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**Maxillary sinus floor augmentation with different bone grafting
materials for dental implant treatment**

A systematic review

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Abstract

Aims: The objective was to test the hypothesis that there is no difference in implant treatment outcome using different bone graft material for sinus floor augmentation.

Material and methods: This systematic review is based on searches in PubMed, the Cochrane Library and the Web of Science and a hand search of relevant publications. Autologous bone, anorganic bovine bone (Bio-Oss), a combination of these two and elevation of the Schneiderian membrane with no graft material was evaluated. The quality of each publication was assessed according to criteria based on the STROBE-statements.

Results: The search provided 818 titles and 15 were found relevant according to the predetermined inclusion criteria. One study was a randomized controlled trial (RCT) and one was a controlled clinical trial (CCT). The remaining 13 studies were observation studies. The follow-up time varied between one and nine years and the number of patients between 10 and 191. Studies on elevation of the Schneiderian membrane with no bone graft material reported an implant survival rate between 97.7% and 100% and studies on only autologous bone graft material 98.8%. Bio-Oss as bone graft material resulted in 86.3%-98.1% survival rate and a combination of Bio-Oss and autologous bone graft resulted in a survival rate of 90.7%.

Conclusion: There was no difference in implant outcome of the different bone graft material. More studies designed as RCT and CCT, which analyze the implant outcome involving sinus floor augmentation and different bone graft material are needed to improve evidence on survival and success rate.

Key words: Autogenous bone, Bone substitutes, Sinus bone formation, Sinus floor augmentation and Sinus floor elevation

Sammanfattning

Syfte: Syftet med denna systematiska litteraturöversikt var att testa hypotesen att det inte är någon skillnad rörande lyckandefrekvensen gällande implantatbehandling vid sinuslyft med olika bentransplantatmaterial **Material och metod:** Studien baseras på sökningar i PubMed, Cochrane Library och Web of Science i kombination med en manuell granskning av relevanta publikationer. Inkluderade publikationer var prospektiva studier av ≥ 10 patienter och med en uppföljningstid på ≥ 1 år. Autologt bentransplantat från mandibel/maxilla, oorganiskt ben (Bio-Oss), en kombination av dessa två samt sinuslyft utan insättning av bentransplantat utvärderades. Kvaliteten på varje publikation bedömas enligt kriterier baserade på en modifiering av STROBE-statment.

Resultat: Sökningen resulterade i 818 titlar och 15 inkluderade publikationer relevanta enligt förutbestämda inklusionskriterier. En studie var en randomiserad kontrollerad studie (RCT) och en var en kontrollerad klinisk studie (CCT). De återstående 13 studierna var observationsstudier. Uppföljningen varierade mellan ett och nio år, och antalet patienter mellan 10 och 191. Sinuslyft utan insättning av bentransplantat hade en implantatöverlevnad på 97,7% -100% och studier rörande autologt bentransplantat 98,8%. Bio-Oss resulterade i 86,3% -98,1% överlevnad och en kombination av Bio-Oss och autologt ben resulterade i en överlevnad på 90,7%.

Slutsats: Enligt denna undersökning fanns ingen skillnad i implantat överlevnad mellan de olika bentransplantaten. Beroende på studiernas karaktär behövs fler RCT och CCT studier, som analyserar implantatutfallet, involverar sinuslyft och olika bentransplantat rörande implantatöverlevnad och lyckandefrekvens.

Introduction

Implant treatment is an excellent alternative to replace a missing tooth. Brånemark et al. (1) was 1977 the first to describe the bone to implant contact, called osseointegration.

Albrektsson et al. (2) defined the term at the light microscope level “direct contact between living bone and implant”. Loss of teeth will in itself result in reduced bone volume as well as trauma from removable dentures or from different pathologies. (3).

In the posterior maxilla, the bone height can be limited due to maxillary sinus and this may impair implant installation in this region (4).

Technique

The lack of bone volume can be treated with various bone grafting techniques before the implant installation (1). Boyne & James (5) (1980) was the first to introduce maxillary sinus floor augmentation with autologous bone graft. This technique has been modified and improved by Tatum (1986) (6) who introduced the lateral approach by fenestrating the buccal wall of maxillary sinus and lifting the Schneiderian membrane. This technique was modified by Wood and More in 1988 (7).

The sinus floor augmentation procedure can be divided into two different techniques. The first of the two techniques is called the osteotomy technique and it is performed by the use of osteotomes to create a controlled fracture of the floor of the maxillary sinus. This method creates space by elevating the sinus membrane and provides room for the dental implant and bone grafting material (8). The advantage of this technique is that it is less invasive and thereby reduced surgical time and lower morbidity compared to other sinus lift techniques.. This technique is suggested to be used when the vertical bone height is more than 4-6mm (9, 10).

The second technique is the lateral window technique and is performed by surgically preparing of the bone, lateral to the maxillary sinus, and thereby exposing the Schneiderian membrane which will be elevated. The bone graft material is carefully packed and placed on the sinus floor (4). This technique is more invasive than the osteotome technique due to the fenestration of the lateral sinus wall (9, 11). The lateral window technique is preferred when there is less than 6 mm residual bone height (12).

