Materials & methods

Patient population
In a private practice setting, 50 consecutive patients were prospectively recruited to receive dental implants – either one dental implant or multiple implants per patient. When multiple implants were placed, one implant was randomly selected for a patient to be included in the statistical assessments. Randomization was accomplished by blindly selecting a number assigned to each implant from an envelope. Patients had to meet the following inclusion criteria: good health (no uncontrolled systemic diseases), and sufficient ridge width at the implant site so that the implant would be surrounded by at least 1 mm of bone. Patients were excluded if they were taking bisphosphonates, long term steroid medications or if they smoked more than one-half pack of cigarettes per day. Patients were taking a variety of other medications.

Radiographic distortion and measurement error
The author and one surgical assistant were calibrated with respect to taking radiographs using the long-cone paralleling technique (Rinn film-holding instruments, Dentsply-Rinn, Elgin, IL). The distortion factor was less than 10 per cent. For a radiograph to be used for measurements, the implant threads had to be bilaterally discernible [2]. Before commencing the assessment, the author and the assistant calibrated themselves with regard to operator measurement error on radiographs and continued until a mean error on 20 consecutive radiographs was less than or equal to 0.2 mm (range 0.0 to 0.3 mm). The assistant was blinded with respect to the purpose of the assessment and was responsible for performing one-half of the radiographic measurements.

Surgical and maintenance protocol
All patients were pre-medicated with a loading dose of antibiotics (Amoxicillin 2 g or Clindamycin 600 mg for Amoxicillin-allergic patients) before implant surgery. Postoperatively, patients took antibiotics for up to seven days. Standard surgical procedures were employed to place the implants [3-5]. The implants were inserted at, or coronal to, or apical to the osseous crest as dictated by the available interocclusal space and expected prosthetic design. Chromic gut sutures were used to approximate the flaps. Patients were instructed in oral hygiene techniques (brushing and flossing) two weeks after implant placement or...
Implant uncovering surgery. When necessary, soft tissue was allowed to heal for six to eight weeks after implants were uncovered or longer in the aesthetic zone. Standard prostodontic protocols were used to fabricate single crowns or fixed implant prostheses. Subsequently, patients were seen every six months for an examination and prophylaxis.

Calculation of survival rates and assessment of proximal bony alterations

Implant survival was assessed and calculated in accordance with previously established parameters and methods (for example, functionality, patient comfort) [6,7]. Data pertaining to changes of proximal bone levels relative to the most coronal aspect of the implant’s periphery were recorded. Bony changes were assessed at the time of the definitive restoration (first time period) and five years later (second time period). The total sample of implants (n = 50) were available for the first time period assessment. Thereafter, data pertaining to proximal bone changes for each implant were recorded at five years post-restoration (n = 46). Four patients were not available for the five year assessment (8 per cent lost to follow up). Of the group that was lost to follow up, one patient was deceased and three others were seen by different dentists. These clinicians provided a radiograph of the other three implants at five years post- restoration, which demonstrated implant survival; however, the x-rays were not adequate for proximal bone level measurements.

At the end of the first time period (definitive restoration), proximal bone levels were measured on radiographs from the most coronal aspect of the implant’s body, just apical to the platform-switched incline, to the first bone to implant contact (BIC) that could be visually determined. The measurement points are depicted in Figure 1. Two radiographs per patient were used to make measurements for time period 1: The first radiograph was taken at surgical insertion and the second at definitive restoration. Bone change per surface (mesial and distal) was calculated as the net difference between the first and second readings. Mean bony change on the mesial and distal aspect of each implant was calculated independently. It was determined on each side by adding the sum of all differences between the two time points and dividing that sum by the total number of patients in the group. For the second time period assessment (five years later), proximal bone changes were recorded using the same procedure as described for the first time period. The mesial and distal measurements were collapsed into a single reading per implant because the mean numbers pertaining to the proximal surfaces were within 0.01 mm of each other.

If an implant was submerged, the time computed for osseointegration to occur was the number of weeks until uncovering surgery. If an implant was not submerged, integration time was considered to be the number of weeks until the healing abutment was removed for the first time.

Results

Implant lengths, diameters, location within the jaws, whether submerged or non-submerged, local bone quality and restoration type are presented in Table 1. All 50 patients were available for radiographic analysis for the first time period: surgical insertion through definitive restoration. There were 21 males and 29 females representing three age groups: 20–40 years old (n = 2), 41–60 years old (n = 9) and 61–80 years old (n = 39).

