: Mandibular posterior blade implants. A twelve year clinical and statistical evaluation.- Rev Odontol P R. 1986 Jan-Jul;23(1):9-17.
126. Cremonese G.: Su un caso di mono-impianti protesici con lama di Pasqualini e ago di Mondani – Atti del 1° Seminario Internazionale di C linica Implantologica ANIO, Bari 4-6 Novembre 1982 – Dedalo Litostampa spa, Bari 1986
127. Babbush CA.: Endosteal blade-vent implants.- Dent Clin North Am. 1986 Jan;30(1):97-115.
128. Veterans Administration Cooperative Dental Implant Study: Comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part I: Methodology and comparisons between treatment groups at baseline. - J Prosthet Dent. 1987 Oct;58(4):499-512.
129. Bert M.: Blade implants - Actual Odontostomatol (Paris). 1987 Sep;41(159 Spec No):507-20.
130. Smithloff M, Fritz ME.: The use of blade implants in a selected population of partially edentulous adults. A 15-year report. - J.Periodontol. 1987 Sep;58(9):589-93.
131. Torres MD, Yelos E.: Linkow implants (blade-vent) - Rev Ateneo Argent Odontol. 1987 Apr-Oct;22(2):41-4, 46-9.
132. Jandl P.: Surgical problems with blade-shaped intraosseous implants - Prakt Zubn Lek. 1987 Mar;35(2):33-6.
133. Aceveco AI.: Success and survivability of endosteal blade implants managed in the practice of Dr. Linkow. - J Oral Implantol. 1987;13(3):488-91.
134. Ismail YH, Pahountis LN, Fleming JF.: Comparison of two-dimensional and three-dimensional finite element analysis of a blade implant. - Int J Oral Implantol. 1987;4(2):25-31.
135. Schwarz WD.: Comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. - J Prosthet Dent. 1988 Aug;60(2):260.
136. Heller AL.: Blade implants.- CDA J. 1988 Jan;16(1):78-86.
137. Morimoto K, Kihara A, Takeshita F, Akedo H, Suetsugu T:Differences between the bony interfaces of titanium and hydroxyapatite-alumina plasma-sprayed titanium blade implants. _ J Oral Implantol. 1988;14(3):314-24.
138. Fischer R.: Herskovits double blade implant system - Zahnarztl Prax. 1989 Dec 8;40(12):452-3.
139. Kapur KK.: Veterans Administration Cooperative Dental Implant Study--comparisons between fixed partial dentures supported by blade-vent implants and removable partial

dentures. Part II: Comparisons of success rates and periodontal health between two treatment modalities. - J Prosthet Dent. 1989 Dec;62(6):685-703.
140. Takeshita F, Akedo H, Kihara A, Morimoto K, Suetsugu T.: Quantitative study on the interface between bone tissue and Blade-vent implants using the image processing system. - J Oral Implantol. 1989;15(3):154-9.
141. Feigel A, Makek M.: The significance of sinus elevation for blade implantology--report of an autopsy case.- J Oral Implantol. 1989;15(4):237-48.
142. Dietsh FF, Misch CE, Piesco NP, Ismail YH.: Surface alteration during blade implant modification. - Int J Oral Implantol. 1989;6(1):11-5.
143. Valen M, Schulman A.: Establishment of an implant selection protocol for predetermined success. - J Oral Implantol. 1990;16(3):166-71.
144. Bartonova M.: Rehabilitation of the dentition using intraosseous blade implants _ Sb Lek. 1990 Sep;92(8-9):262-8.
145. Hahn JA.: The blade implant. _ J Am Dent Assoc. 1990 Sep;121(3):394, 396, 400
146. Kapur KK.: Veterans Administration Cooperative Dental Implant Study--comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part IV: Comparisons of patient satisfaction between two treatment modalities. - J Prosthet Dent. 1991 Oct;66(4):517-30.
147. Barfield DJ, Abele T.: Clinical realities of endosseous blade vent implants. - N Y State Dent J. 1991 Jun-Jul;57(6):36-9.
148. Kapur KK.: Veterans Administration Cooperative Dental Implant Study--comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part III: Comparisons of masticatory scores between two treatment modalities.- J Prosthet Dent. 1991 Feb;65(2):272-83.
149. Lum LB, Beirne OR, Curtis DA.: Histologic evaluation of hydroxylapatite-coated versus uncoated titanium blade implants in delayed and immediately loaded applications. - Int J Oral Maxillofac Implants. 1991 Winter;6(4):456-62.
150. Telsey B, Oshrain HI, Joondeph NH, Mandel ID.:Retrospective radiographic study of blade implants.J Oral Implantol. 1991;17(2):140-5.
151. Sisk AL, Steflik DE, Parr GR, Hanes PJ.: A light and electron microscopic comparison of osseointegration of six implant types. - J Oral Maxillofac Surg. 1992 Jul;50(7):709-16; discussion 716-7.
152. Steflik EE, Sisk AL, Parr GR, Hanes PJ, Lake FT, Brewer P, Horner J, McKinney RV.: Correlative transmission electron microscopic and scanning electron microscopic observations of the tissues supporting endosteal blade implants. - J Oral Implantol. 1992;18(2):110-20.
153. Linkow LI, Donath K, Lemons JE.: Retrieval analyses of a blade implant after 231 months of clinical function.- Implant Dent. 1992 Spring;1(1):37-43.
154. Nicolucci B.: Dental implants: the blade implant. - Oral Health. 1993 Sep;83(9):55-6, 58, 60.
155. Trisi P, Quaranta M, Emanuelli M, Piattelli A.: A light microscopy, scanning electron microscopy, and laser scanning microscopy analysis of retrieved blade implants after 7 to 20 years of clinical function. A report of 3 cases. - J Periodontol. 1993 May;64(5):374-8.
156. Grafelmann HL.:The latest developments in blade implant clinical applications.- Dent Implantol Update. 1993 Mar;4(3):22-5.
157. Pasqualini U: Le Patologie Occlusali - Masson 1993
158. Fritz ME, Lemons JE, Jeffcoat M, Braswell LD, Reddy M.: Evaluation of consecutively placed unloaded root-form and plate-form implants in adult Macaca mulatta monkeys. - J Periodontol. 1994 Aug;65(8):788-95.
159. Eke PI, Braswell L, Fritz M.: Succession of putative peri-implant pathogens after root-form and plate-form implant placement in partially dentate adult monkeys. - J Periodontal Res. 1995 Mar;30(2):88-96.
160. Linkow LI.: A surgical perspective: immediate placement of blade-/plate-form and self-tapping vent-plant screw implants into fresh extraction sites. - J Oral Implantol. 1995;21(2):131-7.
161. Linkow LI, Giauque F, Ghalili R, Ghalili M.: Levels of osseointegration of blade-/plate-form implants. - J Oral Implantol. 1995;21(1):23-34.
162. Commissionat Y, Poulmaire F.: Blade implants: new ideas - Rev Stomatol Chir Maxillofac. 1996 Oct;97(5):283-7.

163. Takeshita F, Ayukawa Y, Iyama S, Suetsugu T, Kido MA.: A histologic evaluation of retrieved hydroxyapatite-coated blade-form implants using scanning electron, light, and confocal laser scanning microscopies. - J Periodontol. 1996 Oct;67(10):1034-40.
164. Takeshita F, Matsushita Y, Ayukawa Y, Suetsugu T.: Fractures of hydroxyapatite-coated blade implants connected with natural teeth. A histological study using SEM, light microscopy, and an image processing system. - J Periodontol. 1996 Feb;67(2):86-92.
165. Roberts RA.: Types, uses, and evaluation of the plate-form implant. - J Oral Implantol. 1996;22(2):111-8.
166. Linkow L.I., Mangini F.: Tecniche Implantari ed Implantoprotesiche – Piccin 1997
167. Garrett NR, Kapur KK, Hasse AL, Dent RJ.: Veterans Administration Cooperative Dental Implant Study--comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part V: Comparisons of pretreatment and posttreatment dietary intakes. - J Prosthet Dent. 1997 Feb;77(2):153-61.
168. Narkhede PR.: A histologic evaluation of the effect of electrical stimulation on osteogenic changes following placement of blade-vent implants in the mandible of rabbits. - J Oral Implantol. 1998;24(4):185-95.
169. Bianchi A.: Implantologia ed Implantoprotesi – UTET 1999, pagg. 374-375
170. Pasqualini M.E.: Implantoprotesi in un caso di monoedentulismo: Analisi retrospettiva a 27 anni - Dental Cadmos 10/1999, Pagg. 61-64
171. Shen TC.: The use of different implant modalities in the atrophied ridge.J Oral Implantol. 1999;25(2):109-13.
172. Noack N, Willer J, Hoffmann J.: Long-term results after placement of dental implants: longitudinal study of 1,964 implants over 16 years. - Int J Oral Maxillofac Implants. 1999 Sep-Oct;14(5):748-55.
173. Strietzel FP, Krueger H, Semmler R, Hopp M.: Morphological study of Osteoplate 2000-extension implants after bending. - Implant Dent. 2000;9(3):261-7.
174. Dal Carlo L.: Agenesia dell'incisivo laterale superiore_ Soluzione implantologica di un caso clinico – Gazzetta Medica Italiana Vol.159 N°1 Febb. 2000, pagg. 23-27
175. Thomson DH.: Salvage of a blade-implant bridge. - Aust Dent J. 2001 Sep;46(3):216-9.
176. Dal Carlo L.: Nuova Tecnica per l'Inserzione di Impianti a Lama: Estensione Distale Endoossea - Dental Cadmos 16/2001, pp.41-49
177. Manenti P.A.: La riabilitazione di creste mandibolari atrofiche distali con l'ausilio di lame bicorticali – Atti del 4° Congresso Internazionale A.I.S.I. Verona 18-19 Ottobre 2002, pagg. 327-328 Edizioni ETS 2002
178. Proussaefs P, Lozada J.: Evaluation of two vitallium blade-form implants retrieved after 13 to 21 years of function: a clinical report. - J Prosthet Dent. 2002 Apr;87(4):412-5.
179. Dal Carlo L.: Modulabilità del carico immediato nello sviluppo del piano terapeutico – Atti del 4° Congresso Internazionale A.I.S.I. Verona 18- 19 Ottobre 2002, pagg. 216-217 Edizioni ETS 2002
180. Dal Carlo L.: Endosseous Distal Extension: A new Technique that is useful to solve Clinical Cases characterized by scarceness of Cancellous Bone Tissue in the Lower Distal Sector – Stomatologhieski Journal (Minsk) N° 3(8) 2 002
181. Dal Carlo L., Brinon E.N.: Influencia de la lengua en la integraciòn de los implantes intra-òseos – Revista Espanola Odontoestomatològica de Implantes N° 2 ;Vol. XII; 102-111 Abril-Junio 2004
182. Knöfler W., Knöfler A., Graf H.-L.: Survival analysis of implants in a dental office over a period of 10 years - ZZI, Zeitschrift für Zahnärztliche Implantologie 2004;20(4), Deutscher Ärzte-Verlag, Cologne, Germany, tab 7
183. Di Stefano D., Iezzi G., Scarano A., Perrotti V., Piattelli A.: Immediately Loaded Blade Implant Retrieved From a Man After a 20-year Loading Period: A Histologic and Histomorphometric Case Report - Journal of Oral Implantology Vol 32:44;171-176, 2006
184. Pasqualini U, Pasqualini ME: Treatise of Implant Dentistry – AriesDue srl Carimate Como 2009
185. Covani U, Marconcini S, Crespi R, Barone A.: Immediate implant placement after removal of a failed implant: a clinical and histological case report. - J Oral Implantol. 2009;35(4):189-95
186. M.E. Pasqualini: Implantoprotesi in un caso di monoedentulismo.Analisi retrospettiva a 38 anni - Dental Cadmos anno 78 n. 10 dicembre 2010 pag. 65
187. Strecha J., Jurkovic R., Siebert T., Prachar P., Bartakova S.: Fixed Biscortical Screw and Blade Implants as a Non-Standard Solution to Edentulous (Toothless) Mandible – Int J Oral Sci, 2(2): 105-110, 2010

188. Studio Statistico su 6200 impianti inseriti in 20 anni in 2800 interventi – Odontoline 2011
189. Iezzi G., Scarano A., Perrotti V., Tripodi D., Piattelli A.: Impianti a lama a carico immediato. Analisi istologica e istomorfometrica dopo un lungo periodo di carico. Analisi retrospettiva a 20 anni (1989 - 2009) – Journal of Osseointegration Ottobre 2012;3(4):99-104
190. Mangano F, Bazzoli M, Tettamanti L, Farronato D, Maineri M, Macchi A, Mangano C.: Custom-made, selective laser sintering (SLS) blade implants as a non-conventional solution for the prosthetic rehabilitation of extremely atrophied posterior mandible. - Lasers Med Sci. 2012 Sep 14
191. Dal Carlo L, Pasqualini ME, Carinci F, Corradini M, Vannini F, Nardone M, L.Linkow. A brief history and guidelines of blade implant technique: a retrospective study on 522 implants. Annals of Oral & Maxillofacial Surgery 2013 Feb 01;1(1):3.
192. FDA U.S. Food and Drug Administration Prtecting and Promoting Public Health – Classification Discussion: Endosseus Dental Implants (Blade-form ClassIII) Meeting of Dentall Products Panel of the Medical Devices Advisory Committee – Gaithersburg, MD – July 18, 2013.
193. FDA U.S. Food and Drug Administration Department of Health and Human Service Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant
FEDERAL REGISTER Vol .79, No.117 June 18,2014 (34623)
194. Rossi F, Pasqualini ME, Grivet Brancot L, Corradini M, Lorè B, Calabrese L
Minimally invasive piezosurgery for a safe placement of blade dental implants in jaws with severe bone loss
Journal of Osseointegration October 2014; 6(3)

CONTRIBUTO PUBBLICAZIONI

- Dal Carlo L, Pasqualini ME, Carinci F, Corradini M, Vannini F, Nardone M, . Linkow LI
  A brief history and guidelines of blade implant technique: a retrospective study on 522 implants.
  Annals of Oral & Maxillofacial Surgery 2013 Feb 01;1(1):3

- FDA (Food and Drug Administration) Executive Summary
  Classification for Endosseous Dental Implants (BLADE –FORM)
  Prepared for the July 18, 2013 meeting of Dental Devices Panel

- **FDA** (Food and Drug Administration)
  Department of Health and Human Service
  Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant
  FEDERAL REGISTER Vol .79, No.117 June 18,2014 (34623)

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Original research study

Implantology

A brief history and guidelines of blade implant technique: a retrospective study on 522 implants

L Dal Carlo[1], ME Pasqualini[2], F Carinci[3*], M Corradini[4], F Vannini[5], M Nardone[6], LI Linkow[7]

Abstract

Introduction

Despite initial enthusiasm, blade implants have received bad press over the years due to fairly high failure rates reported in some publications of non-users. We aim to discuss the techniques of blade implants to improve the understanding of the technique.

Materials and methods

A total of 522 blades were inserted in 20 years (1989–2009): 309 in females and 213 in males. The median age was 59 ± 11 years (min–max: 24–80 years). The implants were inserted in deep and atrophic narrow crests.

Results

The success rate was 93.4% (488/522) globally, 98.9% (369/373) at 5 years, 89% (261/293) at 8 years and 86.2% (200/232) at 10 years. These data show very good results at 5 years, but slightly more failures at 8 and 10 years.

Conclusion

The blade implant is a valid therapeutic device useful for treating cases such as narrow bone crest and scarce spongy bone in the lower distal sector. They have demonstrated long-term survival. Nonetheless, to prevent failure, practitioners should be aware that blade implants are not indicated in wide alveolar crests or in areas where bone density is insufficient and that the implant cannot be positioned in the deep cortical layer.

Introduction

The idea of endosseous blade implants was developed by L.I. Linkow and R. Roberts, but its spread all over the scientific community must be attributed to Prof. Leonard Linkow, who published it around 1968, thereby making it possible to treat partial or total edentulism[1,2].

Blade implants can be used in any alveolar crest, but are particularly useful in the thinnest, where the use of root-form implants is difficult and needs bone regeneration procedures. When the ridge is thin, tricortical anchorage is the most suitable technique, according to Manenti[3], that is the implant is stabilised by press-fit in both the internal and external bone cortex, as well as the deep cortex (Figures 1 and 2). This condition represents the *optimum* to allow immediate functional loading of provisional prosthesis.

