INTRODUCTION

Over 2 decades ago, Berglundh and Lindhe have shown that vertical mucosal tissue thickness is one of the most important factors to influence early crestal bone loss (Berglundh & Lindhe, 1996). Authors suggested that if vertical soft tissue dimension is not sufficiently thick, crestal bone loss occurs during formation of biological barrier between implant and oral environment. This animal experiment...
was followed by clinical studies, which proved that mucosal tissues of 2 mm or less in thickness may cause bone loss, while implants placed in thick tissues had significantly less bone remodelling (Linkevicius, Aspe, Grybkauskas, & Puisys, 2009, 2010; Linkevicius, Puisys, Linkeviciene, Peciulienė, & Schlee, 2015; Linkevicius, Puisys, Steigmann, Vindasiute, & Linkeviciene, 2015). Furthermore, numerous studies from other research centres have been published, supporting this relation between tissue thickness and crestal bone loss (van Eekeren, van Elsas, Tahmaseb, & Wismeijer, 2017; Vandeweghe & De Bruyn, 2012; Vervaek, Dierens, Besseler, & De Bruyn, 2012). Finally, entire data of clinical studies were summarized in a systematic review, which states that there is sufficient evidence to conclude that implants placed in initially thinner vertical soft tissues have more radiographic marginal bone loss in short-term follow-up (Suárez-López Del Amo, Lin, Monje, Galindo-Moreno, & Wang, 2016).

Currently, it is accepted that the threshold between thin or thick tissues is 2 mm. This number was used in the first animal study and in subsequent clinical trials as well. However, it is obvious that clinical variations exist and a number of researchers have acknowledged that somewhat medium thickness gingival tissues are also prevalent in the population (Fischer, Kunzberger, Donos, Fickl, & Friedmann, 2018; Fischer, Richter, Kebschull, Petersen, & Fickl, 2017). Still, it is unclear how the bone reacts to medium thickness vertical tissues of 2.5 mm. All previous studies did not distinguish medium thickness tissues as a separate group, as all tissues above 2 mm were considered as thick, and below 2 mm, as thin. Therefore, it would be beneficial to know how marginal bone reacts to vertical soft tissues of medium thickness. It is well known that design of cervical portion of the implant is important in development of marginal bone stability. Recently, newly designed implant was introduced, which has reduction in the neck on three sides, which makes it similar to triangular-shaped implant neck, compared to traditional circular contour, providing “compression-free” zone to alveolar crest during implant placement. Calvo-Guirado and co-workers found thicker peri-implant soft and hard tissues in horizontal dimension around implants with this novel design (Calvo-Guirado et al., 2016). However, the study did not evaluate vertical tissue thickness before implant placement; therefore, it remains unclear how crestal bone around triangle-shaped implants reacts to different tissue thickness.

Thus, the primary aim of this study was to investigate how different vertical mucosal tissue thickness affects crestal bone stability around new design triangular-shaped bone-level implants, restored using short titanium bases and lithium disilicate crowns. Secondary aim was to clarify what is the minimal soft tissue thickness to prevent or greatly reduce crestal bone loss during formation of biological width. Null hypothesis was raised that vertical soft tissue thickness does not have impact of crestal bone levels.

2 | MATERIALS AND METHODS

A sample size calculation was determined by power analysis using G*Power v 3.1.9.2. software. Based on previous systematic reviews and clinical studies analysing tissue thickness impact on marginal bone loss (Akcali et al., 2017; Linkevicius, et al., 2009; Suárez-López Del Amo et al., 2016), the large effect size (f = 0.42) was assumed. A type I error rate of α = 0.05 was set. To achieve a power of at least 80%, under aforementioned assumptions, a sample size of at least n = 18 per group was obtained. To accommodate possible dropouts, the sample size was increased to 20 implants per group.

This clinical prospective cohort study took place from 2015 to 2017 and was conducted in agreement with the Declaration of Helsinki, following STROBE guidelines for cohort studies. Subjects for the study were selected among patients of private dental clinic in Lithuania. The protocol for this study was approved by Kaunas regional ethical committee for biomedical trials (No. BE-2-2).

