



## ORIGINAL ARTICLE

# Non-invasive assessment of peri-implant mucosal thickness: A cross-sectional study

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## Abstract

**Background:** This study aimed to evaluate the reliability and reproducibility of different non-invasive methods for the assessment of peri-implant mucosal thickness.

**Methods:** Subjects with two adjacent dental implants in the central maxillary region were included in this study. Three different methods to assess facial mucosal thickness (FMT) were compared: digital file superimposition using Digital Imaging and Communication in Medicine (DICOM) and stereolithography (STL) files of the arch of interest (DICOM-STL), DICOM files alone, and non-ionizing ultrasound (US). Inter-rater reliability agreements between different assessment methods were analyzed using inter-class correlation coefficients (ICCs).

**Results:** A total of 50 subjects with 100 bone-level implants constituted the study population. Assessment of FMT using STL and DICOM files demonstrated excellent inter-rater reliability agreement. Mean ICC values of 0.97 and 0.95 were observed in the DICOM-STL and DICOM groups, respectively. Comparison between the DICOM-STL and US revealed good agreement, with an ICC of 0.82 (95% CI: 0.74 to 0.88) and a mean difference of  $-0.13 \pm 0.50$  mm ( $-1.13$  to  $0.86$ ). Comparison between DICOM files alone versus US showed good agreement, with an ICC of 0.81 (95% CI: 0.73 to 0.89) and a mean difference of  $-0.23 \pm 0.46$  mm ( $-1.12$  to  $0.67$ ). Comparison between DICOM-STL and DICOM files revealed excellent agreement, with an ICC of 0.94 (95% CI: 0.91 to 0.96) and a mean difference of  $0.1 \pm 0.29$  mm (LOA  $-0.47$  to  $0.46$ ).

**Conclusions:** Quantification of peri-implant mucosal thickness via analysis of DICOM-STL files, DICOM files, or US assessment are comparably reliable and reproducible methods.

## KEYWORDS

3D imaging, cone beam computed tomography, dental digital radiography, phenotype, ultrasound

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## 1 | INTRODUCTION

The peri-implant phenotype has been defined as the morphologic and dimensional features characterizing the clinical presentation of the tissues that surround and support osseointegrated implants.<sup>1</sup> The three essential components of the peri-implant soft tissue phenotype are the peri-implant keratinized mucosa width, the mucosal thickness (MT), and the supracrestal tissue height.<sup>1</sup> These site-specific phenotypic characteristics may change over time as a function of environmental factors and/or therapeutic interventions, and are highly relevant in clinical practice and research.

MT has been defined as the horizontal dimension of the peri-implant soft tissue, which may or may not be keratinized.<sup>1</sup> It has been demonstrated that MT may play a critical role in the functional, health, and esthetic outcomes of implant therapy. A recent systematic review observed that the thicker the MT, the better the esthetic outcomes, patient satisfaction, and the lower the chance of developing peri-implant marginal mucosal defects.<sup>2</sup> Other studies have reported greater apical migration of the mucosal margin after immediate implant placement,<sup>3,4</sup> tissue discoloration due to the effect of the underlying transmucosal implant components,<sup>5,6</sup> and less favorable peri-implant health after the delivery of the final implant-supported prosthesis in the presence of thin peri-implant mucosa.<sup>7</sup>

Different methods have been described to quantify and classify the soft tissue thickness around teeth and implants.<sup>8,9</sup> These methods include the visual inspection of soft tissue features,<sup>10</sup> probe translucency through the mucosa lateral to the sulcus,<sup>11–13</sup> the use of a caliper after tooth extraction or flap reflection,<sup>13</sup> cone beam computed tomography (CBCT)<sup>14–16</sup> with or without the superimposition of stereolithography (STL) files,<sup>17–19</sup> non-ionizing ultrasound (US), ultrasonography,<sup>20,21</sup> and transmucosal horizontal probing.<sup>22</sup> Although clinical outcome measures are still more frequently reported, there is a trend in the field indicating a shift from traditional clinical assessment methods to the use of advanced imaging based on digital technologies.<sup>23</sup>

