Cranio-maxillofacial

Implant Directions®

Vol.3 No.3 September 2008

ISSN 1864-1199 / e-ISSN 1864-1237

Published by IF Publishing, Germany

Editorial board

Single Issue Price
Euro 30
Annual Subscription
Euro 120

Contact
publishing@implantfoundation.org

CMF.Impl.dir.
ISSN 1864-1199
e-ISSN 1864-1237

Disclaimer

Typical contents in ID

- **Evidence Reports** summarize the latest «Hot Topics» from relevant journals putting similar studies «side-by-side». This unique presentation of studies allows you to compare and contrast the patient populations, the treatment interventions, and the quality of the scientific methods. The «evidence-based bottom line» is presented with an overall summary statement at the beginning. Clinical notes by implantologists with special expertise on the topic complete the Evidence Report by providing their expert clinical opinion. **ID** is an implantology publication that provides attention to detail in balancing science with clinical opinion in such a clear, concise, and visually-friendly presentation.

- **Literature Analyses** provide you with an in-depth look at the research on a given topic. A «Literature Analysis» is a critical review of the literature on the epidemiology, treatment methods, and prognosis for implant-related topics or conditions. Literature Analyses are broader than «Evidence Reports» and are written to serve as a reference tool for implantologists to help them make decisions regarding how to manage patients, to assist them in evaluating needs for future research, and to use the material for future presentations.

- **Critical Appraisals** summarize the findings from important papers used for clinical decision making or marketing by implant companies. In addition to the summary, the study's methods and clinical conclusions are critically reviewed in an effort to challenge the implantology community into not accepting everything that is published, while fostering alternative explanations and ideas.

- **Case reports** give implantologists the opportunity to publish on unique patients using innovative or alternative methods for treating challenging patient conditions.

- **Research in Context** is a helpful «what is» section to consult if you've ever read a study and asked «what is a p-value» or any other research method question. It assists clinicians with the critical evaluation of the literature by briefly describing relevant aspects of research methods and statistical analysis that may bias results and lead to erroneous conclusions.

Evidence Report

A comparison of bone grafts with and without barrier membranes in preparation for dental implant placement

Evidence Report Purpose

The use of osseointegrated implants has become an important treatment option for the replacement of missing teeth in fully and partially edentulous ridges. However, insufficient height or width of the alveolar bone at the implantation site hinders the feasibility of such procedures. Bone grafts have been used for bone reconstruction with varying degrees of success, though the rate of resorption remains substantial. Combining a membrane with a bone graft may limit the amount of bone resorption. A barrier membrane may contain and stabilize the graft, allowing bone regeneration in any remaining space and minimizing overall loss of bone volume.

Objective

To critically summarize the recently published literature examining bone characteristics (quality, resorption/gain) and other outcomes in studies of bone grafts placed with and without barrier membranes in preparation for intraoral dental implant placement.

Summary

There were no significant differences in implant success rates between implants placed in bone grafts with membranes compared to bone grafts alone. One study found significantly greater percent reduction in horizontal defect width and percent resorption of the labial plate in the membrane group compared to the graft alone group. Another reported significantly less bone width resorption in the membrane group compared to the graft alone group. Studies were of moderate quality so conclusions based on reported differences should be considered with caution. Additional methodologically rigorous comparative studies with comparable characteristics between groups are needed to better evaluate the effect of membranes associated with bone grafts upon treatment outcomes.

Sampling

A MEDLINE search was performed to identify recent studies published between January 1999 and January 2008 examining treatment outcomes of bone grafts placed with versus without barrier membranes in preparation for dental implant placement. Three articles met our criteria, evaluating the treatment comparison of interest, and are included in this report, Table 1.

Table 1. Medline Search Summary

Terms	Hits	Reviewed
Search **dental implants OR dental implantation, endosseous [MeSH]**	17,277	
Search **(dental implants OR dental implantation, endosseous [MeSH]) AND alveolar ridge augmentation AND comparative study, Limits ENGLISH, Human, Literature containing Abstracts**	101	3
Bibliographies from existing literature	0	0
Total Reviewed		**3**

Common Outcome Measures

- Implant success
- Bone resorption/gain

Interventions

Intraoral dental implants were placed in bone grafts placed with and without barrier membranes and were described as follows:

Chen (2005)

Thirty-nine consecutive patients underwent immediate dental implant placement and were randomized to treatment groups. To repair peri-implant defects, bone grafts were placed without (n=14) or with (n=13) a resorbable membrane. Subjects were followed through 24 months following abutment placement.

Antoun (2001)

A prospective, randomized study was conducted in which subjects were randomized to receive a bone graft alone or a bone graft associated with a non-resorbable membrane. Subjects were followed through 6 months following healing, at the time of implant placement.

Chiapasco (1999)

In a prospective study, patients were non-randomly assigned to receive bone augmentation with autologous bone chips covered with e-PTFE membranes (n=15) or autologous bone blocks alone (n=15). Augmentation was accomplished in order to place second stage screw-type titanium implants.

Table 2. Comparative studies evaluating bone grafts placed with vs. without barrier membranes in preparation for intraoral dental implant placement.

Author (year)	Study Design	Population	Diagnostic Characteristics	Implant Placement		Follow-up (%)	LoE*
				Bone Grafts with Membranes	Bone Grafts without Membranes		
Chen (2005)	RCT	N=39; Ni = 39 female: 43.6% age: 42 ± 3.3 yrs	Immediate implant placement in maxillary anterior or premolar tooth site	N=13; Ni=13	N=14; Ni=14	30 months: NR†	Moderate
Antoun -2001	RCT	N=12 female: 50% age: 34 (18-52) yrs	Maxillary or mandibular ridge requiring width augmentation prior to implant placement	N=5	N=7	6 months: 100%	Moderate
Chiapasco (1999)	Prospective Cohort	N=30 female: 60% age: 41 (19-60) yrs	Edentulous ridge width < 4mm requiring bone augmentation prior to implant placement	N=15; Ni=30	N=15; Ni=44	Mean 28 (24-42) months: NR†	Moderate

N = number of subjects; Ni = number of implants

*Level of Evidence (LoE) is based on study design and methods (Very high, High, Moderate, and Poor)

†NR (not reported) = for follow-up rate either not reported or precise follow-up rate could not be determined since the initial number of eligible patients or number lost to follow-up were not provided.

Table 3. Evaluation of articles comparing studies evaluating bone grafts placed with vs. without barrier membranes.

Study design and methods	Chen (2005)	Antoun (2001)	Chiapasco (1999)
1. What type of study design?	RCT	RCT	Prospective Cohort
2. Statement of concealed allocation?*	YES	YES	N/A
3. Intention to treat?*	YES	YES	N/A
4. Independent or blind assessment?	NO	NO	NO
5. Complete follow-up of ≥85%?	NO	YES	NO
6. Adequate sample size?	NO	NO	NO
7. Controlling for possible confounding?	NO	NO	NO
LEVEL OF EVIDENCE	Moderate	Moderate	Moderate

* Applies to randomized controlled trials only

Results

Implant success

Overall success was defined as pocket probing depth ≤ 5mm, negative bleeding on probing, and bone loss < 0.2mm annually.

•Implant success rates did not reveal any statistically significant differences between implants placed in bone grafts with membranes compared to bone grafts without membranes at a mean of 22.4 months after prosthetic loading of implants (93.3% vs. 90.0%, respectively; p>.05) [Chiapasco].

Bone resorption/gain

•The reduction in vertical defect height and horizontal defect depth were not significant when comparing the membrane group, graft alone group and no membrane or graft group [Chen].

•The percent reduction in horizontal defect width was significantly greater in the membrane group compared to the graft alone group (71.2% vs. 34.1%, respectively; p<.01) [Chen], Figure 1.