Study was conducted according to well-established clinical protocol, used in previous trials by Linkevicius and co-workers (Linkevicius, Puisys, Linkeviciene, et al., 2015; Linkevicius, Puisys, Steigmann et al., 2015). Inclusion criteria were as follows: (a) no less than 18 years of age; (b) generally healthy patients, no medical contraindication for implant surgery; (c) missing teeth in lower and upper jaws posterior, premolar and molar area, Kennedy Class I, II and III; (d) minimum of 6 mm horizontal bone width; (e) healthy soft tissue (BOP<15%, PI<15% CPITN<2); (f) minimum 2 mm keratinized gingiva buccally and 2 mm lingually/palatinally; (g) no bone augmentation procedures before and during implant placement; (h) sufficient primary implant stability (≥20 N/cm) to perform single-stage surgery; (i) single implant restorations; and (j) signed informed consent form for participation and permission to use obtained data for research purposes. Patients, who had poor oral hygiene, history of uncontrolled periodontitis, smoked more than 10 cigarettes a day, had diabetes, alcoholism, or took medication, influencing healing, were excluded. The patients were asked to rinse for 1 min with a 0.12% chlorhexidine solution (Perio-Aid, Dental, Barcelona, Spain) before start of the procedures. After the administration of 4% articaine 40 ml solution (Ubistesin, 3M/ESPE; Germany), a crestal incision on the centre of edentulous ridge was performed. Full-thickness buccal flap was elevated, and lingual flap was not raised. Soft tissue thickness in vertical dimension was registered with 0.5-mm marked periodontal probe (Hu-Friedy; Chicago, IL, USA) at the bone crest in the centre of future implant placement. If vertical tissue thickness was 2 or less mm, tissues were considered as thin (Figure 1). If tissue thickness was 2.5 mm, tissues were defined as medium thickness (Figure 2), while if the probe indicated 3 mm or more, thick tissues were registered (Figure 3).

Triangular-shaped conical connection bone-level implants with platform switching (V3; MIS Implant Technologies Ltd., Bar-Lev Industrial Park, Israel) of 4.3 mm diameter were placed in one-stage approach. These implants are triangular in their coronal part, with a reduction of 0.3 mm in each of three sides at the neck, while the body remaining 4.3 mm in diameter (Figure 4). All implants were placed by skilled surgeon (A.P.) with 15 years of clinical experience in implant surgery. Implants were positioned equally with bone crest that the rough surface would be completely covered with bone, according to the manufacturer’s indications. Due to not even alveolar
ridge in few cases part of the implant neck would be positioned slightly subcrestally (never more than 0.25 mm) that the rough surface would not be exposed (Figure 5). Primary stability of the implant of more than 20 N/m was always achieved; therefore, healing abutments were connected to implants immediately and tissues sutured with 4/0 sutures (Polysorb, USS-DG, Norwalk, CT). Implants were placed adjacent to natural teeth and to implants, received in previous treatments.

Patients were instructed to rinse the operated site with 0.12% chlorhexidine-digluconate (Perio-Aid; Dentaid, Barcelona, Spain) solution twice a day for a week and prescribed 0.5 g of amoxicillin (Ospamox, Biochemie, Austria) three times daily for 5 days. The sutures were removed after 10 days postsurgery.

