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Advances in bone augmentation to enable dental implant placement: Consensus Report of the Sixth European Workshop on Periodontology

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Abstract

Background: Bone augmentation procedures to enable dental implant placement are frequently performed in practice.

Methods: In this session the European Workshop on Periodontology discussed the evidence in support of the procedures and examined both adverse events and implant performance in the augmented bone. While the available evidence improved both in quantity and quality since previous workshops the conclusions that could be drawn were limited by elements of design and/or reporting that are amenable to improvement.

Results: With regards to lateral bone augmentation, a sizable body of evidence supports its use to enable dental implant placement. The group recognized the potential for vertical ridge augmentation procedures to allow implant placement in clinical practice but questioned the applicability of these data to a wider array of operators and clinical settings. With regards to sinus floor augmentation, perforation of the sinus membrane, graft infection and graft loss resulting in inability of implant placement were the major reported adverse events. In cases with <6 mm of residual bone height, 17% of subjects experienced implant loss in the first 3 years following lateral window augmentation. After trans-alveolar sinus floor augmentation 11% of subjects experienced implant loss over 3 years. Significant research activity (both pre-clinical and clinical) was identified in the area of growth factors-induced bone augmentation. Initial clinical trials support the potential of BMP-2.

Conclusions: Clinically, the consensus highlighted that bone augmentation procedures can fail and that implants placed in these areas do not necessarily enjoy the high long-term survival rates of dental implants placed in pristine sites. The consensus emphasized the research need to answer questions on: (i) long-term performance of dental implants placed in augmented bone; (ii) the clinical performance of dental implants placed in augmented or pristine sites; and (iii) the clinical benefits of bone augmentation with respect to alternative treatments.

Key words: bone augmentation; complications/adverse events; consensus statement; dental implants; ridge augmentation; sinus graft

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A common problem encountered in implant dentistry is insufficient bone quantity to allow implant placement according to standard procedures.

Various clinical techniques have been developed to address these anatomical problems. Based on the clinical condition either allowing or preventing implant placement with primary stability in the deficient site, two different approaches have been followed. In one condition the bone is augmented in a first step and the implant is placed and stabilized taking advantage of the

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augmented alveolar bone. In the other condition, the available bone allows primary anchorage of the implant but leaving a portion of the implant surface not embedded in bone. Here, the bone can be augmented during the same surgical intervention.

Frequent situations requiring alveolar bone augmentation include developmental defects, periodontal disease, tooth loss, bone resorption due to infection/inflammation, trauma. These conditions result in lack of adequate bone volume in horizontal and/or vertical dimension. Interventions to correct these conditions can be classified in lateral and vertical ridge augmentation as well as sinus floor elevation. With the exception of the more recent introduction of distraction osteogenesis, interventions to correct these situations were proposed 15–20 years ago.

Bone augmentation has been assessed in several previous workshops (Jensen et al. 1998, Hämmerle 1999, Simion 1999, ten Bruggenkate 1999, Hammerle et al. 2002, Fiorellini & Nevins 2003, Wallace & Froum 2003, Chiapasco et al. 2006, Aghaloo & Moy 2007).

The scope of this working group was to critically assess the available evidence with a special emphasis on extending and updating the consensus of the previous workshops in the light of recent findings.

The group focused on methods to augment the local bone volume. Procedures aiming at preserving tissues and preventing their loss were not included.

Quality and Quantity of the Evidence (Methodological Issues)

Since the last Workshops, the group felt that there was an increase in the amount of available evidence to document the performance of the considered bone augmentation procedures. Besides the increase in the quantity of the evidence, the group has also noted a progressive shift in the type of studies being reported: more prospective rather than retrospective studies, more controlled trials, and, in some occasions, randomized-controlled trials. In addition, human data are becoming available for the new areas of distraction osteogenesis and growth factors for alveolar ridge augmentation.

In spite of this important progress, interpretation of study results was in several occasions limited by elements of design and/or reporting that are amenable to improvement.

Difficulties remain in trying to put results in context and in relation to alternative (control) intervention(s). Controlled trials and randomized-controlled clinical trials are needed. While the group fully recognizes the challenges posed by these study designs – in particular in the field of bone augmentation – some of the most relevant clinical questions can best be addressed using comparative original research.

The group identified that the important question of applicability of the evidence to the population, the clinical setting, the specific clinical situation, and the intervention need to be addressed. This should be done preferably in large-scale, multi-center trials.