•The percent resorption of the labial plate was significantly greater in the membrane group compared to the graft alone group (64.1% vs. 39.1%, respectively; p<.01) [Chen], Figure 2.

•One study reported significantly less bone width resorption in the membrane group compared to the graft alone group at 6 months (mean resorption 0.3mm vs. 2.3mm, respectively; p<.01)

[Antoun].

•The same study found that increases in the bone width and graft width were not significant when comparing the membrane group to the graft alone group (bone width 3.7mm vs. 2.9mm, p>.05; graft width 4.0mm vs. 5.1mm, p>.05) [Antoun], Figure 3.

•Another study found a nonsignificant increase in bone width when comparing the membrane group to the graft alone group at 6 months (mean width gain 4.0±0.82mm vs. 2.7±1.22mm, respectively) [Chiapasco], Figure 3.

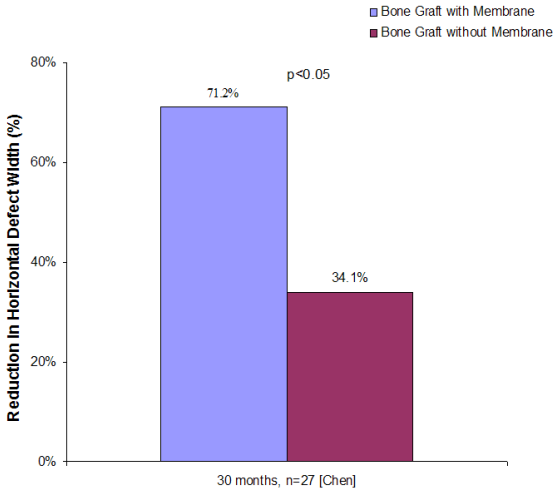
Methodological considerations

•All studies reviewed were randomized controlled trials or cohort studies with a rating of moderate (low quality randomized controlled trials or cohort) level of evidence. No very high quality randomized controlled trials or high quality cohort studies were identified in the literature.

•All three studies had sample sizes that were likely inadequate to show a difference between the study groups for some of the outcomes measured.

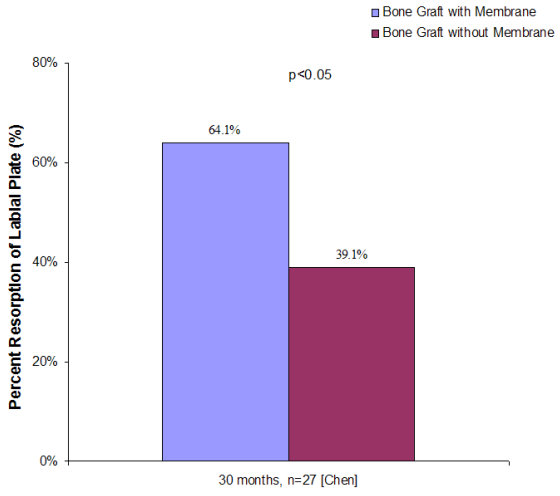
•Since multiple implants in the same subject are not statistically independent, either one implant should be chosen per patient or statistical analysis should account for multiple implants per patient.

•Only one of the studies reported a follow-up rate of ≥85%, which is necessary to ensure valid study results.



Statistical significance noted on graphs if provided by author

Figure 1. Reduction in horizontal defect width for bone grafts placed with membranes compared to bone grafts placed without membranes in preparation for intraoral dental implant placement.



Statistical significance noted on graphs if provided by author

Figure 2. Percent resorption of labial plate for bone grafts placed with membranes compared to bone grafts placed without membranes in preparation for intraoral dental implant placement.

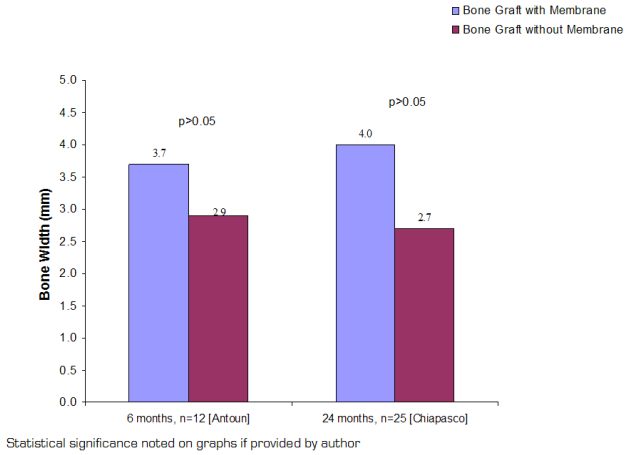


Figure 3. Bone width of bone grafts placed with membranes compared to bone grafts placed without membranes in preparation for intraoral dental implant placement.

Literature Analysis

Effects of Radiation Therapy on Craniomaxillofacial and Dental Implants
SUMMARY of Findings and Implications

Literature Analysis

A "Literature Analysis" is a critical review of the literature on the epidemiology, treatment methods, and prognosis for implant-related topics or conditions. Literature Analyses are broader than "Evidence Reports" (also published in each issue of Implant Directions) which focus on one specific treatment intervention by comparing and contrasting only 3 to 5 high quality articles in greater depth.

Literature Analyses are written to serve as a reference tool for implantologists:

- To help them make decisions regarding how to manage patients;
- To assist them in evaluating needs for future research;
- To use the material for future presentations.

This literature analysis on the effects of radiation therapy will be reported in two parts. Part I will evaluate and report on ANIMAL studies. Part II will be published in the next edition of Implant Directions and will evaluate and report on HUMAN studies.

Purpose

The purpose of this Literature Analysis was to systematically search the literature to identify key articles in an effort to evaluate the effects of radiation therapy on craniomaxillofacial and dental implants. Part I of this literature analysis will address the following objectives:

1. Provide an overview of implantology in irradiated craniomaxillofacial bone.

2. Summarize dental implant failure from ANIMAL studies with respect to the following:
a. Irradiated versus non-irradiated bone
b. Dosing of radiation
c. Implant types
d. Timing of radiation
e. Hyperbaric Oxygen Therapy

3. Summarize the quality of the literature on ANIMAL studies and recommended future studies.

Part II in the next edition of Implant Directions will address the following objectives:

1. Summarize craniomaxillofacial (CMF) and dental implant failure from HUMAN with respect to the same parameters as reported in ANIMAL STUDIES.

2. Summarize complications from HUMAN studies associated with implants in irradiated bone in CMF and dental implants.

3. Summarize quality of literature on HUMAN

studies and recommended future studies.

4. Discuss the role of BOI in the treatment of patients with irradiated bone.

Overview of implantology in irradiated craniomaxillofacial bone

1. Significance of the clinical problem: Acquired or genetic maxillofacial defects can result in severe functional, psychological and aesthetic difficulties for the patient, as well as ongoing reconstructive challenges to the medical professional.[1] Poor quality or insufficient quantity of hard and soft tissue often limit treatment options, with the leading cause of compromised bone in the craniofacial area being radiotherapy.[2]

2. Tissue reactions to radiotherapy and timing of tissue recovery: The traditional theory of irradiation effects proposes that radiation causes endarteritis leading to tissue hypoxia, hypocellularity and hypovascularity, which may lead to tissue breakdown and chronic nonhealing wounds. Also, radiotherapy reduces the proliferation of bone marrow, collagen and periosteal and endothelial cells. New models suggest that damage to osteoclasts occur earlier than vascular alterations and that the subsequent decrease in bone remodelling is the underlying crux of tissue damage.[3]

3. Effects of dose, implant type, and location on implant success rates: Several questions still exist with respect to managing patients with irradiated bone. No correlation between implant material (e.g. titanium- or hydroxyapatite-coated) and survival has been observed in animal studies, with both types eventually achieving acceptable osseointegration.[4-6]Furthermore, animal studies have indicated that increasing dose affects may have a negative effect on the histomorphometric and biomechanical characteristics of bone. However, clinical results differ widely on the importance of dose effect, as well as implant location. A general trend has been observed that orbital implants may have a higher failure rate, but even this observation has been disputed.