The original surgical protocol of Linkow is based on the following simple steps:

- Select the patient correctly
- Consider general health conditions
- Value crestal size
- Open a flap to have a correct ridge overview
- Perform a line of little holes in the superficial cortical bone
- Connect holes and insert blade implant as deep as possible
- Gently bend implant abutment to reach correct position in relation with the antagonist teeth

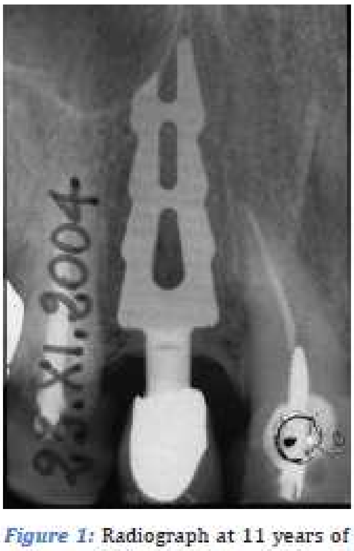

Figure 1: Radiograph at 11 years of submerged blade implant positioned in zone 1.2 in 1993.

Figure 2: Photograph 7 years after fitting the prosthesis on the implant in Figure 1.

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For citation purposes: *Dal Carlo L, Pasqualini ME, Carinci F, Corradini M, Vannini F, Nardone M, et al.* A brief history and guidelines of blade implant technique: a retrospective study on 522 implants. Annals of Oral & Maxillofacial Surgery 2013 Feb 01;1(1):3.

Competing interests: none declared. Conflict of interests: none declared. All authors contributed to the conception, design, and preparation of the manuscript, as well as read and approved the final manuscript. All authors abide by the Association for Medical Ethics (AME) ethical rules of disclosure.

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Figure 3: The guide holes are joined, tracing the site for insertion of a Pasqualini screw-abutment blade implant.

- Gently bend implant body if necessary
- Press the blade inside its implant site till it reaches the correct position
- Control occlusal functions

Osseointegration of titanium blade implants has been confirmed by numerous histological studies. Figure 1 allows you to appreciate bone thickening around the neck and body of a blade implant 11 years after surgery.

If patients are suitably selected, blade implants are successful. In fact, clinical experience shows that the majority of failures occur when surgical protocol is not correctly followed[4,5], implant form was not suitable in a patient, movements of the tongue were not taken into consideration[6–8], and the implant was used in too much atrophic crestal bone.

Types of blade implants

Linkow's original blade implant was performed in different shapes according to the anatomical site of insertion. Subsequently, Linkow has developed numerous improvements to the shape and surface of

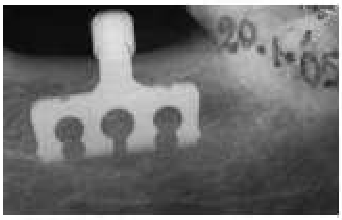

Figure 4: Intra-oral radiograph performed immediately after positioning the Pasqualini blade implant in Figure 4.

his device. At the beginning of the 1970s, Pasqualini proposed a 'polymorphous' blade implant, which could be modelled to suit the most common anatomical conformations and which, with its screw abutment, offered for the first time a solution to the problem of tongue-thrust during swallowing (causing the majority of post-surgical failures)[9]. A provisional abutment with a short temporary screw-on cap should be replaced with a longer one, 3–4 months after surgery (Figures 3 and 4).

Many other authors have developed changes to the shape and prosthetic component: emergent, semi-emergent and submerged forms[10–16].

The advantages of blade implants are as follows:

1. Possibility to insert blades in the narrowest alveolar crests
2. Adaptability to the majority of anatomical conformations
3. Avoiding bone regeneration surgery
4. Mechanical correction of parallelism during implant surgery
5. Easy adaptation to the deep anatomical structures by modifying the implant
6. Presence of numerous contacts with deep cortical layer
7. Possibility of inserting a part of the implant below the intact cortex (as compared with endosseous distal extension (EDE) technique)

Figure 5: Blade implant during implantation in zone 3.5.

8. Adequate management of attached gingiva during implant surgery
9. Simple surgical technique performed with standard instruments

The disadvantages of blade implants are as follows:

1. Invasion of adjacent bone sites with mesio-distally positioned blades
2. Poor adaptability to post-extraction alveolar sites

Biomechanical aspects

The possibility offered by the surgical technique of modelling the blade implant requires the operator to possess skills to evaluate the biomechanical suitability of the implant. Blade implant should have a root/crown depth ratio of 1:1[17].

This study is focused on the techniques attributed to blade implants and their long-term reliability.

Materials and methods

This work conforms to the values laid down in the Declaration of Helsinki (1964). The protocol of this study has been approved by the relevant ethical committee related to our institution in which it was performed. All subjects gave full informed consent to participate in this study.

FOR CITATION PURPOSES: *Dal Carlo L, Pasqualini ME, Carinci F, Corradini M, Vannini F, Nardone M, et al.* A brief history and guidelines of blade implant technique: a retrospective study on 522 implants. Annals of Oral & Maxillofacial Surgery 2013 Feb 01;1(1):3.

Competing interests: none declared. Conflict of interests: none declared.
All authors contributed to the conception, design, and preparation of the manuscript, as well as read and approved the final manuscript.
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Figure 6: The blade implant in its definitive position. The abutment reaches the bone crest.

Figure 7: On the left, note the excellent response of the soft tissues around the blade implant in Figures 5 and 6.

Surgery standard protocol

Patient's anamnesis is mandatory. The preliminary phases of surgery are based on clinical and radiographic examinations. Written informed consent is mandatory. The patient must be thoroughly informed about treatment options to know relative advantages and disadvantages.

The incision must be performed to ensure adequate adherent gum around the prosthesis. To decide about the precise position of the abutment, an intra-operatory surgical mask is required.

After incision, the flap is detached using a periosteal elevator. In case of very thin alveolar crest, flap lifting should be performed cautiously trying not to compromise blood supply to the underlying bone.

A line of small guide holes on the surface of the crest should be designed using a 0.9–1.0 mm gauge multi-blade metal drill mounted on a turbine, or high-speed contra-angle (red band) handpiece. These ideal lines will serve as a guide for the implant insertion (Figure 3). Instead of the drill, a piezo-electric scalpel can be used.

The mesio-distal dimensions of the implant site must be calculated in relation to blade shape, selected on the basis of radiographic images and the anatomy of the implant site. If the bone is not particularly dense, drill a slightly shallower channel, so that the implant will have greater primary stability upon press-fitting. The implant site should be traced with a slow movement of the wrist, following the longitudinal direction of the crest; its depth should be sufficient to maintain a safe distance from the underlying anatomical structures.

Once the mesio-distal implant site has been bored and its depth checked using a gauged probe, the implant can be inserted, ensuring that its shoulder has been positioned at least 2 mm below the superficial cortex. The implant is fitted in its site using pliers, and the mounting device should be tapped gently and safely (Figure 5).

The abutment neck should be surrounded by patient's gum of correct biological width (Figures 6 and 7).

The blade implant can be modified to perfectly suit the crestal bone anatomy (Figure 1) and the body can be curved to follow the anatomical profile. If the abutment needs to be angled, this can be achieved mechanically, up to maximum of 20°, before the implant is positioned[10], using two pair of steel pliers, thereby resolving beforehand any problems that could arise due to incongruous abutment positioning.

The sutures should surround the protruding abutment and not compromise the anatomy of papillae.

Post-surgical protocol

After surgery, patients are likely to experience slight swelling and normal post-surgical symptoms. Five days of antibiotics is a precautionary measure to suggest.

Immediate loading

The blade implant can be immediately loaded if adequate stability has been achieved. Anchoring the implant through two cortical layers and in contact with the deeper cortex should stabilise the implant.

Static and dynamic occlusion should be meticulously checked when temporary or permanent crowns have been positioned.

Oral rehabilitation

Numerous articles have demonstrated the long-term stability of these types of implants[19–25] and documented their histological osteointegration, without connective tissue in the bone/implant interface[26–29].

Strictly following the surgical and prosthetic protocols is the first step towards success. A comparative study published online in 2011[30] has shown that *'blade implants have yielded the best success rates at 5 years. The success rate decreases between the 5th and 8th year.'*

Over the years, several authors have proposed changes to the original technique[3,31]. For instance, the technique known as EDE is particularly useful for treatment of lower posterior sectors with scarce bone density.

First used in 1993, the EDE was published in 2001[31,32]. The best type of blade implant to use is ramus blade, which was designed during the 1970s by Roberts and Linkow.

The technique consists in performing the implant site mesially, so that the blade is gradually rotated distally until it reaches the distal border of implant site.

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Figure 8: The blade has reached its final destination with the abutment against the distal border of the bone site. Implant body has been inserted between the superficial cortical bone and the superior side of the alveolar canal. The cortical bone posterior to the abutment remains intact.

In this way, almost all of the implants are placed beneath the intact bone and soft tissues. The presence of intact superficial bone tissue posterior to the abutment can be controlled with an X-ray (Figure 8).

Since the implant must be surrounded by healthy tissue (superficial cortex, upper cortex of alveolar canal, labial and lingual cortical layers), this type of implant is extremely stable even if it should immediately be loaded with a fixed prosthesis.

Indeed, this kind of procedure is characterised by excellent soft tissue response. The same results could be reached for ramus blade implants inserted using this technique.

Results

Statistical data

Dr L. Dal Carlo inserted immediate- and deferred-load monoblock blade implants in narrow alveolar crests since 1989[30]. The implants were used in both deep and atrophic narrow crests, and their success rate was 93.4% (488/522) globally, 98.9% (369/373) at 5 years, 89% (261/293) at 8 years and 86.2% (200/232) at 10 years. These data show very good results at 5 years, but slightly more failures at 8 and 10 years. This is due to some implants being inserted into particularly atrophic posterior sectors and unfavourable crown/root ratio.

The efficacy of blade implants has also been documented by an independent multi-centre randomised trial (Veterans Administration Cooperative Dental Implant Study) conducted over a 5-year period. This study revealed 91.5% success in cases of partial edentulism treated using fixed prostheses on blade implants[33].

Discussion

The introduction of blade implants by Linkow in the 1960s was a great innovation, inducing numerous implantology neophytes to expertize this method, however, without having a clear idea of indications. Therefore, the improper use of the blade implant was unsurprisingly the main cause of failure of this device. As with any new technique, especially when practiced by non-experts, there have been failures that have been particularly exalted in some published reports over the years. In these reports, implant insertion technique, implant shape and quality of osseointegration have been particularly criticised. At the same time, however, scientific works have been published about the benefits arising from the use of blade implants after failure of root-form implants[32,34–36]. We believe that it is not scientifically correct to assume that this technique is useless on the basis of some case reports. Indeed, a report of blade implants used instead of a failed root-form implant[34] has also been published; however, this does not necessarily mean that one technique is superior to the other. Moreover, when compared with other implants inserted in the same period of time, some studies have shown that the blade implant provided long-term reliability[35,36]. Furthermore, the possibility of replacing a failed blade implant with a new blade implant has been experienced by both the authors of this article and Covani et al.[37]. The idea that blade implants are poorly osteointegrated with respect to other types of implant has been effectively denied by histological examination, which has demonstrated total absence of connective tissue interlayer[26,28]. With regard to this, there are numerous clinical reports that attest the reliability of blade implants.

Conclusion

The blade implant is a valid therapeutic device useful for treating cases such as narrow bone crest and scarce spongy bone in the lower distal sector. It can be used, in its mesio-distally extended form, not only in the upper and lower posterior sectors but also to provide deep anchorage in posterior and anterior (aesthetic) sectors. Furthermore, this method offers excellent response of the surrounding soft tissues. Nonetheless, to prevent failure, practitioners should know that blade implants are not indicated in wide alveolar crests, or in areas where bone density is insufficient and the implant cannot be positioned in the deep cortical layer.

Abbreviations list

EDE, endosseous distal extension.

Acknowledgements

We thank Luca Dal Carlo, Venice, Italy for the images.

References

1. Linkow LI. The blade vent – a new dimension in endosseous implantology. Dent Concepts. 1968 Spring;11(2):3–12.
2. Linkow L. Endosseous bladevent implant – insertion guidelines. Dent Today. 1984;3.
3. Manenti PA. La riabilitazione di creste mandibolari atrofiche distali con l'ausilio

For citation purposes: *Dal Carlo L, Pasqualini ME, Carinci F, Corradini M, Vannini F, Nardone M, et al.* A brief history and guidelines of blade implant technique: a retrospective study on 522 implants. Annals of Oral & Maxillofacial Surgery 2013 Feb 01;1(1):3.

Competing interests: none declared. Conflict of interests: none declared.
All authors contributed to the conception, design, and preparation of the manuscript, as well as read and approved the final manuscript.
All authors abide by the Association for Medical Ethics (AME) ethical rules of disclosure.

Annals of Oral & Maxillofacial Surgery
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di lame bicorticali. In: 4° Congresso Internazionale A.I.S.I. Verona: Edizioni ETS 2002;2002.
4. Linkow L. The endosseous blade: a new dimension in oral implantology. Rev Trim Implant. 1968;5:13–24.
5. Pasqualini U, Pasqualini M. Treatise of implant dentistry. Ariesdue srl Carimate, Como; 2009.
6. Pasqualini U. Le patologie oclusali: Masson; 1993.
7. Dal Carlo L. Tongue's influence on the integration of endosseous implants. Doctor OS. 2003;14:479–84.
8. Dal Carlo L, Brinon EN. Influencia de la lengua en la integración de los implantes intra-óseos. Rev Espanola Odontoestomatol Implante. 2004 Apr–Jun;XII(2):102–11.
9. Pasqualini U. Impianti Endoossei: La protezione dell'osteogenesi riparativa con la metodica del "moncone avvitato". Tecnica personale Dental Cadmos, No. 8; 1972.
10. Viscido AJ. Submerged functional predictive endosteal blade implants. Oral Implantol. 1974 Autumn;5(2):195–209.
11. Babbush CA. Endosteal blade-vent implants. Quintessence Int Dent Dig. 1976 Jun;7(6):9–15.
12. Roberts RA. Types, uses, and evaluation of the plate-form implant. J Oral Implantol. 1996;22(2):111–8.
13. Grafelmann HL. The latest developments in blade implant clinical applications. Dent Implantol Update. 1993 Mar;4(3):22–5.
14. Muratori G. [Blade implants simplified]. Attual Dent. 1986 Apr;2(13):44–5, 47, 49–51.
15. Misch CE. Osteintegration and the submerged blade-vent implant. J Houston Dist Dent Soc. 1988 Jan:12–6.
16. Misch C. Blade vent implant: still viable. Dent Today. 1989;8:34–42.
17. Fallschussel GKH. Implantologia Odontoiatrica – Scienza e Tecnica Milano: Edizioni internazionali; 1986.
18. Strietzel FP, Krueger H, Semmler R, Hopp M. Morphological study of Osteoplate 2000 – extension implants after bending. Implant Dent. 2000;9(3):261–7.
19. Koch WL. Statistical evaluation of success and reasons for failure in 700 endosseous blade implants done in the office. Oral Implantol. 1974 Apr;1(1):108–35.
20. Cranin AN, Rabkin MF, Garfinkel L. [Statistical evaluation of 952 endosseous implants]. Riv Ital Stomatol. 1978 Jan;47(1):53–61.
21. Ricciardi A. Nine years with Pasqualini implants – a full mandibular arch. J Oral Implantol. 1980;9(1):83–94.
22. Ferrer F, Castillo J, Rodriguez H, Guzman J, Korchin L, Cabanas R. Mandibular posterior blade implants. A twelve year clinical and statistical evaluation. Rev Odontol P R. 1986 Jan–Jul;23(1):9–17.
23. Smithloff M, Fritz M. The use of bladevent implants in a selected population of partially edentulous adults: a three year report. Oral Implantol. 1973 Autumn;4(2):145–73.
24. Proussaefs P, Lozada J. Evaluation of two vitallium blade-form implants retrieved after 13 to 21 years of function: a clinical report. J Prosthet Dent. 2002 Apr; 87(4):412–5.
25. Pasqualini ME. Implantoprotesi in un caso di monoedentulismo. Analisi retrospettiva a 38 anni. Dental Cadmos. 2010 Dec;10:65–70.
26. Linkow LI, Donath K, Lemons JE. Retrieval analyses of a blade implant after 231 months of clinical function. Implant Dent. 1992 Spring;1(1):37–43.
27. Bianchi A, Sanfilippo F, Zaffe D. Implantologia e Implantoprotesi. Torino: UTET; 1999.
28. Di Stefano D, Iezzi G, Scarano A, Perrotti V, Piattelli A. Immediately loaded blade implant retrieved from a man after a 20-year loading period: a histologic and histomorphometric case report. J Oral Implantol. 2006 Aug;32:171–6.
29. Trisi P, Quaranta M, Emanuelli M, Piattelli A. A light microscopy, scanning electron microscopy, and laser scanning microscopy analysis of retrieved blade implants after 7 to 20 years of clinical function. A report of 3 cases. J Periodontol. 1993 May;64(5):374–8.
30. Dal Carlo L. Studio Statistico su 6200 impianti inseriti in 20 anni in 2800 interventi 2011.
31. Dal Carlo L. Nuova tecnica per l'inserzione di impianti a lama: Estensione Distale Endoossea. Dental Cadmos. 2001;16:41–9.
32. Dal Carlo L. Endosseous distal extension: a new technique that is useful to solve clinical cases characterized by scarceness of cancellous bone tissue in the lower distal sector. Stomatologhieski J. 2002;3.
33. Krishan KK. Veterans administration cooperative dental implant study – comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part IV: comparisons of patient satisfaction between two treatment modalities. J Prosthet Dent. 1991 Oct;66(4):517–29.
34. Linkow LI, Wagner JR. Management of implant-related problems and infections. J Oral Implantol. 1993;19(4):321–35.
35. Knöfler W, Knöfler A, Graf H-L. Survival analysis of implants in a dental office over a period of 10 years. Z Zahn Implantol. 2004;20(4).
36. Strecha J, Jurkovic R, Siebert T, Prachar P, Bartakova S. Fixed bicortical screw and blade implants as a nonstandard solution to an edentulous (toothless) mandible. Int J Oral Sci. 2010 Jun;2(2):105–10.
37. Covani U, Marconcini S, Crespi R, Barone A. Immediate implant placement after removal of a failed implant: a clinical and histological case report. J Oral Implantol. 2009;35(4):189–95.