The use of CBCT with or without the superimposition of an STL file has been widely applied in recent years in both research and clinical practice to evaluate the periodontal phenotype,<sup>14,17,24–27</sup> with results that are comparable with direct clinical and histologic assessments.<sup>17,18</sup> However, image artifacts due to the presence of dental implants and metal-made restorative components can have an impact on the accuracy of MT assessment using Digital Imaging and Communication in Medicine (DICOM) files.<sup>28</sup> In addition, these methods have the disadvantage of ionizing radiation exposure, which limits their application in daily clinical

practice. Interestingly, it has been reported that the use of non-ionizing US to assess the dimensions of the peri-implant tissues is a reliable method with similar accuracy compared to CBCT-acquired DICOM files.<sup>20,29</sup>

Among preclinical and clinical studies on the topic of assessment of peri-implant phenotypical characteristics, there is limited information and a lack of consensus on whether there is a non-invasive method to quantify MT that is superior to the rest. Hence, this study aimed to evaluate the reliability and reproducibility of facial mucosal thickness (FMT) assessment in subjects with dental implants using three different non-invasive methods.

## 2 | MATERIALS AND METHODS

### 2.1 | Study design, ethical approval, and setting

This clinical investigation was designed as a cross-sectional study and was conducted in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.<sup>30</sup> The clinical study protocol was approved by the standing ethical committee for clinical studies of the state of Bern, Switzerland (KEK-BE-No. 2017-00010), and was conducted in accordance with the Helsinki Declaration of 1975, as revised in 2013. Data acquisition and digital measurements were carried out in the Department of Oral Surgery and Stomatology at the University of Bern, School of Dental Medicine (Bern, Switzerland) between October 2022 and December 2022. However, the clinical and ultrasound measurements were performed between May 2018 and June 2019.

### 2.2 | Recruitment

Adult subjects with two adjacent dental implants in the central maxillary anterior region and periodontally stable adjacent teeth were eligible to participate in this study. These patients were previously enrolled in a clinical trial involving the capture of the region of interest with CBCT. Therefore, none of the subjects involved in this study had additional unjustified exposure to radiation. All potential participants were required to read, understand, and sign the informed consent form, which included a thorough explanation of the study design and purpose. The inclusion criteria were as follows: (1)  $\geq 18$  years of age; (2) ASA status I or II; and (3) presence of two implants located in the maxillary central region. The exclusion criteria were as follows: (1) presence of peri-implantitis<sup>31</sup>; (2) presence of a single-tooth implant in the anterior maxillary region;



**FIGURE 1** Use of an ultrasound device to measure the mucosal thickness 3 mm apical to the mucosal margin.

(3) peri-implant mucosal margin defects  $\geq 1$  mm; (4) pregnancy or nursing mother; and (5) unwilling or unable to sign the informed consent form.

### 2.3 | Clinical procedures and ultrasound measurements

The following clinical measurements were recorded utilizing a periodontal probe<sup>\*</sup>: probing depth (PD), mucosal margin level respective to the implant platform, the absence/presence of pain symptoms and/or suppuration, and the modified sulcus bleeding index (mSBI) at four aspects around the dental implants.<sup>32</sup> Finally, KMW was measured at the mid-facial aspect. Details of the patient's demographic and dental history such as age, gender, systemic factors, implant type, implant dimensions, and type of prosthesis were also recorded. Additionally, a periapical radiograph centered on the adjacent implants was obtained for monitoring radiographic marginal bone levels and diagnostic purposes. FMT was obtained at 3 mm apical to the zenith of the mid-facial mucosal margin measured with a periodontal probe, at an angle perpendicular to the long axis of the dental implant utilizing a non-ionizing US biometer device<sup>†</sup> coupled with a probe frequency of 20 MHz, and 204 DPI resolution by one independent examiner (U.C.B.) as shown in Figure 1.

