Clinical Evaluation of Marginal Bone Level Change Around Multiple Adjacent Implants Restored with Splinted and Nonsplinted Restorations: A 10-Year Randomized Controlled Trial

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Purpose: *The management of occlusal forces on implant restorations may influence their long-term prosthetic success. The purpose of this randomized controlled trial was to compare marginal bone level changes around adjacent splinted and nonsplinted implants, functionally loaded with cemented restorations, up to 10 years in maxillae.* ***Materials and Methods:*** *During 2002 and 2003, all patients who received three adjacent implants in a private office and a university setting were included in this study. All implants featured an external-hexagon design and were placed in the posterior maxilla. Implants in the left maxilla were randomly selected to be restored with splinted cemented restorations; maxillary right implants were restored with nonsplinted cemented restorations. Marginal bone resorption was measured with intraoral radiographs yearly over a period of at least 10 years after placement of abutments and restorations. The amount of bone loss in each group was analyzed with the two-sample Wilcoxon rank-sum (Mann-Whitney) test because variable bone loss was normally distributed at the fifth year only.* ***Results:*** *One hundred thirty-two implants were placed in 44 patients. Three implants failed at stage-two surgery. Five years after initial loading, two patients moved away and were lost to follow-up (6 implants in total); three additional patients did not complete the study (9 implants in total). Of the remaining 114 implants, 60 left implants were restored with splinted cemented restorations and 54 right implants were restored with nonsplinted cemented restorations. At 10 years, the splinted group showed a mean of 1.2 mm (interquartile range: 0.2 mm) of bone loss; the nonsplinted group showed 1.3 mm (interquartile range: 0.2 mm).* ***Conclusion:*** *A significant difference in bone loss was seen between the two groups. However, the difference of 0.1 mm was not considered clinically meaningful.* Int J Oral Maxillofac Implants 2015;30:411–418. doi: 10.11607/jomi.3837

Key words: *bone level change, dental implants, implant-supported partial prostheses, multiple nonsplinted implants, multiple splinted implants*

Marginal bone loss around implants of various systems has been described during the first year of loading and in subsequent years.[1–5] This peri-implant bone loss has been attributed to numerous factors, such as surgical trauma,[6] peri-implantitis,[7,8] occlusal overload,[9–12] biologic width formation,[13,14] implant macroscopic and microscopic characteristics at the neck region in contact with bone,[2,15–17] implant-abutment interface design,[18–20] and position of the microgap.[14,21] To maintain stable gingival levels and profiles around implant-supported restorations, it is fundamental to prevent horizontal and vertical marginal peri-implant bone resorption after loading.[22]

The management of occlusal forces on the restoration influences the long-term success of an implant-supported prosthesis.[9–12] Certain authors have reported that splinting implants helps to distribute functional loads and therefore reduces marginal bone loss. This has been studied using finite element analysis[23] and photoelastic modeling.[24] However, it has been shown that, for a single-tooth implant restoration, marginal bone levels can be optimally

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maintained, even though single implant restorations are subjected to higher forces of differing vectors.[25–29] This has also resulted in an increased use of nonsplinted implants to replace adjacent missing teeth, in an effort to optimize esthetics and circumvent the problem of non–passively fitting frameworks.[30,31] A previous 5-year follow-up report of the current patient population indicated that there was no evidence of a clinically relevant difference in the behavior of the peri-implant marginal bone when nonsplinted implants or splinted implants were used.[32] One advantage of nonsplinted implants is the elimination of large prostheses with large quantities of metal and ceramic; this may reduce the risk of veneer and framework fracture.[31] Also, when nonsplinted single-tooth restorations on multiple adjacent implants are used, if one unit is compromised, only one unit needs to be removed, rather than the entire fixed partial denture. However, it also should be noted that there is a cost benefit in placing three units on two implants, as well as a real benefit in splinting three units if one implant subsequently fails. There is, in effect, a ready-made partial prosthesis with only minimal need for modification and no need to wait for healing and integration of a replacement implant. From an esthetic standpoint, nonsplinted single-tooth restorations on adjacent implants have the potential to give the impression of being more individual than is often obtainable in a splinted situation.[31] Patients also appreciate that they can floss more easily between units than under a fixed partial denture.

The purpose of this randomized controlled trial was to compare the marginal bone loss around adjacent splinted implants with that around adjacent nonsplinted implants functionally loaded with cemented restorations up to 10 years in maxillae. This study was reported following the CONSORT statement (http://www.consort-statement.org).[33] A 5-year follow-up report of the same patients and materials has already been published.[32] The null hypothesis was that there would be no significant difference in the marginal bone loss around splinted and nonsplinted implants functionally loaded with cemented restorations up to 10 years in maxillae.