Table 1: Data pertinent to implants placed in this study population

<table>
<thead>
<tr>
<th>Lengths</th>
<th>Diameters</th>
<th>Position in jaws</th>
<th>Protocol</th>
<th>Bone type¹</th>
<th>Restorations</th>
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<tr>
<td>8 mm (n = 7)</td>
<td>3.7 mm (n=6)</td>
<td>Maxilla (n = 25)</td>
<td>Submerged (n = 7)</td>
<td>Dense (n = 5)²</td>
<td>Single crown (n = 26)</td>
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<tr>
<td>10 mm (n = 17)</td>
<td>4.2 mm (n=44)</td>
<td>Mandible (n = 25)</td>
<td>Non-submerged (n = 43)</td>
<td>Medium (n = 40)³</td>
<td>Fixed bridge (n = 24)</td>
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<tr>
<td>11.5 mm (n = 21)</td>
<td>Anterior (n = 8)</td>
<td>Posterior (n = 42)</td>
<td></td>
<td>Soft (n = 5)⁴</td>
<td>Screw-retained (n = 10)</td>
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<tr>
<td>13 mm (n = 5)</td>
<td></td>
<td></td>
<td></td>
<td>Cement-retained (n = 40)</td>
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¹ For details, see Reference Cavallaro, Greenstein, Greenstein; JADA 2009
² Dense quality bone: During drilling, the bone is mechanically supportive for the entire length of the osteotomy
³ Medium quality bone: There is approximately 3 mm of cortical bone followed by a distinct drop in drilling resistance.
⁴ Soft quality bone: There is an indiscernible layer of cortical bone and little drilling resistance for the entire length of the osteotomy.

1 I Intraoral periapical radiograph depicting the measurement points used in the assessment of proximal bone levels. The top white arrow represents the most coronal aspect of the widest part of the implant body and the bottom white arrow shows the first bone to implant contact that is visibly discernible.
61–80 years old (n = 39). Forty-six patients were available for assessment five years post-restoration of the implants. The mean integration time for all implants was 13.8 weeks (range 10–24 weeks). All implants were surgically placed by the author and the restorations were fabricated by restorative dentists within the practice between February and October 2010.

Implant survival
The implant survival rate was 100 per cent. All implants were immobile and the soft tissues surrounding the implants were healthy (absence of bleeding upon probing). An example of an integrated implant from time period 1 is presented in Figures 2a and b.

Radiographic assessment of proximal bone changes
Mean values related to osseous changes at the two different time points for the proximal aspects of the assessed implants are provided in Table 2. This value for the first time period (definitive restoration) was 0.29 +/- 0.34 mm; range 0.0 to 1.7 mm; 95 per cent confidence interval, CI 0.22 to 0.36. The mean cumulative proximal bone level changes per implant for the second time period (after five years) was 0.34 +/- 0.29 mm; range 0.0 to 1.65 mm; CI 0.26 to 0.42. Therefore, the total mean bone level alterations from implant placement through the end of the study was 0.63 mm.

Examples of the radiographic proximal bone change at five years post-restoration of the implants are presented in Figures 3a to c (a mandibular implant) and Figures 4a and b (a maxillary implant).

Prosthetic restorations
The design of the definitive restorations is provided in Table 2. All patients received either single crowns (n=26) or fixed prostheses (n=24) on the implants. Forty of the restorations were cement-retained on pre-fabricated or custom abutments and ten were screw-retained. To date, no definitive abutments loosened on the restored implants. No other types of prosthetic complications occurred during the study.

Discussion
The implant design assessed in this study performed well over a 72-month evaluation period after implant insertion with respect to survival rates and radiographic proximal bone level changes. This study demonstrated a survival rate of 100 per cent for implants placed into healed ridges. This result is similar to other implants systems used to treat fully and partially edentulous patients [8–13]. Pertinently, Jung et al. [13] demonstrated in a systematic review a survival rate of implants which supported single crowns of 97.2 per cent (95 per cent CI: 96.3–97.9 per cent) after five years.

