



### Three-Year-Analysis of Peri-Implant Bone Level After Allogenic Bone-Block Augmentation

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#### Abstract

**Purpose:** Allogenic bone blocks may be utilized as an alternative pre-implant augmentation procedure for the reconstruction of deficient alveolar bone in cases, in which the transplantation of autogenous bone is impossible or not desired. The present study investigates radiologically detectable changes of peri-implant bone level around dental implants placed into allogenic bone-block augmentations compared to implants placed into non-augmented bone.

**Material and methods:** 14 patients of the study-group received 40 allogenic bone-blocks and 60 implants in both, maxilla and mandible in a two-step approach. The human study was approved by the ethics-commission of the Wilhelms-Universität Münster, Germany. Radiologic examinations were carried out directly after implant insertion, after prosthetic restoration plus one and three years after prosthetic loading. All radiographs were digitalized, calibrated and measured computer-assisted. The control group contained 14 patients who had received 53 implants without augmentation. Data of the two groups were compared statistically, using the non-parametric Wilcoxon-test ( $\alpha=0.05/4=0,0125$ ). The two primary end-points of the study were defined as

- total bone loss 3 years after prosthetic loading and
- bone loss in the years 2 and 3 after prosthetic loading

**Results:** The radiological peri-implant bone loss at the distal sites after 36 months was 0.72 mm in the study group (median; 25-Q: 0.27 mm; 75-Q: 1.11 mm) and 0.37 mm in the control group (25-Q: 0.15 mm; 75-Q: 0.71 mm). The difference between the groups is statistically significant ( $p=0.004$ ). At the mesial sites (study-group: 0.52 mm; control-group: 0.41 mm;  $p=0.179$ ) and at all other examination intervals the differences between the two groups were not significant. Neither did we find any statistically significant differences within the study-group between implants placed in the maxilla versus the mandible or in the anterior versus the posterior region.

**Conclusion:** Loss of peri-implant bone around dental implants with previous allogenic bone block augmentation seems to be slightly greater compared to implants placed into native bone. However, the detected median values for both groups are within the physiological range and are in accordance with data recently published for implants with autogenous bone grafts, GBR and without augmentation.

**Keywords:** Allogenic; Allogeneic; Alveolar bone; Atrophy; Augmentation; Bone block; Clinical-controlled study; Dental implant; Peri-implant bone level; Radiological study

## Introduction

For a prosthetically driven dental implant placement, bone augmentation is often required in order to increase bone volume and to create proper anatomical conditions for a functionally and esthetically satisfying prosthetic result. Several methods and techniques have been described, but for large defects and severe atrophy of the alveolar ridge, autogenous bone blocks are regarded as golden standard [1-10]. Several intra- and extra oral donor sites can be considered, delivering bone transplants of different qualities and limited quantity but each of them is associated with an additional operation site and a raise of complication rates and morbidity [11-13].

In order to avoid bone harvesting, several solutions can be taken into account:

Allogenic bone blocks are available and have been described in the literature [5,8,14-16], presenting high success rates in terms of graft incorporation and implant survival, especially for allogenic bone block transplants [2,17]. However, most studies represent case series with only few numbers of patients and randomized controlled clinical trials are still missing [17]. Avoiding augmentative surgery by using short implants may be an alternative procedure in vertical defects of the lateral mandible [4], but the available data are still limited, especially under a long-term aspect.

Nerve transposition and distraction osteogenesis must be regarded as specialties which cannot generally be recommended and demand specific anatomical requirements and high surgical capability. Guided bone regeneration using barrier membranes and particulate bone or bone substitute material is also well documented, but predictable results can only be expected in small and intra-bony defects, whereas large and discontinuity defects must be provided with block transplants [1,4,18]. The use of allogenic bone blocks is well documented and allows a minimally-invasive approach to three-dimensional bone reconstruction. The availability of pre-operative digital cone-beam tomography allows an exact three-dimensional analysis of the defect morphology and the virtual computer-aided construction of a block-dummy, which can thereafter be transferred into the allogenic graft under sterile conditions. Thus, the actual surgical procedure is reduced to the preparation of a surgical access, conditioning of the recipient bed, fixation of the graft and wound closure [7]. Since allogenic bone blocks are highly available, the reconstruction of complete edentulous jaws becomes possible in local anesthesia and without hospitalisation.