4. Implications for craniomaxillofacial and dental implants: Several questions exist when considering implant therapy in patients with irradiated bone including the following:

- Are patients with irradiated bone at greater risk of implant failure than patients with non-irradiated bone?
- Is there a dose-response to radiation whereby greater doses lead to higher failure rates?
- Is implant survival dependent on when a patient receives radiation – before or after implant placement?
- Are some anatomical areas at greater risk of failure due to radiation than others?
- Are some implants more effective than others in treating patients with irradiated bone?
- Are there adjunctive therapies that may improve the outcome after radiation and implant placement?

The purpose of this overview was to critically

search the literature to try and answer these questions using a combination of ANIMAL and HUMAN studies. We will begin in Part I with an analysis of ANIMAL Studies.

Data sources and search strategy

MEDLINE was searched to identify studies reporting ANIMAL and HUMAN data on the use of implants in irradiated bone with a focus on craniomaxillofacial and dental implants, Table 1. An attempt was made to identify studies of high methodological quality (systematic reviews, RCT and cohort studies). Case studies and in vitro studies were excluded. Studies of diagnostic radiography or radiation from diagnostic exams, imaging, etc. were excluded. Our focus was to identify studies that compared irradiated to non-irradiated bone. Literature reviews were included for background information. Key articles that were identified from this strategy were explored further by using MEDLINE'S "Related Articles" feature. In addition, bibliographies of retrieved articles were reviewed. There was no restriction on year published.

The following strategies were employed to identify literature to meet the objectives:

First strategy: Identify review articles describing success and failure of implants in irradiated craniomaxillofacial bone.

Second strategy: Identify ANIMAL studies comparing histomorphometric, biomechanical and histological measures of craniomaxillofacial (CMF) and dental implants in irradiated and non-irradiated bone.

Third strategy: Identify HUMAN studies or meta-analyses comparing the success/failure of CMF and DENTAL implants in irradiated bone and non-irradiated bone.

Table 1. Medline Search Summary

Terms	Hits	Reviewed
Search „irradiation“ AND (orthopedics OR device OR prosthesis OR implant OR nail OR plate“)	841, 315	
Search „irradiation“ AND orthopedics AND (device OR prosthesis OR implant)	6	6
Search „Radiation, Ionizing“[MeSH] AND „Prostheses and Implants“[MeSH]	337	
Search „bone“ AND „fixation“ AND radiotherapy	173	
Search „Radiation, Ionizing“[MeSH] AND „Prostheses and Implants“[MeSH] AND „Comparative Study“[MeSH]	86	15
Search („Hyperbaric Oxygenation“[MeSH] AND „Radiotherapy“[MeSH] AND „Comparative Study“[MeSH]	38	2
Search „Osseointegration/radiation effects“[MAJR]	34	
Search „Dental Implants“[MeSH] AND „radiotherapy“[Subheading]	40	3
Search (Dental implants AND radiation) AND systematic[sb]		
Studies summarized		**26**

The following are results of the various search strategies:

First strategy:

Review articles describing craniomaxillofacial and dental implants in irradiated bone were identified and used for background information and to identify specific ANIMAL and HUMAN studies for this review.

Second strategy:

Eleven ANIMAL studies exploring the histomorphometric, biomechanical and histological features of implants in irradiated bone were found and summarized in Part I of this Literature Analysis.

Third strategy:

Fifteen HUMAN clinical studies evaluating craniomaxillofacial (n=7) and dental (n=8) implants in irradiated bone were identified and summarized in Part II of this Literature Analysis. No meta-analyses of dental implants in irradiated bone were found. Efficacy studies comparing different implant types in irradiated bone were not found.

Summary of ANIMAL STUDIES on implants in irradiated bone (Table 2)

Eleven animal studies evaluating osseointegration in irradiated bone met our objectives and were included in this review. The following three major parameters were most commonly reported:

•Histomorphometric = quantitative measurements of bone growth around implants
•Biomechanical = quantitative measurements of implant stability
•Histological = qualitative measurements of bone healing over time

1. Irradiated versus non-irradiated bone

a. Irradiation did not appear to affect osseointegration in dog mandible at 6-months post-implantation:

Bone formation occurred around 97% of implants (n=85/88) with minimal difference in outcome between irradiated (pre- and post-implantation) and non-irradiated bone.[4] No implant failure was observed, but 3 implants showed mobility at the end of the study period.

b. Biomechanical findings revealed that breakpoint torque was significantly less in irradiated rat tibia compared to the opposite tibia (control) with increasing doses.[7,8]

Irradiation in rabbit femurs/tibias resulted in a 54% lower biomechanical force (p=0.005) required to unscrew the titanium implants as compared to non-irradiated implants.[9]

c. Histomorphometric findings demonstrated significantly decreased bone thickness measurements in irradiated rat tibia compared to the opposite tibia (control) with increasing doses.[7]

Bone contact surface ratio (BCSR) was decreased 12-19 days post surgery in both titanium and hydroxyapatite mandibular implants (irradiated at post-implant day 5) compared with non-radiated controls and increased after day 9.[6]
Specific trabecular bone volume (sptV) scores were lower in irradiated groups at day 7 but similar to non-irradiated controls by day 61.[6]

d. Histological changes in irradiated bone may include both compromised bone remodelling and changes to the vascular architecture.

A fibrous appearance of the cartilage and signs of venous blood congestion or arteriolar thrombosis are often noted.[4,7]
Inflammation and increased bone resorption is also noted.[10]
Thrombosis or haemorrhage attributable to irradiation is not always evident, and vascular architecture may appear unaltered.[10,11]
At 5 months post-irradiation bone resorption seemed to exceed osteogenesis, but by 8 months post-radiation the balance appeared to be restored in one dog mandible study.[4] A 30-week study in rabbit tibia showed that immature bone may remain unlamellarized following irradiation.[11]
Asymmetrical bone formation and resorption was seen in dog mandible due to incorrect implant positioning.[4]

2. Dosing of radiation

a. Increasing doses of radiation were shown to affect osseointegration of tibial implants in rats at 8-weeks post-implantation:
Animals receiving 30 or 35 Gy of radiation had noticeably less bone formation around their implants than in their control side, or than animals receiving 10 or 20 Gy.[7]

b. Acute, dose-dependent skin reaction following radiation was seen in one study.[7] Most authors did not explicitly report complications.

c. Histomorphometric analyses indicate that radiation dose may influence bone thickness and implant contact
A significant difference in bone thickness measured at 50- and 550- μm from implant threads was seen with increasing radiation dose (10, 20, 30 or 35Gy) (p=0.42, p=0.27, respectively at 8 weeks post implantation.)[7]
A significant difference in bone thickness measured at 50-, 250- and 550 μm from implant threads was seen between the irradiated and control leg in the 30 and 35Gy groups (p=0.008, p=0.020, p=0.012, respectively).[7]

d. Biomechanical studies show some differences in pull-out force and breakpoint torque between increasing dose groups.
No significant difference in pull-out force for tibial implants was seen between rats exposed to 10, 20 or 30 Gy. However, the breakpoint torque and maximal torque decreased significantly compared to the control side (p=0.019, p=0.006, respectively) with increasing radiation doses, indicating decreased mechanical capacity.[7]