After 2 months of healing, direct impression transfers were used for open-tray impression to register the position of an implant and shape of surrounding peri-implant tissues. Titanium bases with 0.5 mm gingival height was selected as supporting interface for lithium disilicate restorations (IPS e.max; Ivoclar Vivadent, Liechtenstein). Lithium disilicate restorations were milled from blocks of different shades, polished, glazed and cemented to titanium interfaces with resin cement (LinkAce; GC, Japan). Restorations were steam cleaned for 5 s at 4 MPa (VAP1; Zhermark, Cologne, Germany) prior sending to the clinic. Before delivery, crowns were cleaned in ultrasonic bath (Pro-sonic 300, Sultan Healthcare, PA), in a 1% mixture of distilled water and detergent (Siladent, Dr. Bohme & Schops GmbH, Goslar, Germany) for 10 min, rinsed with distilled water and dried (Huh, Yang, Park, & Cho, 2017). Then, restorations carefully were screwed to implants. If the blanching was to occur during settling of the restoration, it was delayed till soft tissue regained normal colour and appearance, and then continued till torque of 35 N/cm was reached. Screw access permanently was closed according to the protocol to maintain as good isolation as possible (Moráguez & Belser, 2010). Screw access hole was firmly compacted with autoclaved PTFE tape, leaving at least 2 mm space for insertion of filling material. Then, screw access hole of the restoration was etched with 9.6% hydrofluoric acid (Pulpdent...
Corporation, Watertown, MA) for 10 s, and adhesive with silane (Clearfil Universal Bond Quick; Kuraray Noritake, Okayama, Japan) was applied and air-dried. Then, a layer of light-cured composite (Gradia Posterior; GC, Tokyo, Japan) was inserted to fill the space and light-cured for 40 s; occlusion was checked, and restoration was polished. Post prosthetic treatment, the patients received individual oral hygiene instructions and were monitored in recalls every 6 months to ensure periodontal health (BOP < 20% and PI < 25%) was maintained throughout the study period (Figure 6).

Intraoral radiographs were performed two times in each patient during the study: (a) after implant placement and (b) after 1-year follow-up. This was performed for group 1 implants (Figure 7a,b), group 2 (Figure 8a,b) and group 3 (Figure 9a,b). A digital film holder and individual bite blocks were used to ensure reproducible parallel radiographic images. In addition, the images were obtained in the way that implant/abutment interface and the threads would be clearly visible, as this ensures that radiographic image is parallel. Radiological evaluation and measurements were performed using RVG Windows Trophy 7.0 software measurement program with a magnification (×20) by one examiner, which was not familiar with the study. The calibration of RVG images was performed, using implant diameter of 4.3 as a reference point. Bone loss in millimetres was calculated by comparing baseline radiographs with radiographs obtained during 1-year follow-up recall visit. The edge of the implant neck and first radiographic bone implant contact was selected as the reference points. Bone levels were determined as a distance between these two reference points. The mean of the mesial and distal measurements was recorded for the implant.

**RESULTS**

After recruitment, sample size included 56 patients, consisting of 22 males and 34 females. Subjects’ average age was 47.3 ± 1.2 ranging from 20 to 67 years at the beginning of the experiment. In total, 60 bone-level triangular-shaped implants with platform switching (V3, MIS Implant Technologies Ltd., Bar-Lev Industrial Park, Israel) were placed. Four patients received two implants; however, only one implant per patient was included into the study to keep patient-based study design. The selection which one of two implants will be included into analysis was randomized by envelope drawing. All implants integrated successfully and were restored with 60 lithium disilicate cement screw-retained restorations. By the end of the study, one patient dropped-out; therefore, for 1-year follow-up visit, final sample size consisted of 55 implants—19 in group 1 (thin tissues), 18 in group 2 (medium thickness) and 18 implants in group 3, representing thick vertical soft tissues. Overall, the implant survival rate after 1 year of function was 100% in all groups. No prosthetic complications were recorded during follow-up visits. After 1-year follow-up, implants in group 1 (thin) had 1.25 ± 0.8 mm bone loss, implants in group 2 (medium) had 0.98 ± 0.06, while implants in group 3 (thick) lost 0.43 ± 0.37 mm of crestal bone. Tukey’s HSD test showed that statistically significant differences between thin and thick groups (p < 0.001) and between medium and thick groups...
linkevicius et al.

(p = 0.0014), while between thin and medium groups, it was not significant (p = 0.310) (Table 1, Figure 10). Gingival tissue thickness evaluation is shown in Table 2, and Table 3 represents crestal bone loss differences between jaws.