MATERIALS AND METHODS

From January 2002 to December 2003, all consecutive patients who received three adjacent implants in a private office setting and in the Implantology Department at the University of Padua, Italy, were included in this study according to the following criteria (Fig 1):

- No systemic contraindication for oral surgical therapy
- Multiple edentulous sites on only one side of the posterior maxilla (premolar and molar areas)
- Presence of adequate bone width precluding the need for bone augmentation procedures
- Occlusion of restorations with natural teeth

The second molars were missing in all patients. The study was approved by the Clinical Medical Ethical Committee of the University of Padua, Medical and Dental School (#18/2001). A randomized controlled trial was carried out.[34] At the beginning of the study, a coin was flipped, and maxillary left implants were selected to be restored with splinted cemented restorations, and maxillary right implants would be restored with nonsplinted cemented restorations. All patients were informed about the purposes and details of the study, and their consent was obtained prior to implant placement.

Implant Placement

All implants were 4 mm wide and featured an external-hexagon configuration (Biomet/3i). All implants were surgically placed by the same clinician with the use of surgical guides. All implants were placed at the bone crest level, and radiographs were obtained to show bone levels at the time of implant placement. At stage-two surgery, 4 months after placement of the implants, matching-diameter titanium healing caps (THA54, Biomet/3i) were connected to implants. Radiographs were again obtained and showed similar bone levels at the time of implant uncovering between both groups.

Prosthetic Procedures

The definitive impressions were made 3 weeks after stage-two surgery. Impression trays (2 mm thick) were fabricated (Palatray LC resin, Heraeus Kulzer) in accordance with the manufacturer's instructions. The impression trays included openings to allow access for the coping screws and were previously coated with tray adhesive (Dental-Medizin, 3M ESPE). Prior to each impression procedure, square impression copings (pick-up type, IIC12, Biomet/3i) were secured to both groups of implants. An elastomeric impression material (Impregum Penta, 3M ESPE) was machine-mixed (Pentamix, 3M ESPE), and a standard impression technique was performed for all impressions.[35,36] Implant replicas (ILA20; 3i/Implant Innovations) were connected to the impression copings.[35,36] The impressions were poured with type IV stone (New Fujirock, GC Corp). All laboratory procedures were performed by the same technician, and all prostheses were provided by the same prosthodontist.

For all implants, gold abutments (SGUCA1C, Biomet/3i) were screwed to implant replicas using waxing posts, and wax (Green Inlay Casting Wax, Kerr