Bone biology

The alveolar process of the maxilla has a compact cortical layer with high density and an inner porous cancellous bone filled with bone marrow. The bone has cylindrical channels called Haversian canals and contains blood vessels that supply the bone with nutrition and oxygen. The outermost layer surrounding all compact bone is called periosteum and the inner surface is called endosteum. In bone formation periosteum is more active than endosteum. Bone formation occurs by three main mechanisms: sutural, endochondral and intramembranous. Sutural growth takes place at the sutural margins and endochondral bone formation takes place when cartilage is replaced by bone. Intramembranous bone formation, which occurs in the jaws, is directly within the mesenchyme. (13)

Bone cells

The bone cells are osteogenic cells and osteoclasts and they have different functions and structures. Osteogenic cells include osteoprogenitors, preosteoblasts, osteoblasts and osteocytes. Mesenchymal cells are first converted to osteoprogenitors and later to preosteoblast cells, which in turn are transformed to osteoblast cells.

The osteoblast cells produce osteoid; a noncalcified matrix which contains collagen and non-collagenous protein bone matrix. Osteoblasts also secrete several cytokines and bone morphologic proteins (BMP). The cytokines and hormones play a major part in bone healing

and lead to increased bone regeneration. When osteoblasts stop producing matrix they convert into osteocytes and are buried in the calcified bone.

Osteoclasts are large multinucleated cells that resorb bone. (14, 15).

Bone healing

Bone healing after graft placement takes place in two phases: Repair with an inflammatory response and bone remodeling. In the first phase a blood clot is formed in the injured area where the outer area of the local bone becomes necrotic and the capillaries start to develop and further on migration of inflammatory cells e.g. lymphocytes, granulocytes and monocytes occur. This action restores blood flow and after 1-3 days an inflammatory response is active and granulation tissue is starting to form. The granulation tissue will mature to a collagen matrix and mesenchymal stem cells begin to differentiate into osteoblasts cells forming new bone.

During the second phase, the bone remodels, and is replaced by a more mature lamellar bone and a complete regeneration of a defect occurs when all bone is replaced with lamellar bone. (16, 17)

Bone graft material

The ideal bone grafting material should have both osteoinductive and osteoconductive properties and be able to osseointegrate to the implant surface. These properties vary in different bone grafting materials (18).

Osteoinduction is defined as primitive, undifferentiated and pluripotent cells that are stimulated by an inductive means to become bone-forming cells and osteogenesis is induced.

Osteoconduction means that bone grows on a surface. An osteoconductive surface allows bone growth on the surface and down into the pits and pores (19, 20). The grafting material

used in maxillary sinus floor augmentation is expected to allow new natural bone formation with capillary infiltration and to provide the capacity for replacing the bone graft material and supporting the implants with adequate bone volume(3, 12).

Various categories of bone graft materials can be placed in the maxillary sinus, such as autologous bone, allografts, xenografts and alloplasts.

Autologous bone graft

Autologous bone is considered as the golden standard material. It has both osteoinductive and osteoconductive properties and provides osteoprogenitor cells which has osteogenic potential and develops osteoblasts that produce organic and inorganic matrix. Growth factors and proteins will positively affect the osteoinductive process in the healing of autogenous bone graft(21). Using autologous bone has two major advantages: (i) No immunogenic reaction is triggered and (ii) the bone contains growth factors that trigger bone remodeling. Bone can be harvested from different parts of the body, for example: the iliac crest, mandibular ramus and chin, the tibia and calvarium. (7, 22-24)

Intraoral technique exposes very limited amounts of bone and requires only local anesthesia. Bone graft harvesting from extraoral sites, such as iliac crest, offers large amount of bone but requires general anesthesia and increased postoperative morbidity. The technique is also time consuming and thereby more expensive (21). Autologous bone graft can either be used in a particulated or block form. Dasmah et al. (25) reports large and rapid resorption in both height and width of the bone graft which can be seen as an disadvantage to the procedure.

Xenografts

Xenografts are defined as bone derived from a living tissue from another species. All organic content is eliminated resulting in inorganic and deproteinized cancellous bone to ensure that

no immune reaction can occur. This bone has the same morphological and crystalline structure as the human spongy bone. A xenograft material undergoes no or very slow a physiological remodeling/resorption. One example of xenograft is Bio-Oss which is a deproteinized bovine bone, which has osteoconductive properties and biocompatibility (4). Bio-Oss is today commonly used in maxillary sinus floor augmentation and has the advantage of no need for a donor site bone harvesting. The disadvantage is the absence of osteoinductive properties (26).

Other graft material

Allografts are bone tissue that derives from individual from the same species and are treated with various techniques, e.g. freeze dried, exposed to radiation etc (27).

Alloplastics are synthetic bone graft which are divided into different categories according to its density and morphology. The structure determines how the material is performing. Examples of alloplastic are: beta-tricalcium phosphate, bioactive glass and calcium sulfate (27).

Protein rich plasma

Protein rich plasma (PRP) is obtained when the blood is separated by centrifugation. PRP is mixed with calcium-chloride which gives its anticoagulant effect and the manageable gel mass, which give the increased stability when placed. PRP delivers a high concentration of angiogenic mitogenic growth factors which should accelerate the healing process of soft tissue (18).

Combination of Bio-Oss and Autologous bone

Galindo et al. (28) suggests that this composite graft could from a biological perspective give a better product with the use of both materials advantages in one graft material.

No bone graft material

Lundgren et al. (29) described how dental implants was placed in the posterior maxilla with the implant apices protruding in to the maxillary sinus where only elevation of the Schneiderian membrane have been performed. The method described that no bone graft material was added to the site except the natural developed blood clot which stimulates the natural bone formation ability.

