Critically Appraised Topic (CAT)

Project Team:
3A-5
Project Team Participants:
Nolan Frisch, Jiovannah Campbell, Tyler Grisar, and Ine Suh
Clinical Question:
In patients who require maxillary sinus augmentation, how does the long term prognosis of an endosseous implant placement differ when comparing 1-stage vs. 2-stage surgical procedures?
PICO Format:
P:
Patients who require maxillary sinus augmentation before placement of endosseous implant
I:
1-stage sinus augmentation
C:
2-stage sinus augmentation
O:
Long-term prognosis
PICO Formatted Question:
In patients who require maxillary sinus augmentation before placement of an endosseous implant, does 1-stage or 2-stage sinus floor augmentation provide a better long-term prognosis of the implant?
Clinical Bottom Line:
There is no significant difference regarding implant loss between 1-stage and 2-stage implant surgeries. Both techniques of Maxillary Sinus Augmentation are a reliable treatments to support dental implants in patients with a partial or fully edentulous maxilla and are considered successful in long-term randomized controlled trials (RCTs) and cohort studies.
Date(s) of Search:
9/27/2020
Database(s) Used:
PubMed
Search Strategy/Keywords:
Dental implants, dental implantation, endosseous implant, maxilla/surgery, osseointegration, sinus floor augmentation
MESH terms used:
Sinus augmentation, 1 stage, 2 stage
Article(s) Cited:
Felice P, Pistilli R, Piattelli M, Soardi E, Barausse C, Esposito M. **1-stage versus 2-stage lateral sinus lift procedures: 1-year post-loading results of a multicentre randomized controlled trial.** Eur J Oral Implantol. 2014 Spring;7(1):65-75. PMID: 24892114.
Study Design(s):
Multicenter, comparative randomized controlled trial
Reason for Article Selection:
The article was referred by Dr. Guentsch and directly answered my PICO question. This was also the study with the best level of evidence published at this time and was finalized within the last 6 years.

There is no conflict of interest in connection with the data (by no means did the manufacturer of the dental implants interfere with the conduct of the trial or the publication of the results).

Article(s) Synopsis:

Study includes 60 partially edentulous patients requiring 1-3 implants and having **1-3mm of residual bone height** and at least 5mm bone width below maxillary sinus, as measured by CT scan.

1-stage lateral window sinus lift with simultaneous implant placement vs. 2-stage procedure with implant placement delayed by 4 months. Both procedures used bone substitute. Implants for both procedures were submerged for 4 months, loaded with reinforced provisional prostheses, and were replaced after 4 months by a definitive prostheses.

Patients were followed up to 1 year after loading. Zero sinus lift procedures failed in 1-stage group and one failed in 2-stage group (not statistically significant). Three implants failed in three patients of 1-stage group vs. one implant in 2-stage group (not statistically significant).

- Methods: Recruitment of 60 patients from three different centers (20 per center), three operators, all using standardized procedures. Study included any patient who was partially edentulous in posterior maxilla with residual bone height of 1-3mm and width of at least 5mm measured by a CT.
- All patients received prophylactic abx therapy of 2g of amoxicillin (or 600mg clindamycin if allergic to penicillin) 1 hour before intervention. Patients rinsed with chlorhexidine for 1 minute prior to intervention. All used Articane with epi 1:100,000. Only 1-stage continued abx therapy (1g amox or 300mg clin) bid for 7 days.
- Sealed envelope containing group allocation code was opened after flap was elevated and sinus lining was assessed (or membrane was placed if lining was perforated/ruptured).
- 1-stage patients received one to three 11-15mm long implants. Sites prepared using surgical stents. Neck of implant placed flush to the bone. Residual space in sinus filled with bone substitute granules.
- 2-stage patients received same sinus augmentation, bone substitute and membrane were placed. 4 months to heal before implant placement.
- Patients instructed to use chlorhexidine mouthwash for 1 minute bid for 2 weeks along with other post-op instructions (analgesic).
- Provisional screw-retained acrylic restorations were delivered within 1 month of implant placement. Followed up 1 week (sutures) and 4 months (tightening abutment screws). 6 month recall.
- Dentist not involved in treatment made all clinical assessments of radiographs without knowledge of group allocation (blind).