4 | DISCUSSION

The results of this study showed that vertical soft tissue thickness might be important factor in development of crestal bone stability, as it was shown that bone loss increases, when soft tissue thickness decreases. The least marginal bone loss equalled to 0.43 mm and was registered in thick tissues, which, according to proposed allocation, was ≥3 mm in thickness. Medium thickness mucosa showed significantly more bone loss, compared to thick tissues, and, however, was not different from thin tissues. Based on this, null hypothesis should be rejected.

Thin tissue group had 1.25 mm, while medium thickness tissues showed 0.98 mm of crestal bone loss and the difference was not statistically significant. These results bring out the fact that bone loss was similar in both groups; therefore, modification of division between thin and thick tissues might be brought into discussion. Originally proposed by Berglundh and Lindhe, 2 mm was used in most of the followed studies (Berglundh & Lindhe, 1996). Under currently accepted definition, 2.5 mm of tissue thickness would be considered as thick; however, bone loss of 0.98 mm,
which was registered, is higher than usually present in thick tissues. Some clinical studies already implemented the use of 3 mm, as a minimal tissue thickness to avoid the factor of gingival height in etiology of marginal bone loss (Blanco et al., 2018). In addition, it must be remembered that original article was an animal study; therefore, the findings from clinical trial usually are expected to have higher clinical impact. Previous studies by Linkevicius et al. involved the evaluation of implants with different connections in vertically thin and thick tissues. It should be noted that thick tissue was 3.32 mm around regular connection implants and 2.98 mm in thickness in platform-switched implants, which indicates that thick tissues could be considered as 3 mm or more (Linkevicius, Puisys, Linkeviciene, et al., 2015; Linkevicius, Puisys, Steigmann et al., 2015). Subsequently crestal bone loss was reduced to 0.22 mm around platform switching implants, when tissue thickness was more a little more than 3 mm (Puisys & Linkevicius, 2015). On the contrary, Canullo, Fedele, Iannello, & Jepsen, 2010 reported bone loss around implants in thick tissues (>2 mm) to be 0.11 and in thin tissues (≤2 mm) to be 0.35 mm after 3-year follow-up, without statistical difference, claiming no difference between thin and thick tissues (Canullo et al., 2017). The dissimilarity from currently presented data can be explained by several differences in the study design. For example, tissue thickness was measured by taking biopsies, which may be considered as more precise, compared to manual measurement with 0.5-mm periodontal probe, however not clinically convenient. It should be noted that implants were positioned slightly subcrestally; however, the exact depth of the placement was not provided and sample size of implants evaluated in thick tissues (only 10 implants) was rather small, indicating lack of firm conclusions. Finally, conversely to presented study, adjacent implants were evaluated and longer follow-up period was

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean (SD)</th>
<th>SE</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thin</td>
<td>19</td>
<td>−1.25 (0.80)</td>
<td>0.19495</td>
<td>−3</td>
<td>−0.05</td>
</tr>
<tr>
<td>Medium</td>
<td>18</td>
<td>−0.98 (0.42)</td>
<td>0.09569</td>
<td>−2</td>
<td>−0.4</td>
</tr>
<tr>
<td>Thick</td>
<td>18</td>
<td>−0.43 (0.37)</td>
<td>0.09046</td>
<td>−1.1</td>
<td>0.2</td>
</tr>
</tbody>
</table>

**Table 1** Crestal bone loss (mm) around implants after 1-year follow-up and statistical difference (one-way ANOVA, Tukey’s HSD post hoc test, significant when $p \leq 0.05$) between groups

**Figure 9** Bone loss in thick tissues (3 mm), after placement (a), 1-year follow-up (b)

**Figure 10** Graphical visualization of significant differences between soft tissue groups
TABLE 2  Vertical soft tissue thickness (mm) and statistical difference (one-way ANOVA and Tukey’s HSD post hoc tests, significant when p ≤ 0.05) between groups