Competing interests: none declared. Conflict of interests: none declared.
All authors contributed to the conception, design, and preparation of the manuscript, as well as read and approved the final manuscript.
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FDA Executive Summary

Prepared for the
July 18, 2013 meeting of the
Dental Devices Panel

Classification for Endosseous Dental Implants
(Blade-form) [21 CFR 872.3640(b)(2)]

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1. Introduction

Per Section 513(b) of the Food, Drug, and Cosmetic Act (the FD&C Act), the Food and Drug Administration (FDA) is convening the Dental Products Advisory Panel (the Panel) for the purpose of obtaining recommendations regarding reclassification of blade-form endosseous dental implants [21 CFR 872.3640(b)(2)].

Blade-form endosseous dental implants intended for the treatment of edentulous sites in the mandible or maxilla for restoration of chewing function as defined under 21 CFR 872.3640(b)(2), hereinafter referred to as "blade-form implants" are one of the remaining preamendments Class III medical devices currently cleared for marketing through the premarket notification [510(k)] pathway.

FDA is holding this panel meeting to obtain comments and recommendations from the Panel regarding whether blade-form implants should remain in Class III (subject to premarket approval application [PMA]) or be reclassified to Class II (subject to premarket notification [510(k)s]). The Panel will be asked to provide input on the risks to health and benefits of blade-form implants. The panel will also be asked to discuss the FDA's proposed reclassification strategy for blade-form implants based upon the available safety and effectiveness information. FDA believes that these devices can be reclassified into class II (Special Controls) because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of these devices. If the Panel believes that Class II is appropriate for blade-form implants, the Panel will also be asked to specifically comment on the adequacy of the proposed special controls to mitigate the identified risks to health.

1.1. Current Classification

<u>As currently defined in 21 CFR 872.3640:</u>

(a)*Identification.* An endosseous dental implant is a device made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b)*Classification.* (1) Class II (special controls). The device is classified as class II if it is a root-form endosseous dental implant. The root-form endosseous dental implant is characterized by four geometrically distinct types: Basket, screw, solid cylinder, and hollow cylinder. The guidance document entitled "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments" will serve as the special control. (See 872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval). The device is classified as class III if it is a blade-form endosseous dental implant.

It should be noted that this classification regulation is currently split between Class II and Class III. The focus of this panel today is only on part (b)(2) of the classification regulation. Any modifications to part (b)(1) would be subject to a different regulatory process.

Blade-form implants are currently reviewed through the 510(k) pathway, and are allowed onto the market if their indications for use and technological characteristics are determined to be "substantially equivalent" to a legally marketed predicate device. There are 4 total submissions for blade-form implant devices that FDA has found to be substantially equivalent (first in 1979).

1.2. Device Description

1.2.1. Blade-form Endosseous Dental Implants

The blade-form implant is a device placed into the maxilla or mandible and composed of biocompatible material, such as titanium alloy or commercially pure titanium, with sufficient strength to support a dental restoration, such as a crown, bridge, or denture, intended for the purpose of replacing tooth (or teeth) roots and extending a support post through the gingival tissue into the oral cavity to restore chewing function.

The blade-form implant is generally a rectangular shape or rounded corner rectangle shape (in the mesio-distal plane) with a narrow tapered (narrow at the apical edge) edge (in the bucco-lingual plane) similar in shape to a razor blade. Other blade designs, such as square, V-shaped, and triangles have also been used. The blade generally contains open vents of various shapes and various sizes. Traditionally marketed blade-form implants had a blade width of 1 to 3.25mm, a blade depth of 5 to 21mm, and a blade length of 4 to 36mm.

The blade-form implants are either one-piece or two-piece implants designed with one to three cylindrical abutment posts extending from the coronal aspect of the blade through the soft tissue and into the oral cavity. For the two-piece design, the separate abutment post is retained to the blade implant with a screw.

The blade-form implant as described in the four cleared 510(k)s contains only an as-machined titanium surface with no additional surface treatments or modifications.

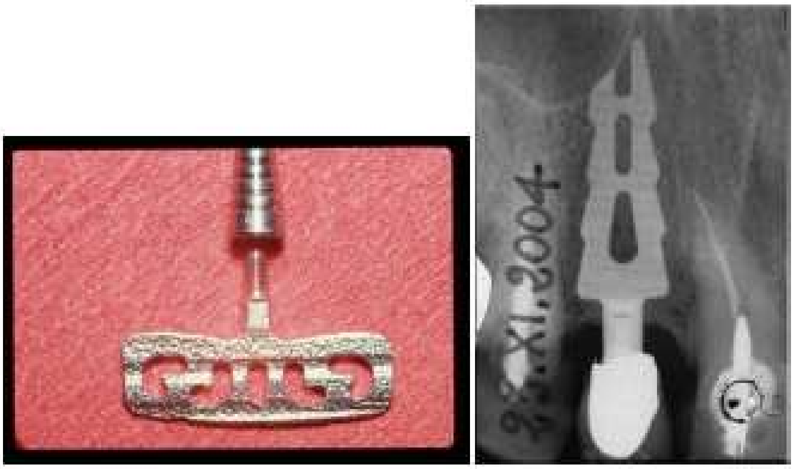

Figure 1 – Examples of blade-form endosseous dental implants (http://www.dental-vacation.com/wordpress/?p=252) (http://www.oapublishinglondon.com/article/390)

1.2.2. Ramus Frame Blade-form implant

A ramus frame blade-form implant is a sub-set of the blade-form implant specific to the mandible and fully edentulous patients. A ramus frame is a full arch, supra-mucosal bar with an implanted blade at each end which are placed in the retro-molar area of the ramus of the mandible and is supported by a single blade in the anterior of the arch.

Figure 2 – Ramus frame blade-form implant (http://www.indianhealthguru.com/dental-implants-India-low-cost-benefits.html)

1.2.3. Distinction between Root-form and Blade-form Endosseous Dental Implants

There are two types of endosseous dental implants: Root-form and Blade-form. Root-form implants is defined in 21 CFR 872.3640(b)(1) as a endosseous dental implant with one of four geometrically distinct types: basket, screw, solid cylinder, and hollow cylinder. All four root-form types are similar in that they possess a cylinder or conical shape and fill the space left by removed tooth roots in the maxilla or mandible.

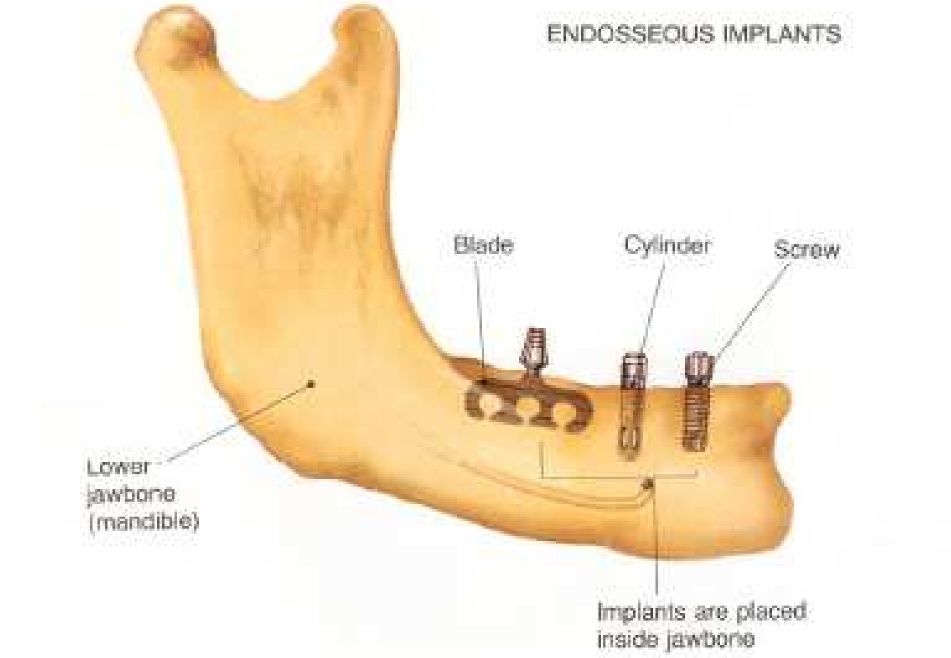

Figure 3 – Comparison of endosseous dental implants
(http://dentalimplants.uchc.edu/images/about_implants/image_page19_endosseous.jpg)

An additional distinction between blade-form and root-form implants is found in the directions for use or surgical manual. The direction for blade-form implants may include specific instructions for bending the abutment post or a one-piece implant design for the purposes of angle correction. Also, the directions for use of previously cleared devices reference cutting or bending the blade portion of the blade-form implant to fit the edentulous site and prepared osteotomy shape, e.g. anterior jaw sites.

Root-form endosseous dental implants are already classified as Class II devices and outside the scope of the panel's discussion today.

2. Regulatory History

A brief summary of the regulatory history for endosseous dental implant (blade-form) devices is provided within this section.

2.1. 1980 Proposed Rule and 1991, 1997 and 1998 Classification Panel Meetings

FDA established several advisory committees to make preliminary recommendations on dental device classification. The 1998 Dental Device Classification Panel, hereinafter referred to as "the Panel," recommended splitting the classification for Endosseous dental implant devices. Endosseous dental implant devices that are "root-form", characterized by four geometrically distinct types (basket, screw, solid cylinder, and hollow cylinder), were recommended to be Class II. Endosseous dental implants devices that are "blade-form" were recommended to be Class III. The Panel members at the Panel and Subcommittee meetings of October 24, 1991, November 4, 1997, and January 13, 1998 discussed these devices.

It was stated by the January 13, 1998 Panel that the clinical data demonstrating safety and effectiveness of the blade-form implants had not been presented to the panel to justify reclassification to Class II in contrast to the root-form endosseous dental implants for which a remarkable amount of information had been obtained since the 1991 panel meeting.

2.2. 1980 Classification Proposed Rule, 1991 & 1998 Dental Products Board Reclassification Panel, 2002 Classification Final Rule

Following the classification panel meetings, the FDA published a proposed rule on December 30, 1980 (45 FR 86025) for classification of endosseous dental implants (blade-form as well as root-form) as Class III requiring premarket approval with the following identification:

> "An endosseous implant is a device of a material, such as titanium, that is surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function."

The panel recommended Class III because the device is implanted in the body and presents a potential unreasonable risk of illness or injury including risks of abnormal spontaneous pain due to nerve impingement and a risk of perforation of the lingual and labial bony plates of the upper and lower jaws.

The Agency agreed with the Panel that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information existed to establish a performance standard to provide this assurance. On August 12, 1987 (52 FR 30082), a final rule was published for endosseous dental implants (without subdividing based on geometry) classifying these devices as Class III.

On December 7, 1989 (54 FR 50592), the FDA published a proposed rule to require PMA submissions for all dental implants. A reclassification petition was subsequently submitted on December 12, 1989, by the Dental Implant Manufacturers

Association (DIMA) requesting reclassification of dental implants. The FDA held reclassification panel meetings on October 24, 1991, and the panel voted to deny the reclassification petition. At the request of the FDA, additional panel meetings were held on November 4, 1997, and January 13, 1998, during which the FDA presented new information regarding root-form endosseous dental implants. During the January 1998 panel meeting, the panel stated that sufficient clinical information was presented to the panel to justify reclassification of root-form implants, implants with special retention features, and temporary implants, as Class II (Special Controls) requiring a premarket notification [510(k)]. However, the panel also stated that sufficient evidence with respect to the blade-form dental implant (including Ramus type implants) had not been presented to the panel even though it was stated by the public that sufficient evidence was available in the literature and from use of the blade-form implant in Europe. The panel did not discuss any specific concerns related to retaining blade-form implants in Class III, but instead stated that sufficient evidence had not yet been presented to reclassify blade-form implants to Class II.

In response to the January 1998 panel statement that sufficient evidence for blade-form dental implants had not been provided, additional information was provided on July 13, 2001 and December 20, 2001, respectively. This information was provided to the FDA outside of the classification docket.

On May 14, 2002 (67 FR 34416) and May 12, 2004 (69 FR 26032) respectively, proposed and final rules were issued reclassifying only root-form implants into Class II. Blade-form endosseous dental implants remained Class III, however, the proposed rule requiring PMA submissions was not finalized, and blade-form implants remained class III 510(k) devices.

2.3. 2009 515(i) Notice for Remaining Class III Preamendments Devices

On April 9, 2009, pursuant to Section 515(i) of the FD&C Act, FDA published a 515(i) notice in the Federal Register that applied to the remaining preamendment Class III 510(k) device types, as the first step in finalizing the classification process. Included in this group of devices were Endosseous Dental Implants (Blade-form) as defined under 21 CFR 872.3640(b)(2). Manufacturers were required to submit information concerning the safety and effectiveness of these devices.

The April 9, 2009 Federal Register Notice [Docket No. FDA-2009-M-0101] requiring safety and effectiveness information from industry, to support either a reclassification of blade-form implants or to require a PMA submission, received responses from one sponsor (TMJ Implants, Inc.). The TMJ Implants, Inc. response stated that the company does not currently manufacture blade-form endosseous dental implant but wanted to provide information regarding four devices marketed before 1976 which the company may market in the near future. These four devices, as described, are not actually blade-form endosseous dental implants. TMJ Implants, Inc. did not provide any information relevant to blade-form endosseous dental implants

2.4. 2013 Proposed Order to Require Premarket Notification for Blade-form implant devices

On January 14, 2013 (78 FR 2647), FDA published a proposed order proposing to reclassify blade-form implant devices. In this order, FDA has proposed

"that the device subject to this proposal be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls applicable to the devices, would provide reasonable assurance of their safety and effectiveness. FDA believes that the identified special controls in this proposed order, if finalized, together with general controls applicable to the device, would provide reasonable assurance of safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device."

3. Responses to the Docket for the 2013 Proposed Order

The proposed order provided for a 90-day comment period that was open until April 14, 2013. FDA received 2 comments to the docket. The comments are available at the following address: http://www.regulations.gov/#!docketDetail;D=FDA-2012-N-0677.