After 1 year of loading, 1-stage treated patients lost an average of -1.01mm of peri-implant bone and 2-stage sites about -0.93mm. No statistical significance in bone level change between groups 1 year after loading.

Limitation: Small sample size. However, both techniques were tested in real clinical conditions and patient inclusion criteria was broad, reflecting everyday clinical reality. Therefore, results of trial can be generalized to larger populations with similar characteristics. (14 smokers, most of which were heavy smokers, included in study; 8 for 1-stage and 6 for 2-stage.)

Levels of Evidence: (For Therapy/Prevention, Etiology/Harm)

See http://www.cebm.net/index.aspx?o=1025

☐ **1a** – Clinical Practice Guideline, Meta-Analysis, Systematic Review of Randomized Control Trials (RCTs)

[x] **1b** – Individual RCT

☐ **2a** – Systematic Review of Cohort Studies

☐ **2b** – Individual Cohort Study

☐ **3** – Cross-sectional Studies, Ecologic Studies, "Outcomes" Research

☐ **4a** – Systematic Review of Case Control Studies

☐ **4b** – Individual Case Control Study

☐ **5** – Case Series, Case Reports

☐ **6** – Expert Opinion without explicit critical appraisal, Narrative Review

☐ **7** – Animal Research

☐ **8** – In Vitro Research

Strength of Recommendation Taxonomy (SORT) For Guidelines and Systematic Reviews

See article **J Evid Base Dent Pract 2007;147-150**

[x] **A** – Consistent, good quality patient oriented evidence

☐ **B** – Inconsistent or limited quality patient oriented evidence

☐ **C** – Consensus, disease oriented evidence, usual practice, expert opinion, or case series for studies of diagnosis, treatment, prevention, or screening

Conclusion(s):

No statistically significant differences were observed between implants placed according to 1- or 2-stage sinus lift procedures. However this study may suggest that in patients having residual bone height between 1 to 3 mm below the maxillary sinus, there might be a slightly higher risk for implant failures when performing a 1-stage lateral sinus lift procedure.

Article Cited:

Kim HJ, Yea S, Kim KH, Lee YM, Ku Y, Rhyu IC, Seol YJ**. A retrospective study of implants placed following 1-stage or 2-stage maxillary sinus floor augmentation by the lateral window technique performed on residual bone of <4 mm: Results up to 10 years of follow-up.** J Periodontol. 2020 Feb;91(2):183-193. doi: 10.1002/JPER.19-0066. Epub 2019 Aug 2. PMID: 31372997.

Study Design(s):

Retrospective Cohort Study

Reason for Article Selection:

The article directly answered my PICO question and the study design was one of the highest I could find to answer this PICO question, especially since the inclusion criteria included patients with up to 10 year follow-up after implant placement post sinus floor augmentation by lateral window technique (SFALW). The Journal of Clinical Periodontology is ranked 3rd of all Periodontology journals for its impact and prestige, and is published by the American Academy of Periodontology. There is no conflict of interest in connection with the article. Study was published within the last year.

Article(s) Synopsis:

There was no statistically significant difference between the 10-year cumulative survival rate of implants in the 1-stage group and that of the 2-stage group (**96.8%** ± 1.4% in the **1-stage group**, **92.5%** ± 3.1% in the **2-stage group**, *P* = 0.656).
The 10-year cumulative survival rates of implants were 93.9% (Residual Bone Height <2mm) and 98.1% (RBH 2-4mm), respectively, in the 1-stage group and 93.2% (RBH <2mm) and 91.5% (2-4mm), respectively, in the 2-
stage group.

- Methods: Retrospective study conducted by two periodontists based on dental records and radiographic data obtained from patients who received 1-stage and 2-stage SFALW surgery in maxillary posterior area with residual bone height <4mm from March 2006-June 2014. Includes patients who received one or more implants by four providers.
- Mean follow-up period was 5.7 ± 2.4 years (range of 2.1 to 10.8 years).
- Radiographs provided for: Pre-surgical, Post-surgical, Post-Prosthetic, and >2 year follow up after prosthetic loading.
- 156 implants placed with 1-stage SFALW. 239 implants placed with 2-stage SFALW.
- 1-stage technique: Half graft material mixed with saline solution placed before implant placement; half placed after. Resorbable collagen membrane placed, flap repositioned and sutured. Patients prescribed abx therapy 5-7 days and chlorhexidine mouth rinse for 2 weeks postoperatively.
- 2-stage technique: Implant placed 5-8 months after sinus surgery.
- Radiographs evaluated by single investigator to rule out interexaminer variation.