The mean amount of bone loss detected up to definitive restoration was 0.29 mm. This osseous resorption is attributable to the effects of the surgical procedure [14,15], formation of biologic width [16–18], factors such as bone quantity and quality [19,20], proximity to adjacent implants [21] or natural teeth [22] and the effects of abutment disconnection and reconnection [23,24]. Formation of the biologic width is a normal physiologic process sur-
intraoral radiograph. Pertinently, the findings in this study demonstrate less bone loss than is normally found in the absence of platform switching (0.29 mm up to definitive restoration) reported above. This finding is in agreement with others [27–31] who rounding dental implants. In this regard, Adell et al. [25] reported a mean bone loss of 1.5 mm for Brånemark implants the first year after insertion and Cox and Zarb [26] showed a mean bone loss of 1.6 mm from surgical placement to the end of the first year. These data pertain to the platform-matched design (the implant-abutment connection and the widest part of the coronal aspect of the implant are the same diameter). However, the implant assessed in this study is platform-switched (the implant-abutment junction is located medially to the widest part of the implant’s periphery). This enables part of the biologic width to form on the platform-switched incline available on this implant design. Consequently, since part of the biologic width forms on the platform switched area, less bone is lost when biologic width forms around an implant, as evidenced on an intraoral radiograph. Pertinently, the findings in this study demonstrate less bone loss than is normally found in the absence of platform switching (0.29 mm up to definitive restoration) reported above. This finding is in agreement with others [27–31] who

<table>
<thead>
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<th>Table 2: Proximal bony changes at delineated time periods</th>
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<td>Time period 1, n = 50, at definitive restoration:</td>
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<tr>
<td>0.29 +/- 0.34 mm mean change</td>
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<td>Range: 0 to 1.7 mm</td>
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<td>Confidence interval, CI 0.22–0.36</td>
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<td>Time period 2, n = 46, 5 years post-restoration:</td>
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<tr>
<td>0.34 +/- 0.29 mm cumulative change</td>
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<tr>
<td>Range: 0 to 1.65 mm</td>
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<tr>
<td>Confidence interval, CI 0.26–0.42</td>
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reported a smaller amount of marginal bone loss around platform-switched implants when compared to non-platform-switched implants (Fig. 5).

The stability of marginal bone over time (five years) is an important consideration. Historically, the definition of implant success proposed by Albrektsson et al. [32] was based upon clinical immobility, minimum radiographic bone loss over time, an absence of exudate, persistent inflammation, patient discomfort or peri-implant radiolucencies. The same authors also considered an implant “successful” if it did not demonstrate progressive bone loss greater than 0.2 mm annually after the first year of implant placement. Subsequently, a Consensus Conference sponsored by the International Congress of Oral Implantologists (ICOI) developed four clinical categories to be used to define implant success, survival and failure [33]. All of the implants in this study meet the criteria of the ICOI Early Success category. With respect to the present study, mean cumulative proximal bone loss five years post restoration was 0.34+/-. 0.29 mm. These results are comparable to the results of Telleman et al. [34] who reported interproximal crestal bone level changes of 0.38 ± 0.61 mm at five years after implants had been placed into healed ridges. Another investigator also had similar results [35].

The implant in this study also had coronal mini-threads that were textured to the top of the implant. The effects of complete texturing upon bone levels has been previously studied and found to improve peri-implant bone preservation [36]. This is in agreement with the results of the current assessment. With respect to the coronal mini-threads, several investigators proposed a positive bone preserving effect associated with this characteristic [37–42]. However, this claim remains controversial, because previous study designs were either experimental [37], did not isolate mini-threads as the sole variable and demonstrated relatively small differences (0.14–0.5 mm mean differences) [38–42]. Hence, it remains unclear which implant design feature has the greater bone preserving effect – the complete texturing or the mini-threads.

In this study, radiographs were done with a Rinn holder to reduce measurement errors. This is a practical method used in private practice for the purpose of monitoring proximal bone levels around implants. Both rehearsal of the radiographic technique and operator calibration took place before this study, and this resulted in reproducible measurements [18]. Additionally, all periapical radiographs used for measurements clearly portrayed the implant threads, which indicated that there was minimal radiographic distortion [2].

This clinical trial reviewed the combined effect of platform-switching, coronal mini-threads and a fully textured body on survival of an implant and bony alterations. In this regard, the author observed that when procedures are properly performed with the assessed implant, it was straightforward to achieve primary stability, the implants experienced minimal osseous changes over the short and intermediate time frames, the survival rate was excellent, the internal connection was stable and no definitive abutments became loose.

Conclusions
1. With respect to the time frame of the study, the assessed implant demonstrated favourable implant survival (100 per cent).
2. Five years after definitive restoration, the assessed implant demonstrated minimal radiographic bone changes.
3. Further clinical studies would be valuable in monitoring the performance of this dental implant over longer periods of time.

Acknowledgment: Thanks to Mr. Angelo Cacciatare for taking half of the radiographic measurements needed for this assessment.

The references are available at www.teamwork-media.de/literatur