The additional use of palatal-derived ecto-mesenchymal stem cell homing from the human palate, as recently published

by Grimm et al. could be a future trend to induce osteogenic processes and therefore enhance the healing capabilities in critical size defects of the jaw [19,20]. Disadvantages of allogenic bone blocks are the theoretical risk of transmitting infectious diseases, immunological aspects [21] and the lack of osteoinductive and osteogenic properties. By being solely osteoconductive, it must be assumed that graft incorporation and remodeling is slower and less effective compared to autogenous bone blocks, thus resulting in higher resorption rates. Since the implant shoulder is usually located at the outer surface of the grafted site, where most of the resorption takes place, it must be assumed, that crestal bone loss is higher in implants placed into bone grafted with allogenic blocks than in implants placed into non-augmented bone. The purpose of the present study is to identify and compare differences in the change of peri-implant bone levels and clinical parameters of inflammation between implants placed into allograft bone and implants placed into native bone over three years.

## Materials and Methods

### Study group

14 Patients who required bone block augmentation for subsequent implant placement but refused harvesting of autogenous bone received 40 allogenic bone blocks (Tutogen Spongiosablock-P, Tutogen Medical, Neunkirchen, Germany) [22] Figure 1-2. Written consent with reference to the utilized allograft material and the participation in the study (Figure 3) was obtained from all patients and the human study was approved by the ethics commission of the Wilhelms-Universität Münster, Germany. Defect morphologies were categorized according to the CCARD classification [23] Table 1:

DeFeKt- Code	Description	Number of Cases
H2e	horizontal defect of 4-8 mm, outside the ridge contour	5
H3e	horizontal defect, larger than 8 mm, outside the ridge contour	1
V2i	vertical defect of 4-8 mm, inside the ridge contour	1
V2e	vertical defect of 4-8 mm, outside the ridge contour	2
V3i	vertical defect, larger than 8 mm, inside the ridge contour	1
K2i	combined defect of 4-8 mm, inside the ridge contour	2
K2e	combined defect of 4-8 mm, outside the ridge contour	2

**Table 1:** Bone-defect morphologies according to the CCARD-classification (study group).

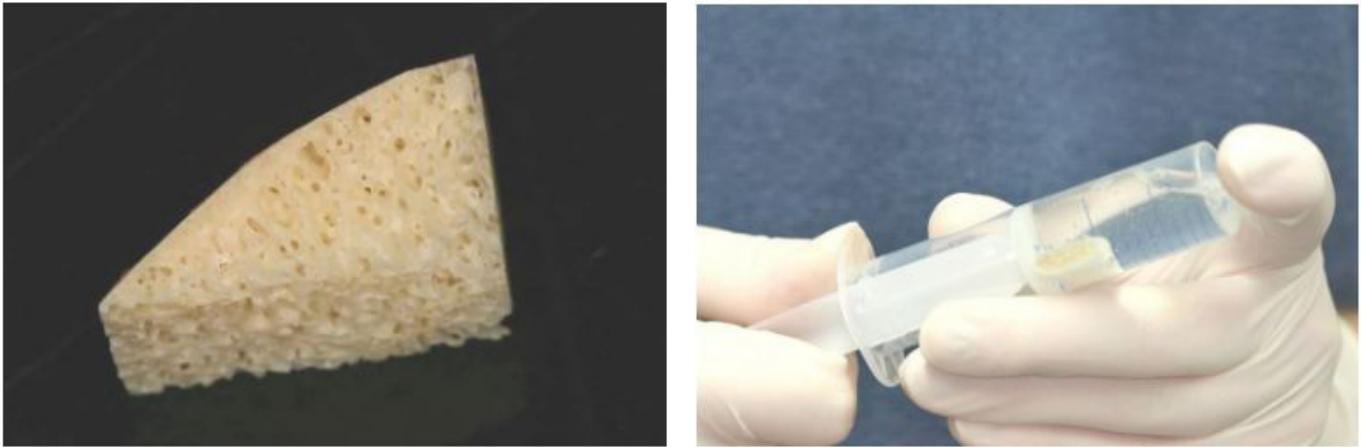


Figure 1,2: Sample of the utilized Tutogen Spongiosablock-P (1) and rehydration of the allogenic bone block under vacuum condition (2).