Aim:

1. In a systematic review study if there is any difference in implant treatment outcome at different bone graft materials for sinus floor augmentation?

Hypotheses:

1. Sinus floor augmentation is a safe and a predictable method to enhance the alveolar bone underneath the maxillary sinus previous to implant treatment.
2. There is no difference in survival rate, function and complications with the different bone grafting materials studied.

Methods and Material

This systematic review was conducted according to Goodman's systematic approach (30).

1. Specification of the problem.
2. Formulation of a plan for the literature search
3. Literature search and retrieval of publications
4. Data extraction, interpretation of data and evaluation of evidence from literature retrieved.

Specification of the problem

Regarding bone regeneration in the maxillary sinus in order to increase the volume of the alveolar bone processes prior to dental implant treatment.

- What is the outcome of implant treatment when using various bone graft materials in sinus floor augmentation?

Definition for the following keywords was searched before the literature search using Medical

Subject Heading terms (MeSH):

- Maxillary Sinus: The air space located in the body of the MAXILLARY BONE near each cheek. Each maxillary sinus communicates with the middle passage (meatus) of the NASAL CAVITY on the same side
- Dental Implants: Biocompatible materials placed into (endosseous) or onto (subperiosteal) the jawbone to support a crown, bridge, or artificial tooth, or to stabilize a diseased tooth
- Bio-Oss: an inorganic bovine bone matrix; appears to be as good as porous hydroxyapatite in terms of biocompatibility and osteoconductivity.

- Sinus floor augmentation: Guided bone transplantation of the maxillary sinus surface with a bone substitute grafting. It increases the bone volume at the site of the dental implant and helps stabilize it.
- Bone Substitutes: Synthetic or natural materials for the replacement of bones or bone tissue. They include hard tissue replacement polymers, natural coral, hydroxyapatite, beta-tricalcium phosphate, and various other biomaterials. The bone grafts inert materials can be incorporated into surrounding tissue or gradually replaced by original tissue (Defined 1992).

Definitions of keywords, not defined in MeSH:

Primary outcomes were defined as survival and success of implant treatment according to Roos et al (31):

Survival

“An implant not belonging to the failure or the unaccounted for groups is included in the survival group.”

Success

“From observations in the survival category, implants can be elevated towards success, if they meet with specified criteria. The success category is a part of the survival category; hence, successes are always survivals also. Clinical and/or radiographic examinations are prerequisites. Success is graded in three qualities, depending on the extent and results of performed examinations. All successful implants are in clinical function.”

Grade 1.

1. Absence of mobility is checked by individual stability testing of the unattached implant, using a light tightening force of an abutment screwdriver without simultaneous counteracting

of the force via an abutment clamp. Any mobility or sensation/pain from the anchorage unit is regarded as a sign of lost osseointegration.¹⁰

2. Radiographic evaluation of each implant reveals not more than 1.0 mm of marginal bone loss during the first year of loading, followed by not more than 0.2 mm resorption per year, as well as absence of peri-implant pathosis, such as a peri-implant radiolucency.

3. Severe soft tissue infections, persistent pain, paresthesia, discomfort, etc, are absent.”

“*Grade 2.*

1. Radiographic evaluation of each implant reveals not more than 1.0 mm of marginal bone resorption during the first year of loading, followed by not more than 0.2 mm of resorption per year, as well as absence of peri-implant pathosis, such as a peri-implant radiolucency.

2. Severe soft tissue infections, persistent pain, paresthesia, discomfort, etc, are absent.”

“*Grade 3.*

1. Radiographic evaluation of each implant reveals not more than 0.2 mm of marginal bone resorption during the last year, but previously more than 1.0 mm of bone loss has taken place. Peri-implant pathosis, such as a peri-implant radiolucency is absent.

2. Severe soft tissue infections, persistent pain, paresthesia, discomfort, etc, are absent.

To clarify the examinations being performed, a flow chart of the different examination levels has been presented in Fig 1.”

Secondary outcome was defined as implant failure according to Roos et al(31):

Failure

“An implant is regarded as a failure if it has been removed for any reason. Clinical mobility is an absolute indication for implant removal. Relative indications for implant removal could be e.g. severe incurable soft tissue infections, persistent pain, paresthesia or discomfort. Any

adverse event is recorded, including information on onset, duration, measures taken, and recovery, although adverse events do not always result in removal.” (31)

Formulation of a plan for the literature search

The first step of the search comprised searches with the aid of MeSH and free text terms in the databases PubMed, the Cochrane Data base of Systematic reviews (the Cochrane Library) and the Web of Science under the guidance of a tutor at the library in Malmo University. The searches of the databases are presented in Table 1. The second step of the search was to study the reference lists of the systematic reviews that we found in the first step. Titles containing words that matched the search terms were included and the abstracts retrieved. Books and reviews were excluded.

Literature search and retrieval of publications

The abstracts of the retrieved publications were assessed by two students and a supervisor of the thesis on the basis of inclusion and exclusion criteria (Table 2). Patients had to be examined clinically and radiographically at least 1 year after the prosthetic loading of the dental implant. Studies of direct implant placement after tooth extraction were excluded.

When a publication was assessed to meet the inclusion criteria, it was ordered and read in full text.

