ARTICLE ANALYSIS & EVALUATION // DIAGNOSIS/TREATMENT/PROGNOSIS

CASE SELECTION IS CRITICAL FOR SUCCESSFUL OUTCOMES FOLLOWING IMMEDIATE IMPLANT PLACEMENT IN THE ESTHETIC ZONE

REVIEWERS
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To compare immediate and delayed implant placement (>12 weeks after extraction) in terms of the need for bone augmentation at the time of implant placement (primary outcome). Radiographic marginal bone loss was evaluated up to 36 months after functional loading. Other peri-implant parameters (ie, probing depth, bleeding on probing, and buccal keratinized mucosa width), postsurgical complications, surgeon- and patient-reported outcomes, and esthetic outcomes were assessed up to 12 months after functional loading.

ARTICLE TITLE AND BIBLIOGRAPHIC INFORMATION

Immediate versus delayed implant placement after anterior single tooth extraction: the timing randomized controlled clinical trial. ***Tonetti MS, Cortellini P, Graziani F, Cairo F, Lang NP, Abundo R, Conforti GP, Marquardt S, Rasperini G, Silvestri M, Wallkamm B, Wetzel A.*** *Journal of Clinical Periodontology 2017;44(2):215-24.*

SORT SCORE

A	B	C	NA

SORT, Strength of Recommendation Taxonomy

LEVEL OF EVIDENCE

1	2	3

See page 11A for complete details regarding SORT and LEVEL OF EVIDENCE grading system

SOURCE OF FUNDING

Nonprofit, Foundations: European Research Group on Periodontology, Genova, Italy Industry: Thommen Medical AG, Switzerland and Geistlich AG, Switzerland (biomaterials).

TYPE OF STUDY/DESIGN

Randomized controlled trial.

SUMMARY

Subjects

Medically healthy, periodontally stable patients in need of anterior single tooth extraction (ie, incisors, canines, and premolars) for periodontal, restorative, and/or endodontic reasons, with the exception of symptomatic periapical lesions, acute abscesses, or sinus tracts, were considered for enrollment in this randomized controlled trial (RCT). Upon tooth extraction, adequate bone availability to attain immediate implant placement with primary stability was required for inclusion. In addition, adequate restorative interdental space (defined as ≥6.5 mm) and a sufficient band of keratinized mucosa were required. Smokers were included, but they could not smoke more than 20 cigarettes daily, nor use more than 14 mg of nicotine replacement per day. The final study sample consisted of 124 patients (40 males and 84 females) who were randomly allocated into 2 interventional groups of 62 subjects each: immediate implant placement group (IMI; mean age: 50 ± 14 years), and delayed (≥12 weeks after extraction) implant placement group (DI; mean age: 55 ± 13 years).

Key Exposure/Study Factor

The primary intervention was minimally traumatic tooth extraction involving flap elevation, followed by either immediate or delayed implant placement. After tooth extraction and confirmation of the feasibility of immediate implant placement on clinical inspection, randomization took place. In the IMI group, after implant placement in a restoratively favorable position was achieved, bone

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grafting was indicated when the sum of the crestal bone thickness and horizontal gap between the bone and the implant was <2 mm on the buccal aspect. In the DI group, bone augmentation was indicated when the endosteal portion of the implant was exposed coronal to the bone crest. In both groups, the bone augmentation technique consisted of the combination of bovine xenograft particles covered with an absorbable collagen membrane. Primary closure was attempted in all surgical interventions by approximating the flaps around a transmucosal healing abutment.

Main Outcome Measure

The primary outcome in this RCT was the need for bone augmentation at the time of implant placement. Secondary outcomes included intergroup comparisons of implant survival, incidence of surgical complications, patient-reported outcomes at different time points, as well as changes in plaque scores, probing depth (PD), bleeding on probing, attachment levels, and width of keratinized mucosa from the time of crown delivery to 1 year after loading. Esthetic outcomes using pink esthetic score (PES) and white esthetic score (WES) at 12 months after crown delivery were assessed.[1] In addition, pooled mesial and distal radiographic marginal bone level changes from the time of crown insertion to 1, 2, and 3 years after loading were analyzed in both groups using standardized radiographs.

Main Results

The need for bone augmentation at the time of implant placement was higher in the IMI group than that in the DI group (72% vs 43.9%; $P = .01$). Primary closure was achieved in 61.7% and 82.1% of the IMI and ID sites, respectively. Wound healing complications were more frequent in the IMI group than those in the DI group (26.1% vs 5.3%; $P = .02$). Only one implant failure occurred; it was in IMI group. Deeper PDs were noted around immediately placed implants compared with delayed implants at 1 year postloading (4.1 ± 1.2 vs 3.3 ± 1.1 mm, $P < .01$). PES at 1 year was superior in the DI group, whereas no differences were observed in WES between the 2 groups. A trend for greater radiographic bone loss at 3 years after loading was observed in the IMI group as compared with implants placed following a DI approach. Patients in both groups tolerated the interventions well, with no significant differences noted regarding perioperative and 1-week postoperative pain and discomfort.

Conclusions

Authors did not recommend immediate implant placement at sites where achieving an esthetic result is a priority. Since a trend for greater marginal bone loss over the 3-year observational period was noticed, the authors underscored the need for longer follow-ups to ascertain the true differences in long-term complication rates between the 2 treatment modalities.