If the comments included relevant references, these references were checked against the list of references used in the literature review to determine if they had been considered as part of the Agency's assessment.

None of the comments openly stated an opinion, but did include statements for the proposed order that could reasonably be interpreted as support for a Class II designation. Both comments were received from dentists.

4. Indications for Use

A necessary component of a device description and labeling is an indication for use (IFU) statement. The IFU identifies the condition and patient population for which the device should be appropriately used, and for which the device has demonstrated a reasonable assurance of safety and effectiveness. 21 CFR 872.3640(a) defines an endosseous dental implant as "*An endosseous dental implant is a device made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.*"

There are slight variations on the indications for use of the devices that have been found substantially equivalent through the 510(k) process. It was not until 1996 that FDA began to use an official indications for use page, so it is difficult to ascertain the precise statement for blade-form implant cleared prior to 1996. These 510(k)s for blade-form implants generally describe the device with references which include "for insertion into oral bone", "for the maxilla or mandible", "substitute for the roots of the teeth replaced", or "functions as an attachment of a dental bridge. There is one blade-form implant cleared by FDA with an official indications for use page which states "Blade-form endosseous dental implants are intended for use in the edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a terminal abutment or intermediate abutment for fixed or partial dentures, or a single tooth replacement."

As part of our classification process, we consider all of the devices included within 21 CFR 872.3640(b)(2) that have been found to be substantially equivalent as part of the device type.

5. Clinical Background

5.1. Conditions

5.1.1. <u>Full or Partial Edentulism</u>

Teeth may be lost due to diseases of the periodontium resulting in bone loss and eventual tooth loss; trauma causing exfoliation, fracture, or non-restorable damage to teeth, as well as primary or secondary dental caries rendering the tooth nonrestorable. Teeth may also be congenitally missing.

Teeth transmit masticatory stresses to adjacent alveolar bone. These stresses maintain the alveolar bone in a manner following Wolff's Law where form follows function. When the alveolar bone is not stressed, or teeth are lost or removed, the alveolar bone loses this stressing and begins to resorb. The parts of the mandible and maxilla that house teeth can resorb to the point where only maxillary and mandibular "basal bone" remains.

Prior to dental implant placement, alveolar bone resorption generally results in a thinner and shorter alveolar process, depending on the amount of time the alveolar process remains unstressed. Thinner alveolar processes are harder to restore functionally and aesthetically because there is less bone present into which dental implants can be placed.

To augment the alveolar process in preparation for dental implant placement, bone grafting may be performed. Bone grafting may be used as a ridge preservation measure and also at the time of implant placement. Implants may transmit occlusal stresses to the alveolar bone, minimizing the amount of alveolar bone lost over time.

5.1.2. <u>Alternative Restorative Measures</u>

The restoration of masticatory function is achieved by prosthetic restoration of missing teeth. This may be accomplished with the placement of fixed or removable partial or full dentures, or endosseous dental implants.

Dental bridgework, also known as fixed bridgework or fixed partial dentures, has been used for many years, and is quite successful. The main drawbacks to the use of fixed bridges are recurrent caries and the destruction of good tooth structure needed to create space for aesthetic and functional bridge material to be placed. Recorded use of fixed partial dentures date back to the ancient Egyptians. At the present time, the use of partial dentures has been reduced with the advent of dental implants. Partial dentures are removable for daily cleaning and clasp teeth for retention. There is minimal tooth structure removal.

Unlike fixed bridges, removable partial dentures can be removed daily for cleaning and to permit the tissues under them to "breathe". Less than meticulous cleaning of teeth and removable partial dentures can facilitate recurrent caries, and if not properly made, can cause the loosening of teeth.

Like the use of partial dentures, removable full dentures (tissue supported) have a long history. They are intended to replace all of the teeth in the maxillary or mandibular arches. Full dentures do not transmit masticatory stresses to the alveolar process, and therefore are associated with a progression of bone loss over time. This requires intermittent relining of the dentures. Eventually, full dentures become so loose that they are almost non-functional. Some patients may not adapt well to full dentures.

6. Systematic Literature Review on Blade-form implants

The FDA conducted a systematic literature review to assess the safety and effectiveness of blade-form implant by analyzing the existing clinical literature from 1990 to the present to generate clinical information subsequent to the 1989 classification panel recommendation and FDA's concurrence to deny a reclassification petition for any form of endosseous dental implant. Some pre-1990 references were also included as they were provided to the FDA independent of the literature search.

We sought to address the following question:

1. What is the evidence for safety and effectiveness of blade-form implant for the treatment of replacing teeth in partially or fully edentulous patients for restoration of chewing function?

6.1. Methods

The following three literature searches were performed, which yielded a total of 95 articles related to blade-form endosseous dental implants:

- On December 20, 2001, 10 citations were provided by to the Dental Devices Branch
- On July 31, 2001, 42 citations were provided to the Dental Devices Branch in support of reclassifying blade-form endosseous dental implant as Class II along with root-form endosseous dental implants.

- In September 2011, a literature search for published clinical data related to blade dental implants was conducted between the years of 1990 and May 2010. The limit of 1990 was set due to the panel meeting in 1989, which rejected the petition to down-classify dental implants (both root-form and blade-form) from Class III to Class II. The primary strategy involved the search of published literature in: PubMed, Academic Search Complete, Alt Health Watch, Cambridge Scientific Abstract, CINAHL, Embase, ScienceDirect, and Web of Science (WOS), using the following terms:

  - "dental blade implant" or "dental blade implants" or
  - "blade implant" or ""blade implants"
  - "dental blade endosseous" or "dental endosseous"
  - "surface treatment"
  - "tooth implantation/syn"

The initial search was limited to studies conducted in humans, English language, and publication years from January 1990 to May 2010, which yielded 43 additional citations.

Titles and abstracts were reviewed and screened to identify articles that underwent full-text review (Figure 4 below). Articles were excluded for the following reasons: (i) blade-form implants were not involved; (ii) the article did not contain clinical data; were not human studies; (iii) were not a journal article; and/or (iv) were not in English. Summary assessments were collected for each of the studies and included in Table 3 at the end of this review.

In April 2013, the search was updated using three electronic databases, PubMed, Embase, and WOS, using the same search terms and limitations as the initial search conducted by FDA to support the intent to reclassify blade-form implants as identified in the proposed order that issued on January 14, 2013 (78 FR 2647). The time period for the updated search was from May 1, 2010 to April 18, 2013. The update search yielded 25 additional abstracts, and only two articles were selected for full text review and one was excluded because the study did not examine blade-form implants.

After going through the pre-specified exclusion criteria (Figure 4) a total of 9 publications were included in this FDA's literature review as depicted in Figure 3 and identified in Table 1.

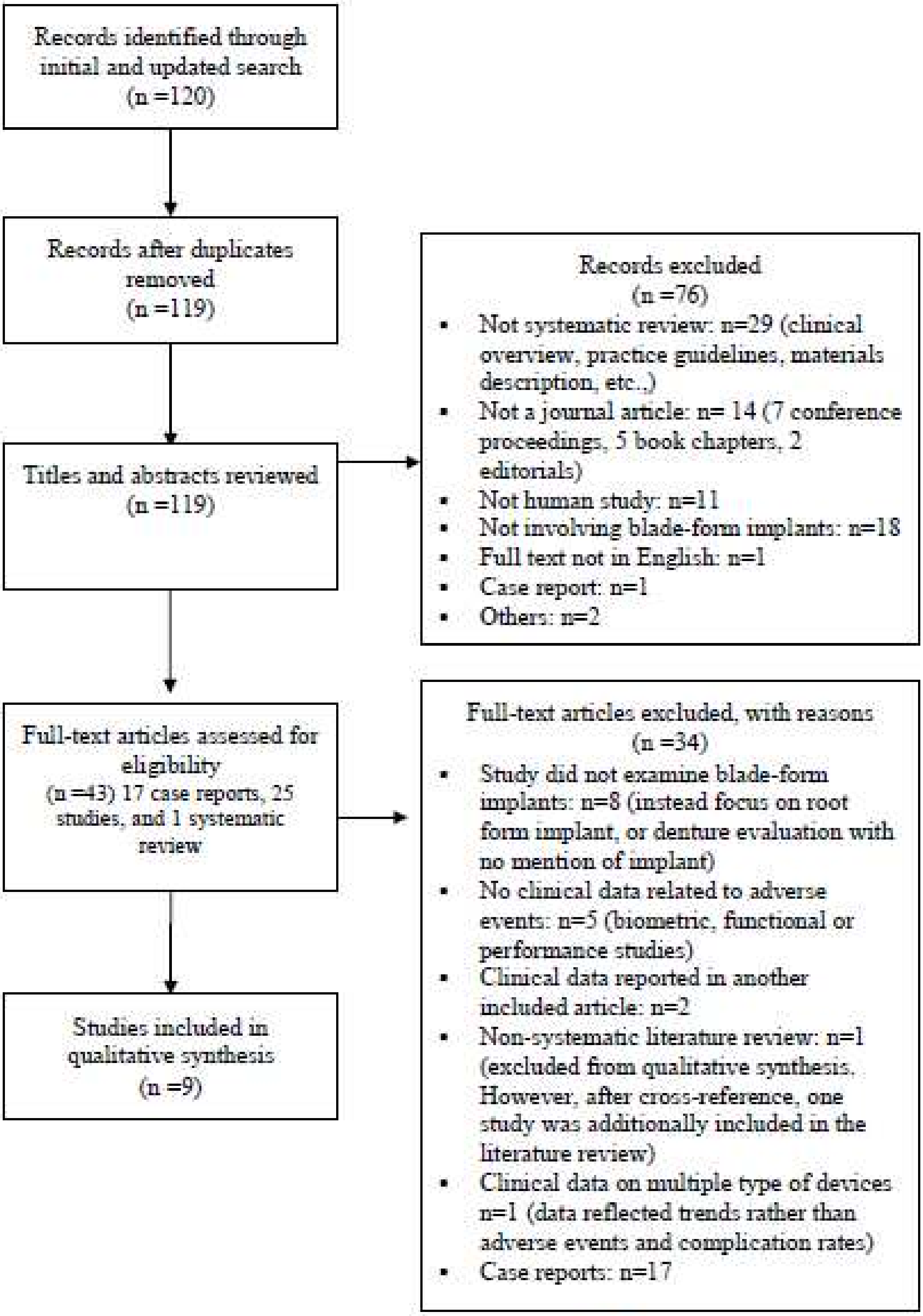

Figure 4 – Diagram of Article Retrieval and Selection

6.2. Summary of Results

A full diagram of the article retrieval and selection process appears in Figure 4 above. In summary, 119 articles were filtered by titles and abstracts. Seventy-six abstracts were excluded due to the following reasons: clinical overview/practice guidelines/materials description (n=29); non-journal article (n=14); non-human study (n=11); not related to blade-form implants (n=18); non-English article (n=1); case report (n=1); and others (n=2). The remaining 43 articles include 17 case reports, 25 studies, and one systematic review. Full-text articles were assessed for eligibility. Thirty-four articles were further excluded due to various reasons listed in the flow chart above. Nine articles were included in the systematic literature review (Table 2).

Data from eight retrospective studies and one randomized controlled trial were extracted and included in the qualitative analysis (Table 2)

6.3. Study Designs and Methodology

Data from one randomized controlled trial and eight retrospective studies were extracted and included in the qualitative analysis (Table 2). Success was consistently defined across studies as the device remaining implanted/not being removed.

The sample size for these studies ranged from 7 – 131 patients with blade-form implants. The age range was 50.1- 54 years from two articles [2, 6]. The follow-up period ranged from 3 to 20 years. The success rate and device survivability were the outcome measures for this literature review.

Success rate was defined using the following criteria as explicitly described in Noack, 1999 (based on Buser et al.): (1) absence of persistent subjective complaints, such as pain, foreign body sensation, and/or dysesthesia, (2) absence of recurrent peri-implant infection with suppuration, (3) absence of mobility, and (4) absence of a continuous radiolucency around the implant. However, Kapur et al. defined success rate as the absence of treatment and implant failure. The remaining articles used the term "success rate" but did not define it. In this literature review success rates ranged from 90% to 100% at five years.

Survivability refers to those implants still in function beyond the first five year period [1]. Survivability across the studies ranges from 86%-100% after 5 years. The most common adverse events were: (1) mobility, (2) swelling/pain, (3) implant fracture, and (4) bone loss or bone deterioration.

6.4. Safety/Effectiveness Findings for Tooth Replacement

Randomized Controlled Clinical Trial (N=1)

Kapur KK, et al. (1989) conducted a randomized controlled trial in US in 1987. Male patients in five Veteran Affairs centers in southern California were recruited. The patients' mean age at baseline was 51years old. The study compared two devices:

fixed partial dentures (FPD) supported by blade-vent implants and removable partial dentures (RPD). There were 119 patients with RPD and 114 patients with FPD. FPD has 84.2% five-year success rate (95% confidence interval [CI] 77.7, 97.7) and RPD has 74% five-year success rate (95% CI 66.0, 82.0). This 10.2% difference was not statistically significant. During the five-year period, treatment failures occurred in 19 FPD patients and 30 RPD patients. Ten (10) FPD failures occurred before FPD insertion and 9 failures after FPD insertion. For overall (FPD and RPD combined) bone deterioration at six-years, 29.6% did not have deterioration, slight: 25.4%, moderate: 15.9%, marked: 27%, severe: 2.1%.

Retrospective Observational Studies (N=8)

There were eight retrospective observational studies published from 1987 to 2010. Every study had at least three-years of follow-up. Two studies had three years[2, 6], four studies had five-year follow-up [1, 3, 5, 8]; the study in Germany had 16 year follow-up on average [7]; and Acevedo AL, et al. had up to 20 year follow-up on average.

There were four studies from the US. Sample sizes varied from 31 patients [3] to 131 patients [2]. The baseline clinical status varied between the studies. Patients were treated according to the indications for use.

There are two studies from Japan that examined retrieved devices and described reasons for failure [5, 6]. These two papers used the same dataset, which contained 59 patients with 78 hydroxyapatite-coated blade-form implants. However, the first one published in February 1996, described the entire sample (59), while the second one published in October of the same year, only described seven patients.

The outcome measures under evaluation for this literature review included device survivability and success rate. Acevedo AL also showed survival rate at intervals of 6-10 yrs, 11-15 yrs, and 16-20 yrs. Overall success proportion at five-year was above 90%. After 5 years, Acevedo et al. showed 100% survivability for interdental for mandible; 86% survivability with 50-57% grade I bone loss for interdental for maxilla; 67% survivability with 66% grade I bone loss for free-end for mandible. The Germany study that followed up patients for 16 years showed a 76% success rate.

. Adverse Events Associated with Blade-form Implants

The literature review identified several adverse events reported in the nine assessed articles. Table 1 lists the adverse events and the reporting article.

Table 1. Summary of adverse events reported in publications included in systematic literature review

Author, year	Range of follow-up	Bone loss or Bone deterioration	Swelling/Pain	Infection/Periodontal Disease	Implant fracture	Mobility
Takeshita F, 1996	1 – 8 years	100% * (7/7)	43%* (3/7)	43%* (3/7)	14%* (1/7)	43%* (3/7)
Telsey B, 1991	1 – 15 years	9.1% (6/66)	9.1% (6/66)	9.1% (6/66)	1.5% (1/66)	
Takeshita F, 1996	1 – 6 years		1% (1/78)		2% (2/78)	1% (2/78)
Roberts RA, 1996	1 – 26 years	1.7% (4/235)		0.4% (1/235)	1.3% (3/235)	
Kapur KK, 1989	1 – 5 years	3.9% (6/155)	3.9% (6/155)			1.3% (6/155)
Acevedo AI, 1987	1 – 5 years	18% (16/91)				
Hahn JA, 1990	1 – 3 years					
Noack N, 1999	1 – 16 years					
Strecha J, 2010	1-5 years					

Number of adverse events/number of implants placed
*Proportion of adverse events among seven implants that were removed

FDA has identified several potential risks of blade-form implant. Based on the literature and prior panels, the panel will be asked whether they believe this list is complete and accurate.