With regards to choice of outcomes, the group felt encouraged and supports the studies that have started reporting patient-centered outcomes, including patient satisfaction, adverse events, complications and cost–benefit analyses. The group also commended efforts to add success (of the procedure, of the implant and of the implant-borne restoration) to the more traditional survival analyses.

Lateral Bone Augmentation (Donos et al. 2008)

The focus question of this systematic review was to assess implant survival/success following different lateral ridge augmentation procedures in comparison with implants placed in sites with no need for lateral ridge augmentation (pristine sites). The techniques evaluated encompass guided bone regeneration (GBR), bone grafts and ridge expansion. Both surgical approaches regarding timing of augmentation and implant placement, namely the one-stage/simultaneous approach and the two-stage/staged approach, were considered.

The systematic review is based on four studies fulfilling the inclusion criteria. Only prospective studies with a control group and where functional loading of the implants was present for at least 6 months were included. These studies were identified from a search strategy that retrieved 125 publications. The conclusions are based on three studies with the simultaneous approach (two with GBR, one with bone substitutes alone), and one with the staged approach applying block bone grafts. In total these studies reported on 126 patients and 450 implants.

The group agrees that the data in the systematic review are the best available evidence relevant to answering the focused question of the comparative fate of implants and marginal bone loss around implants placed in regenerated or pristine bone. Because of the importance of the conclusions drawn by the systematic review, the group felt the need to examine in depth each piece of

the evidence presented. In doing so the group felt that the significance of the findings reported in the original papers could not be fully captured by a formal qualitative assessment of study design but that more subtle elements such as the actual performance of the surgical intervention needed to be included. In doing so the group was not confident that conclusions comparing implants in regenerated bone and in pristine sites could be drawn at this time.

Because of the large body of evidence reviewed in previous consensus conferences that supports the use of lateral bone augmentation procedures to enable dental implant placement, the group determined an important need to answer a comparative question in terms of marginal bone levels and implant survival.

Vertical Bone Augmentation to Enable Dental Implant Placement (Rocchietta et al. 2008)

This review addressed the focused question of what is the predictability of vertical ridge augmentation techniques for patients, who were diagnosed with insufficient alveolar bone volume for the placement of dental implants.

A meta-analysis was not performed due to the heterogeneity and the limited number of data reported.

Techniques included GBR, distraction osteogenesis, and onlay bone grafting. The initial search identified 189 papers. Seven identified articles reported on GBR, 13 on distraction osteogenesis, five on onlay bone grafting. The evidence comprised 460 patients with 1334 dental implants.

Studies on GBR procedures reported a range of vertical bone gains of 2–8 mm. The most common complication was barrier membrane exposure and its sequelae, which in some patients prevented implant placement. Mean marginal bone loss at implants in augmented sites ranged from 1.8 to 2.0 mm over a 1–7-year follow-up. Dental implant survival rates in the augmented sites of 92.1–100% over 1–7 years were reported. A broad range of incidence of complications was detected (0–45.5%).

For distraction osteogenesis, the vertical bone gain reported ranged from 5 to 15 mm. Mean marginal bone loss at implants in augmented sites ranged from 1 to 1.4 mm over a 1–5-year follow-up. Implant survival rates ranged from 90% to 100%. However, a high prevalence of complications was reported (10–75.7%) such as lingual–palatal inclination of the bone segments during distraction.

For onlay bone grafting, mean gain of vertical height ranged from 4.2 to 4.6 mm. Significant resorption of the blocks was observed in one paper before implant placement (42%). Mean marginal bone loss at implants in augmented sites ranged from 0 to 4.9 mm over a 1–3-year follow-up. The overall survival rate of the implants ranged from 76% to 100% for the studies analysed.

The group recognizes the potential for vertical ridge augmentation procedures to allow implant placement in clinical practice. However, it was noted that the evidence base is circumscribed to a limited number of studies performed by few investigators. Hence, the applicability of these data to a wider array of operators and clinical settings remains unclear at this time.

For future research in this area, it is recommended that treatment protocols involving more reproducible, less invasive and less technique-sensitive vertical bone augmentation procedures and biomaterials should be developed. Patient treatment factors considered important for further evaluation should also consider esthetic and functional endpoints.

Lateral Approach Sinus Floor Elevation (Pjetursson et al. 2008)

The focused question of this review was to assess the survival rate of grafts and implants placed in sites with sinus floor elevation using the lateral approach, with a mean residual bone height of 6 mm or less, and to evaluate the incidence of surgical complications.