3. Implant types

Both titanium coated- and hydroxyapatite-coated (HA) implants were successfully integrated in irradiated bone with no statistically significant difference in survival rates.

a. At 6 months post-implantation, there was no difference in bone-implant interface between the ITI Bonefit titanium plasma spray-coated- and Steri-Oss hydroxyapatite-coated implants in dog mandible.[4] Damage to the surface of both implant types was observed, however.

b. A study comparing titanium- and HA-coated implants in rabbit mandible showed implant failure in 25% (n=2/8) of HA implants over 56 days, probably due to loss of stability following irradiation of the new bone.[6]

c. Both titanium coated- and hydroxyapatite-coated implants were integrated successfully over a 16-week study of irradiated rabbit tibia.[5]

4. Timing of radiation

An increase in time interval between irradiation and implant placement appears to improve osseointegration:

a. A study in rabbit tibia and femur comparing implants placed at 12 weeks or 1 year post-ir-

radiation showed that the biomechanical force needed to unscrew the implants was significantly increased when placement occurred one year post-irradiation compared to those placed directly (p=0.04). Implants placed both 12 weeks and one year after radiation showed improved bone healing compared to direct implant placement.[8]

b. Results of a study in rabbit mandible showed that most implant surfaces were directly covered with new bone within 60 days when implants were placed 6-12 months after irradiation, versus 30 days for the control group and 90 days for implants placed within 3 months of radiation treatment.[12]

c. Bone regeneration was depressed by 70.9% when implants were placed 4-weeks post-radiation, compared to 28.9% at 1-year post-radiation, a recovery factor of almost 2.5.[13]

d. No improvement in bone formation between immediate drilling or a 12- or 52-week delay from time of irradiation was seen in one study where a biopsy defect in rabbit tibia was created.[10]

e. Large osteoclast foci were observed in post-implant irradiated dog mandible and were significantly greater than the pre-implant or non-irradiated group.4 However, following qualitative histological analysis the authors were unable to recommend one sequence over the other, i.e. radiation therapy before implantation, or vice versa.[4]

f. Several animal studies suggest that a delay between irradiation and implant placement is beneficial to implant survival. A delay of even 12 weeks shows a significant increase in success.[8,12,13]

5. HBO therapy

Results of hyperbaric oxygen therapy were reviewed in several studies of rabbit femur and/or tibia. Results varied widely.

a. A study of irradiated rabbit femurs demonstrated no statistically significant differences in bone-forming capacity were observed regarding irradiation and HBO.[10]

b. A significant increase in amount of mature bone was seen between irradiated bone with or without HBO therapy (P=0.035) when compared to the corresponding control leg.[2] Based on this study of irradiated rabbit femurs, HBO may improve bone formation, and does improve bone maturation.

c. The biomechanical force required to remove the implants in irradiated femurs/tibias following HBO increased 44% (p=0.011) versus 22% (not significant) in non-irradiated bone.9 Biomechanical force needed to unscrew implants was 54% lower in irradiated vs. non-irradiated bone without HBO treatment (p=0.005).

d. A fourth study showed that rabbits receiving HBO following irradiation and femoral implants differed in bone formation between irradiated and control legs by 9.52% (P=0.0008), as com-

pared with the non-HBO group who differed by 36.2% .[5]

Quality of literature and need for future research

In general, the quality of studies comparing implant failure/success and complication rates in irradiated versus non-irradiated bone is poor. For animal studies, no studies evaluated all important parameters such as timing, histomorphometric, biomechanical, and histological measurements in the same study using irradiated bone with a non-irradiated control leg. Furthermore, few animal studies were designed to compare implant types in irradiated bone.

We recommend the following ANIMAL study for future research and publication:

A well-designed animal study with adequate sample size that compares different implant types in irradiated and non-irradiated bone. This study should assess the following important parameters with respect to the implants evaluated:

a. Timing of radiation
b. Histomorphometric characteristics
c. Biomechanical characteristics
d. Histological characteristics

Conclusion

The following is a brief summary of findings from the ANIMAL study literature that match our objectives and clinical questions:

1. Increasing radiation dose appears to increase the risk of implant failure. There are no established thresholds in the literature.

2. The literature does not support any one implant as superior in treating patients with irradiated bone. There are few ANIMAL studies and findings are inconclusive.

3. ANIMAL studies suggest that a delay between irradiation and implant placement is beneficial to implant survival. A delay of even 12 weeks shows a significant increase in success compared to immediate implantation.

4. ANIMAL studies seem to indicate that hyperbaric oxygen therapy (HBO) is a significant factor in implant survival.

These findings will need to be verified by HUMAN studies for valid clinical application. Part II of this Literature Analysis will be published in the next edition of Implant Directions and will focus on the same objectives and clinical questions in HUMAN studies.

A final summary of both ANIMAL and HUMAN studies will be reported.

Table 2: Detail of Animal Studies: Implantation in Irradiated Bone								
Author	**Population**	**Implant**	**Radiated**	**Non-**	**Histomorphometric**		**Histological**	**Clinical/ Other**
Brogniez -2002	Dog/mandible	Nonsubmerged ITI Bonefit titanium plasma spray-coated;	Dose: 4.3 Gy ^{60}Co daily for 10 days				• Bone formation: 97% (n=85/88 implants) • Balance between resorption and osteogenesis restored after 8 months • No major histological difference between irradiated and nonirradiated group outcome at 6 months post-implantation	
	N=11 male Beagles	Submerged Steri-Oss hydroxyapatite-coated	4 wks post-	n=3	NP	NP		NR
	N=8 implants/ dog (4 of each type, pre-molar)		8 wks pre-implantation (n=4)					
	Observations at 6-months post-implantation:							

Matsui -1994	Rabbit/ mandible N=40 adult male rabbits, ~3kg	Hydroxyapatite-coated implants installed 3, 6 and 12 months after irradiation	15Gy ^{60}Co (N=30)	(n=10)	NP	NP	• Success rate of osseointegration increased with the interval after radiotherapy. • Most implant surfaces directly covered with new bone at 30 days in the control group, 60 days in the 6- and 12-month group, and 90 days in the 3-month group.	• Author recommended installing implants to increase weight bearing by the cortical bone
Schön -1996	Rabbit/ mandible N=16 adult male Japanese rabbits, ~3 kg N=2 implants/ dog (1 of each type, incisor)	2.0mm titanium-alloy (Ti) and 2.0mm cylindrical solid hydroxyapatite (HA) **Placed PRIOR to irradiation**	Single dose, 15Gy ^{60}Co, 5 days post-op (n=8)	(n=8)	• IR: BSCR scores decreased day 12-19 for both implants vs nonIR; After d19, BCSR increased • Lowest BSCR scores in the IR bone for HA implant □ sptV –lower vs nonIR at day 7; Increased volume 12-19 days in HA implant; • sptV scores similar for IR vs nonIR by day 61	NP	• Mature bone relatively radioresistant • New bone damaged by irradiation: bone formation delayed, less new bone • Bone-implant contact less in IR bone • IR group n=2/8 HA implants failed (no direct bone contact at 19 days)	• Immature bone damage by IR most severe with Ti implant • Less damage in immature bone not in direct implant contact
	Observations over 56 days post-irradiation							

Ohrnell -1997	Rat/proximal tibia N=26 male Sprague-Dawley rats N=3 implants/ tibia	Pure titanium	^{60}Co Dose: 10Gy (n=6); 20Gy (n=6); 30Gy (n=10); 35Gy (n=4) 12 wks pre-implantationleft leg	Contralateral tibia (n=26)	NP	• Shear stress and shear moduli not correlated to rad dose at 8-weeks post-implantation • Pull-out load significantly reduced at 30Gy • Torsion significantly reduced compared with the control leg with increasing dose (breakpoint torque, p=0.023, maximal torque, p=0.008).	• Mean bone thickness measured at 50-, and 550 µm from implant threads was significantly decreased with increasing radiation dose (p=0.042, p=0.027, respectively).	• Acute dose dependent skin reactions appeared after all but 10Gy doses, but subsided in 2-3 weeks