### 2.4 | CBCT and STL files acquisition

A CBCT scan limited to the region of interest was acquired for all participants. All subjects were asked to maintain cotton rolls placed on the vestibulum to separate the soft tissue structures that could potentially affect the digital

quantification of FMT. The field of view was approximately  $4 \times 4$  cm with a voxel size of 0.08 mm for all scans.<sup>‡</sup> Subsequently, a high-quality polyvinyl siloxane impression of the arch containing the region of interest was obtained. Dental stone casts were fabricated and scanned to generate high-quality STL files using a laboratory scanner.<sup>§</sup>

### 2.5 | DICOM-STL superimposition

DICOM and STL files were imported into an implant treatment planning software<sup>\*\*</sup> and were superimposed allowing for the visualization of the hard and soft tissue structures beneath the overlying surface as shown in Figure 2. Superimposition was semi-automatically performed by manually matching at least six comparable intraoral hard tissue landmarks (e.g., adjacent teeth). When the software generated an inadequate superimposition, the alignment was manually refined using reproducible landmarks (e.g., the outline of the palatal vault).

### 2.6 | Digital assessments

To standardize digital measurements, a sagittal section at the middle of each dental implant was obtained and analyzed independently by two examiners (E.C.Q. and C.R.) not involved in the clinical assessment of FMT with the non-ionizing US device. Superimposed STL and DICOM files, and DICOM files alone were analyzed separately, as depicted in Figure 3. Intra- and inter-examiner calibration were performed by measuring a total of 10 random sites by both examiners to verify that an intra- and inter-class correlation coefficient (ICC) of at least 0.8 was achieved, after which full data collection ensued.

A single MT measurement was obtained for each implant site in millimeters (mm). This was done only at the facial site by first placing a vertical line parallel to the long axis of the implant 3 mm apical to the zenith of the mid-facial mucosal margin. Consecutively, a horizontal line meeting the apical-most point of the vertical line was drawn perpendicularly to measure the distance in millimeters between the alveolar bone crest/implant fixture/transmucosal abutment surface to the external line that represents the superimposition of an STL onto the DICOM file (DICOM-STL group), or to the surface of the gray mucosa area in the DICOM group, as shown in Figure 3.

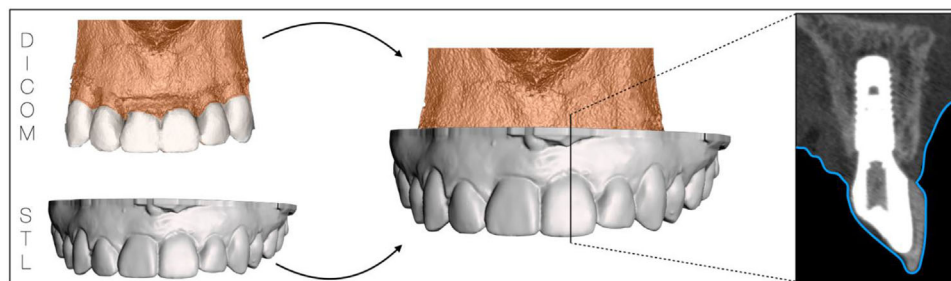
<sup>\*</sup> Marquis probe; Hu-Friedy, Chicago, USA.

<sup>†</sup> PIROP, Echo-Son, Pulawy, Poland.