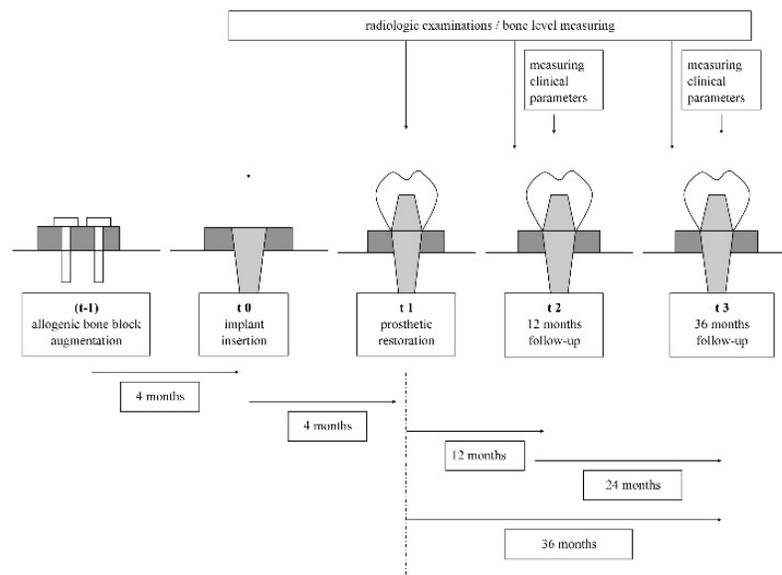


Figure 3: Study design.

Prior to surgery, all patients received full-mouth disinfection and systemic antibiotics with amoxicillin 1000 mg plus metronidazole 400 mg, which was continued for 5 to 10 days, according to the duration and severity of the intervention. In case of allergy or intolerance, clindamycin 600 mg was prescribed.

After local anaesthesia (Ultracain DS forte, Sanofi-Aventis, Frankfurt a.M., Germany), recipient sites were surgically opened via crestal incisions and bleeding points were set in order to provide proper nutrition of the grafts. All allogenic grafts were rewetted with sterile saline solution under vacuum conditions and

adapted extraorally until congruent coverage to the recipient bed was perfectly fulfilled, Figure 2. Rigid fixation of the block grafts was executed using at least two osteosynthesis screws (Mondeal Medical Systems, Germany) for each graft. For a tension-free wound closure, the periosteum had to be slit, and the buccal portion of the mucosa flaps was undercutting prepared with blunt scissors until the wound edges attached freely. Single and continuous sutures were performed, using monofilament material (Prolene 5/0, Ethicon / Johnson & Johnson Medical GmbH, Norderstedt, Germany), Figure 4-7. After a 4-months healing period, grafted

sites were reopened, osteosynthesis material was removed and a total of 60 implants (MIS Seven, MIS Implant Technologies, Minden, Germany) were inserted manually into the augmented bone and panoramic radiographs were made, Figure 8-13. Implant lengths and diameters are shown in Table 2 for the study group, and in Table 4 for the control group. The number of allogenic blocks, implants and type of restoration within the study group (ffd: fixed full denture, fpd: fixed partial denture; sc: single crown, rd: removable implant-supported denture) is shown in Table 3.