Jacobsson, Johnsson -1985	Rabbit/tibia	N=40 implant chambers (1/tibia)	Single dose, 15Gy ^{60}Co (n=20)	Contra-lateral tibia (n=20)	• Bone regeneration was depressed 70.9% when implants were placed within 4-weeks post-irradiation • Bone regeneration was depressed 28.9% when implants were placed 1 year post-irradiation	NP	• Poor lamellarization and more fibrous tissue in the irradiated bone than the control leg • No obvious vascular changes were observed.	NR
	N=20 adult lop-eared rabbits, 10-16 months, both sexes	Titanium vital microscopic bone chamber placed directly (N=10) or 1-year post-radiation (N=10)						

Jacobsson, Albrektsson -1985	Rabbit/proximal tibia N=15 adults, Belgian hare, 10-16 months, both sexes, 4.5-6.0 kg F/U period: minimum 30 weeks (30wks-2 years) Observations through 30-week study period:	N=30 implant chambers (1/tibia) Titanium vital microscopic bone chamber placed **Raditation after tissue steady state reached** Observed 4-6 wks post-irradiation	Single dose: 14, 25 or 40 Gy ^{60}Co following steady-state bone formation around implant (n=15)	Contra-lateral tibia (n=15)	NP	NP	• Mature bone relatively radioresistant, remodelling not affected by single dose radiation up to 40Gy • Previously existing immature woven bone remained unlamellarized throughout the study, as did new de novo woven bone following radiation. • Vascular architecture largely unchanged in all dose groups throughout the study period. Any changes could not be correlated with dose levels. • In all dose groups, fat cells tended to decrease in number following irradiation. Migration of fat cells into the chamber was also seen in some animals with no observable fat prior to treatment.	NR

Johnsson[10] -2000	Rabbit/femur N=30 adult New Zealand white rabbits, both sexes Observations at 8-weeks post-drilling:	No Implant- Defect created by drill biopsy	Single dose, 15Gy ^{60}Co Group1,2: just before biopsy, ±HBO* Group 3: 12 weeks before biopsy Group 4: 52 weeks before biopsy	Contra-lateral femur (n=30)	NP	NP	• Bone formation varied widely between animals of all groups	• No evidence to recommend HBO therapy or delayed surgery for any group • Hypothesized that cancellous bone recovers more quickly than cortical bone following radiation trauma.
Johnsson -1999	Rabbit/femur, tibia N=12 adult New Zealand white rabbits, >9 months old, both sexes N=48 implants (1/femur and tibia) Observations at 8-weeks post-placement:	Titanium screws	Single dose, 15Gy ^{60}Co ±HBO (n=6 +HBO) (n=6 –HBO)	Contra-lateral femur, tibia (n=12)	• Significant reduction of bone in thread areas was seen in irradiated bone without HBO for both total implant analysis and 3 best threads (P=0.046, P=0.028, respectively), and in irradiated bone with HBO therapy when calculating the 3 best threads (P=0.046).	NP	• Periosteal bone formation and bone remodelling decreased after irradiation, ± HBO treatment • HBO improved bone formation in nonirradiated bone, somewhat in irradiated bone • HBO improved bone maturation after irradiation	NR

Johnsson -1993	Rabbit/femur, tibia N=10 adult New Zealand white rabbits, both sexes Observations at 8-weeks post-placement:	N=40 implants (1/tibia and femur) Titanium plates	Single dose, 15Gy ^{60}Co ±HBO (n=5 +HBO, n=5 –HBO)	Contra-lateral femur, tibia	NP	• Force needed to unscrew implants 54% lower in RAD vs. nonRad bone without HBO treatment (p=0.005) • Force needed to unscrew implants was 54% higher in non-IR vs. IR bone with HBO treatment, versus 69% without HBO • HBO treatment increased force needed to unscrew implants by 44% in IR bone (p=0.011) and 22% (not significant) in non-IR bone as compared non-HBO group.	NP	NR

Larsen -1993	Rabbit/tibia N=20 adult rabbits, type unspecified N=5 titanium implants N=15 hydroxyapatite-coated implants	Titanium plasma-sprayed implants Hydroxyapatite-coated plates	4500rad in 10 doses over 3 weeks, ^{137}Ce, ±HBO (n=10 +HBO, n=10 –HBO)	Contra-lateral tibia (n=20)	• No difference in implant performance with respect to integration. • HBO treatment improved integration in IR bone in all groups compared with the control leg: • Difference in mean integration between IR leg and control with HBO at 12 weeks was 36.2% vs. 9.52% with HBO (P=0.0008). At 16 weeks, the difference was 13.9% and 6.38, respectively (P=0.047).		• Increased healing time improved integration in non-HBO groups: At 12 weeks difference in mean percent integration between IR leg and control was 36.2%, vs. 13.9% at 16 weeks (P=0.023).	• Wound dehiscence in all animals receiving HBO was 7%. Dehiscence in IR animals without HBO was 54% vs. 15% in the control leg. There was significantly less dehiscence in IR rabbits with HBO than without (P=0.014).

NP = not performed; NR= not reported; *HBO=hyperbaric oxygen; IR = irradiated Group; nonIR= non-irradiated group; TIS = total implant surface; TCS= total contact surface; BCSR= bone contact surface ratio= TCS/TIS x 100; TBT=Total bone tissue; TTBV= total trabecular bone volume; sptV=specific trabecular bone volume =TTBV/TBT x 100;

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Critical Appraisal

Sinus floor augmentation with beta-tricalciumphosphate (beta-TCP): does platelet-rich plasma promote its osseous integration and degradation?

Reference:
Wiltfang J, Schlegel KA, Schultze-Mosgau S, Nkenke E, Zimmermann R, Kessler P. Sinus floor augmentation with beta-tricalciumphosphate (beta-TCP): does platelet-rich plasma promote its osseous integration and degradation? Oral Impl. Res. 2003 Apr; 14(2): 213-18.

Performing Clinic:

Department of Oral and Maxillofacial Surgery, University of Erlangen-Nuremberg, Erlangen, Germany.

ARTICLE SUMMARY

Authors' Summary:

When platelet-rich plasma (PRP) was added to beta-tricalcium phosphate (TCP), bone regeneration was supported to a small extent. However, the resorption of beta-TCP was not accelerated and foreign-body giant cells and soft tissue surrounding the beta-TCP granules were present.

Study Objectives:

To determine whether the application of PRP in combination with tricalcium phosphate ceramics can accelerate the degradation and bony substitution of the allogenic material in sinus floor elevation.the resorption of beta-TCP was not accelerated and foreign-body giant cells and soft tissue surrounding the beta-TCP granules were present.

Study Design:

Quasi-randomized trial of 35 sinus floor elevations performed in 35 patients.

Inclusion/Exclusion Criteria:

- Healthy patients with normal blood thrombocyte concentrations
- Absence of a history of maxillary sinus inflammation.
- Patients were excluded after randomization for the following events:
  - Perforation of the maxillary sinus mucosal lining during surgical intervention
  - When the PRP concentration factor was below 3.

Interventions:

- In the anterior maxillary sinus wall, a bone lid was created using the window technique.
- After careful elevation of the mucosal layer, 1-

1.5g Cerasorb® containing beta-TCP ceramic granules of 1000-2000µm diameter were instilled for augmentation of the sinus floor.
- As a result of randomization, one milliliter of PRP was added to the ceramic material in 17 of the 35 sites. PRP was prepared from patients' own blood concentrated to a level at least 3 times the normal platelet concentration.
- Implant insertion of 2-3 implants per augmentation site was performed 6 months following augmentation. During this procedure a biopsy was taken from the augmented site for histological examination.