The present systematic review is based on 48 papers fulfilling the inclusion criteria. Prospective and retrospective studies reporting on implants with a mean follow-up time of at least 1-year after functional loading were included. These studies were identified from a search strategy that retrieved 175 articles. The conclusions were based on a material reporting the outcomes of 12,020 implants in about 4000 patients. Patient based data could be retrieved from 30 papers reporting on 1300 patients with 4528 implants.

The following conclusions were drawn from this systematic review. The estimated annual failure rate of implants inserted in combination with sinus floor elevation was 3.5%, translated into a 3-year implant survival of 90.1%.

However, when failure rates was analysed on subject level, the estimated annual failure increased to 6% translating into 16.6% of the subjects experiencing implant loss over 3 years. The annual failure rate of machined surface implants (6.9%) was significantly higher than that for rough surface implants (1.2%). Moreover, when no membrane was used to cover the lateral window after the grafting procedure the annual failure rate was significantly higher (4.0% *versus* 0.7%) compared with procedures performed with membrane coverage.

When only studies reporting on rough surface implants were analysed, the 3-year survival rate were 96.5%. However, when failure rates was analysed on subject level, the estimated annual failure rate increased to 2.4% translating into 7% of the subjects experiencing implant loss over 3 years The high survival rate of rough surface implants inserted in combination with sinus floor elevation was irrespective of whether autogenous particulated bone, combinations of autogenous bone and bone substitutes, or bone substitutes alone were utilized.

The most frequent complication reported was the perforation of the sinus membrane that occurred in 19.5% of the procedures. The mean incidence of postoperative graft infection was 2.9% and graft loss resulting in inability of implant placement was reported in 1.9% of cases.

A limitation of the present review is that prospective studies with a follow-up time of 5 years are scarce; therefore studies with shorter follow-up time and open cohort studies were included. However, if only prospective studies with at least 5 years of functional loading would have been included in this systematic review, only three studies with 126 patients and 418 implants would have fulfilled the inclusion criteria. Therefore, retrospective studies were also included in the analysis. As prospective and retrospective studies are on different levels of evidence, the results were also analysed separately for the two groups of studies. The annual failure rate, however, did not reveal significant difference between the two groups indicating an absence of design effect.

Residual bone height has frequently been cited as a significant predictor of the success of sinus floor augmentation and implant survival/success. The systematic review could not assess the impact of residual bone height due to the aggregated nature of the data reported in individual studies.

Cigarette smoking is considered to have a negative prognostic effect for implant survival/success (Strietzel et al. 2007). The present systematic review tried to assess the effect of cigarette smoking on sinus augmentation and the survival of implants inserted in association with the elevation of sinuses. The effect of smoking was specifically addressed in five studies encompassing 3032 implants. An annual failure rate of 3.5% [95% confidence interval (CI): 1.8–7%) in smokers and 1.9% (95% CI: 1.1–3.3%) in non-smokers was reported. The difference failed to reach statistical significance. More research with more precise definition of cigarette smoking exposure is needed.

Sinus membrane perforation was the most frequently reported complication. The impact of perforation on the success of the procedure and the later survival of the implant could not be comprehensively evaluated in this systematic review. No clear conclusions can be drawn at this time. Better documentation and characterization on the impact of this complication is warranted in future studies.

Out of 48 studies, one reported that antibiotic prophylaxis and/or administration was not performed. Eleven studies did not report on this important issue. From this material, the effect of use of antibiotics cannot be established. It seems, however, that since the majority of protocols reporting on this element used antibiotics, antibiotic prophylaxis and/or administration should be considered a part of this procedure.

In order to evaluate the outcome of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation prospective long-term cohort studies reporting on patient-based and implant-based data are needed. Those studies should include information on residual bone height, cigarette smoking, surgical techniques, material used, post-surgical protocols, complications, implant survival, marginal bone levels and graft stability.

In order to compare different surgical techniques and different materials, large scale randomized-controlled clinical trials are needed.

Transalveolar Sinus Floor Elevation (Tan et al. 2008)

The focused question of this review was to assess the survival rate of implants placed with transalveolar sinus floor elevation technique, and to evaluate the incidence of surgical and post-operative complications of the procedure:

The present systematic review is based on 19 papers fulfilling the inclusion criteria. Prospective and retrospective studies reporting on implants with a mean follow-up time of at least 1-year of functional loading were included. These were identified from a search strategy that retrieved 176 articles. Conclusions were based on a material reporting the outcomes of 4388 implants in 2830 patients.