A reasonable assurance of safety is defined in 21 CFR 860.7(d)(1) as the probable benefits to health from use of the device outweighing any probable risks for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use. The regulation also states that the evidence shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

The panel will be asked whether the evidence demonstrates a reasonable assurance of safety for the indications for use of "surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function."

6.6. Discussion of Limitations of Systematic Literature Review

The one randomized controlled trial available only recruited male veteran patients, therefore gender bias cannot be ruled out and possible effects by gender could not be examined. In addition, the patients were veterans, a subgroup of patients who may differ from non-veterans. The study focused mainly on effectiveness and not safety.

One of the advantages for a RCT is that randomization avoids treatment selection bias, because the investigator does not have control selecting treatments based on the patient's profile. Also, if the patient was randomized and the sample size was large enough, the confounding factors known and unknown may be equally distributed.

Out of eight retrospective studies, most of them had small sample sizes ($n<50$) and were from single dental offices. Therefore, the power and generalizability of the results to overall patient population are limited. The overall success proportion at five-years was above 90%, this data comes from half of the studies which retrospectively extracted data from radiographic images. Most of the studies reported success/failure rates without providing information describing the reasons for implant failure. Therefore, it is difficult to make determinations about individual adverse events. Additionally, none of the papers systematically reviewed adverse events. The only conclusion to be derived is a general observation of the success rate. Of note, some of the reported studies did not provide information about the gender of the subjects, so the effects of how the device would perform in one gender as compared to the other are less clear.

6.7. Overall Literature Review Conclusions

An important strength of this review is that a systematic literature review reduces uncertainty by a rigorous methodology that is comprehensive, transparent or explicit, leading to minimum bias and providing objective and reproducible results. This process prevents bias in favor or against any unconsciously preferred outcome, providing more balanced answers to the systematic literature review questions. Well-defined methodology, like in this review, prevents bias, although does not protect against publication bias in the primary studies. If studies give consistent results, such as in this review, conclusions can be drawn that there is robust and generalizable evidence about the effectiveness and long-term safety profile of the device. In contrast, a systematic review methodology could be so rigorous that some publications could be excluded. Case reports and articles that were published in other languages were not selected in this review. Such studies may include reports for unusual adverse events. This limitation may prevent from identifying the presence of unusual adverse events.

In summary, nine articles were reviewed systematically for the safety and effectiveness of blade-form endosseous dental implants based on the five year survivability and success rates. Data from these nine articles show the success rate being consistently above 90% with the exception of one study reporting 84.2% success in males only. A long-term 100% device survivability was widely reported, except in one article reporting 90% 5-year survival. Although information about the blade-form implant is limited, and there were few studies that reported adverse events. The available evidence suggests that the device is effective and has a satisfactory long-term safety profile.

6.8. Manufacturer and User Facility Device Experience Database

The Manufacturer and Use Facility Devices Experience (MAUDE) database contains adverse events and reportable product problems with medical devices. The database was fully implemented in August 1996, and contains individual adverse event reports submitted by manufacturers, user facilities, importers, and voluntary reporters. The reports are associated with all legally marketed devices. FDA has not received any adverse events reports associated with blade-form implants as of May 30, 2013.

7. Risks to Health

The 1980 proposed rule for endosseous dental implants (both root-form and blade-form) included the following risks to health as previously identified by the Panel:

- *Tissue degeneration:* Localized tissue degeneration may be cause by endosseous implants due to excessive mobility.

- *Pain:* Nerve impingement by the device may cause pain.

- *Bone perforation:* Improper design of the device may cause excess mobility of the implant following surgical placement and subsequent perforation of the bony plates of the upper or lower jaws.

- *Infection:* Micro-organisms may be harbored between the implant and the gums and cause localized infection.

In the 2013 proposed order, FDA reiterated the concerns of the original classification panels, as well as those identified in the 2004 final rule for endosseous dental implants (root-form) and the systematic literature review. The following are proposed as the risks to health for blade-form implants:

- *Local tissue or existing dentition degeneration:* Localized tissue and existing dentition degeneration may be caused by endosseous implants due to excessive mobility, loss of integration, incompatibility of the device components, or structural failure of the device.

- *Pain:* Nerve impingement by the device may cause pain.

- *Bone or nerve damage:* Improper design or use of the device may cause injury during surgery related to sinus perforation, alveolar plate perforation, or nerve damage resulting in transient or chronic pain/facial nerve paresis.

- *Infection:* Implantable devices may introduce microorganisms that may cause local or systemic infections.

- *Adverse tissue reaction*: Inadequate tissue compatibility of the materials used in this device could cause an immune reaction.

- *Migration or thermal injury*: Incompatibility with magnetic resonance imaging may cause the device to migrate or heat.

The panel will be asked to discuss the risks to health identified by FDA for blade-form implant and whether these risks are appropriate, and/or whether there are additional risks to health that should be considered for these devices.

8. Mitigation of Risks to Health

8.1. Overview of Proposed Special Controls

Based on the safety and effectiveness information provided in the responses to the 515(i) Order, as well as information gathered by the FDA, FDA has recommended the establishment of special controls to adequately mitigate the risks to health as described in Section 7 above for blade-form implants,

When evaluating the adequacy of the special controls, it is important to understand that the FDA correlates the ability of each special control identified to mitigate an identified risk to health.

8.2. Proposed Special Controls

The FDA has proposed special controls be enacted in conjunction with reclassification as identified in FDA's proposed order recommending reclassification that issued on January 14, 2013 (78 FR 2647).

It is important to note that the classification of the device type and the special controls to support Class II must be based on the data that are available now, not the data that could be collected in the future. FDA believes that the following special controls, together with general controls, are sufficient to mitigate the risks to health described in Section 7 of this document:

- The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

- Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads.

- Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system.

- The device must be demonstrated to be biocompatible.
- Sterility testing must demonstrate the sterility of the device.
- Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment.
- Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, and relevant precautions and warnings based on the clinical use of the device.
- Patient labeling must contain a description of how the devices works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications.
- Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Blade-form endosseous dental implants are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device.

The panel will be asked to discuss the adequacy of these proposed special controls in providing a reasonable assurance of safety and effectiveness in light of the available scientific evidence.

Summary

For the purposes of classification (see the Regulatory Reference Sheet for additional information), FDA considers the following items, among other relevant factors, as outlined in 21 CFR 860.7(b):

1. The persons for whose use the device is represented or intended;
2. The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;
3. The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and
4. The reliability of the device.

Part (g)(1) of this regulation further states that it "is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and performance standards, may support a determination that the device be classified into Class III."

Based on the available scientific evidence and proposed special controls, the panel will be asked whether a Class II designation is warranted for blade-form implant to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function."

10. Tables

Table 2 – Publications included in the systematic literature review (n=9)

Author	Year	Study Design	Location
Acevedo AI[1]	1987	Retrospective	US
Hahn JA[2]	1990	Retrospective	US
Telsey B[3]	1991	Retrospective	US
Roberts RA[4]	1996	Retrospective	US
Takeshita[5]	1996	Retrospective	Japan
Takeshita[6]	1996	Retrospective	Japan
Noack N[7]	1999	Retrospective	Germany
Strecha J[8]	2010	Retrospective	Slovak and Czech Republics
Kapur KK[9]	1989	Randomized controlled clinical trial	US

Table 3 – Description of the Publications Evaluated in the Systematic Literature Review

Source [Author, Citation]	Study Design Level of Evidence	Study Population	Sample Size	Devices Studied	Study Endpoints	Relevant Study Results	Study Strengths and Limitations
Acevedo AI. [1]Success and survivability of endosteal blade implants managed in the practice of Dr. Linkow. J Oral Implantol 13:113-119, 1987.	- Retrospective observational study	-US (New York) -92% of 171 implants were full-arch fixed bridge restoration -Interdental and free-end blade implants only	-81 patients, 171 implants	-Interdental and free-end endosteal blade (brand unknown)	-Implant success/failure within 5 yrs -Implant survivability after 5 yrs (6-10 yrs, 11-15 yrs, 16-20 yrs) -Bone loss (Grade I, II, III)	-Interdental and mandible implant site favorable -91 cases with implant duration within 5 yrs have 91.2% success rate -Interdental for mandible (19 cases): Within 5 yrs, 100% success rate with isolated case of grade II bone loss due to gingival infection; After 5 yrs, 100% survivability -Interdental for maxilla (12 cases): Within 5 yrs, 100% success rate with 50% grade I bone loss; After 5 yrs, 86% survivability, 50%-57% grade I bone loss -Free-end for mandible (30 cases): Within 5 yrs, 93% success rate with 13% grade I bone loss, 7% grade II bone loss; After 5 yrs, 90% success rate with 37% grade I bone loss -(?)Free-end data not specified: Within 5 yrs, 85% success rate with 12% grade I bone loss, 7% grade II bone loss; From 6-10 yrs, 67% survivability, 66% grade I bone loss	*Strengths:* long follow-up (5-15 years) *Limitations:* - Small sample size - Single private dental office practice. - The table and chart referred in the text were not included
Telsey B, Oshrain HI, Joodeph NH, Mandel ID.[3] Retrospective radiographic study of blade implants, J Oral Implantol 17:140-145, 1991.	- Retrospective observational study	-US -Blade-implant patients aged 31-72 yrs -20 implants in 11 males and 46 implants in 20 females	-31 patients, 66 implants (25 in maxilla and 41 in mandible)	-13 two-post blades and 53 one-post blades -Implant location: 7 incisor, 17 canine, 42 molar (brand unknown)	-Status of blade implant in use at least 5 yrs	-5-yearImplant survival 90%, favorable in mandible site -6 total implants removed in 5 patients (5 maxilla and 1 mandible) located in 1 incisor, 3 canines, 2 molars -1 maxillary molar blade and 1 mandibular molar blade failed -2 implants removed after 3.5 yrs due to pain -1 implant removed after 4 yrs due to an adjacent natural teeth severely decaying -1 implant removed after 6 yrs due to head breakage -1 implant removed after 10 yrs due to operator error (implant not placed deep enough) -1 implant removed after 11 yrs due to suppuration, loss of bone, and pain -11 progressive periodontal disease patients with 23 implants had 5 failures -18 stable periodontal disease patients with 34 implants had 1 failure	*Limitations:* - Small sample size - Single private dental office practice
Noack et. al.[7] Long-term results after placement of dental implants: Longitudinal study of 1964 implants over 16 years, 1999	Retrospective observational study	-Germany -530 females, 353 males -Ages 15 to 86 years -Patients with history of uncontrolled diabetes, ongoing chemotherapy, radiation therapy (head and neck), psychologic instability were excluded	-883 patients -1250 IMZ in 527 patients -349 Branemark in 144 patients -286 Frialit-1 and Frialit-2 in 151 patients -79 Linkow blade in 61 patients	-Branemark -Frialit-1 -Frialit-2 -IMZ -Linkow blade	-16-year study -Follow-up every 3 months for first 2 years, at least annually thereafter	-Linkow blade: 13/53 (24%) failure rate	*Strengths* -Long-term follow-up -1 surgeon performed all implantations and follow-ups *Limitations* -Some patients received more than one type of implant -74 patients with 153 implants lost to follow-up (refusal to follow-up, death) -Branemark (mandible) -Frialit-2 (maxilla) -IMZ, Linkow (mandible) -Higher failure rates in older implant systems (Frialit-1, Linkow)
Roberts RA[4] Types, uses, and evaluation of the plate-form implant. *J Oral Implantol* 22:111-118, 1996.	Retrospective observational study	-US - gender not reported	-Ramus Blades (51 SS, 184 Ti) -RA-1 (14 SS) -RA-2 (21 SS, 66 Ti) -RA-3 (66 Ti) -STR (7 SS, 249 Ti)	-Ramus Blades -RA-1 -RA-2 -RA-3 -Single Tooth Replacements (stainless steel and titanium)	-9/1969-3/1995 (SS) -5/1982-3/1995 (Ti)	-8/51 Ramus Blades (SS) failure rate -2/184 Ramus Blades (Ti) failure rate -failure due to mobility, settling, non-resolvable local inflammation, paresthesia, anesthesia, significant pain	*Strengths* - Kaplan-Meier survival and hazard curves for Ramus Blades *Limitations* -No mention of number of patients by age, gender etc. -Ti use primary after 1982
Hahn JA.[2] A preliminary clinical evaluation of the steri-oss implant	Retrospective observational study	-US -58 males -73 females -14-83 years	-131 implants -97 (root form)	-Steri-Oss System	-3-year period -4-6 months follow-ups	-0/50 implant failure rate	*Strengths* -100% success rates

Source [Author, Citation]	Study Design Level of Evidence	Study Population	Sample Size	Devices Studied	Study Endpoints	Relevant Study Results	Study Strengths and Limitations
system. *Int J Oral Implan* 7:31-36, 1990.			-7 (blade) -27 (root and blade)				*Limitations* - Small sample size
Takeshita et. al.[6] Fractures of hydroxyapatite-coated blade implants connected with natural teeth. A histological study using SEM, light microscopy, and an image processing system. J Periodontol 67:86-92, 1996	Retrospective observational study	-Japan -of the 5 cases presented -3 males -2 females -45-69 years	-78 HA-coated blade implants in59 patients	-HA-coated blade-form implants	-Over 3-year period -4-6 months follow-ups	-5 failures occurred due to superstructure mobility, swelling/pain, implant fracture	*Strengths* - Scanning electron microscopic analysis *Limitations* -Small sample size
Kapur KK. J [9]Prosthet Dent 59:499, 1987. Part II, 1989	Randomized controlled trial	-5 VA centers in south California, US -dental implants -All male patients -- Mean age: =51 at baseline, age categories: 25-54yr, 55+ yr. - Exclusion criteria : prespecified medical conditions that make patients not suitable for surgery; oral/teeth conditions not suitable for surgery.	-119 patientsts with RPD -114 patientsts with FPD	compare 2 devices: fixed partial dentures supported by blade-vent implants (FPD) and removable partial dentures (RPD)	-Success rate at 5 yrs -Periodontal health -Bone deterioration at 5 yr	-5-yr success rates = 84.2% for FPD and 74% for the RPD - During 5-yr period, treatment failures occurred in 19 FPD patients and 30 RPD patients -10 FPD failures occurred before FPD insertion and 9 failures after FPD insertion - Bone deterioration at 6-yr: - 29.6% No deterioration - 25.4% slight - 15.9% moderate - 27% marked - 2.1% severe	-gender bias was introduced because only male patients were recruited -not clear how age cut-off was selected -mainly focused on effectiveness
Takeshita et. al.[5] A histologic evaluation of retrieved hydroxyapatite-coated blade-form implants using scanning electron, light, and confocal laser scanning microscopies. J Periodontol 67:1034-1040, 1996	Retrospective observational study	-Japan -of the 7 cases presented -4 males -3 females -33-61 years	-78 HA-coated blade implants -59 patients	-HA-coated blade form implants	-Over 5-yr period -Time of restoration between 2-4 months	-7 failures occurred due to discomfort (swelling), implant fracture, pain (purulent discharge), mobility w/and w/out purulent discharge	*Strengths* - Scanning electron microscopic analysis *Limitations* -Small sample size
Strecha J et. al.[8] Fixed Bicortical Screw and Blade Implants ans a Non-Standard Solution to an Edentulous (Toothless) Mandible Int J Oral Sci, 2(2): 105-110, 2010	Retrospective observational study	4 Clinics: 3 in the Slovak Republic and 1 in the Czech Republic. - dental implants - Male and female patients were studied - no specific demographics for those implanted with the blade implant	- 84 blade implants	- blade dental implants were made of biocompatible titanium by fy. Martikan from the Slovak Republic (www.martikan.eu)	- implant success/failure in a maximum of 5-year follow-up	- 5-year success rate: 98.8% -Only one failure reported	*Strengths:* Success rate of blade implants (98.8%) is slightly higher than bicortical implant (98.4%). *Limitations* Small sample size No specific demographics included Not clear how many patients were followed for 5 years No data analysis methods included No inclusion/exclusion selection criteria included

Abbreviations
Yrs = years

11. References

1. Acevedo, A.I., *Success and survivability of endosteal blade implants managed in the practice of Dr. Linkow.* J Oral Implantol, 1987. **13**(3): p. 488-91.
2. Hahn, J.A., *A preliminary clinical evaluation of the Steri-Oss implant system.* Int J Oral Implantol, 1990. **7**(1): p. 31-6.
3. Telsey, B., et al., *Retrospective radiographic study of blade implants.* J Oral Implantol, 1991. **17**(2): p. 140-5.
4. Roberts, R.A., *Types, uses, and evaluation of the plate-form implant.* J Oral Implantol, 1996. **22**(2): p. 111-8.
5. Takeshita, F., et al., *A histologic evaluation of retrieved hydroxyapatite-coated blade-form implants using scanning electron, light, and confocal laser scanning microscopies.* J Periodontol, 1996. **67**(10): p. 1034-40.
6. Takeshita, F., et al., *Fractures of hydroxyapatite-coated blade implants connected with natural teeth. A histological study using SEM, light microscopy, and an image processing system.* J Periodontol, 1996. **67**(2): p. 86-92.
7. Noack, N., J. Willer, and J. Hoffmann, *Long-term results after placement of dental implants: longitudinal study of 1,964 implants over 16 years.* Int J Oral Maxillofac Implants, 1999. **14**(5): p. 748-55.
8. Strecha, J., et al., *Fixed bicortical screw and blade implants as a non-standard solution to an edentulous (toothless) mandible.* Int J Oral Sci, 2010. **2**(2): p. 105-10.
9. Kapur, K.K., *Veterans Administration Cooperative Dental Implant Study--comparisons between fixed partial dentures supported by blade-vent implants and removable partial dentures. Part II: Comparisons of success rates and periodontal health between two treatment modalities.* J Prosthet Dent, 1989. **62**(6): p. 685-703.
10. Buser D, Brägger U, Lang NP, Nyman S. Regenaration an enlargement of jaw bone using guided tissue regeneration. Clin Oral Implants Res 1990; 1(1):22-32.