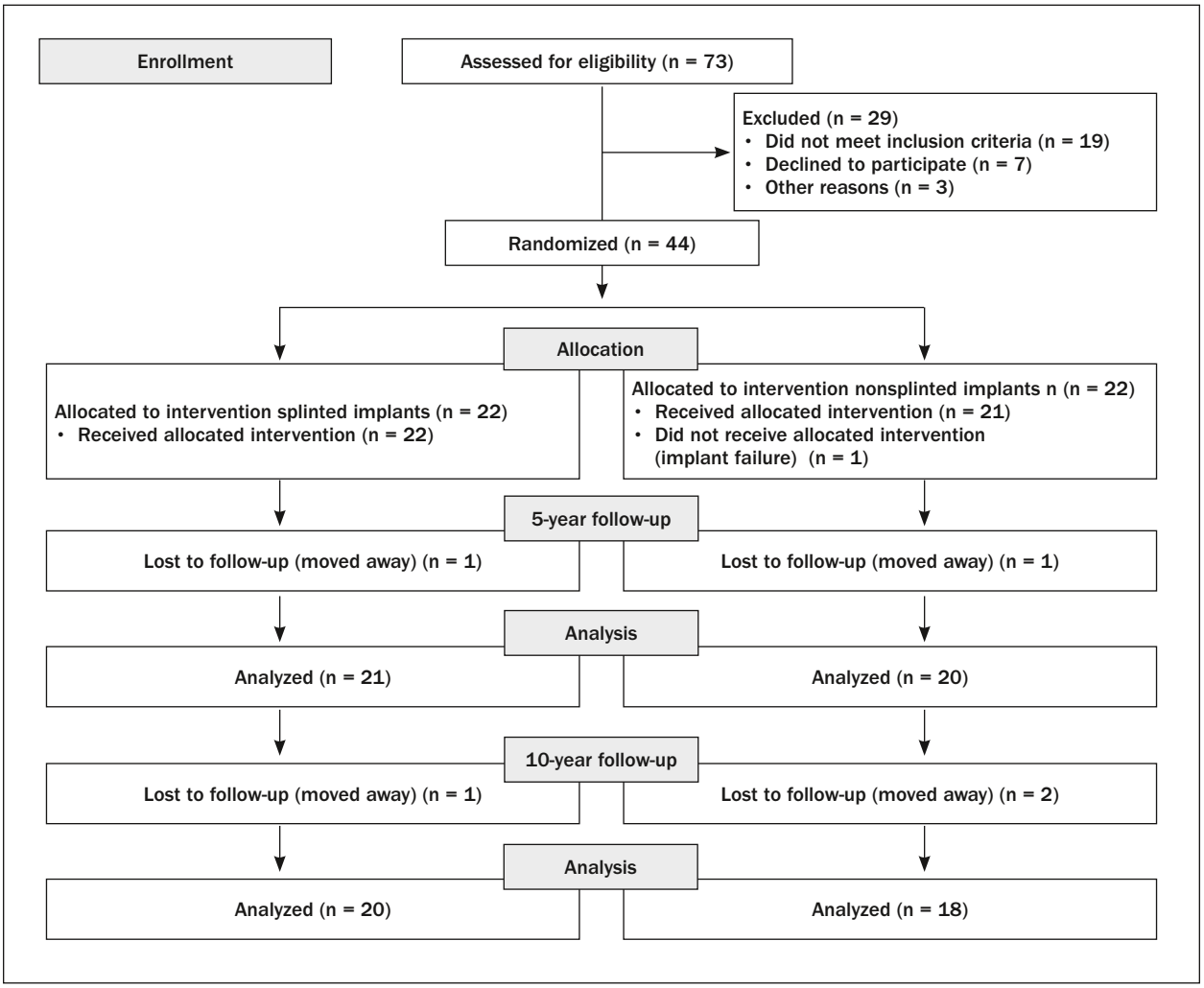
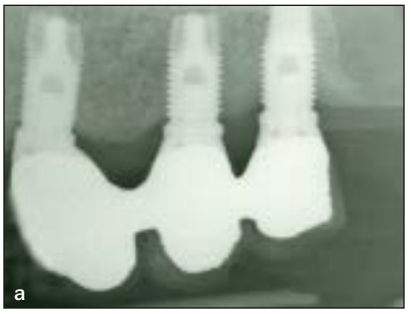


Fig 1 Flow diagram according to the CONSORT statement.

Dental Laboratory Products) was added directly to the gold cylinders following standard waxing procedures. The waxed cylinders were then invested in a carbon-free, phosphate-bonded investment (Ceramicor, Cendres & Métaux SA) and cast in a noble alloy (Esteticor Plus, Cendres & Métaux SA; composition: gold 45.0%, palladium 38.9%, silver 5.0%, indium 8.6%). The custom abutments were clinically screwed to implants using Gold-Tite screws (Biomet/3i) and torqued to 32 Ncm (Torque Driver CATDO, Biomet/3i).

Conventional metal-ceramic fixed partial restorations were fabricated for the patients who received multiple splinted restorations, and conventional metal-ceramic single crowns were fabricated for the patients who received multiple nonsplinted restorations. The occlusal surfaces in both types of prostheses were made with ceramic. All custom abutments were prepared by the technician with a chamfer preparation line, and all metal-ceramic restorations, splinted and nonsplinted, had a 0.4-mm-thick circumferential metal margin. For esthetic reasons, all margins were placed 1 mm subgingival on the buccal surfaces and at the gingival level on other surfaces. The restorations were handled carefully in the dental laboratory to avoid further contamination of the abutment surfaces.[37] The occlusal surfaces of all restorations were designed to avoid premature occlusal contacts during lateral and protrusive movements. A canine-protected articulation was the occlusal scheme for all patients. Radiographs were obtained during all prosthetic phases (impression phase, abutment try-in, final try-in). All definitive restorations, splinted and nonsplinted, were bonded with provisional cement (Temp Bond NE, Kerr Italia).