Histological Exam:

Patients were evaluated pre-operatively and then post-operatively at 6 months for the following:
- Light microscope evaluation was used to measure bone regeneration as well as the relation between ceramic substitute and bone.
- Bone area ratio was defined as the area of new bone inside a defined area of $9mm^2$ / total area of $9mm^2$.

Follow-up:

Patients were evaluated immediately after surgery, and again at 6 months post-up. Follow-up rate and mean follow-up per treatment group was not reported.

Results:

- Average patient age in the PRP group was 45 years (range 37-54) with 76.5% women (n=13) women and 23.5% men (n=4).
- Average patient age in the non-PRP group was 47 years (range 32-64) with 77.7% women (n=14) women and 22.3% men (n=4).
- Healing was uneventful in all patients. Abnormal swelling or signs of infection were absent.
- All augmentation sites were acceptable for implant insertion.
- All implants showed acceptable osseointegration.
- Osseous regeneration without PRP instillation reached an average of 29% versus 38% in the PRP group.
- Bone formation without PRP instillation was 25-37% versus 32-43% in the PRP group.
- More foreign body giant cells were observed in the soft tissues of the PRP group.
- Faster degradation of □-TCP was not observed in the PRP group versus the non-PRP group (relation between □-TCP granules and new bone was 13.8% in the PRP group compared to 15% in the non-PRP group.)

Conclusions provided by authors:

The study suggests that the application of PRP will only result in accelerated new bone formation if target cells such as osteoblasts and osteocytes are present. A faster degradation of ceramic bone substitutes cannot be expected. Further studies are needed to investigate the effect of PRP on wound healing processes alone and in combination with other bone substitutes.

REVIEWER'S EVALUATION

Methodological Principle	
Randomized design	YES
Blinded surgeon	NO
Independent or blind assessment	NO
Adequate sample size	NO
Appropriate analysis	NO
Controlling for possible confounding	NO*
Appropriate measures	
Histological analysis	YES
Biomechanical analysis	NO
Patient-centered outcomes	NO

*Randomized design usually accounts for confounding; however, authors did not provide full table of baseline factors to assess this.

- **What were the study's methodological strengths?**
  - Bad study design: although the call for studies on real life patients is tremendous, reliable results can only be gained on animals, because it is necessary to evaluate all of the augmented area rather than limited to only small cylinders
  - Clearly defined objective

- **What were the study's methodological limitations?**
  - The data in the abstract do not match the data in the body of the manuscript. The abstract reports 45 sinus floor elevations in 39 patients and the manuscript reports 35 augmentations in 35 patients. Which is it? Inconsistency between these calls into question the integrity of the data.
  - Authors did not describe their random allocation process. This is important to disclose to ensure true random allocation was employed and to allow for reproducibility in further studies.
  - Patients were excluded after random allocation for various reasons. It is unclear how many patients per treatment group were excluded and the status of their baseline characteristics. This violated the important principle of intent-to-treat. These subjects should have remained enrolled and the outcomes of these patients should have been analyzed in the respective groups to avoid outcome bias. Breaking intent to treat changes an RCT into an observational study.

- Surgeons were not blind to the treatment nor were the evaluators of the histological exam both of which weaken the validity of the findings.
- The authors provided baseline age and gender data in both groups but other important baseline factors that may have influenced outcomes were not reported by treatment group. A table 1 should have been included that demonstrated the balance between other factors such as bone quality, smoking status, and other important predictive factors. Random allocation, especially with a small sample size does not always result in an adequate balance between these factors.
- The authors did not clearly report the follow-up rate. It was implied that all patients achieved their 6 month follow-up but without a table or summary of mean follow-up times and ranges between groups, we cannot be confident that all subjects were evaluated at the same point in time.
- Though the authors reported they used the Wilcoxon test, none of their measures were compared using analytical methods (i.e., no p-values were reported). Without such measures, it is difficult to determine treatment superiority.
- The authors omitted several other important outcomes which would have been easy to measure and would have added to the clinical application of this study including time to loading and patient-centered measures such as quality of life.

- **Problems relating to the histologic examination**

The histologic examination used the technique described by Donath. The magnification and the screen size (9sqmm) was reported; however, important information was missing to establish validity of the results:

1. **One** osseous cylinder, gained when the implant was placed, only displays a small area of the augmented part of the maxilla. It is not advisable to draw generalized conclusions from this small area. From experience, we know that the punching and rotating instrument usually destroys or squeezes at least part of the histologic cylinder. This makes it impossible to obtain reliable data for appropriate analysis. Since friction of the cylinder to the hollow punch will vary, destruction will be different with different materials enclosed within the bony cylinder. Despite this, to our astonishment, the authors report that all of the specimens obtained were in an acceptable condition and good for evaluation.
2. **The** results would have been more valid if two staining techniques would have been used and compared in each specimen.
3. **It** would have been important to know how many cuts were made from each cylinder and which one was chosen. We assume that not more than two cuts are possible per cylinder. How were the surfaces chosen? A realistic survey requires the examination of five different areas per patient and the examination should be carried out with two different staining techniques.

4. **The** group does not consider or fails to disclose that a 10% error should be expected when using digital histomorphometric evaluation. If the values are not reliable, statistics become difficult and results invalid. All things considered, the following should be concluded:
    - The technique of evaluation is appropriate; however, the reliability of the results are moderate (+-10%)
    - The method of achieving samples is inadequate and we should question whether all samples obtained were usable.

- **Are there benefits for patients to be expected?**

Since the "results" do not justify the conclusions, real benefits for patients are not generalizable. It has been true for many years that sinus lift procedures without PRP preparation may give a good result in a considerable number of cases; however, the use of PRP does not provide any advantages.

- **Are the likely treatment benefits worth the potential harm and costs?**

The study may lead to a situation where private health insurances will cover costs for PRP preparation and application of the method on patients. Since the effect of these measures is unknown, the money paid for this part of the treatment may be a complete loss leaving it unavailable for supporting other treatments or patients.

Case Report

Internal sinus lift at the time of an upper first premolar extraction in absence of sub-apical bone followed by subsequent implant placement.

AUTHOR:
Nasr Wissam
Chiyah, Chamoun blvd.
Beirut
e-mail: wmnasr@inco.com.lb

ABSTRACT

Immediate implant placement after tooth extraction is becoming a common procedure in implant-supported oral rehabilitation[1].

However, it must fulfill a series of conditions among which is the achievement of a good initial fixation known as "primary stability". Normally, this anchorage is achieved by the presence of the residual bone beyond the apex of the extracted tooth (sub-apical bone) of which, 3mm to 5mm are required, as stated by some authors.

However, in certain situations, it is not possible to go beyond the apex due to anatomical limitations (sinus floor, dental nerve...). Thus, clinicians are often faced with challenging decisions regarding the timing of implant placement; what would be the adequate approach to be adopted?

This report projects a treatment procedure where an internal sinus lift is carried out through the alveolar socket of an upper first premolar in absence of sub-apical bone, followed by an immediate implant placement. The advantages and disadvantages of this approach are elaborated below.

Immediate implant placement has become widely accepted since the available literature consistently cites high levels of success (94-100 percentage on average).[2,4,6]

However, once they are applied in a clinically appropriate situation, immediate implants provide clinically recognizable benefits.

Broadly speaking, these benefits are time and cost effective, let alone the reduction of morbidity and alveolar bone resorption, preservation of gingival tissues and papilla in the esthetic zone, reduction of treatment cost and time[2,3,5,7,8].