The following conclusions were drawn from this systematic review:

The estimated annual implant failure rate was 2.5%. This translated into a 3-year implant survival of 92.8%. Furthermore, subject-based analyses revealed an estimated annual failure of 3.7%, translating to 10.5% of the subjects experiencing implant loss over 3 years.

The most frequent complication reported was the perforation of the sinus membrane, which occurred in 3.8% of the procedures and the mean incidence of post-operative graft infection was 0.8%.

Residual bone height has frequently been cited as a significant predictor of the success of transalveolar sinus floor augmentation and implant survival/success. Two papers retrieved in the systematic review specifically reported an increased survival rate as the amount of residual bone increased: better results were reported for sites with $\geqslant 5$ mm of residual bone.

Given the body of evidence available for transalveolar and lateral approach for sinus floor elevation the question of choice of the most appropriate procedure needs to be addressed. The group felt that the choice of treatment is influenced by the anatomy of the area as well as a number of other factors. Comparative trials, however, have yet to be reported.

Potential of Growth Factors (Jung et al. 2008)

The focused question of the present systematic review was to assess the clinical, histological and radiographic outcome of growth factors for localized alveolar ridge augmentation.

Based on the available evidence, the following growth factors were evaluated: bone morphogenetic protein (BMP)-2, BMP-7, growth/differentiation factor 5 (GDF-5), platelet-derived growth factor (PDGF) and parathyroid hormone (PTH). The group noted that much of the evidence available for craniofacial applications is limited to early stage preclinical animal studies, of which a total of 68 were available for evaluation.

The review process identified six human clinical studies (including four RCTs) with a total of 163 patients studying rhBMP-2 to promote localized ridge augmentation (specifically for sinus floor augmentation, extraction socket repair and lateral ridge augmentation). These early studies in the literature suggest good potential for rhBMP-2 application in terms of regeneration and decreased morbidity (as compared with bone autografts).

The information available for the other growth factors have demonstrated encouraging early evidence for regeneration, most of these results are confined to lower level animal models. The refinement of relevant intraoral animal models is needed to better study growth factor-mediated alveolar ridge repair. Clinical and animal studies should address the questions regarding the clinically effective doses required, the adequate carrier materials needed, and the optimal release kinetics for the clinical applications of growth factors.

At this time, the group concluded, that this field remains overall at an early stage of development as compared with other bone regenerative technologies used clinically (GBR, bone grafting, biomaterials, etc.). Future studies need to identify the full range of clinical conditions that may benefit from the application of growth factors including comparison with standard-of-care procedures.

Recommendations for Practice

There is a broad base of evidence supporting the use of lateral bone augmentation and sinus floor augmentation to place dental implant in sites with insufficient bone volumes. Less evidence is available for vertical ridge augmenta-

tion. Evidence for growth factors is emerging.

The consensus highlighted that bone augmentation procedures have significant and sometimes frequent adverse events and can fail to produce adequate bone volumes to allow dental implant positioning. Furthermore, available indications suggest that implants placed in augmented areas do not necessarily enjoy the high long-term survival rates of dental implants placed in pristine sites.

In the field of bone augmentation, lots of different procedures have been advocated to solve a specific problem. At present the lack of comparative research makes it difficult to select the most appropriate procedure.

Similarly lack of research comparing solutions based on bone augmentation procedures with other alternatives (e.g. the use of shorter implants in the posterior maxilla) does not allow evidence-based choices.

Recommendations for Research

Consensus participants felt that future research should capitalize on improvements in study design and reporting that were noted since more recent workshops. Further efforts need to be made to ensure that (surgical) interventions satisfy accepted methodological standards and are adequately validated before they are used in the assessment of new technologies or approaches.

The consensus emphasized the research need to:

1. gather long term data on the performance of dental implants placed in augmented bone using both true outcomes (including patient outcomes) and validated surrogate outcomes to capture early changes relevant to implant success/survival;
2. answer comparative questions to establish the clinical benefits of bone augmentation with respect to alternative treatments;
3. compare the clinical performance of dental implants placed in augmented or pristine sites;
4. compare different techniques in terms of effectiveness, adverse effects, long-term outcomes, morbidity, patient satisfaction and cost and do so in the context of patient age and needs. In order to do so, efforts should be made to identify protocols that can be accepted as standard of care to resolve the different conditions.

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