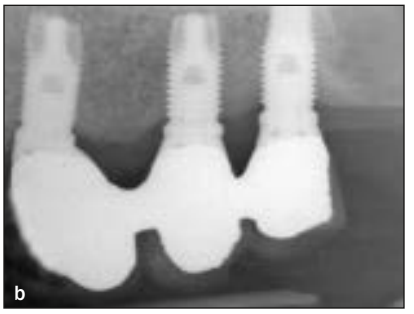
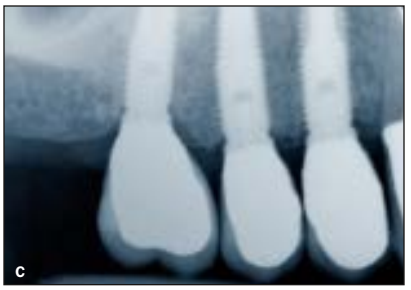


Fig 2a Radiograph showing three definitive splinted restorations in the maxillary left quadrant at the time of abutment and prosthesis placement.

Fig 2b Radiograph showing three definitive splinted restorations in the maxillary left quadrant 10 years after abutment and prosthesis placement.



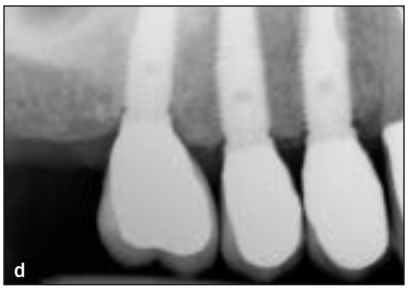


Fig 2c Radiograph showing three nonsplinted definitive single-tooth restorations in the maxillary right quadrant at the time of abutment and prosthesis placement.

Fig 2d Radiograph showing three nonsplinted definitive single-tooth restorations in the maxillary right quadrant 10 years after abutment and prosthesis placement.

Table 1 Lengths of Implants Used

		No. of implants	
Implant length (mm)	Code	Splinted	Nonsplinted
10	OSS 410	26	24
11.5	OSS 411	23	22
13	OSS 413	17	20

Follow-up Procedures and Outcome Measures

The follow-up protocol included patient assessments every 3 months during the first year, every 6 months in the subsequent 5 years, and every 12 months in the remaining 5 years of the study. Outcome measures were:

- Implant failure. Implant survival was based on the absence of painful symptoms or paraesthesia, absence of peri-implant radiolucency during radiographic evaluation, clinical absence of mobility, and the absence of progressive marginal bone loss (mean vertical bone loss had to be < 0.2 mm annually after the first year in function).[38–40] The clinical absence of mobility was confirmed visually and manually by percussing the implants vertically and horizontally with a metallic instrument and obtaining a pleasing "crystal" sound for both. No electronic devices were used to monitor initial degrees of implant mobility.
- Any biologic or prosthetic complications.
- Bone levels. These were assessed on radiographic films using a ×6 magnifying lens, and measurements were rounded to the nearest 0.1 mm. The baseline measurement of marginal bone levels was recorded at the time of definitive prosthetic restoration. The apical end of the smooth collar of the implants was considered the coronal reference point, whereas the crestal bone level was considered the apical reference point. Once a year, intraoral radiographic examinations were performed using the paralleling technique and an adjusted film-holding device. This device was designed to control imaging geometry by consistently placing the films at a standard distance from the x-ray cone, parallel to the long axis of the implant and perpendicular to the central ray, to allow standardization of consecutive radiographs (Figs 2a to 2d).[41–46] All radiographic measurements were performed by the same investigator, who was not involved in patient treatment. Radiographic measurements were performed at the time of definitive prosthetic restoration (T0), at 5 years after definitive prosthesis delivery (T1), and at the last follow-up appointment 10 years after implant placement (T2), always by the same assessor.

During the 10 years following prosthetic rehabilitation, disconnection and reconnection of the abutments was avoided to prevent bone loss, as described in previous animal studies.[47] The number and lengths of implants used are summarized in Table 1.

Methodologic Aspects

Comparisons of the amount of bone loss in each group at the 5- and 10-year follow-ups were performed using the two-sample Wilcoxon rank-sum (Mann-Whitney) test. The variable bone loss was normally distributed at the fifth year only. The α level was fixed at $P < .05$.