Levels of Evidence: (For Therapy/Prevention, Etiology/Harm)

See http://www.cebm.net/index.aspx?o=1025

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Levels of Evidence for Prognostic Studies*

Level	Type of evidence
I	High quality prospective cohort study with adequate power or systematic review of these studies
II	Lesser quality prospective cohort, retrospective cohort study, untreated controls from an RCT, or systematic review of these studies
III	Case-control study or systematic review of these studies
IV	Case series
V	Expert opinion; case report or clinical example; or evidence based on physiology, bench research or "first principles"

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Conclusion(s):

The 10-year cumulative survival rates showed no statistically significant difference between implants following 1-stage and 2-stage maxillary SFALW performed on residual bone height of <4 mm.

Article(s) Cited:

Raghoebar, GM, Onclin, P, Boven, GC, et al**. Long-term effectiveness of maxillary sinus floor augmentation: A systematic review and meta-analysis**. *J Clin Periodontol*. 2019; 46(Suppl. 21): 307– 318. https://doi.org/10.1111/jcpe.13055

Study Design(s):

Systematic Review and Meta-Analysis of Cohort studies

Reason for Article Selection:

The article directly answered my PICO question and the study design was one of the highest I could find to answer this PICO question, especially since the inclusion criteria included studies with at least 5 years follow-up after implant placement post maxillary sinus floor augmentation. (The original study design was to include only randomized clinical trials with at least a 5-year follow up, but there is a lack of RCTs published on this topic at the moment.) The Journal of Clinical Periodontology is ranked 2nd of all Periodontology journals for its impact and prestige. There is no conflict of interest in connection with the article. Study was published within the two years.

Article(s) Synopsis:

Aim: Systematic review of cohort studies to assess the long-term effectiveness (>5 years) of MSFA applying the lateral window technique and to determine possible differences in outcome between simultaneous and delayed implant placement in patients with <6mm residual bone height.

- Methods: Systematic review conducted by a biomedical specialist using Medline (via PubMed), Embase, and Cochrane Central Register of Controlled Trials.
- Inclusion criteria: edentulous or dentate, requiring MSFA (lateral window technique) and presented with mean RBH under sinus at site of implant placement <6mm.
- Intervention: Mixture of Autogenous bone (AB) and/or Bone substitute (BS), solely Bone substitute, or no graft material.
- Goal was to pool RCTs with follow up >5 years, but no RCTs directly answered PICO question. Nevertheless, 11 cohort studies with sufficient quality were included.
- A variety of studies included MSFA with Autogenous Bone (AB) harvested from maxillary sinus region: chin, tuberosity, ascending mandibular ramus, anterior or posterior iliac crest.
- 2-stage healing period for graft material ranged from 3 to 18 months.

Results:

- MSFA (lateral window technique) is a safe and predictable procedure as part of oral rehabilitation of severely atrophic maxillae with dental implants. Meta-analysis reveals the survival of implants is high with no difference in simultaneous or delayed implant placement or using AB or BS as augmentation material.
- Overall cumulative weighted average annual implant loss was 0.43 representing a 5-year implant survival rate of 97.8%.
- Annual implant loss was higher when implants placed in mixture of AB and BS compared with placement in AB or BS alone.
- Not possible to draw conclusion about optimal healing time of graft material and implant before loading after MSFA. Prolonged healing period before implant placement is advisable.

Levels of Evidence: (For Therapy/Prevention, Etiology/Harm)

See http://www.cebm.net/index.aspx?o=1025

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Conclusion(s):

Maxillary sinus floor augmentation is a reliable treatment for patients with partially or fully edentulous maxilla. There is no significant difference regarding implant loss between 1-stage and 2-stage implant surgeries.