COMMENTARY AND ANALYSIS

In light of the available evidence, it is generally acknowledged that the main therapeutic advantages associated with IMI are shortening of the total treatment time and reduced number of surgical interventions, which may contribute to increased patient satisfaction. On the other hand, numerous preclinical and clinical investigations have shown that IMI by itself, without supporting bone augmentation, does not contribute to the preservation of the alveolar ridge architecture after tooth extraction.[2-4] However, there is a paucity of long-term studies that explore the differences between immediate and delayed implant placement protocols considering relevant clinical, radiographic, and patient-reported outcomes that may be used for the development of contemporary clinical practice guidelines. Hence, this RCT is very timely.

This trial identified the need for bone grafting to allow for adequate implant placement to be significantly higher in the IMI group, compared with the DI group. The inability to achieve primary closure and wound healing complications occurred more frequently in the IMI group. In addition, deeper PDs and greater radiographic bone loss were observed in the IMI group after 1 and 3 years after loading, respectively. No differences in patient-reported outcomes were noted between the groups.

Although this RCT does not completely adhere to the Consolidated Standards of Reporting Trials (CONSORT) Statement guidelines,[5] the study design and execution are generally sound. The authors minimized the selection bias by recruiting subjects using eligibility criteria and by effectively randomizing and concealing subject allocation to the trial arms. A proper power analysis was conducted to determine the minimum number of subjects to be recruited ($n = 54$ per group). Investigators aimed at recruiting a minimum of 120 subjects to compensate for attrition bias and possible missing data on completion of the study. The interventions allowed for single blinding, which was performed by not disclosing the intervention to the clinical and radiographic outcome examiners, who were reported to be calibrated. It is important to mention that feasibility for immediate implantation on tooth extraction was determined before randomization. The subjects allocated to the DI group did not receive any intervention to preserve the alveolar ridge dimensions, making this trial "ethically challenging," as the authors recognize in the manuscript.

The fact that this multicenter trial was done by experienced clinicians in different countries and in private practice settings contributes to the external applicability of the study

findings. Nonetheless, some other important aspects affect the generalizability of the study findings. Two major concerns inherent to the study design are the significant structural and healing dynamics differences between the baseline clinical scenarios in each group (ie, a fresh extraction socket in the IMI group and a healed ridge in the DI group), as well as the criteria used to assess the need for simultaneous bone augmentation, which could have contributed to the observed difference in the primary outcome. In addition, the amount of grafting material used for bone augmentation did not seem to have been standardized, which may have substantially affected several outcomes, such as radiographic bone loss, PES values, and the ability to achieve primary closure. Although the investigators assessed several key clinical parameters, they did not consider the periodontal phenotypic features of the site. In particular, the underlying buccal bone thickness is known to be a critical factor in alveolar bone remodeling dynamics after tooth extraction, whether or not immediate implant placement is performed.[6-8] Because of the distinct anatomy and morphology of the dentoalveolar complex, the thickness of the buccal bone drops significantly as we move from the maxillary first premolar site toward the central incisor.[9] Therefore, site-specific analysis would have given more clinically meaningful, undiluted information, provided there was a homogeneous site distribution. Alternatively, the authors could have reported the implant site distribution in the maxillary and mandibular arch (premolars, canines, lateral, and central incisors) independently for the 2 treatment arms. In addition, the implant restorative platform position in respect to the bone crest (particularly on the buccal) is another factor that may impact the observed outcomes, in particular radiographic bone levels over time. Unfortunately, this parameter was not reported to be standardized or considered. The authors used only 1 implant type from a single manufacturer, thereby eliminating implant-related variables, but this may affect the generalizability of the findings to other implant systems with a different macrostructural design. In addition, the meaning of "restoratively driven implant placement" is very broad. It would have been ideal if the authors provided more information in this regard because the buccolingual implant position within the available alveolar bone housing can substantially vary depending on whether a screw- or cement-retained restoration is planned (especially in the maxillary anterior sextant). This may have affected both the peri-implant gap dimensions in the IMI group and the amount of buccal bone present after implant insertion in the DI group, which has a potential direct impact on the primary outcome of the study.

Another important limitation of the manuscript is that the authors opted to use graphs instead of actual numeric values to depict radiographic bone level changes and PES/WES values between the groups. Graphical presentation makes it difficult to elucidate the magnitude of the observed effect. Although statistically significant, the difference observed in these parameters between IMI and DI group may arguably be clinically inconsequential (ie, 1 point difference in PES between IMI and DI and ~0.5 mm of discrepancy in terms of marginal bone loss at 3 years between groups). In addition, probing attachment levels were not reported in the results, despite being included in the list of secondary outcomes. Surprisingly, the effect of buccal soft tissue grafting at the time of implant placement, which has been shown as an effective strategy to enhance the esthetic outcomes around immediately placed implants in several recent publications,[10-12] was not considered as a point of discussion by the authors. Whether the teeth included in the study were tooth bound or not was not reported. This is important to know because the healing dynamics and ridge remodeling of sites with adjacent healthy teeth may be different as compared with sites adjacent to an edentulous space, unilaterally or bilaterally. Other methodological issues include lack of a clear definition of "sufficient" band of keratinized mucosa; lack of information regarding average PD determination (per site); and the validity of composite wound failure index.

Overall, this is a well-powered RCT that assessed several clinical, esthetic, radiographic, and patient-centered outcomes following IMI and DI placement procedures. Inclusion of other variables, such as buccal bone thickness and clear reporting of study parameters and outcomes would have enhanced the relevance and applicability of the results. A longer term follow-up (>1 year) on clinical and esthetic outcomes, which the authors stated is currently underway, is expected to provide more meaningful information on this topic. We agree with the authors that meticulous case selection considering systemic and local anatomic factors, patient compliance, and clinical expertise is the key for successful implant-related outcomes, especially when immediate implant placement is being considered in the esthetic zone.

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