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Mean (SD)</th>
<th>SE</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thin</td>
<td>19</td>
<td>1.76 (0.26)</td>
<td>0.06239</td>
<td>1.5</td>
<td>2</td>
</tr>
<tr>
<td>Medium</td>
<td>18</td>
<td>2.5</td>
<td>-</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Thick</td>
<td>18</td>
<td>3.91 (0.59)</td>
<td>0.14371</td>
<td>3</td>
<td>5</td>
</tr>
</tbody>
</table>

TABLE 3  Crestal bone loss (mm) in maxilla and mandible and statistical difference (one-way ANOVA, significant when p ≤ 0.05) between locations

<table>
<thead>
<tr>
<th>Location</th>
<th>N</th>
<th>Mean (SD)</th>
<th>SE</th>
<th>Min</th>
<th>Max</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maxilla</td>
<td>12</td>
<td>−1.12 (0.67)</td>
<td>0.25281</td>
<td>−2</td>
<td>−0.15</td>
<td>p = 0.311</td>
</tr>
<tr>
<td>Mandible</td>
<td>43</td>
<td>−0.85 (0.64)</td>
<td>0.09481</td>
<td>−3</td>
<td>0.2</td>
<td></td>
</tr>
</tbody>
</table>

Bold values show statistically significant differences between groups.

Utilized, which also might be attributed to reasons why results are different. Nevertheless, the dispute whether thick vertical soft tissues preserve more crestal bone stability still continues, as it was shown that tissue-level implants did not have more bone resorption in thin tissues (van Eekeren et al., 2017). Recent systematic review failed to confirm superiority of thick over thin tissues in maintaining bone stability as well (Akcali et al., 2017).

Generally, information from the current study suggests that vertical soft tissue thickness should be at least 3 mm in height that the establishment of biological width to proceed without crestal bone resorption. Consequently, if vertical soft tissue height is of a smaller dimension, clinicians should use available methods to increase tissue thickness, or accept initial bone remodelling. Several methods have been proposed to accommodate reduced vertical soft tissue thickness. An emerging clinical evidence is presented in favour of vertical soft tissue thickening, using allogenic membranes in one and two-stage approach, both for platform-switched and nonswitched implants. Clinical studies reported reduction in crestal bone loss from 1.74 to 0.34 mm around regular connection implants and from 1.21 to 0.2 mm in platform-switched fixtures (Linkevicius, Puisys, Linkeviciene, et al., 2015; Linkevicius, Puisys, Steigmann et al., 2015). Some authors claim that subcrestal placement of implant and subsequent controlled bone remodelling can accommodate the problem. Recent study by Vervaek et al. showed that subcrestal placement of conical connection implants could be a choice as well, as subcrestally placed implants had only 0.03 mm of bone loss, compared to 0.77 mm of epicrestally positioned implants (Vervaek et al., 2018).

To our knowledge, this is the first prospective cohort clinical study on triangular-shaped bone-level implants. The advantages of triangle-shaped implants at the neck area are suggested to be enlargement of bone width by reducing titanium part, compared to standard cylindrical implants, and reduction in alveolar crest compression during the insertion. The reduction by 0.3 mm on each side of the implant neck is expected to create reservoir for blood collection, formation of blood clots and later growth of the bone. That in turn would provide more stability for surrounding soft tissues and give more esthetical restorations in the end. And indeed, thicker crestal plate, compared to traditional cylindrical implants, was observed in several animal studies (Calvo-Guirado et al., 2016; Sanz-Martín et al., 2017). It was reported that vertical soft peri-implant tissue dimensions did not differ, regardless of the design of the implant. Clinical results show that vertical bone height around triangular-shaped implants depends on biological factors, such as initial soft tissue thickness, and just modification of implant design might not be sufficient to obtain better marginal bone level.