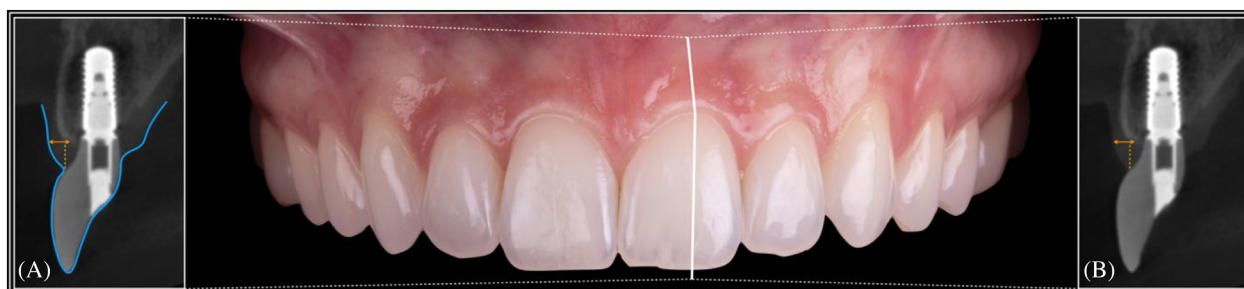
<sup>‡</sup> 3D Accuitomo 170, J. Morita Corp, Osaka, Japan.

<sup>§</sup> E4; 3Shape A/S, Copenhagen, Denmark.

<sup>\*\*</sup> coDiagnostiX, version 10.5, Dental Wings Inc, Montreal, Canada.



**FIGURE 2** Composite image demonstrating the process of Digital Imaging and Communication in Medicine and stereolithography (DICOM-STL) file superimposition.



**FIGURE 3** Visual depiction of the methodology followed to determine facial mucosal thickness at 3 mm apical to the zenith of the mid-facial mucosal margin utilizing the superimposition of stereolithography (STL) and Digital Imaging and Communication in Medicine (DICOM) files (A), and the DICOM files alone (B).

## 2.7 | Statistical analysis

Mean and standard deviation (SD) values of the three types of measurements were obtained. For all statistical analyses, FMT on each site was considered the statistical unit and was analyzed independently. Inter-rater reliability of digital measurements was assessed using ICCs.<sup>33</sup> The agreement between assessment modalities was also evaluated by calculation of ICCs. Additionally, Bland-Altman plots were constructed to identify the limits of agreement (LOA) between different measurement modalities, thereby evaluating the clinical significance of the resultant mean differences.<sup>34</sup> Scatter plots were also constructed to identify the correlation between different measurement modalities. All data analyses were conducted using SPSS version 29.0.<sup>††</sup> Additionally, the magnitude of the ICC was scored based on a 95% confidence interval. Values less than 0.5, between 0.5 and 0.75, between 0.75 and 0.9, and greater than 0.90 were indicative of poor, moderate, good, and excellent reliability, respectively.<sup>35</sup>

## 2.8 | Sample size calculation

FMT in mm was the primary outcome of interest. The sample size was calculated with an assumed power of 95% to detect a minimal clinically significant difference of 0.2 mm (adjusted for two-sidedness), and an SD of 0.23 mm as reported in a previous study.<sup>29</sup> Therefore, a sample size of 70 FMT measurements per digital assessment modality, assuming equal group sizes, was deemed necessary. These results translated into a minimum of 35 patients per group since every subject had two adjacent dental implants in the region of interest.

## 3 | RESULTS

### 3.1 | Population and sample characteristics

A total of 60 subjects were initially screened. Ten subjects were not eligible upon initial screening due to the excessive blooming effect (imaging artifact) present in the CBCT scans. Therefore, a total of 50 subjects with 100 implants<sup>‡‡</sup>

<sup>††</sup> IBM Corporation, New York, NY, USA.

<sup>‡‡</sup> Bone Level, Straumann AG, Basel, Switzerland.