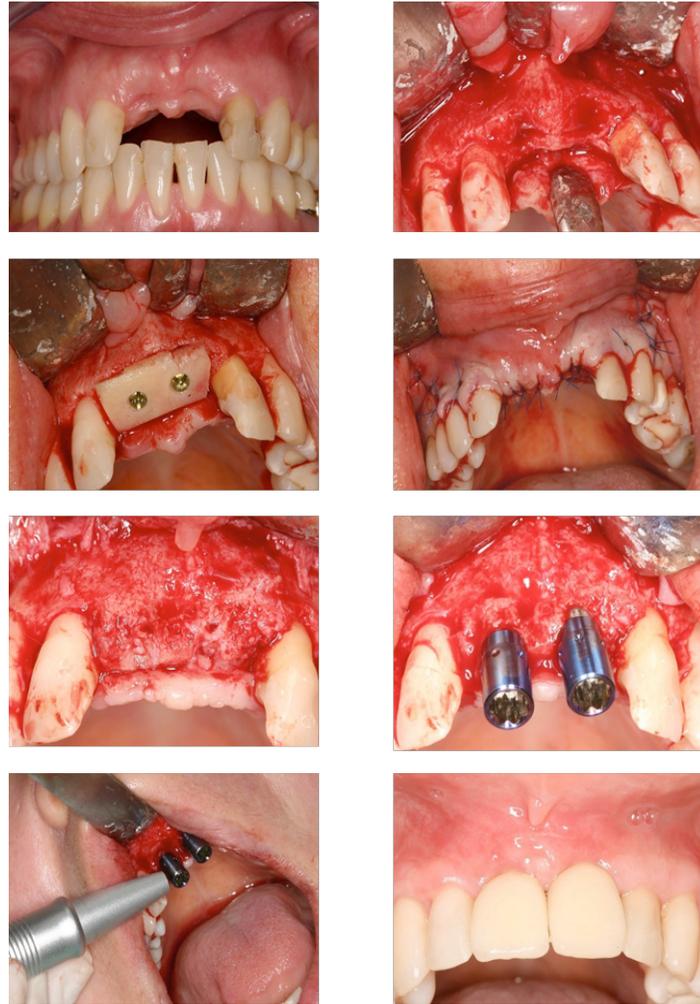


Figure 4-11: Bone-block augmentation (4-7), re-entry after 4 months (8-10) and final prosthetics (11).

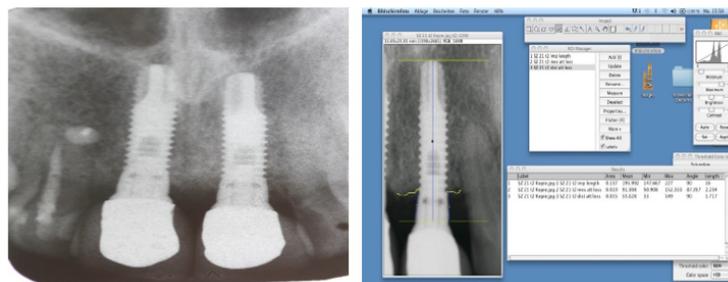


Figure 12,13: Intraoral rectangular radiograph after crown cementation (12; left) and computer-aided measurement of marginal peri-implant bone loss (13; right).

Implant Diameters	Implant Lengths				
	8 mm	10 mm	11.5 mm	13 mm	16 mm
3.3 mm	0	0	1	1	3
3.75 mm	1	3	8	12	2
4.2 mm	1	6	4	12	4
5.0 mm	0	0	0	1	0
6.0 mm	0	0	0	1	0

**Table 2:** Chosen implant lengths and diameters within the study group (n=60).

Patient (Number)	Number of Allogenic Blocks	Number of Implants	Prosthetic Restorations
1	3	8	ffd
2	14	18	ffd
3	1	2	fpd
4	1	2	sc
5	1	2	sc
6	1	1	sc
7	1	2	sc
8	2	3	fpd
9	1	2	fpd
10	2	3	ffd
11	3	6	ffd
12	2	2	fpd
13	6	4	rd
14	2	5	rd
Sum	40	60	

**Table 3:** Number of allogenic blocks, implants and type of restoration within the study group (ffd: fixed full denture, fpd: fixed partial denture; sc: single crown, rd: removable implant-supported denture).

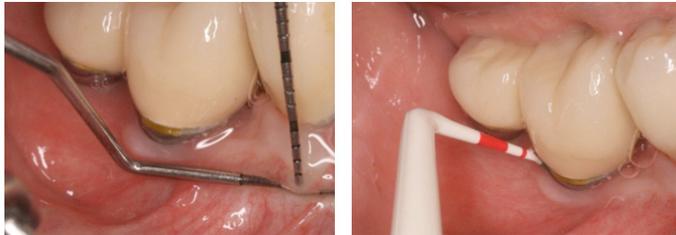
Implant Diameters	Implant Lengths				
	8 mm	10 mm	11.5 mm	13 mm	16 mm
3.3 mm	0	1	0	1	0
3.75 mm	3	2	4	15	6
4.2 mm	0	0	4	8	6
5.0 mm	0	0	1	2	0
6.0 mm	0	0	0	0	0

**Table 4:** Chosen implant lengths and diameters within the control group (n=53).

After a second healing period of another 3 to 4 months, implants were uncovered and provided with fixed or removable full- or partial dentures Figure 11. Radiographs were made immediately after restoration and patients were informed about the correct maintenance, care and follow-up intervals Figure 12. After 12 and 36 months of functional loading, radiologic and clinical examinations were conducted, documenting probing depths, bleeding indices, width of keratinized mucosa and periotest-values (Periotest, Gulden Medizintechnik, Modautal, Germany) Figure 14,15, Table 5. This approach is in accordance with Salvi et Lang, who suggest radiologic controls of dental implant after 12 and 36 months [24].