FDA – Food and Drugs Administration 18 giugno 2014

Federal Register / Vol. 79, No. 117 / Wednesday, June 18, 2014 / Rules and Regulations 34623

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2012–N–0677]

Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

to agency procedure and practice and, thus, is not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, these regulations are not a "rule" as defined by the Regulatory Flexibility Act, 5 U.S.C. 601(2), and no initial or final regulatory flexibility analysis is required.

VI. Paperwork Reduction Act

The Bureau has determined that the regulations in this subpart do not impose any new recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would constitute collections of information requiring approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects in 12 CFR Part 1081

Administrative practice and procedure, Banking, Banks, Consumer protection, Credit, Credit unions, Law enforcement, National banks, Savings associations, Trade practices.

Authority and Issuance

For the reasons set forth above, the interim final rule amending 12 CFR part 1081 published at 78 FR 59163, September 26, 2013, is adopted as a final rule without change.

Dated: June 10, 2014.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2014–14228 Filed 6–17–14; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2012–N–0677]

Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the blade-form endosseous dental implant, a preamendments class III device, into class II (special controls). On its own initiative, based on new information, FDA is revising the classification of blade-form endosseous dental implants.

DATES: This order is effective July 18, 2014.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283, *michael.ryan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon "new information." FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)) or in light of changes in "medical science" (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the "new information" to support reclassification under section 513(e) of the FD&C Act must be "valid scientific evidence," as defined in section 513(a)(3) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Manufacturers Association* v. *FDA,* 766

F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986).)

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the "valid scientific evidence" upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act, added by FDAMA, provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 513(e)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket.

II. Regulatory History of the Device

FDA published a proposed order to reclassify this device in the **Federal Register** of January 14, 2013 (78 FR 2647) (the "proposed order"). As discussed in the proposed order, the Agency originally issued a final rule classifying all endosseous dental implants (without distinguishing based on geometry) into class III (52 FR 30082, August 12, 1987). After later consideration by a reclassification panel, root-form endosseous dental implants were reclassified into class II in a final rule issued on May 12, 2004 (69 FR 26302), but blade-form endosseous dental implants remained in class III.

After consideration of available information on blade-form endosseous dental implants, the proposed order indicated that FDA believed these devices could also be down classified to class II, subject to the identified special controls. As required by section 513(e)(1) of the FD&C Act, on July 18, 2013, FDA also convened a meeting of the Dental Products Panel (the Panel) to consider the existing valid scientific evidence to support reclassification of blade-form endosseous dental implants into class II.

The Panel discussed and agreed that the risks to health for this device were adequately captured as presented by FDA. The Panel deliberations included discussion of whether the risk of bone loss is higher for blade-form dental implants as compared to root-form dental implant devices. The Panel also discussed the technique-sensitive nature of this device and expressed a concern that additional training, which may not be found in the current curriculum for dental schools, is needed prior to the use of this device to address the identified risks to health.

The Panel agreed that the proposed special controls were reasonable to mitigate the identified risks to health but recommended the device labeling include specific patient selection criteria and recommendations for training and education requirements for clinicians using this device. The Panel recommended that companies marketing this device ensure that device-specific training is available to clinicians. The Panel also recommended clinical data as a special control for the purpose of capturing failure rates and adverse event detection.

The special controls as previously proposed by FDA included documented clinical experience for effective use and observed adverse events which addresses the recommendations for patient selection criteria, and failure rate and adverse event detection. Additionally, the special controls include patient labeling which must contain instructions for reporting complications. The patient labeling will also address the concern for failure rate and adverse event detection. To address the Panel's concern related to recommendations for training and education requirements, FDA has added a special control for the device labeling to include qualifications and training requirements for clinicians using this device.

The Panel concluded that general controls alone are not sufficient due to the identified risks to health; however, special controls, in combination with the general controls, can be sufficient to assure the safety and effectiveness of blade-form endosseous dental implants. The Panel agreed that this device should be reclassified into class II (special controls).

III. Public Comments in Response to the Proposed Order

In response to the proposed order, FDA received two comments from practicing clinicians. Both of the comments supported reclassification of the devices into class II, and described positive clinical experience regarding the safety and effectiveness of the device. FDA agrees with the comments.

IV. The Final Order

Under section 513(e) of the FD&C Act, FDA is adopting its findings as published in the preamble to the proposed order. FDA is issuing this final order to reclassify the blade-form endosseous dental implant from class III to class II and to establish special controls. Following the effective date of this final order, firms marketing blade-form endosseous dental implants will need either to: (1) Comply with the particular mitigation measures set forth in the special controls or (2) use alternative mitigation measures, but demonstrate to the Agency's satisfaction that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the devices. FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of blade-form endosseous implants; and therefore, this device type is not exempt from premarket notification requirements.

V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231;

and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

VII. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) of the FD&C Act provided for FDA to issue regulations to reclassify devices. Although section 513(e) of the FD&C Act as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i) of the FD&C Act, as amended by FDASIA, in this final order, we are revoking the requirements in 21 CFR 872.3640 related to the classification of blade-form endosseous implants as class III devices and codifying the reclassification of blade-form endosseous into class II.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 872.3640 is amended by revising paragraph (a) and (b)(2) to read as follows:

§ 872.3640 Endosseous dental implant.

(a) *Identification.* An endosseous dental implant is a prescription device made of a material such as titanium or titanium alloy that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) * * *

(2) *Classification.* Class II (special controls). The device is classified as class II if it is a blade-form endosseous dental implant. The special controls for this device are:

(i) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use;

(ii) Mechanical performance (fatigue) testing under simulated physiological conditions to demonstrate maximum load (endurance limit) when the device is subjected to compressive and shear loads;

(iii) Corrosion testing under simulated physiological conditions to demonstrate corrosion potential of each metal or alloy, couple potential for an assembled dissimilar metal implant system, and corrosion rate for an assembled dissimilar metal implant system;

(iv) The device must be demonstrated to be biocompatible;

(v) Sterility testing must demonstrate the sterility of the device;

(vi) Performance testing to evaluate the compatibility of the device in a magnetic resonance (MR) environment;

(vii) Labeling must include a clear description of the technological features, how the device should be used in patients, detailed surgical protocol and restoration procedures, relevant precautions and warnings based on the clinical use of the device, and qualifications and training requirements for device users including technicians and clinicians;

(viii) Patient labeling must contain a description of how the device works, how the device is placed, how the patient needs to care for the implant, possible adverse events and how to report any complications; and

(ix) Documented clinical experience must demonstrate safe and effective use and capture any adverse events observed during clinical use.

Dated: June 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14216 Filed 6–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9669]

RIN 1545–BM25

Participation of a Person Described in Section 6103(n) in a Summons Interview Under Section 7602(a)(2) of the Internal Revenue Code

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations modifying regulations promulgated under section 7602(a) of the Internal Revenue Code relating to administrative summonses. Specifically, these temporary regulations clarify that persons with whom the IRS or the Office of Chief Counsel (Chief Counsel) contracts for services described in section 6103(n) and its implementing regulations may be included as persons designated to receive summoned books, papers, records, or other data and to take summoned testimony under oath. These temporary regulations may affect taxpayers, a taxpayer's officers or employees, and any third party who is served with a summons, as well as any other person entitled to notice of a summons. The text of these temporary regulations serves as the text of the proposed regulations (REG–121542–14) set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on June 18, 2014.

Applicability Date: For date of applicability, see paragraph (d) of this temporary regulation.

FOR FURTHER INFORMATION CONTACT: A M Gulas at (202) 317–6834 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

These temporary regulations amend Procedure and Administration Regulations (26 CFR part 301) promulgated under section 7602 of the Internal Revenue Code. These temporary regulations make clear that persons described in section 6103(n) and Treas. Reg. § 301.6103(n)–1(a) with whom the IRS or Chief Counsel contracts for services may receive books, papers, records, or other data summoned by the IRS and take testimony of a person who the IRS has summoned as a witness to provide testimony under oath. While IRS officers and employees remain responsible for issuing summonses and developing and conducting examinations, the temporary regulations clarify that contractors are permitted to participate fully in a summons interview. Full participation includes, but is not limited to, receipt, review, and use of summoned books, papers, records, or other data, being present during summons interviews, questioning the person providing testimony under oath, and asking a summoned person's representative to clarify an objection or an assertion of privilege.

Minimally invasive piezosurgery for a safe placement of blade dental implants in jaws with severe bone loss

Rossi F, Pasqualini ME, Grivet Brancot L, Corradini M, Lorè B, Calabrese L

Journal of Osseointegration October 2014; 6(3)

LA MINIINVASIVITA' DEL BISTURI PIEZOELETTRICO PER L'INSERIMENTO IN SICUREZZA DEGLI IMPIANTI PLAT-FORM A LAMA NELLE ATROFIE MASCELLARI

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TO CITE THIS ARTICLE
Rossi F, Pasqualini ME, Grivet Brancot L, Colombo D, Corradini M, Lorè B, Calabrese L. Minimally invasive piezosurgery for a safe placement of blade dental implants in jaws with severe bone loss. J Osseointegr 2014;6(3):56-60.

ABSTRACT

Aim Severe atrophies of edentulous jaws require major reconstructive bone surgery in order to allow the placement of root-form implants with standard diameter. These bone augmentation techniques represent the best option reported in the literature, but they are often rejected by patients because of their high economic and biological costs in addition to the possibility of failure in the short and/or long term. In the maxilla regenerative methods (onlay, inlay, and distraction) have high success rates, whereas in the mandible, especially in the distal atrophic area, they are not so predictable. In such situations an alternative technique for fixed prosthethic rebilitation is the insertion of platform blade implants, which have their elective indication for atrophic bone ridges with reduced width, owing to their reduced thickness. The aim of this study is to assess the effectiveness of the use of piezoelectric ultrasonic handpieces, in order to simplify the placement of blade implants, making it safer and less traumatic than with conventional surgical procedures.

Materials and methods Platform blade implants are extension implant functionally and aesthetically reliable, even if they require a more difficult surgical technique compared with the one currently in use for screw implants. A minimally invasive procedure by means of piezosurgery that was performed on 142 subjects is presented and a case is reported which highlights the successful results.

Results and conclusion The use of piezoelectric ultrasonic handpieces simplifies the surgical procedure for the placement of blade implant, making it safer and less traumatic.

KEYWORDS Blade implants, Inferior alveolar nerve; Minimally invasive surgery; Piezosurgery; Posterior mandibular atrophy.

INTRODUCTION

The scientific progress in oral implantology gave rise to enhanced surgical techniques aimed at increasing the volume of atrophic ridges in view of the subsequent placement of implants. These bone regeneration procedures are achieved mainly by means of bone grafts (onlays-inlays) or of distraction osteogenesis (1-7). However, they imply different levels of stress that risk patients can not afford. Furthermore, their outcomes are not enough predictable and complications are numerous (8-18). Consequently, bone regeneration procedures can be performed only in selected cases. In particular, in the lower jaw the use of standard diameter root-form implants often results in problems during insertion owing to insufficient bone volume.

Atrophic areas, being generally highly mineralized and poorly vascularized, do not respond positively to the various grafting techniques because of the possibility of failure and their high biological cost. For these reasons, according to EBM (Evidence Based Medicine), these techniques are not sufficiently predictable (19 -22).

An alternative to augmentation techniques in posterior areas of the jaw with severe horizontal and vertical resorption and with bone width less than 3 mm, is offered by the placement of platform or blade implants with reduced thickness.

Blade implant were developed by Linkow and Roberts at the end of the 60s of the last century, when they created an endosseous implant with an all-in-one abutment with a fixture of variable form, for the adaptation in different bone sites. Over the years, Leonard Linkow modified and improved both the shape and the implant surface (23-26).

In 1972 Ugo Pasqualini presented the "polymorphic blade", which is the only implant that can be shaped according to the morphological characteristics of the bone in which it has to be inserted.

The polymorphic blade is a one stage implant, structured with an emerging threaded part which prevents that external mechanical stresses (caused by swallowing,

	AGE	N. IMPLANTS	5 YEAR SUCCES RATE	AVG SUCCESS RATE
Male (59)	51-60	3	94,8	93,4
	61-70	31	93,1	
	> 71	25	92,4	
Female (83)	51-60	12	95,3	94,2
	61-70	39	94,6	
	> 71	32	92,7	
TOTAL		142	93,8	

TABLE 1 The table summarizes the 142 cases of mandibular distal atrophy treated with blade implants.

tongue and jaw muscles) reach the submerged structures. In 1972 Ugo Pasqualini wrote: «The best conditions for rapid healing of surgical wounds, unavoidable for the insertion of implants, with bone recovery around, above and through implants themselves, occur only when these have been completely submerged, without communication with the outer site. This is useful not so much to eliminate the dreaded but unlikely risk of microbial contamination, but rather to prevent that the lever arm of the external abutment transfers dangerous mechanical stresses to the inner part, thus subjecting the implant to continuous mobilizations that could affect the achievement of including osteogenesis (that is osseointegration)» (27-30).

Conventional blade implant insertion is performed in open flap surgery, in order to expose the bone ridge where a sagittal cut is performed for the placement of the submerged part of the blade (minimum bone thickness required is 2 mm). Grooves are made by means of a fissure bur (according to the length of the shank) mounted on a handpiece. They should accommodate all the intraosseous part of the blade. The drilling of the bone requires simultaneous cooling of the surgical site by means of irrigation with saline solution. The blade is manually placed on the groove, and then locked in place by gently hammering it with a mallet. The blade should lie at least 2 mm below the edge of the ridge, in order to be completely covered by bone tissue during the healing period (31-33).

This technique requires considerable surgical skill during groove preparation, the cut has to be very accurate and precise. In order to overcome problems connected to inaccuracy of the operator's hand or unpredictable movements of the patient, Linkow recommended to perform a series of small holes on the cortical surface and subsequently merge them using a fissure bur. We recommend the use of Geyer's cog wheel, which is a low speed contra-angle bur, made of an indented disk 1 mm thick and 5 mm in diameter, which is used to draw a grove along the cortical bone, and then the cut is deepened through the bone with a fissure bur (34-36).

Recently thanks to piezosurgery, the placement of blade implants has become more precise and safer since deeper soft tissues, particularly those inside the mandibular canal, are not traumatized (37-38).

A protocol was devised using an ultrasonic surgery device and, in order to assess its advantages, in terms of selective micrometric, precise and secure cutting, a multicenter study was performed.

MATERIALS AND METHODS

In order to assess the procedure, a multicenter study was carried out in five Italian private practices (Busto Arsizio, Milano, Torino, Como, and Trento) on 142 subjects with atrophic edentulous posterior jaw (Table 1), between 2005 and 2008, and the 5 years follow up in 2013. The study was carried out in accordance with the ethical standards specified in the Declaration of Helsinki and written informed consent was obtained from all participants, prior to their inclusion in the study.