Data extraction, interpretation of data and evaluation of evidence from literature retrieved

Two students and a supervisor independently read the full-text publications and data was inserted in tables. The quality of each publication was assessed according to criteria presented in Table 4. The criteria were based on the STROBE-statement(32). Level of evidence was rated according to GRADE (33) guidelines in one of four quality levels – high, moderate, low or very low.

Results

Literature identification

The number of publications retrieved, read, and interpreted are presented in Figure 1. From the PubMed search, 20 studies were included and read in full text and four additional studies from the Web of Science and two additional studies from the Cochrane Library were read in full text. The searches yielded ten systematic reviews and the searches of the reference lists of the reviews resulted in 13 full text publications.

From the total of 39 publications read in full text, 15 were found relevant according to our inclusion criteria (Figure 1). The remaining studies were excluded as presented in Table 4: two were retrospective studies, ten reported on other graft materials, eight studies had too short follow-up time, one study did not report on primary outcome, one study presented only a clinical examination of the implant and in two studies the attrition was too high.

Treatment outcomes of sinus floor augmentation with bone graft material (Tables 5 - 8).

In general

The studies included in this review were prospective studies. One study was designed as a randomized controlled trial (RCT), one as a clinical controlled trial (CCT) and remaining studies were observational studies. The follow up time of the studies varied between 1 and 9 years. The number of patients varied between 10 and 191 and the mean age of the patients was 55 year. The implant system used were the Brånemark system, Astra tech system, Straumann system, Seven MIS implants, Ossoetite Biometri 3i system, and Camlog, Frihex(Friatec). The number of implant placed varied between 21 and 286 implants. The technique of implant placement was as often direct as indirect technique.

In most studies the primary outcome was defined as survival rate but in five studies also the cumulative survival/success rate was presented. In four studies there was a histological examination of the graft material and residual bone tissue.

Sinus floor augmentation with elevation of the Schneiderian membrane (Table 5)

Sinus floor augmentation with elevation of the Schneiderian membrane is defined as no insertion of bone graft material. Of the four observation studies included, one study was evaluated to present low study quality and three moderate. The follow-up time was 1 to 6 years and the numbers of patients varied between 10 and 84 patients. The primary outcome ranged between 97.7 and 100% and secondary outcome between 0 and 2.3%.

Sinus floor augmentation with autologous bone graft material (Table 6)

Only one study with moderate study quality presented results on autologous bone graft material with 61 patients and a follow-up time of 5 years. The survival rate was 98.8%.

Sinus floor augmentation with only Bio-Oss as graft material (Table 7)

Two observational studies, one RCT and one CCT were retrieved. The study quality of the RCT was evaluated as high, two observation studies as moderate study quality and the CCT as low. The follow-up time was 1 to 5 years and the minimum number of patient was 15 and maximum 87 patients. Two studies presented a histological examination. The primary outcome for success was 96.2%, for survival rate between 86.3 and 98.1%, and for cumulative survival 100%. The secondary outcome was 0-13.7 %

Sinus floor augmentation with a combination of autologous bone and Bio-Oss (Table 8)

Six observation studies with a follow-up time between 1 to 9 years were of moderate study quality. The minimum number of patient was 20 and maximum 191. One study included a histological examination. The primary outcome was presented as cumulative survival/success rate in four studies and ranged between 86% and 99.6%. One study had a survival rate of 90.7%, and one a success rate of 99%. The secondary outcome ranged between 0.4% and 3.5%.

Evaluation of evidence

The study quality according the criteria described of the included publication was low in 3 studies (42-44), moderate in 11 studies (10, 33, 37, 45-52) and high in one study (53), Table 3. The quality level of evidence was low concerning the outcome of various bone graft materials used in sinus floor augmentation. The quality level of evidence was assessed to be very low to determinate which graft material that was the most effective.

Discussion

In the present study, different bone graft materials were evaluated such as intraoral autologous bone, Bio-Oss, a combination of autologous bone and Bio-Oss and elevation of the Schneiderian membrane with no bone graft material. No difference was found in implant survival rate, function and complications of different bone grafting materials but the quality level of evidence was low concerning the outcome of various bone graft materials used at the sinus floor augmentation. Implant placement performed with sinus augmentation and bone graft material have many different variables that can be responsible to the survival and the failure rates such as the bone graft material, grafted bone volume, residual bone volume, implants surface and design, patients' age, smoking habits, bone graft and implant healing time etc (34). It is more appropriate to harvest bone from an intraoral donor site due to few

disadvantages compared to bone coming from an extraoral site. Depending on where the donor site is located, different anatomical structures can be affected resulting in devitalization of mandibular incisors and sensory disturbance from the inferior alveolar nerve when using chin as a donor site (28).

Johansson et al. (35) reports of two different bone harvesting techniques. A single-use bone harvesting device connected to the suction (Astra Tech BoneTrap) was used during implant preparation, collecting the bone dust from the drilling which was used as graft material. The other technique, a disposable manual cortical bone harvesting device (Safescraper; Meta, Reggio Emilia, Italy) was used to harvest particulate cortical bone chips from the outer cortical bone layer in the local operating area. The result in this study shows that the cortical bone harvesting device collected larger bone volume more efficient.