	Periodontally Comprised	Periodontally Healthy	Edentulous
study-group	9	4	1
control-group	9	4	1

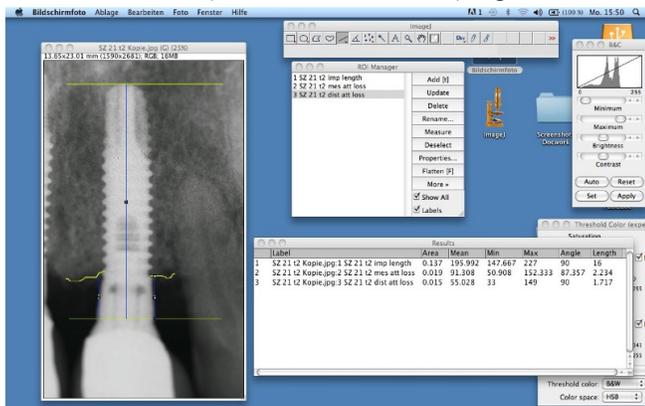
**Table 5:** Periodontal condition of patients in the study- and control-groups.



**Figure 14,15:** Measuring of pocket depth with a peril-probe (14) and “Roll-test” for measuring width of keratinized mucosa (15).

All radiographs were digitalised and imported into a scientific image analysis software (Image J 1.46r, Wayne Rasband, National Institutes of Health, USA) Figure 13. Thus, a total of 240 digital image files was created within the study group (60 implants × 4 time-points: implant insertion, prosthetic restoration, 12 months and 36 months follow-up).

The digital image files were rotated into an exact vertical position of the corresponding implant and then calibrated, using the “calibration tool” of the software and the known implant length as a reference. Auxiliary lines were drawn to explicitly define the apical and crestal borders of the implant bodies and the bone level at the mesial and distal aspects of the implants. The distance between the implant neck and the bone level was defined as “region-of-interest” for both, mesial and distal aspects of each implant and measured and recorded digitally for all images. The actual bone-loss was calculated by subtraction of t1-values (implant insertion) from t2- or t3-values (12 months / 36 months) Figure 16.



**Figure 16:** Computer-aided measurement of marginal peri-implant bone loss.

## Control group

14 patients who had received a total of 53 MIS-Seven implants within the same period of time but without augmentation were included in the control group. Age, gender, health status, periodontal diseases, implant sizes and prosthetic restorations were similarly to the study group. Radiographic controls were conducted after implant surgery, immediately after restoration plus at 12 and, 36 months’ follow-up examinations. The clinical parameters probing depths, bleeding index, width of keratinized tissue and periotest values were recorded at 12 (t2) and 36 month-checkups (t3). Radiographs were digitalized, post processed and measured as described above.

## Clinical parameters

Probing depths were measured at t2 and t3 on 4 sites per implant, using a periodontal resin-probe (Hawe PerioProbe, Kerr Dental, Rastatt, Germany). Only the largest value was documented. Presence or absence of subgingival plaque and bleeding-on-probing were recorded in a binary fashion, using the same probe. The width of keratinized mucosa was registered using by a different periodontal probe (Parodontometer, Hu-Friedy, Tutlingen, Germany) and for periotest- values, the Periotest-M device (Gulden Medizintechnik, Modautal, Germany) was applied.

## Statistics

For the comparison of the two groups relating to the change of bone level, two primary end-points were defined:

- the change of bone level 36 months after functional loading and
- the change of bone level within the last 24 months.

Medians and quartiles were calculated, since a normal distribution of the collected data could not be expected. The software SPSS Statistics (IBM Corporation, Armonk, NY, USA) was used and the non-parametric Wilcoxon test was chosen for inductive statistics. Due to the two primary end- points and two measuring points per implant, we had to adjust the level of significance in terms of  $\alpha=0.05/4=0,0125$ .

## Results

All patients completed the study and all implants survived, thus resulting in a total of 60 implants (study group, SG) and 53 implants (control group, CG) which could be examined over the complete follow-up period of 36 months.