Inclusion criteria were the following: atrophic edentulous posterior jaw requiring implant-supported prosthetic rehabilitation.

All subjects were treated following the same surgical procedure, local anesthesia included. Local anaesthesia was performed by injecting a reduced dose (0.90 ml x 1) of articaine 40 mg/ml with adrenaline 1: 100,000 on both sides of the bone crest, or with the use of intraligamentary anaesthesia (Peripress) along the edentulous ridge (39).

These topical anesthetics allow to keep a deep sensitivity, which is perceived by the patient even close to the mandibular nerve, and it guarantees the absolute respect of the vascular-nervous structure. Nerve-block anesthesia is absolutely contraindicated even with any other implant technique.

Surgical procedure

The flap should be raised on the ridge without vertical incisions, allowing for adequate blood supply to the atrophic bone and direct observation of the entire morphology and topography of bone itself. Once the bone is exposed, the muco-periosteal tissues are dissected with the periosteal elevator and gently folded down. A surgical gap is achieved, using the flat serrated insert (ES071) of the Ultrasonic Bone Surgery unit (Italia Medica Srl; Milano, Italy). After radiographic and anatomic analysis by means of OPT and Cone Beam CT, a blade implant of adequate size is inserted (in the case presented it is 12 mm in length).

The surgical gap should meet the following requirements: equal or slightly longer than the mesio-distal length of the implant selected, a width in the buccal lingual sense slightly narrower than the width of the upper edge of the implant blade (blade's shoulder thickness 1.4 mm, lower edge thickness 0.5 mm), so as to prevent its passive insertion in the furrow but for some millimeters, in order to immediately achieve primary stability, after implant insertion (press-fit). The depth should be equal to the height of the implant blade, from its lower edge to the basis of the screw abutment. The height of commercially available blades generally varies from 5 to 12 mm (in this case it is 9 mm). The implant blade is inserted into the grove by locking it in place with a special chisel awl; the groove is prepared by means of a special serrated piezosurgery device. The shoulder of the implant must lie at least 2 mm below the edge of the bone crest. The mucosa is then sutured with interrupted sutures (40).

Post-surgical procedure

In our multicenter study, polymorphic one-stage blade implants were used with screwable abutments (approved with CE 0301, CE 0476 Single-stage blade, CE 0476 Mini blade, Single-stage double-abutment blade EC 0068/ QCO-DM038-2009, validated in the European Union).

After a period of at least 3 months, healing caps are removed, the final abutments are placed and the prosthetic phase can start. The prosthesis may include a natural tooth when it is not possible to connect the blade with another implant, according to the American Dental Association (ADA) which has established the validity of this procedure (41). It should be noted that in 2013, the FDA (Food and Drug Administration), in the United States, has proposed the requalification of the blade implant, bringing the surgical risk from grade 3 to grade 2 as for all other standard root form implants (42).

CASE REPORT

Here we report the case of a 46 years old female patient with severe atrophy of the right mandible.

CAT (computerised axial tomography) highlighted the severe atrophy of the edentulous area with the presence of an impacted third molar and an ankylosed residual root, which was asymptomatic and kept in situ according to the wish of the patient (Fig. 1). After the millimetric controls for the choice of the fittest polymorphous blade for the specific site and having exposed the ridge bone into plain sight, osteotomy was performed using exclusively the specific insert ES071 applied to the piezoelectric handpiece for ultrasonic surgery (Fig. 2).

This surgical technique allowed a selective micrometric, precise and secure cutting (Fig. 3), ensuring a good view of the operative field, furthermore the healing of the bone and soft tissue occurred without any

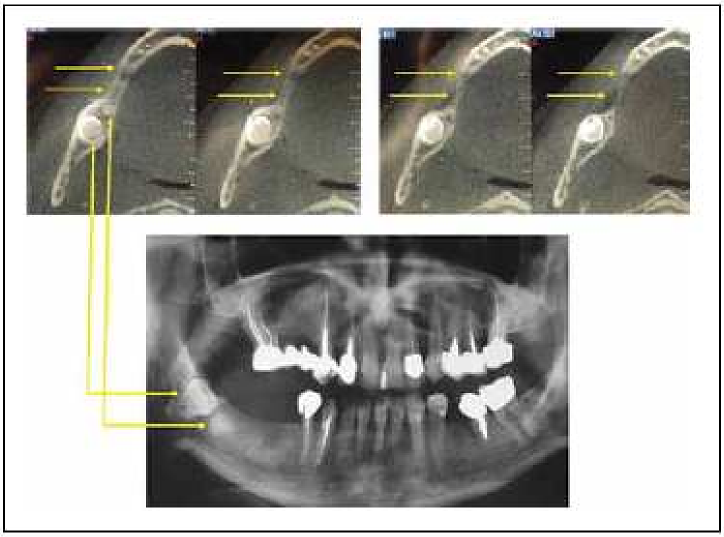


FIG. 1 CAT scan series, highlighting the bone atrophy, and the panoramic radiograph. Yellow arrows mark the implant area, the impacted third molar and the ankylosed residual root.

FIG. 2 A The serrated insert working in depth. B Profile of the polimorphic blade with Pasqualini's screw abutment, just inserted. C Osteotomy with the correct insertion of the implant.

FIG. 3 A The definitive prothesis in gold and porcelain. B Final radiographic control (2008).

FIG. 4 Soft tissues and the X-ray evidence the success of the implant-prosthetic rehabilitation with blade and natural teeth after 5 years (2013).

complications and with minimal pain.
After a healing period of three months, enough for the complete achievement of osseointegration, the prosthetic rehabilitation was started, which included two natural teeth, that had previously undergone endodontic treatment (Fig. 4).
At the 5-year follow-up, periodontal and peri-implant soft tissues health was assessed, as a result of the periodic check ups and the adequate hygiene, and a stable occlusal harmony was achieved (Fig. 5, 6).

DISCUSSION AND CONCLUSION

Blade implants are part of the evolution of prosthetic implants started in the late 60's with its maximum development in the 70's, during which blade implants were modified and improved, playing for a certain period the role of the most widely used implant system in the world. With the advent of root form implants, blades went into gradual disuse: only a few operators still use this technique, which is the elective procedure in terms of success and reliability in the rehabilitations of atrophic edentulous distal areas of the mandible, without discrediting the insertion techniques used for biphasic implants. This elective use, however, does not exclude the excellent behavior of blade implants in areas with severe deficiency of bone thickness in the upper jaw (43-45).
The conventional surgical technique still is a complex procedure where the slightest mistake inevitably leads to failure. Most blade implant failures reported in the literature are in fact related to the surgeon's inadequate skill in performing the technique. Indeed, it requires strict patient selection and adherence to its crucial steps. When properly used, blade implants can be very successful in atrophic conditions with reduced thickness, for which they were in fact originally devised (46, 47).
These difficulties are greatly reduced by piezosurgery, which results in: less invasive procedures, micrometric and selective cuts are more easily performed, advantages determined by the cavitation effect, extreme precision and safety with respect of the soft tissues, in particular the vascular-nervous components, reduced tissue heating, provided that the serrated insert is gently pressed and abundant irrigation with saline solution is supplied. Moreover, clear view of the surgical field, reduced rehabilitation time, pain reduction are also provided. As drawbacks, there are extended surgical times, which need sensitiveness and patience from both the surgeon and the patient. However, the increased working comfort amply compensates for the extended surgical time.

ACKNOWLEDGEMENTS

This multicentric study was carried out with the assistance of the colleagues: Luca Dal Carlo, PierAngelo Manenti, Enrico Belotti, Lucio Bilucaglia, Enrico Moglioni, Federico Meynardi, Marco Gnalducci, Emanuele Morella, Giancarlo Cortese, Giorgio Galassi, Michele Nardone, Francesco Grecchi.

REFERENCES

1. Basa S, Varol A, Serer ID, Sertgoz A. Posterior maxillary segmental osteotomy for restoring the mandible with dental implants: a clinical report. J Prosthet Dent 2008 May; 99(5):340-3.
2. Buser D, Dahlin C, Schenk RK. Guided bone regeneration in implant dentistry. Chicago: Quintessence; 1994.
3. Chiapasco M, Zaniboni M, Boisco M. Augmentation procedures for the rehabilitation of deficient edentulous ridges with oral implants. Clin Oral Implant Res 2006 Oct;17 suppl 2:136-59.
4. Chiapasco M, Romeo E, Casentini P, Rimondini L. Alveolar distraction osteogenesis vs. vertical guide bone regeneration for the correction of vertically deficient edentulous ridges: a 1-3 years retrospective study on humans. Clin Oral Implants Res 2004 Feb; 15(1):82-95.
5. Chiapasco M, Zaniboni M, Rimondini L. Autogenous onlay bone grafts vs alveolar distraction osteogenesis for the correction of vertically deficient edentulous ridges: a 2-4 years prospective study on humans. Clin Oral Implants Res 2007 Aug;18(4):432-40.
6. Felice P, Iezzi G, Lizio G, Piattelli A, Marchetti C. Reconstruction of atrophic posterior mandible with inlay technique and mandibular ramus block graft for implant prosthetic rehabilitation. Oral Maxillofacial Surg 2009 Feb; 67(2):372-80.
7. Jensen OT. Distraction osteogenesis and its use with dental implants. Dent Implantable Update 1999;10:33-6.
8. Kamal D, Abida S, Jammet P, Goudot P, Yachouh J. Outcome of oral implants after autogenous bone reconstruction. Rev Stomatol Chir Maxillofac 2009 Apr;110(2):86-8.
9. Melloning JT, Nevins M. Guided bone regeneration of one defects associated with implants: an evidence-based outcome assessment. Int J Periodontics Restorative Dent 1995;15:168-85.
10. Nystrom E, Nilson H, Gunne J, Lundgren S. A 9-14 year follow up of onlay bone grafting in the atrophic maxilla. Int J Oral Maxillofac Surg 2009 Feb; 38(2):3-6.
11. Barone A, Covani U. Maxillary alveolar ridge reconstruction with non vascularised autogenous block bone: clinical results. J Oral Maxillofac Surg 2007 Oct;65(10):2039-46.
12. Enislidis G, Fock N, Millesi-Schobel G, Klug C, Wittwer G, Yertt K, Ewers R. Analysis of complications following alveolar distraction osteogenesis and implant placement in the partially edentulous mandible. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2005 Jul;100(1):25-30.
13. Garcia A, MartinM, Vila P, Maceiras J. Minor complications arising in alveolar distraction osteogenesis. J Oral Maxillofac Surg 2002;60:496-501.
14. Maurer P, Eckert AW, Kriwalsky MS, Scubert J. Scope and limitations of methods of mandibular reconstruction: a long term follow-up. Br J Oral Maxillofacial Surg 2009 Jul; 31.
15. Perdijk FB, Meijeer GJ, Strijen PJ, Koole R. Complications in alveolar distraction osteogenesis of the atrophic mandible. Int J Oral Maxillofac Surg 2007 Oct;36(10):916-21.
16. Saulacic N, Martin MS, Comacho M, Garcia A. Complications in alveolar distraction osteogenesis: a clinical investigation. J Oral Maxillofac Surg 2007;65:267-74.
17. Smoka W, Brosshardt DD, Mercske Spurn R, Iizuka T. Reconstruction of the severely atrophic mandible using calvarial split bone grafts for implant supported oral rehabilitation. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2006 Jan;101(1):35-42.
18. Troulis MJ, Kaban LB. Complications of mandibular distraction osteogenesis. Oral Maxillofac Surg Clin North Am 2003 May;15(2):251-64.
19. Mangano F, Bazzoli M, Tettamanti L, Farronato D et al. Custom-made, selective laser sintering (SLS) blade implants as a non conventional solution for the prosthetic rehabilitation of extremely atrophied posterior mandible. Lasers Med-Sci. Springer-Verlag: London; 2012.
20. Mangano C, Mangano F, Shibli JA et al. Prospective clinical evaluation of 201 direct laser metal forming implants: results from a 1-year multi center study on 62 patients. Lasers Med Sci 2012 Jan;27(1):181-9. Epub 2011 Apr 26.
21. Chaushu G, Mardinger O, Peleg M, Ghelfan O, Nissan J. Analysis of complications following augmentation with cancellous block allografts. J Periodontol 2010 Dec;81(12):1759-64. Epub 2010 Aug 3.
22. Flanagan D. Avoiding osseous grafting in the atrophic posterior mandible for implant-supported fixed partial dentures: a report of 2 cases. J Oral Implantol 2011 Dec;37(6):705-11.
23. Linkow LI. The blade vent- a new dimension in endosseous implantology. Dent Concepts 1968;11:3-12.
24. Linkow L. Endosseous bladevent implant-insertion guidelines. Dentistry Today 1984;3.
25. Linkow L. The endosseous blade: a new dimension in oral implantology. Rev Trim Implant 1968;5:13-24.
26. Roberts RA. Types, uses, and evaluation of the plate-form implant. J Oral Implantol 1996;22:111-8.
27. Pasqualini U. Endosseous implants. Protection of reparative osteogenesis with the "screw stump". Dent Cadmos 1972 Aug;40(8):1185-94.
28. Pasqualini U, Pasqualini ME. Treatise of Implant Dentistry. The Italian tribute to the modern implantology. Ariesdue: Carimate (Co); 2009. p 105-113.
29. Pasqualini U. Le patologie occlusali. Masson Milano; 1993.
30. Pasqualini ME. Implantoprotesi in un caso di monoedentulismo. Analisi retrospettiva a 38 anni. Dental Cadmos 2010 Dic;78(10):65-70.
31. Ricciardi A. Nine years with Pasqualini implants--a full mandibular arch. J Oral Implantol 1980;9:83-94.
32. Misch CE. Osteintegration and the submerged blade-vent implant. J Houston Dist Dent Soc 1988:12-6.
33. Iezzi G, Scarano A, Perrotti V, Tripodi D, Piattelli A. Immediately loaded blade implants. a histological and histomorphometrical evaluation after a long loading period. a retrospective 20 years analysis (1989-2009). J Osseointegr 2012;3(4):39-42.
34. Grafelmann HL. The latest developments in blade implant clinical applications. Dent Implantol Update 1993;4:22-5.
35. Viscido AJ. Submerged functional predictive endosteal blade implants. Oral Implantol 1974;5:195-209.
36. Dal Carlo L, Brinon E.N. Influencia de la lengua en la integración de los implantes intraóseos. Revista Espanola Odontoestomatológica de Implantes 2004; 12(2):102-11.
37. Seshan H, Konuganti K, Zope S. Piezosurgery in periodontology and oral implantology. J Indian Soc Periodontol 2009 Sep;13(3):155-6.
38. Vercellotti T. Technological characteristics and clinical indications of piezoelectric bone surgery. Minerva Stomatol 2004 May;53(5):207-14.
39. Castagnola L, Chenaux G, Colombo A. Intra-ligament anesthesia with the Peripress syringe. Dent Cadmos 1976 Nov; 44 (11):7-14.
40. Pasqualini U, Pasqualini ME. Treatise of Implant Dentistry. The Italian tribute to the modern implantology. Ariesdue: Carimate (Co); 2009. p 114-128.
41. Blade Dental Implants information: atlantadentalimplants.com; 2013.
42. Dental Tribune International: "FDA considers reclassification of dental implants". News Americas 05/feb/2013.
43. Strecha J, Jurkovic R, Siebert T, Prachar P, Bartakova S. Fixed bicortical screw and blade implants as a non-standard solution to an edentulous (toothless) mandible. Int J Oral Sci 2010 Jun;2(2):105-10.
44. Di Stefano D, Iezzi G, Scarano A, Perrotti V, Piattelli A. Immediately loaded blade implant retrieved from a after a 20-year loading period: a histologic and histomorphometric case report. J Oral Implantol 2006;32(4):171-6.
45. Dal Carlo L, Pasqualini ME, Carinci F, Corradini M, Vannini F, Nardone M, Linkow LI. A brief history and guidelines of blade implant technique: a retrospective study on 522 implants. Annals of Oral Maxillofacial Surgery 2013 Feb 01;1(1):3.
46. Koch WL. Statistical evaluation of success and reasons for failure in 700 endosseous blade implants done in the office. Oral Implantol 1974 Apr; 1(1): 105-38.
47. Smithloff M, Fritz ME. The use of blade implants in a selected population of partially edentolous adults. A 15- year report. J Periodontol 1987 Sept; 58(9): 589-93.