In a histomorphometric comparison, in one of Valentini's studies, biopsies were taken from both grafted and non-grafted areas in maxillary sinus where Bio-Oss had been placed six months earlier. Biopsies were then repeated after another six months and the histological results showed a well-vascularized vital bone marrow and no physiological resorption of the Bio-Oss at a 12 months biopsy (36). Other suggest similar results, such as that the resorption of Bio-Oss takes place only in the primary healing phase and that no major changes occurred later on (37). In a RCT study Bio-Oss and Bio-Oss with PRP were compared to analyze if PRP had an impact on bone formation and the result showed no significant effect in bone formation. It only made the bone graft material (Bio-Oss) more easily manageable by its fibrin gel mass capacity (38). Galindo et al. reported the same result in combination of PRP, Bio Oss and autogenous bone which confirms the previously mentioned fact (28). Hallman et al. (39). compared implants placed in grafted bone with a combination of 20% Bio Oss and 80% autologous bone graft. There was no statistical significant difference between the groups

and histological results after six months of healing indicated mainly immature bone. This could result in a poor primary stability of the implant which could cause a disosseointegration (39). Revascularization has been mentioned in different studies as an important factor for survival of the implants and bone formation is clearly dependent on well-vascularized bone grafts. Autologous bone requires shorter healing time compared to only using Bio-Oss due to more rapid revascularization. A healing period of six to eight months is therefore necessary for a composite graft, i.e. autogenous bone and Bio-Oss, to allow revascularization (40).

In an one histological analysis of composite bone graft material, 20% autologous bone and 80% Bio-Oss, Mordenfeld et al. (41) found no statistically significant difference in comparison to the two methods after a healing period of six months. The histological analysis from these different studies and different stages in the healing period indicate that Bio-Oss particles are still retained even after 11 years. Other authors reported similar result (28). The biocompatibility properties can be confirmed considering the time Bio-Oss stays in the body without resorption (28, 40, 41).

Sinus floor elevation with no graft material except a blood clot under the Schneiderian membrane, is the latest method in sinus floor augmentation. Sohn et al.(42) reported a six months postoperative CT follow-up that showed new bone formation after sinus floor elevation, similar to new bone formation in a tooth extraction socket. When the Schneiderian membrane is carefully elevated with an instrument a part of the inferior, buccal and medial wall of the sinus bony cavity is exposed and mesenchym cells can migrate to the blood clot. Recruitment, migration and differentiation of osteogenic cells into osteoblasts are necessary for bone formation and the most important factor is the closed compartment with the blood clot underneath the Schneiderian membrane to provide a possibility for bone formation. The implant also helps to keep the Schneiderian membrane from collapsing (42).

Criccho et al. (43, 44) demonstrated on primates the importance of the elevation of the Schneiderian membrane to allow blood clot and provide space for new bone formation. Experimentally they placed implants penetrating the membrane and no result of bone formation was seen but when the membrane was elevated bone formation was achieved. Thor et al. (10) showed that with longer implant, larger bone amount was formed and the new bone is formed directly around the implant. Another advantage could be that there is no remodeling time for the graft material (45). Sinus floor elevation with no graft and simultaneous installation of an implant left to osseointegrate for three to six months depending on the residual bone height, will result in optimal treatment time (10).

When one stage procedure is used in residual bone height with five mm or less, it resulted in more failures (10). The two stage procedure improved the survival rates of the implants in patients with less than four mm residual bone height in the posterior maxilla (34, 37).

Marchetti et al and Torres et al. (38, 46) reported an increased survival rate in the two stage technique with 97.2% compared to 87.5 % in the one stage technique. This clarify the importance of when one or two stage procedures should be performed. In a prospective study, they concluded that the clinical success and survival of implants with a healing time of six months with autologous bone and Bio-Oss is as equal with implants placed in residual bone. The two stage procedure in cases with a bone height of 3mm or less, provided the same implant survival as for implants placed in residual bone without bone augmentation(47).

Different studies show that repeated trauma to the implant or the nearby bone during the healing period is one of the factors causing failure of the implant survival (48-50). Lundgren et al (51) has shown that if the implant is installed after six months of bone healing the degree of osseointegration is increased . Esposito (52) reported in a review that most implant failures occurred during the healing period and at the second stage surgery.

Implant surface and length might have an important role in implant survival. Rough surfaces are recommended to be used in sinus floor augmentation and are supposedly associated with higher implant survival rates (34).

Tawil et al. (34) reported that an implant length of 10 mm or shorter resulted in higher failure rate. Aparicio et al. (14) suggests when the maxillary sinus augmentation method is not used, the vertical limitations of the residual bone induces the use of shorter implants which have higher failure rates compared with longer implants. An alternative to maxillary sinus floor augmentation techniques is the placement of tilted implants when the neighboring residual bone volume allows. Cricchio et al. (53) concluded based on several reports that maxillary sinus augmentation with lateral window technique using different graft material, seems to be a well-documented method with high clinical survival rate. However, it can be difficult to compare studies and understand their results because of varying inclusion- and exclusion criteria concerning the amount of residual alveolar bone, different surgical techniques, different periods of healing, different implant surfaces and the time of implant healing, prosthetic technology and quality on monitoring (53).

Hallman et al. (39) reported higher postoperative morbidity when comparing bone harvesting from the mandible symphysis with harvesting from the mandibular ramus. Hallman et al. (39) recommended the mixture of autologous bone and Bio-Oss instead of using autologous bone only. In the same study they examined sinuses postoperatively to see if sinusitis occurred. The presurgical CT treatment report showed that 67% of the sinuses were healthy which increased to 71% three years after the surgery. This indicates that there was minor risk for sinusitis after sinus floor augmentation (39).