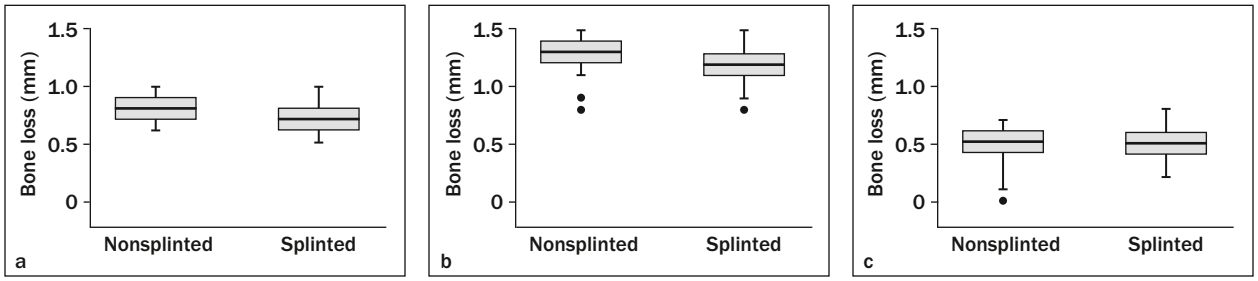


Fig 3 Box plots of the median amounts of bone loss in the nonsplinted and splinted groups at (*a*) 5 years and (*b*) 10 years after implant insertion and (*c*) during the interval from 5 to 10 years.

The reliability of the operator was calculated by the intraclass correlation coefficient (ICC). All data were statistically analyzed with STATA12 (StataCorp LP).

RESULTS

The study ended at the time of the 10-year follow-up appointment of the last patient. One hundred thirty-two implants were placed in 44 patients. At implant placement, patient age ranged from 37 to 58 years (mean age, 51 years). Twenty-three patients were women, and 21 were men.

Each of the 44 patients had received three implants, which were restored either with nonsplinted cemented restorations (nonsplinted group) or with splinted cemented restorations (splinted group). The proportion of subjects in each group was 50%.

Three implants in one patient failed at stage-two surgery, before the definitive prosthetic rehabilitation was completed (maxillary right implants). At the 5-year appointment, two patients, one per group, had moved away and were therefore lost to follow-up (six implants in total). At 10 years, three patients did not complete the study (nine implants total: one patient in the splinted group and two patients in the nonsplinted group). Therefore, 123 implants (21 patients in the splinted group and 20 patients in the nonsplinted group) were evaluated at the first follow-up, and 114 implants (20 patients in the splinted group and 18 patients in the nonsplinted group) were evaluated at the second follow-up.

During the surgeries, the postoperative period, and the follow-up visits, no patient showed any biologic complications, such as mucosal recession, peri-implantitis, peri-implant mucositis, or fistula, or any prosthetic complications, such as loosening of the abutments or crowns, fracture of the porcelain, or loosening of provisionally cemented definitive crowns. The emergence profile was carefully studied for all restorations; no food impaction events were detected in either group.

The changes in bone level between the two follow-up appointments were analyzed with a two-sample Wilcoxon rank-sum test (α level, $P < .05$). A nonparametric test had been applied because the variable bone loss did not show a normal distribution, as confirmed by the Shapiro-Wilk test ($P < .001$). The data collected at 5 years only ($P = .99$) were distributed normally. Consequently, the Wilcoxon rank-sum test was more robust than the Student *t* test. The reliability of the operator was calculated by the ICC. The same operator repeated the measurements on 80 implants at 1 week after the first elaboration. The outcome was nonsignificant (ICC, 99.01%).

Table 2 Statistical Analysis of the Amount of Bone Loss (mm) in Each Group at Different Time Intervals

Time/group	Median bone loss (IQR)	*P* value*
5 y		
Nonsplinted (n = 60)	0.8 (0.2)	< .001
Splinted (n = 63)	0.7 (0.2)	
10 y		
Nonsplinted (n = 54)	1.3 (0.2)	.0042
Splinted (n = 60)	1.2 (0.2)	
5 to 10 y		
Nonsplinted (n = 60)	0.5 (0.2)	.7171
Splinted (n = 63)	0.5 (0.2)	

IQR = interquartile range.
*Two-sample Wilcoxon rank-sum (Mann-Whitney) test.

As reported in Table 2 and shown in box plots (Fig 3), at 5 years the splinted group showed mean bone loss of 0.7 mm (interquartile range [IQR], 0.2) and the nonsplinted group showed mean bone loss of 0.8 mm (IQR, 0.2) ($P < .001$). The same amount of difference (0.1 mm) was maintained until the last follow-up ($P = .004$): 1.3 mm (IQR, 0.2) in the nonsplinted group vs 1.2 mm (IQR, 0.2) in the splinted group. In fact, the change from 5 to 10 years was equal in the two groups (median 0.5 mm, IQR 0.2; $P = .717$). In this statistical analysis, a significant difference between the two groups in the amount of bone loss was found. However, although it could be concluded that there was a difference not attributable to chance, 0.1 mm was not considered clinically meaningful 10 years after implant insertion.