## Socio-demographic data

Patient’s median age was 57 (21-77) years in the study-group and 49.5 (29-70) years in the control- group, which is a non-significant difference ( $p=0.403$ ). Within the study-group, 10

patients were male (71.4%) and 4 were female (28.6%). In the control- group, there were 7 females (58.3%) and 5 male patients (51.7%). Two patients took part in both groups, so their socio-demographic data were assigned exclusively to the study group.

### Primary outcome

The radiological peri-implant bone loss at the distal sites after 36 months was 0.72 mm in the study group (median; 25-Q: 0.27 mm; 75-Q: 1.11 mm) and 0.37 mm in the control group (median; 25-Q: 0.15 mm; 75-Q: 0.71 mm). The difference between

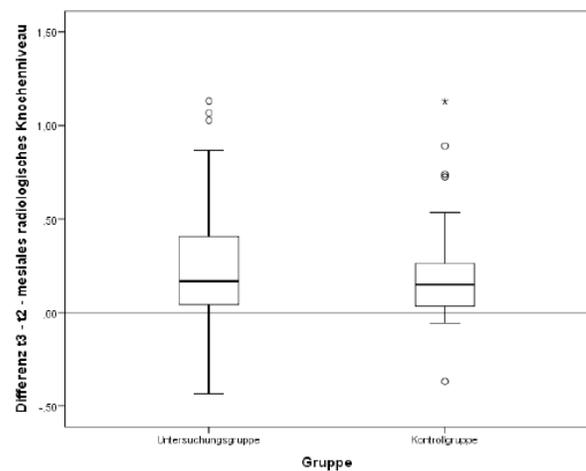
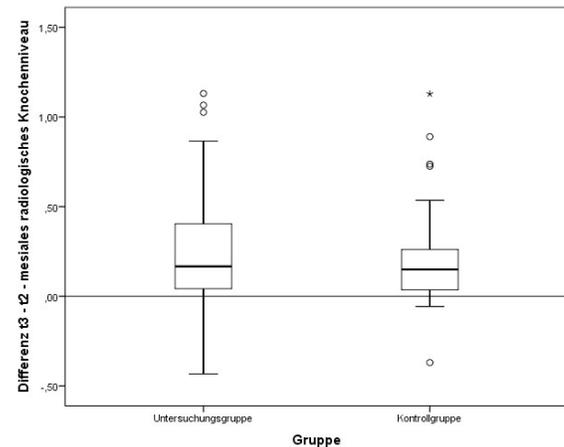
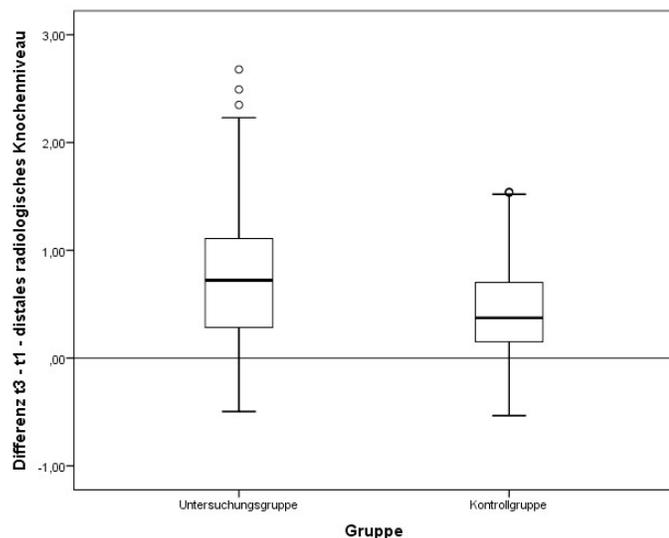
the groups is statistically significant (p=0.004). At the mesial sites (study-group: 0.52mm; control-group: 0.41 mm; p=0.179), the median bone loss is not significantly larger in the study group compared to the control group, Table 6. Regarding only the years 2 and 3 after prosthetic loading, the median bone loss in the study-group amounts 0.17 mm at mesial sites and 0.22 mm at distal sites. Within the control-group, the corresponding median-values are 0.15 mm at mesial and distal sites, the difference to the study-group being not statistically significant (p=0.583 mesial / p=0.149 distal).