The development of the sinus floor augmentation method over the last two decades is remarkable because of its transformation from an invasive surgical approach using donor bone from the hip in general anesthesia, to just a lifting of the Schneiderian membrane and

letting the blood clot form new bone. This development means less pain, less discomfort, less risk for other postoperative complications and less sick leave.

Bio-Oss has been proven to be osteoconductive and functions as a help to preserve the new formed bone. The necessity of Bio-Oss can be questioned when it seems that smaller amount of autologous bone graft material and/or only blood clot placed in underneath the Schneiderian membrane is sufficient to create satisfactory amount of new bone formation.

The implant surface and its design is an important variable, when you analyze implant survival rate. Today, the major implant companies have roughly the same implant surfaces texture but any difference in survival rate is not yet concluded and could thereby be of importance in implant survival rate analyzes. Another variable for success is the surgeon's skill and experience when performing the sinus floor augmentation.

One of the exclusion criteria in this study was follow-up time < 1 year, which might have led to exclusion of relevant publications and loss off valuable data for this review.

Conclusion

The hypothesis of no difference in survival rate, function and complications of different bone grafting materials was confirmed. Sinus floor augmentation without any additional bone graft even had higher survival rate according to several studies. This method seems to eliminate important risk factors like bone harvesting procedure, morbidity related to the harvesting and cost of grafting material. As the quality level of evidence was assessed to be very low to determinate which graft material that was the most effective more studies designed as RCT and CCT, are required to establish evidence in implant outcome involving sinus floor augmentation and different bone graft material.

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Table 1 Search terms and number of publications retrived in three databases.

Search in MEDLINE (PubMed)	Search performed on the 2012-08-21					Number of publications
#1	Sinus floor augmentation					435
#2	Sinus floor elevation					266
#3	Sinus bone formation					526
#4	#1 OR #2 OR #3					919
#5	Bone substitutes					3516
#6	Autogenous bone					3135
#7	#5 OR #6					6259
#8	#4 AND #7					372
Search in web of science						
Search performed on the 2012-08-22						
#1	Sinus floor augmentation					795
#2	Sinus floor elevation					524
#3	Sinus Bone Formation					588
#4	#1 OR #2 OR #3					965
#5	Bone substitutes					6403
#6	Autogenous bone					3489
#7	#5 OR #6					9356
#8	#4 AND #7					389
Search in cochraine library	Search performed on the 2012-08-22	Cochrane review	Other review	Trials	Other	
#1	Sinus floor augmentation	0	4	51		
#2	Sinus floor elevation	0	4	29		
#3	Sinus Bone Formation	0	0	38		
#4	#1 OR #2 OR #3	0	7	78		
#5	Bone substitutes	12	17	422	10	
#6	Autogenous bone	4	1	235	1	
#7	#5 OR #6	12	17	587	10	
#8	#4 AND #7	0	2	55		
Limits criteria in the search was only humans and English.						

Table 2 Inclusion and exclusion criteria for studies on sinus floor augmentation with and without bone graft material.

	Inclusion criteria	Exclusion criteria
Study design	RCT (randomized clinical trial) CCT (controlled clinical trial) Prospective observational study	Original studies (review etc) Case reports Retrospective study
Observation time after implant installation	≥ 1 year	< 1 year
Measurement of outcome	Clinical examination Radiographic examination	Only clinical examination
Outcome	Survival/Success rate of implant treatment.	-
Language	English	Studies not written in English
Patients	≥10 individuals in each groups of RCT and CCT ≥10 individuals in observational study Participants described concerning radiographic examination at base-line.	-
Attrition	≤ 20 % and presentation of reasons for dropout.	> 20%
Surgical method Implant surface Insertion of implants	Lateral window technique Surface-modified titanium.	Osteotomy technique Hydroxylapatit surface Direct implant insertion after extraction.
Bone graft material	Mandibular and maxillary autologous bone, Bio-Oss and blood.	Synthetic bone, bone from iliac crest and stemcells.

Table 3
Quality assessment of each study modified by Strobe statement

High	Moderate	Low
Prespecified hypotheses	State specific objectives	
Setting and locations well described concerning relevant dates, including periods of recruitment, exposure, follow-up, and data collection described	Setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection described	Setting for trial not described
RCT – Give the eligibility criteria, sources and methods of selection of participants. Describe methods of follow-up	Observation study - Give the eligibility criteria, sources and methods of selection of participants. Describe methods of follow-up	Observation study vague described
Diagnostic criteria. Primary and secondary outcomes and assessment methods well described	Primary and secondary outcomes and assessment methods described	Primary outcome described but assessment methods vague described
Describe clearly any efforts to address potential sources of bias	Describe any efforts to address potential sources of bias	No description of bias
Well described how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	-
Method clearly described any evident explanation for how the study size was arrived at	-	-
Stringent representative of each included patient and of drop-out	Stringent representative of the group of patients and of drop-outs	Presentation of the group of patient
Stringent presentation of primary and secondary outcome of each patient	Stringent presentation of primary outcome of the group	Only secondary outcome reported
Histological presentation of the sinus floor augmentation		
Well described external validity and applicability of study results.	Described external validity and applicability of study results.	Generalizability (external validity) of the study results not discussed.
Limitations of the study, sources of potential bias or imprecision well discussed. Discuss both direction and magnitude of any potential bias	-	-
Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	-	-