However, the treatment always poses a great challenge to clinicians, especially when the apex of the tooth to be extracted, is in close proximity to maxillary sinus floor.

Because of the high risk of sinus perforation, clinicians often opt for a staged approach.

The purpose of this article is to report on a one-step procedure aimed at replacing an upper first premolar with an implant-supported crown:

By using surgical technique based on extraction, sinus floor augmentation through the alveolar socket and immediate implant placement, the implant surgery was fully accomplished and the esthetic effects were maximized.

Case study:

A 52-year-old woman suffering from a mobility of the upper right first premolar. **(Fig.1)** Clinical examination diagnosed a vertical sub-gingival root fracture and revealed a probing depth of 5 mm on the mesio- labial aspect with no sign of suppuration.
On the X-ray, a single-rooted premolar was detected. A huge defective restoration and an uncompleted endodontic treatment were clearly visible: the apex was in contact with the sinus floor. **(Fig.2)**
The patient's medical status revealed no systemic or oral diseases capable of compromising dental care. Several treatment options were suggested to our patient including the following:

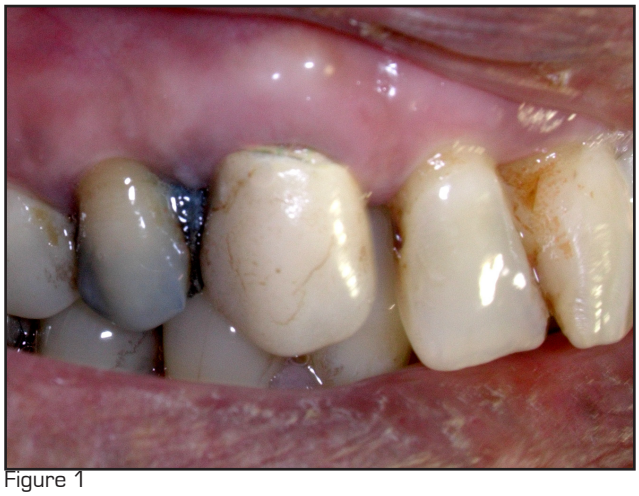
Figure 1

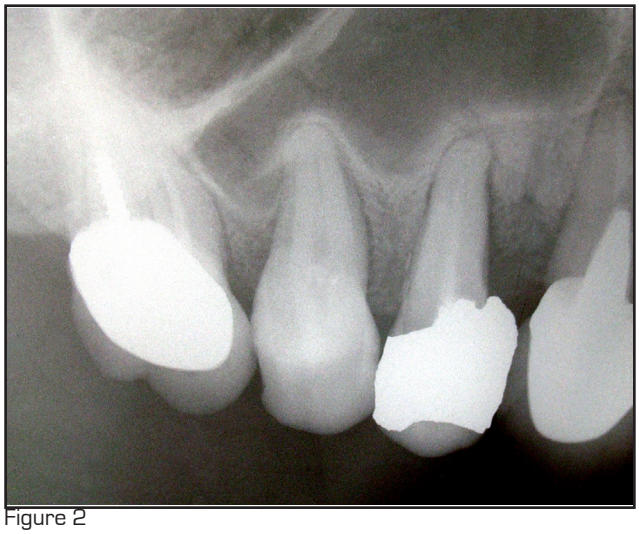
Figure 2

- Option 1: Tooth extraction 14 to be followed by Bio-col technique, re-entry of the site after 3 months for an internal sinus lift procedure simultaneous with implant placement.

- Option 2: The confection of a conventional removable partial denture, since a fixed dental prothesis on the adjacent teeth is not feasible due to their unfavorable periodontal status.

- Option 3: Tooth extraction 14, internal sinus lift simultaneous with immediate implant placement.

After considering and discussing in detail all the treatment options and risk factors, option 3 was welcomed by the patient in view of reduction in morbidity and treatment timeframe.

Surgical procedure:

Tooth 14 was carefully and gently extracted through periotome. It is note worthy that the remaining bone walls are crucial for achieving primary stability since the available vertical bones were obviously limited. Subsequently, the socket was thoroughly curetted followed by irrigation with saline water.

A mucoperiosteal flap was elevated at the palatal aspect in order to get a clear access to bone walls, which ensure the proper use of an osteotome into the socket, without damaging the surrounding bone.

The internal sinus floor elevation technique, which was introduced by Summers in 1994, was adopted.[4]

The socket depth, measured with a periodontal probing, indicates 7mm from the highest point of the buccal bone plate to the bottom of the socket. The drilling was unnecessary to prepare the implant bed. An osteotome 3.5 mm positioned at 8mm was introduced into the sokket, making sure not to lean on any bone walls during the maneuver. By slightly tapping on the mandrin grip, the compacta was fractured resulting in an elevation of the membrane.

However, the integrity of the sinus mucosa must be repeatedly checked with a negative nose-blowing test.

Bio-oss particles were introduced into the cavity and pushed apically with a gauge. The integrity of the sinus mucosa was once again checked via the blowing test.

An Allfit® SSO® implant, double- sandblasted endosseous section, Ø 4.1 mm (L: 11 mm) was inserted.

As a result, a primary stability was ensured thanks to the sidewalls of the residual alveolus. As to the void between the implant and the bone, it was filled with bone substitutes (d> 2 mm): a 3.5 mm beveled healing cape was applied enabling a non-submerged healing. **(Fig, 3)**

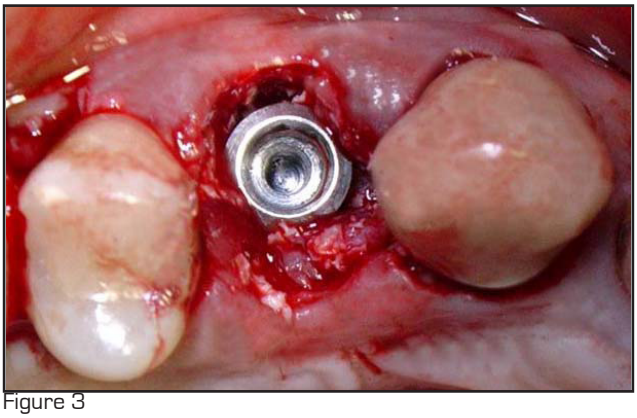

Figure 3

Furthermore, the palatal flap was repositioned by using horizontal mattress sutures in order to minimize the tension coronally. Consequently, the post-operative radiograph reflected the inserted implant and revealed a 6 mm- elevation of the sinus floor. The radio-opaque augmentation material with Bio-oss was easily detected. **(Fig.4)**

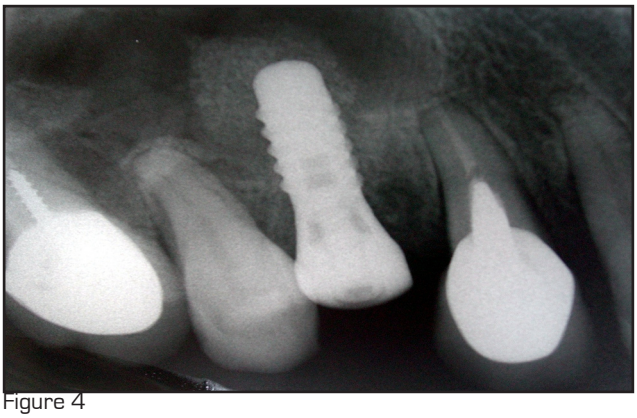

Figure 4

Five months later, the soft tissue around the implant neck was completely mature. **(Fig.5)**

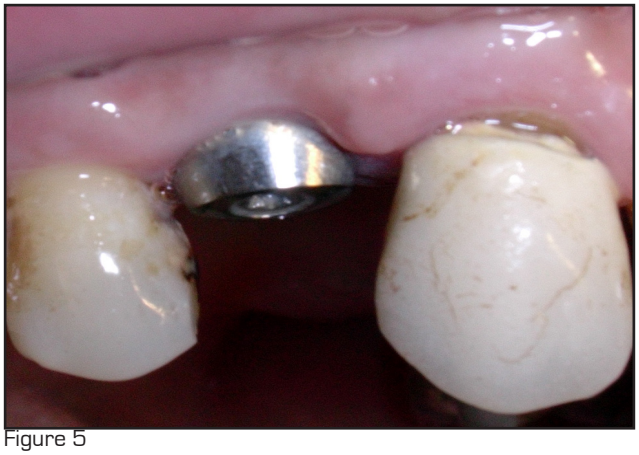

Figure 5

Figure 6 below reveals a totaly healed peri-implant soft tissue and an easily accessible implant shoulder, which facilitates the prosthetic procedures.