Current investigation has produced an interesting information about influence of other factors on bone stability. Interestingly, it could be suggested that gingival height of titanium base and restoration material had shown their negative effect on bone stability. Study has used 0.5-mm-height titanium bases for the support of lithium disilicate crowns. This means that cementation margin was located in close proximity to the bone. Of course, the restorations were luted to titanium bases in the laboratory on the model, however, there is always a thin layer of cement, which is exposed to peri-implant tissues. As titanium base is 0.5 mm height, it means that resin cement film was in this exact distance from the bone. It has been well documented that resin cement, which is usually used for luting, may be toxic to the tissues. Kraus et al. have showed that monomers from resin cement can be detrimental to osteoblast-like cells (Kraus et al., 2017). Several clinical studies, like Novoa et al., detected statistically significant more bone loss around 1-mm-height multiunit abutment, compared to 2.5 mm (Novoa et al., 2017) or 3.0 mm heights (Blanco et al., 2018). Similar results were presented by Galindo-Moreno et al., revealing more bone loss if multiunit abutment was shorter than 2 mm (Galindo-Moreno et al., 2015). It can be suggested that close proximity of implant-abutment prosthetic connection to the bone is more detrimental.

Another prosthetic factor, which could influence bone loss probably, was restoration material. Monolithic lithium disilicate is becoming the choice of many clinicians recently. It offers the increased strength of 400 Mpa for occlusion and advanced digital...
workflow; however, there might be some biological aspects with the biocompatibility of this material. Messer et al. and Brackett et al. suggested that lithium disilicates are not biologically inert and are more cytotoxic, compared to composites or other dental materials (Brackett et al., 2008; Messer et al., 2003). It is well known that ceramics do not maintain soft tissue adhesion, what may result in recession and bone loss (Abrahamsson, Berglundh, Glantz, & Lindhe, 1998). In case of monolithic screw-retained implant restoration, lithium disilicate is located below the gingiva in direct contact to peri-implant tissues and close proximity to the bone. It may result in adverse reaction of peri-implant tissues, resulting in bone loss. Most likely, zirconium oxide would be a better option for subgingival positioning, based on number of studies highlighting biologic qualities of zirconia (Degidi et al., 2006; Scarano, Piattelli, Caputi, Favero, & Piattelli, 2004). It may appear that lithium disilicate is more suitable for supragingival location and can be connected to zirconium oxide substructure with cement or by fusing procedure. On the other hand, it was shown that fibroblasts have adhesion to polished lithium disilicate, what indicates good biocompatibility of the material (Mehl et al., 2017). Apparently, the finishing procedure of lithium disilicate surface, was it polished or glazed, might have influence on adhesion of the cells and biological outcome. Of course, results from in vitro studies and an animal experiment preclude the drawing of definitive conclusions, regarding the use of lithium ceramics below the gingival line, and alternatives, such as zirconium oxide, could be considered.

Like every clinical trial, the current study has several limitations. First of all, periapical radiographic images do not represent buccal dimensions of the bone level; therefore, final conclusions how triangular-shaped implants maintain crestal bone stability might be limited. The allotment of implants in the study showed not equal distribution between maxilla and mandible; however, this parameter could not be influenced by researchers. Although some differences exist between both jaws in bone quality, marginal bone levels did not differ. Peri-implant soft tissue parameters were not meticulously presented in this study, as it aimed specifically on radiologic evaluation of bone levels. This precludes of seeing the whole picture; however, important soft tissue parameters, such as presence of 4 mm keratinized tissues buccolingually and healthy status (BOP < 15%, PI < 15% CPI1TN < 2), were ensured by inclusion criteria. In addition, good oral hygiene was maintained throughout the study period, as patients received individual oral hygiene instructions and were monitored in recalls every 6 months to ensure periodontal health (BOP < 20% and PI < 25%).

5 | CONCLUSIONS

Within the limitations of this study, which evaluated only radiologic parameters, it can be concluded that significantly less bone loss occurs around triangular-shaped bone-level implants in thick mucosal tissues, compared to medium or thin tissue biotype. Crestal bone loss does not differ between medium and thin tissues.

ACKNOWLEDGEMENTS

This clinical trial was sponsored by MIS Implant Technologies Ltd., Bar-Lev Industrial Park, Israel.

ORCID

Tomas Linkevicius https://orcid.org/0000-0001-9587-5560

REFERENCES


SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.