Table 4 Excluded studies in this review

Author Country Year	Reason
Clavero Sweden, Spain 2003 (23)	Method: No primary outcome reported.
Mardinger Israel 2011 (54)	Study design: Retrospective
Jeong Korea 2011 (55)	Material: Other graft material
Lindgren Sweden 2012 (56)	Material: Other graft material
Cordaro Italy 2008 (57)	Material: Other graft material
Schaaf Germany 2008 (58)	Follow up time: < 1 year
Thor Sweden 2007 (59)	Follow up time: < 1 year
Steigmann Florida. USA 2005 (60)	Material: Other graft material
Hallman Sweden 2001 (61)	Follow up time: < 1 year
Cabbar Turkey 2011(62)	Material: Other graft material
Urban Hungary 2011 (63)	Material: Other graft material
Becktor Sweden 2008 (21)	Follow up time: < 1 year
Wannfors Sweden 2000 (64)	Material: Other graft material
Khoury Germany 1999 (65)	Material: Other graft material
Rodriguez Brazil 2003 (66)	Few patients with follow-up > 1 year
Valentini, France 1997 (67)	Material: Other graft material
Ferreira Brazil 2009 (68)	Study design: Retrospective
Galindo-Moreno Spain 2010 (69)	Follow up time: < 1 year.
Piattelli Italy 1999 (70)	Few patients with follow-up > 1 year
Galindo-Moreno Spain 2010 (71)	Follow up: < 1 year.
Marchetti USA 2007 (46)	Material: Other graft material
Lee Australia 2011(72)	>20 % drop out of the patients
Mordenfeld Sweden 2010 (41)	>20 % drop out of the patients
De Vicente Spain 2010 (40)	Only clinical and histological examination but no radiologic examination

Table 5 Sinus floor augmentation with elevation of the Schneiderian membrane

First Author	Study design	Patients (n)	Implant System	Method to measure outcome	Primary outcome (implant survival/success rate)	Secondary outcome (implant failure rate)	Study quality
Year	Follow-up (years)	Sinus (n)	Sample				Comments
Country		Sex	Direct or indirect surgical technique				
Reference		Age					
Sohn 2008	Observation 0.5-1 year after prosthetic loading.	Male n=7	N= 21 (seven, MIS implants technologies Ltd, Israel)	Clinical Radiography and computed tomograms. Histological examination in 4 patients after 6 months.	All implants were clinically stable.	No notable differences.	Low
Republic of Korea (42)		Female n=3					Not reported primary and secondary outcome.
		Sinus n=10					Replaceable bony window to seal the lateral window was more cost effective and time saving procedure than to use a nonresorbable membrane.
		Mean age: 50 year					
Cricchio 2011	Observation 1 Minimum 6 Maximum	Male n=46	N= 239	Clinical: Stability Periapical radiography and CT.	Survival rate 98.7%	1.3% (3 implants failed in 3 different patients)	Moderate
Umeå, Sweden		Female n=38	Brånemark system, TiUnite implants (Nobel Biocare)				A total of 11 perforation (11.5%) occurred when sinus membrane was elevated.
Palmero, Italy (73)		Sinus n=96					
		Mean age:					

		54		AB)				
Thor 2007	Observation	Male n=9	n=	N= 44	Clinical examination of the implant and prosthetic restoration was removed. Periapical radiographs and orthopantomograms	Survival rate 97.7%	2.3%	Moderate
Sweden (10)	4	Female n=11		(Fixture Microtread Astra Tech)				Perforation of the maxillary sinus mucosal lining occurred in 41 %
		Sinus n=27						
		Mean age: 59 (19 to 78)						
Lundgren 2004	Observation	Male n=2	n=2	N=19	Clinical investigation.	Survival rate 100%	0%	Moderate
Gutenberg, Sweden.	1	Female n=9	n=9	Brånemark system	Radiography CT. Resonans frekvens analys (RFA)-implant stability measurement.			Patient were primary implant stability was not achieved were excluded from the trial. Left 10 patients included.
(29)		Sinus n=12	n=	TiUnite, MK III, Nobel Care AB.				
		Mean age: 51.		3.75mm in diameter and 10/15 mm in length.				
				Direct technique				

Table 6 Sinus floor augmentation with autologous bone graft material

First Author	Study design	Patients (n) Sinus (n)	Implantat system (n) Sample	Method to measure outcome	Primary outcome (implant survival/success)rate	Secondary outcome (implant failure rate)	Study quality
Year	Follow-up (years)	Sex	Direct or indirect surgical technique				Comments
Country		Age					
Reference							
Johansson 2010	Observation 1-5	Female n=42	N= 81 Straumann system	Clinical Radiography	Survival rate 98.8%	0.2%	Moderate
Sweden (35)		Male n= 19 Age= 18 to 85 years	Indirect technique				Lateral window. "Bone trap" and "Bone scraper"