TRADUZIONE LINGUA ITALIANA

LA MINIINVASIVITA' DEL BISTURI PIEZOELETTRICO PER L'INSERIMENTO IN SICUREZZA DEGLI IMPIANTI PLAT-FORM A LAMA NELLE ATROFIE MASCELLARI

Abstract:
Le gravi atrofie dei mascellari edentuli necessitano di importanti chirurgie ossee ricostruttive per permettere l'inserimento di impianti root form di diametri standard. Queste tecniche di augment che rappresentano attualmente l'opzione più proposta dalla Comunità Scientifica Internazionale sono spesso non accettate dai pazienti per i costi economici e biologici elevati e per la possibilità di insuccesso a breve e/o a lungo termine.
Una tecnica alternativa per ridare una masticazione fissa al paziente resta quella dell'inserimento di un impianto plat-form a lama che per l'esiguità dello spessore strutturale ha la sua indicazione elettiva nelle creste ossee con atrofia di spessore. Questo impianto endoosseo nasce dagli studi di L. I. Linkow (1968), R. Roberts (1970) negli Stati Uniti, rielaborato in Italia da Ugo Pasqualini (1972) e da parecchi altri Autori nell'arco di un range temporale ancora in corso. Questo impianto di estensione risulta funzionalmente ed esteticamente affidabile anche se comporta una tecnica operatoria più difficoltosa rispetto alle normali tecniche attualmente in uso.
L'utilizzo del bisturi piezoelettrico ad ultrasuoni semplifica, rendendo più sicure e meno traumatiche, le manovre di inserzione di questo impianto.
Parole Chiave
Piezosurgery
Impianto a lama
Atrofia posteriore mandibolare
Nervo alveolare inferiore
Miniinvasività

Introduzione

Le riabilitazioni implantoprotesiche fisse nelle edentulie dei distretti distali atrofici della mandibola con l'uso degli impianti root form di diametro standard presentano spesso problemi di inserimento chirurgico. L'area atrofica, normalmente altamente mineralizzata e poco vascolarizzata, non si presta positivamente alle varie tecniche di innesto per la possibilità di insuccesso e per l'alto costo biologico. L'EBM (Evidence Base Medicine) non rende questa tecnica sufficientemente predicibile.(1,2,3,4.)
Un'alternativa alle tecniche di "augment" nei distretti posteriori della mandibola con severi riassorbimenti orizzontali e verticali e diametri ossei inferiori a 3 mm è l'uso di impianti di diametro sottile (1,6 mm) plate form o impianti a lama.
La storia dell'impianto a lama nasce con Linkow e Roberts alla fine degli anni 60 del secolo scorso come un impianto endosseo a moncone fisso con forme variabili per l'introduzione in siti ossei edentuli anatomicamente differenti.
Nel corso degli anni, Leonard Linkow modificò e migliorò sia la forma che la superficie dell'impianto (5,6,7,8).
Nel 1972 Ugo Pasqualini presentò alla Comunità Scientifica Internazionale la "lama polimorfa" che, unico impianto, può essere modificato e modellato a seconda delle caratteristiche morfologiche dell'osso in cui deve essere inserito. La lama polimorfa è un impianto bifasico a moncone avvitabile che impedisce alle sollecitazioni meccaniche esterne (deglutizione, lingua e muscoli masticatori) di raggiungere le strutture sommerse. Cosi' scriveva il Prof. Pasqualini (1972) "le migliori condizioni per la rapida guarigione delle ferite chirurgiche necessarie alle immissioni degli impianti con ripristino di tessuto osseo intorno, al di sopra ed attraverso i manufatti scheletrati, si verificano solo quando essi siano stati completamente sommersi, senza comunicazioni con l'esterno. E ciò non tanto per eliminare il paventato e in realtà inesistente pericolo di contaminazioni microbiche, ma per escludere il braccio di leva dei monconi esterni, che trasmetterebbe alla parte interna pericolose sollecitazioni meccaniche, sottoponendole a continue mobilizzazioni che potrebbero compromettere l'evoluzione dell'osteogenesi includente (leggi osteointegrazione)". (9,10,11,12).
L'intervento classico di inserimento dell'impianto a lama è eseguito a cielo scoperto per visualizzare la cresta ossea in cui è praticato un solco sagittale per l'alloggio della parte sommersa delle lame. I solchi si preparano con frese a fessura (siglate 700 XL o 700 XXL secondo la lunghezza del gambo) montate su turbo trapano ad alta velocità. I solchi devono accogliere tutta la porzione endoossea delle lame. La fresatura dell'osso richiede il

contemporaneo raffreddamento del sito chirurgico (soluzione fisiologica). La lama posizionata manualmente all'imbocco del solco è poi affondata con uno scalpello leggermente battuta da un martelletto chirurgico. Il dorso della lama va sommerso almeno 2 mm al di sotto del bordo del solco operatorio, cosicché nel successivo periodo di guarigione, richiudendosi, il tessuto osseo la ricopra completamente(13,14,15).
Eseguire la preparazione del solco con questa tecnica necessita di notevole perizia chirurgica, per ottenere un taglio preciso e senza la minima slabbratura del solco stesso, tenendo conto della possibile imprecisione della mano dell'operatore o degli imprevedibili movimenti del paziente. Per migliorare e semplificare l'incisione dell'osso Linkow consiglia di eseguire una serie di forellini sulla corticale superficiale per poi unirli più facilmente con la fresa a fessura. La nostra scuola consiglia l'uso della ruota di Geyer, che è una fresa per contrangolo a bassa velocità, costituita da un disco dentato di 1 mm di spessore e di 5 mm di diametro: si utilizza per tracciare rapidamente lungo la corticale ossea un solco di invito alla fresa a fessura che poi dovrà estenderlo in profondità (16,17,18).
Recentemente con l'utilizzo del bisturi piezoelettrico ad ultrasuoni la tecnica di preparazione del solco chirurgico per l'inserimento di un impianto "plate form" (lama) si è reso facilitato per precisione aumentando nel contempo la sicurezza di non ledere i tessuti molli di profondità ed in particolare le componenti vasculo-nervose del canale mandibolare (19,20).

MATERIALI E METODI

Il dispositivo per chirurgia ad ultrasuoni è stato utilizzato in uno studio multicentrico di 142 casi di edentulie dei distretti atrofici posteriori della mandibola.
Tutti i casi sono stati risolti seguendo la medesima procedura operativa in anestesia plessica. Assolutamente controindicata, come per qualsiasi altra tecnica implantologica, l'anestesia tronculare. L'anestesia locale può essere eseguita sia iniettando una dose ridotta di articaina con adrenalina al 1: 100.000 vestibolarmente e lingualmente alla cresta ossea oppure con l'uso dell'anestesia intraligamentosa (Peri press) lungo il decorso della cresta edentula stessa. Queste anestesie topiche permettono di mantenere una sensibilità profonda che in vicinanza del decorso del nervo mandibolare è percepita dal paziente permettendo il rispetto assoluto della struttura vasculo-nervosa.
Il lembo di apertura va eseguito in cresta senza svincoli laterali, per non sottrarre nutrimento all'osso atrofico consentendo di osservare direttamente l'intera morfologia e topografia dell'osso stesso. Esposto, si ribaltano delicatamente i tessuti muco periostei con lo scolla periostio.
Utilizzando il bisturi piezoelettrico ad ultrasuoni (Ultrasonic bone Surgery) con una fresa di metallo a punta seghettata a 5 denti (ES071)si esegue la breccia chirurgica in cui inserire l'impianto. Le dimensioni del solco vanno calcolate in senso mesio distale in base alla misura della lama che dopo un'analisi radiografica e anatomica si è deciso di introdurre (consigliabile OPT e TC Cone Beam) . Il solco chirurgico deve avere i seguenti requisiti. Una lunghezza pari o leggermente maggiore alla lunghezza mesio distale dell'impianto selezionato, una larghezza in senso vestibolo linguale lievemente inferiore alla larghezza del bordo inferiore dell'impianto scelto, così da rendere impossibile l'inserimento passivo dello stesso nel solco se non per qualche millimetro, in modo che, dopo l'inserimento a percussione (press-fit), si abbia una stabilità primaria immediata. La profondità deve essere pari all'altezza della lama misurata dal suo margine inferiore fino alla base del moncone protesico avvitabile.
Il collocamento nella sede chirurgica preparata con il taglio selettivo della fresa seghettata del bisturi piezoelettrico avviene affondando con apposito percussore la lama all'interno del solco stesso.
La spalla dell'impianto deve affondare di almeno 2 mm al di sotto del margine della cresta ossea. La mucosa viene poi suturata con punti staccati (21).
Nel nostro studio multicentrico sono stati usati impianti a lama polimorfa bifasica a moncone avvitabile approvata con certificazione CE 0301, Lama singola CE 0476, Lama mini CE 0476, Lama bifasica CE 0068/QCO-DM038-2009, validati nell'Unione Europea.
Dopo un periodo di almeno 3 mesi si rimuovono le cappette di guarigione, si posizionano gli abutment definitivi e si procede alla protesizzazione che può comprendere anche un elemento naturale quale pilastro portante quando non è possibile collegare la lama con altro impianto (l'ADA American Dental Association ha stabilito la validità di questa procedura) (22).
Si fa notare che nel 2013 è stata riproposta dall'FDA (Food and Drug Administration) negli Stati Uniti la riqualificazione dell'impianto a lama portando il rischio chirurgico dal grado 3 al grado 2 come per tutti gli altri impianti standard root form (23).

Gli Autori dichiarano che lo studio presentato è stato realizzato in accordo con gli standard etici stabiliti nella Dichiarazione di Helsinki, e che il consenso informato è stato ottenuto da tutti i partecipanti prima del loro arruolamento allo studio.

DESCRIZIONE DEL CASO CLINICO

Paziente femmina di anni 46 con grave atrofia emimandibolare destra. La Tac evidenza la grave atrofia del distretto edentulo con presenza dell'ottavo incluso asintomatico che per volontà della paziente è stato mantenuto (Fig.1). Dopo i controlli millimetrati per la scelta della lama polimorfa specifica per il sito ricevente e dopo l'apertura del lembo è stata eseguita l'osteotomia usando esclusivamente la fresa specifica applicata al bisturi piezoelettrico per chirurgia ad ultrasuoni (Fig.2). Questa metodica chirurgica ha permesso un taglio selettivo micrometrico preciso e sicuro (Fig.3) permettendo una buona visione del campo operatorio, inoltre la guarigione del tessuto osseo e dei tessuti molli è avvenuta priva di alcun tipo di complicazioni e con minimo dolore. Dopo un periodo di guarigione di 3 mesi sufficiente per avere una completa osteointegrazione si è passati alla protesizzazione includendo due elementi naturali stabili già precedentemente trattati endodonticamente (Fig.4). Il follow up a 5 anni evidenzia il buon mantenimento dei tessuti perimplantari e del parodonto degli elementi naturali grazie ai controlli periodici che hanno permesso un'igiene congrua e mantenuto una stabile armonia occlusale.(Fig.5,6)

DISCUSSIONE E CONCLUSIONI

L'impianto a lama cronologicamente fa parte delle novità implantoprotesiche della fine degli anni 60 ed ebbe il suo massimo sviluppo nel decennio successivo durante il quale fu modificato e migliorato assumendo per un certo periodo il ruolo dell'impianto più diffuso nel mondo. In seguito all'avvento degli impianti root form l'utilizzo delle lame è andato in progressivo disuso. Solo pochi operatori hanno mantenuto l'uso di questa tecnica, specificando l'elettivo utilizzo con successo ed affidabilità nelle zone atrofiche edentule nei settori distali della mandibola , senza nulla togliere alle tecniche per l'inserimento degli impianti bifasici. Non si esclude l'ottimo comportamento anche in settori con grave deficit di spessore osseo del mascellare superiore.(24,25,26).

La tecnica chirurgica classica rimane una tecnica complessa che non perdona eventuali errori che portano inevitabilmente all'insuccesso. Queste difficoltà sono notevolmente diminuite con l'introduzione in campo chirurgico dei dispositivi ad ultrasuoni. I vantaggi del bisturi piezoelettrico possono essere sintetizzati nella minor invasività, nella facilità di tagli micrometrici e selettivi, vantaggio dell'effetto cavitazione, riduzione del riscaldamento dei tessuti, estrema precisione e sicurezza con il rispetto dei tessuti molli (in particolare le componenti vasculo-nervose). Massima visione del campo operatorio e diminuzione dei tempi di riabilitazione con la riduzione del dolore. Unico modesto svantaggio è il sensibile allungamento dei tempi operativi, supplito dalla relativa maggior tranquillità lavorativa.

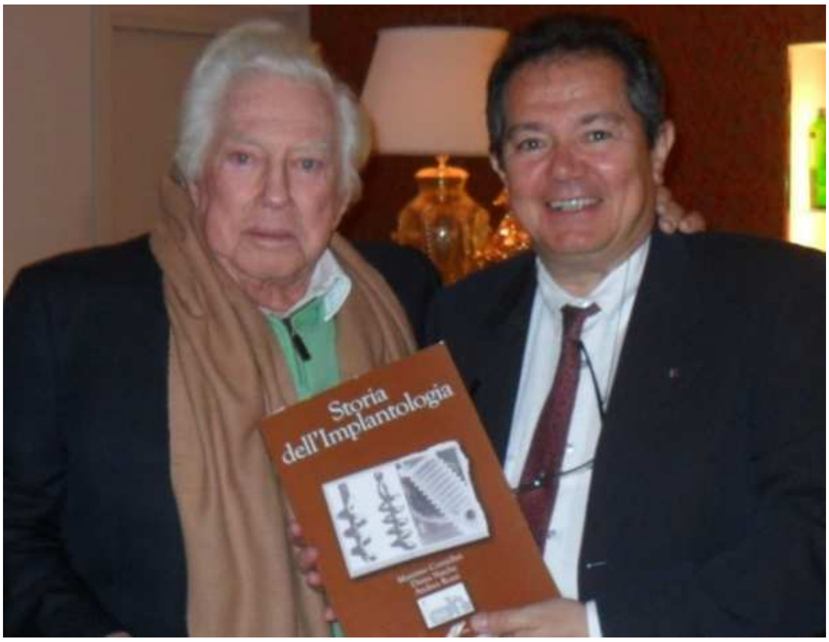
RINGRAZIAMENTI

Nello studio multicentrico hanno partecipato i Dottori: Luca Dal Carlo (Venezia), PierAngelo Manenti (Bergamo), Enrico Belotti (Palazzolo sull'Oglio- Brescia), Enrico Moglioni (Roma), Federico Meynardi (Cuneo), Marco Gnalducci (Milano), Emanuele Morella (Milano), Giancarlo Cortese (Torino), Giorgio Galassi (Padova), che ringraziamo.

Dedica a Linkow

Dedico questo lavoro di Tesi Specialistica al prof. Leonard Linkow,
indiscusso Pioinere dell'Implantologia Odontoiatrica,
Clinico per eccellenza e Maestro di molti Grandi Colleghi italiani,
che poi hanno contribuito allo sviluppo mondiale della disciplina.

M. Corradini



Il materiale scientifico-iconografico relativo all'Implantologia a Lama proviene sostanzialmente da:

- ***"Quaderni di Bioimplantologia - 2. Implantologia a Lama"***
  Accademia Internazionale di Odontoiatria Integrale - Edizione Originale 2002
  con il contributo di: Luca Dal Carlo, Silvano Tramonte, Marco Pasqualini, Pierangelo Manenti, Domenico Colombo, Giorgio Lorenzon, Pietro Lazzarini, Enrico Belotti, Roberto Conte, Franco Rossi, Marco Gnalducci, Mauro Galli, Rosario Acampora, Fabio Feresini, Luciano Riccardi, Giuseppe brusca, Ulisse Mazzoleni, Luciano De Feo, Paolo Pasqualini, Franco Lasagni, Lucio Bilucaglia

- ***"I Quaderni NuovoGISI di Implantologia Orale- Implantologia a Lama"***
  rivisitato e corretto nel 2012 dal dott. Luca dal Carlo