DISCUSSION

This 10-year randomized controlled trial presents the results from 132 implants placed in 44 patients in 2002 and 2003. Adjacent implants were restored with metal-ceramic splinted restorations or with metal-ceramic nonsplinted restorations. These implants were evaluated radiographically for 10 years following prosthodontic rehabilitation with respect to peri-implant marginal bone levels. The bone level around the nonsplinted implants used in the present study was found to be equivalent to that observed around the splinted implants.

Three implants failed at stage-two surgery, before the definitive prosthetic rehabilitations were completed. One male patient, after implant surgery, had experienced some systemic cardiac complications, and it was decided that a removable partial denture would be more appropriate. No patient reported any prosthetic complications. No loosening of the abutment screws was seen in either group. Accurate evaluation of the occlusal scheme and the provision of appropriate variations in the occlusal contacts, both static and dynamic, may explain the lack of prosthetic complications, such as porcelain fracture and loosening of provisionally cemented definitive splinted or nonsplinted metal-ceramic restorations. All patients had a class I canine relationship, and canine-protected occlusion was maintained for all patients.

In this study, all patients who received three adjacent implants were included. Maxillary left implants were restored with splinted cemented restorations, and maxillary right implants were not splinted. In this study, one ideal inclusion criterion would have been implants with a direct occlusal load; however, this is difficult to accomplish in partial edentulism cases because of the different amounts of axial displacement between teeth and implants. Bone remodeling is related to the amount of load; the published data have suggested that functional loading of implants did not result in marginal bone loss. Therefore, splinted implants would typically be indicated in a clinical situation with a risk of mechanical overload to reduce the forces on implants and surrounding tissue.[9–12,48–51] One of the limitations of this study, therefore, is the absence of functional loading; it would be more interesting if functional loading was present and the distributions of occlusal loads could be evaluated. This includes, for example, immediate function with low primary stability, nonaxial loading, and narrow or short implants. In the majority of patients in both groups, the bone quality at implant sites as determined at the time of surgery was judged to be type 1 or type 2.[52] All implants in both groups were 4 mm in diameter (Table 1).

Nonsplinted implant restorations can be a better treatment option when superior esthetics is essential. The results of the present clinical study indicate that nonsplinted implants can be successfully included in implant treatments. They showed an overall survival rate comparable to that obtained with splinted implants. Regarding bone loss, although the statistical analysis showed a significant difference between the two groups, the additional 0.1 mm of bone loss in the nonsplinted group after 5 years was not considered clinically meaningful. The null hypothesis was therefore accepted.

One limitation of this study may be represented by the measurement technique used in the research protocol. Accurate and reliable measurement methods are required to evaluate bone levels proximal to oral implants.[42] All radiographs in this study were taken with a standardized film holder. This device was designed to control imaging geometry by consistently placing the films at a standard distance from the x-ray cone, parallel to the long axis of the implant and perpendicular to the central ray. The radiographic films were then evaluated with a ×6 magnifying lens. However, a previous study compared the microscope-assisted measurement technique of standardized radiographs to a computer-assisted measurement technique. The computer technique showed low intraoperator and interoperator variability, and operators found fewer "unreadable" sites compared to the microscope technique.[45]

It should be emphasized that in this study only external-hexagon implants were used. However, similar conclusions were found for internal-connection implants.[31] Both groups were restored with cemented definitive prostheses; different results may be achieved using screw-retained restorations. Furthermore, the influence of the cementation space acting as a stress release when compared to the passivity problems associated with screw-retained prostheses should be examined.[53–56] In this study, many factors related to implant prostheses were not considered, including soft tissue thickness, implant positioning (buccolingual vs mesiodistal), the implant interdental and interarch distance, the contour of the prosthesis (square vs triangular), and adjacent restorations. Further studies would be helpful to determine to what degree these factors may influence the outcomes.

CONCLUSIONS

Within the limitations of this investigation, the following conclusions can be drawn:

1. The peri-implant marginal bone level change around the nonsplinted implants used in the present study was comparable to that observed in splinted implants.

The statistical analysis found a statistically significant difference between the two groups regarding the amount of bone loss. However, the difference of 0.1 mm was not considered clinically meaningful 10 years after implant insertion.

2. Multiple nonsplinted implants can be successfully included in many clinical situations.

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