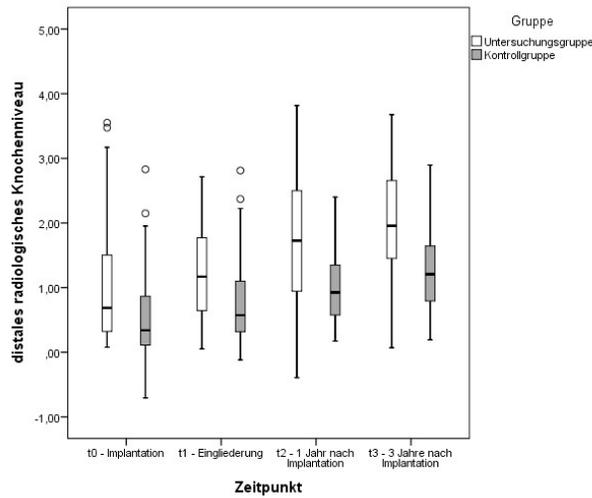
	Measuring Site	Study Group	Control Group	P
Total Bone Loss After 12 Months	mesial	0.28 mm	0.19 mm	0.503
	distal	0.35 mm	0.15 mm	0.067
Total Bone Loss After 36 Months	mesial	0.52 mm	0.41 mm	0.179
	distal	0.72 mm	0.37 mm	0.004
Cumulated Bone Loss in The Years 2+3	mesial	0.17 mm	0.15 mm	0.583
	distal	0.22 mm	0.15 mm	0.149

**Table 6:** Median-values of the peri-implant bone loss after 12 months (secondary end-point), 36 months (primary end-point) and in the years 2+3 (primary end-point) after functional loading; p-values are related to the comparison between groups.

### Secondary outcome

Within in the first 12 months of functional loading, median bone loss was 0.28 mm at mesial sites and 0.35 mm at distal sites in the study-group and 0.19 mm / 0.15 mm in the control-group. The result is not statistically significant (p=0.503 mesial / p=0.067 distal), Figure 17-20. The 60 implants of the study group were additionally analyzed for detectable differences in peri- implant bone loss between maxilla versus mandible and anterior versus posterior region. No statistically significant results were obtained at t2 (maxilla 0.34 mm vs. mandible 0.23 mm; p=0.149 / anterior 0.26 mm vs. posterior 0.31 mm; p= 0.923) or t3 (maxilla 0.61 mm vs. mandible 0.41 mm; p= 0.338 / anterior 0.70 mm vs. posterior 0.41 mm; p= 0.146).





**Figure 17-20:** Boxplot displaying crestal bone loss 36 months after loading (t3-t1) / comparison of groups (17); boxplot displaying crestal bone loss in the years 2+3 after loading (t3-t2) / comparison of groups (18); boxplot displaying crestal bone loss 12 months after loading (t2-t1) / comparison of groups (19); change of peri-implant bone level between t0 (implant insertion), t1 (prosthetic restoration), t2 (12 months' follow-up) and t3 (36 months follow-up) / comparison of groups (20).

### Clinical parameters

Median probing depths were 2 mm at t2 (12 months) and 2 mm at t3 (36 months) in the study group versus 2 mm at t2 and 3 mm at t3 in the control group, which are non-significant results. At t2, 23.6% (SG) versus 26.4% (CG) were accounted for positive bleeding-on-probing. At t3, 26.7% versus 30.2% of implants showed bleeding on probing. Plaque was found on 36.4% versus 32.1% of implants at t2 and on 56.7% versus 37.7% of implants at t3. When comparing the groups, no statistically significant differences were found for probing depths, bleeding index or presence of plaque, Table 5,7. The median width of keratinized mucosa was 1 mm (SG) versus 2 mm (CG) at t2 and 0 mm (SG) versus 2 mm (CG) at t3. These findings are statistically significant (t2: p=0.007; t3: p=0.004). Periotest values were not analyzed since those implants provided with fixed dentures are permanently interlocked, thus delivering unexploitable data.

	Study-Group		Control-Group		Wilcoxon-Test	
	t2	t3	t2	t3	p (t2)	p (t3)
probing depths	2 mm	2 mm	2 mm	3 mm		0.367
bleeding-on- probing	23.60%	26.70%	26.40%	30.20%	0.825	0.683
presence of plaque	36.40%	32.10%	56.70%	37.70%	0.688	0.059
width of keratinizes mucosa	1 mm	0 mm	2 mm	2 mm	0.007	0.004

**Table 7:** Clinical findings; median values; comparison between groups via Wilcoxon-test.

### Discussion

The radiologic evaluation of peri-implant bone loss is a key determinant for the definition of implant health and successful Osseo integration, especially under a long-term aspect [24,25]. Lots of studies have been published regarding the reliability and informative value of panoramic versus intraoral x-rays [26-28] and the influence of different implant designs and implant-abutment connections on the peri-implant bone and soft-tissue [29-31].