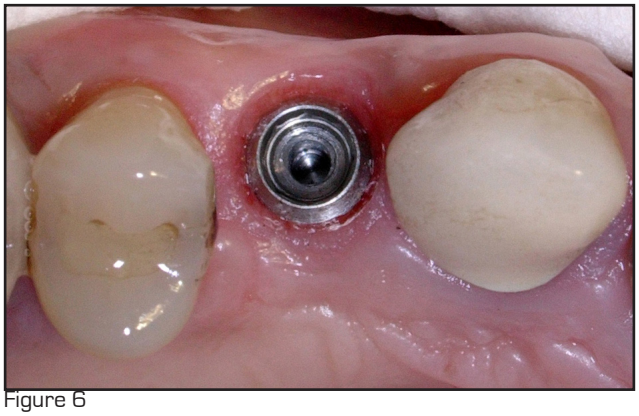

Figure 6

The ultimate radiograph taken 6 months after the implant surgery confirmed the stable peri-implant bone conditions. **(Fig.7)**

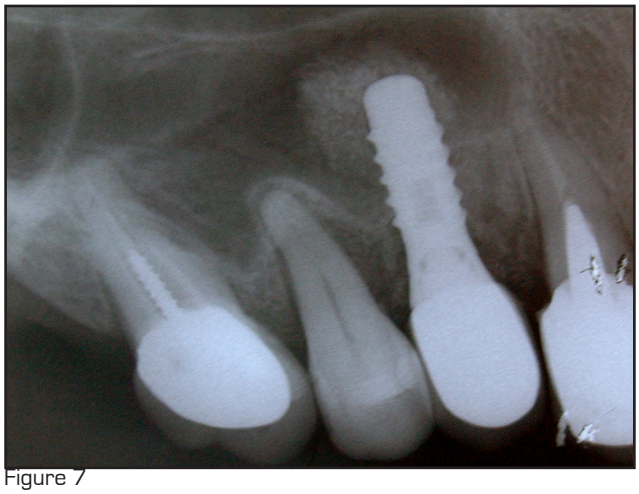

Figure 7

Finally, the clinical situation showed the implant crown immediately after seating. **(Fig.8)**

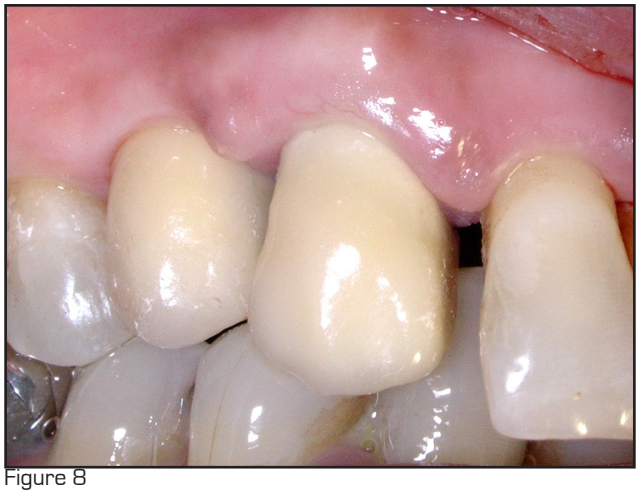

Figure 8

Constraints:

Two main obstacles may hamper the said surgical approach:

1. **The** absence of sound bone beyond the apex of the extracted tooth, which may compromise the achievement of implant primary stability.
2. **The** high risk in perforating the sinus membrane. (The osteotome technique is a "Blind technique").

Conclusion:

The proper application of this one-step delicate procedure can provide both the clinician and patient with highly satisfactory results, mainly an increase of treatment success and decrease of treatment cost and time.

Despite the lack of data on this approach, the above-mentioned technique can be standardized. Additional case studies will help improve this clinical application and attract wide public utilization.

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Research in Context – Part VI

Determining if the appropriate analyses were performed in an important dental implant paper

When reviewing a paper, were there appropriate analyses that included descriptive statistics, analytic statistics using the primary outcome, ample sample size, and adjustment of potential confounding variables?

Without knowing too much about statistical analysis, there are a few concepts you can easily check.

Is the population described or characterized in summary fashion (descriptive statistics)?

The presentation of descriptive data on the study population is important for a number of reasons.

- It enables you to determine the comparability of study groups at baseline and evaluate the likelihood of any selection bias or confounding (see definition below).
- The descriptive tables presented in a study report typically describe all enrolled patients. This can allow you to determine, when not explicitly stated, the extent of loss to follow-up.
- The baseline characteristics of the study population can help in determining the generalizability of the results to your own study population.

A confounding factor is both associated with the exposure of interest (e.g. treatment) and is a risk factor (or prognostic factor) for the outcome. Furthermore, these factors often influence which treatment the subject receives. As a result, studies with groups where there is an imbalance of a confounding factor between groups can lead to misleading results like overestimating or underestimating the treatment effects if these factors are not carefully identified beforehand and controlled for in the analysis. A common example is smoking. If there are more patients in one group that are smoker then in another group, the group with more smokers is at an unfair disadvantage when comparing outcomes. This is known as confounding bias. By looking closely at the descriptive statistics (often in table 1 of a manuscript), you can quickly discern this possibility.

Are the results reported analytically (analytic statistics)?

The purpose of analytical statistics is to assess the effects of treatment and risk factors on specific outcomes. This evaluation/assessment relies on the testing of statistical hypotheses. The testing of statistical hypotheses (sometimes called testing of statistical significance) is an important application when using outcomes measures to declare treatment safety or superiority. Statistical tests aim to distinguish true differences (associations) from chance. As all research is performed on samples of subjects, there is always a possibility, at least in theory, that the results observed are due to chance only and that no true differences exist between the

compared treatment groups. Statistical tests help sort out how likely it is that the observed difference is due to chance only. Commonly, an arbitrary test threshold value (e.g., alpha=.05) is used to distinguish results that are assumed to be due to chance from the results that are due to other factors. If the probability that the results are due to chance is less than the threshold value ($p<.05$), it is assumed the differences are due to these other factors (e.g., true differences in treatment effects). Choosing the correct statistical test to compare outcomes depends on the study design and on the types of outcome variables collected (concepts discussed in previous Research in Context articles).

There are four main things to consider when evaluating the statistical analyses used for testing the hypothesis.

Four questions to consider when evaluating the statistical analyses:
(1) Is the primary outcome used for the statistical analysis?
(2) Is any difference between the groups likely due to chance?
(3) Is the sample size large enough to test the hypothesis adequately?
(4) Are potentially confounding variables considered in the analysis?

Each of these questions as they related to the analytical statistics of a manuscript will be discussed in detail in the next Implant Directions.....

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Cranio-maxillofacial

Implant Directions

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