Table 7 Sinus floor augmentation with only Bio-Oss as graft material

First Author	Study design	Patients	Sample= n	Method to	Primary	Secondary	Study quality
Year	Follow-up	(n)	Implantat	measure outcome	outcome	outcome	Comments
Country	(years)	Sinus (n)	system		(implant	(implant	
Reference		Sex	Direct or		survival/	failure rate)	
		Age	indirect		success rate)		
			surgical				
			technique				
Torres	RCT	Male n=	N= 286	Clinical	Success rate	3.8% Bio-	High
2009	2	40	Osseotite	Radiography	96.2% Bio-Oss	Oss	
Spain		Female n=	Biomet 3i	Histologic	98.6 % Bio-	1.4% Bio-	
(38)		47	system		Oss and	Oss + RPR	
		Sinus n=	Indirect		protein rich		
		144	technique		plasma (PRP)		
		Mean age:					
		(52-78					
		years)					
Tawil	Observation	Male n=	N= 61	Clinical (Prosthetic	Survival rate	13.7 % Bio-	Moderate
2001	1-3	20	Brånemark,	construction was	86.3% Bio-	Oss	
Lebanon		Female n=	machined-	removed)	Oss.	5.4% Bio-	15 sinuses filled with Bio-Oss
(34)		9	surface	Periapical	95.6 % Bio-oss	Oss +	without membrane and 15 with
		Sinus n=	implants.	radiography	+ membrane	membrane	membrane cover
		30	n= 41 direct		cover	cover	
			technique.				

		Mean age: 56 (38-75)	n= 20 indirect technique.				
Valentini 2000 France (36)	Observation 4± 0.5	Male n=6 Female n=9 Sinus n= 20 Mean age: 57 (36-68)	57 implants (Frihex, Friatec 4mm x 13/15mm) Indirect technique (0.5 year healing time)	Clinical Radiography: tomodensitometry Periapical radiography Histological evaluation in three patients.	Survival rate 98.1%	1.9%	Moderate Clinical outcome: Successful grafting considered when implants at least 13 mm in length could be inserted. Removed implant of any reason was considered as failure.
Özkan 2011 Turkey (37)	CCT 5	Male n=12 Female n=16 Sinus n= 42 Mean age: 49.6 (28- 60)	N=44 ITI Strauman N= 40 Camlog Direct technique	Clinical Panoramic radiography.	Cumulative survival rate 100%	0%	Low Observation study vague described.

Table 8 Sinus floor augmentation with a combination of autologous bone and Bio-Oss

First author	Study design	Patients (n)	Implant system	Graft Material	Method to measure outcome	Primary outcome (implant survival/success rate)	Secondary outcome (implant at failure rate)	Study quality
Year	Follow-up (years)	Sinus (n)	Sample (n)					Comments
Country		Sex	Direct and indirect surgical technique.					
Reference		Age						
Hallman 2002 Sweden (45)	Observation 1	Male n=6 Female n=14 Sinus n=30 Mean age: 62 (48-69 years)	N=108 Brånemark System (length 7-18 mm wide 5.5, 4, 3.75 mm) Indirect.	20% autogenous bone. 80% Bio-Oss	Clinical. Prosthetic removed when implants were examined. Radiography	Survival rate 90.7%	2.4%	Moderate 4 patients showed paresthesia in mandibular symphysis. Residual bone height was 1.6 mm at the lowest and 3.8mm at the highest portion.
Hallman 2005 Sweden (39)	Observation 3	Male n=6 Female n=14 Sinus n=27	N= 108 Brånemark System (length 7-18 mm wide 5.5, 4, 3.75 mm) Indirect.	20% autogenous bone. 80% Bio-Oss	Clinical Stability Radiography	Cumulative survival rate 86 %	14%	Moderate Same material as in Hallman One patient had diseased and two had moved and could not attend the 3-year follow-up examination.

				Mean age: 62 years (48-69 years)					
Hallman 2007 Sweden (74)	Observatio n 5	Male 6	n= N=108	Brånemark System (length 7-18 mm wide 5.5, 4, 3.75 mm)	20% autogenous bone. 80% Bio-Oss	Clinical Stability Radiography	Cumulative survival rate 86 %	14%	Moderate Same material as in Hallman
		Female n=14	n= N= 426	Brånemark titanium implants (length 8.5–15 mm, wide 3.75–6 mm)	Autogenous bone and Bio- Oss 2:1	Clinical Radiography Histological measurement	Cumulative success rate 94.2%	7.8%	Low Observation study vague described.
		Sinus 27	n= N= 106	Direct technique					
				Mean age: 62 years (48-69 years)					
Hatano 2004	Observatio n 9	Male 60	n= N= 426	Brånemark titanium implants (length 8.5–15 mm, wide 3.75–6 mm)	Autogenous bone and Bio- Oss 2:1	Clinical Radiography Histological measurement	Cumulative success rate 94.2%	7.8%	Low Observation study vague described.
		Female n=131	n= N= 106	Direct technique					
		Mean age: 55.5+- 9.7 (27-79 years)							
Urban 2010	Observatio n 5	Male 30	n= N= 106	Brånemark System Mk IV,	Autogenous and Bio-Oss	Clinical Radiography	Cumulative success rate 96.5%	0.4%- 3.5%	Moderate
		Female							

(47)		n=40		100 Brånemark System Mk III, 30 NobelReplace, and 9 NobelSpeedy implants				Cumulative survival rate 99.6%		
Galindo-Moreno	Observation	Male 48	n=	N= 171 Astra Tech with Tio-Blast surface. 92 Microdent implants with sandblast surface treatment.	Autogenous bone PRP Bio-Oss	Clinical Radiography	Success rate 99%	1%	Moderate	
2007	2	Female n=22								
(28)		Sinus n= 82								
		Mean age: years								

Figure 1 - Flowchart

Literature search in databases PubMed, the Cochrane Data base of Systematic reviews (The Cochrane Library) and the Web of Science. The included publications from the search in Web of Science were duplicates to included publications retrieved in Medline.