In the present study, we investigated 60 tapered screw-form

implants with an internal hexagon- connection (MIS Seven), which were inserted into 40 allogenic bone-block grafts in 14 patients in a two-step approach. The hypothesis was, that allogenic bone blocks suffer higher resorption rates and less effective graft revitalization than autogenous grafts, which are regarded as golden standard, thus leading to a greater decrease of marginal bone level after functional loading. In order to eliminate implant-dependent factors on the peri-implant bone like surface characteristics and implant-abutment connection, an internal control-group was established, containing 14 patients who had received the same implant system

within the same time period, but without augmentation.

Age, gender and periodontal preconditions were similarly to the study group. The detected median bone loss after 1 year of functional loading was 0.35 mm in the study group and 0.19 mm in the control-group. After 36 months, the bone loss amounted 0.72 mm in the study- group and 0.37 mm in the control-group, which is statistically significant. These findings can be interpreted as a verification of the hypothesis, that implants after allogenic block grafting suffer higher bone loss than implants in non-augmented bone. Nevertheless, these results compare favorably to values formerly published by Bratu, et al. [32], who investigated MIS Lance and MIS Seven implants without augmentation and found an average bone loss of 0.57 mm after 6 months and 0.9 mm after 12 months of loading for the Seven-implant. The marginal bone loss around implants following allogenic bone augmentation was previously investigated by Nissan et al., although not being a primary outcome. Values amounted 0.5 mm +/- 0.2 mm after an average test period of 37 months [33]. Chiapasco, et al. reported marginal bone loss of 0.42 mm in implants placed into autogenous mandibular grafts after 12 to 36 months [34]. Boronat, et al. found an average bone loss of 0.64 mm after 1 year for implants inserted into autogenous bone block grafts [3].

Dasmah, et al. compared the bone loss of implants placed into autogenous mandibular block grafts versus particulate material plus PRP over a 5-year period. They found no statistically significant difference between the groups but a significantly higher degree of marginal bone alteration in the first year of loading [35]. This is consistent with our findings. In a recently published meta-analysis concerning marginal bone loss around single versus multiple prostheses, Firme, et al. reported bone loss values of 0.58 mm (95% CI, 0.37 to 0.80 mm) for single and 0.9 mm (95% CI, 0.49 to 1.32 mm) for multiple prostheses after follow-up periods of 1 to 20 years [31]. Measuring- and interpretation errors must be assumed and lots of different influencing factors must be regarded, when comparing different studies on the radiologically detected marginal bone loss around dental implants. According to Braegger, et al, an error of +/- 0.2 mm must be estimated when interpreting dental radiographs [30]. Peñarrocha, et al. discuss the “intra-observer error” to be 0.25 mm for panoramic x-rays and 0.11 mm for intraoral x-rays [28]. Cone beam computed tomography still seems unsuitable for detecting changes in peri-implant bone level [36]. Concerning clinical parameters, the obtained data do not deliver significant differences between the groups, except for the width of keratinized gingiva, which is less present in the study-group. This is due to the proceeded grafting procedure and the involved wound closure technique outlined above. Gobatto, et al. found out that gingival index, plaque index, modified plaque index and modified bleeding index were significantly higher in groups with keratinized mucosa widths < 2 mm than in groups with keratinized mucosa widths > 2 mm [37]. According to these

findings, it could have been expected that our study-group suffers more bleeding on probing and shows more plaque accumulation than our control-group, but this suspicion cannot be confirmed.

Due to the anatomy of peri-implant tissues, probing depths around dental implants lack repetitious accuracy. According to Mombelli, et al. recorded probing depths are direct proportional to probing forces and reproducibility of values rises with increased probing forces [38]. Hence, the recorded probing depths should be considered with caution. With the hereby presented data, it is impossible to draw conclusions regarding the utilized allogenic grafting material and its influence on the marginal bone level. However, the marginal bone loss around implant inserted into allogenic bone block grafts coincides well with data formerly published for the same implant system but without augmentation [32], implants inserted into auto grafts [3,34] and implants inserted with simultaneous GBR [35].

## Disclosure

The authors have no conflicts of interests.

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