were included in this study, of which 50 were placed in the maxillary right central incisor and 50 in the position of the maxillary left central incisor. The study population included 30 females (60%) and 20 males (40%), with a mean age of  $47.1 \pm 15.8$  years (range: 20.2 to 77.6). Forty subjects were non-smokers, whereas 6 subjects were light smokers (<10 cigarettes/day), 2 subjects were heavy smokers (>10 cigarettes/day), and 2 subjects were former smokers. Implant diameters were as follows: 3.3 mm ( $n = 18$ ) and 4.1 mm ( $n = 82$ ). Implant lengths were as follows: 10 mm ( $n = 42$ ), 12 mm ( $n = 52$ ), and 14 mm ( $n = 6$ ). Implants were supporting a screw- (43%) or cement-retained (57%) prosthesis and restored with either metal-ceramic (60%) or all-ceramic (40%) prostheses. The mean PD values were  $3.9 \pm 0.8$  mm. None of the study implants presented or had a history of peri-implantitis. All sites exhibited minimal signs of inflammation ( $mSBI = 0.15 \pm 0.33$ ). The mean value of KMW was  $3.8 \pm 0.9$  mm. The inter-rater mean FMT values for the DICOM-STL and DICOM groups were  $1.78 \pm 0.63$  mm (range: 0.70 to 3.50 mm) and  $1.88 \pm 0.62$  mm (range: 0.85 to 3.60 mm), respectively. The mean FMT assessed with the non-ionizing US device was  $1.65 \pm 0.72$  mm (range: 0.23 to 3.60 mm).

### 3.2 | Inter-rater reliability

Mean ICC values of 0.97 (95% 0.96 to 0.98) and 0.95 (95% CI: 0.93 to 0.97) were obtained in the DICOM-STL and DICOM groups, respectively, which is indicative of excellent inter-rater reliability agreement. Inter-rater reliability could not be assessed for US measurements as they were obtained by a single examiner.

### 3.3 | Superimposed DICOM-STL files versus non-ionizing US

The comparison between DICOM-STL and US assessments demonstrated good agreement. The mean ICC value between these two modalities was 0.82 (95% CI: 0.74 to 0.88). The mean difference for FMT values was  $-0.13 \pm 0.50$  mm (LOA  $-1.13$  to 0.86), as shown in Table 1 and Figure 4A,D.

### 3.4 | DICOM files versus non-ionizing US

The comparison between the DICOM and US assessments demonstrated good agreement. The mean ICC value between these two modalities was 0.81 (95% CI: 0.73 to 0.87). The mean difference for FMT values was  $-0.23 \pm 0.46$  mm (LOA  $-1.12$  to 0.67), as shown in Table 1 and Figure 4B,E.

### 3.5 | Superimposed DICOM-STL files versus DICOM files

The comparison between the DICOM-STL and DICOM assessments demonstrated excellent agreement. The mean ICC between these two modalities was 0.94 (95% CI: 0.91 to 0.96). The mean difference for FMT values was  $0.1 \pm 0.29$  mm (LOA  $-0.47$  to 0.46) as shown in Table 1 and Figure 4C,F.

## 4 | DISCUSSION

This cross-sectional study aimed at evaluating the reliability and reproducibility of FMT measurements using three non-invasive methods. To the best of our knowledge, this is the first clinical study comparing the superimposition of DICOM-STL files and DICOM files alone between themselves, and with non-ionizing US for the assessment of peri-implant FMT. It must be noted that digital assessment methods (CBCT-STL and CBCT alone) showed an excellent agreement between themselves, whereas a good agreement was observed between these methods and the ultrasound assessment.

Digital workflows utilizing the superimposition of DICOM-STL files or DICOM files alone for periodontal and peri-implant phenotype assessment are non-invasive, highly reliable, and reproducible methods, that have contributed to expanding the scope of research methodologies in the field of implant dentistry.<sup>9,14,17,18,36</sup> However, the presence of blooming effects due to metallic artifacts, and the use of low diagnostic image quality (i.e., deficient machine performance, inadequate file processing, high voxel size, and patient motion during the scanning process) can affect the precision of these assessment modalities.<sup>28,37–39</sup> Non-ionizing US has also been tested as another non-invasive assessment approach, demonstrating adequate reliability.<sup>20,21,40,41</sup> Nevertheless, this method is not widely available, probably because of its cost and limited clinical applicability due to the technical difficulties (i.e., accessibility of posterior areas), narrow field of view, or the need to use a medium for sound conduction.<sup>9,12,20</sup>

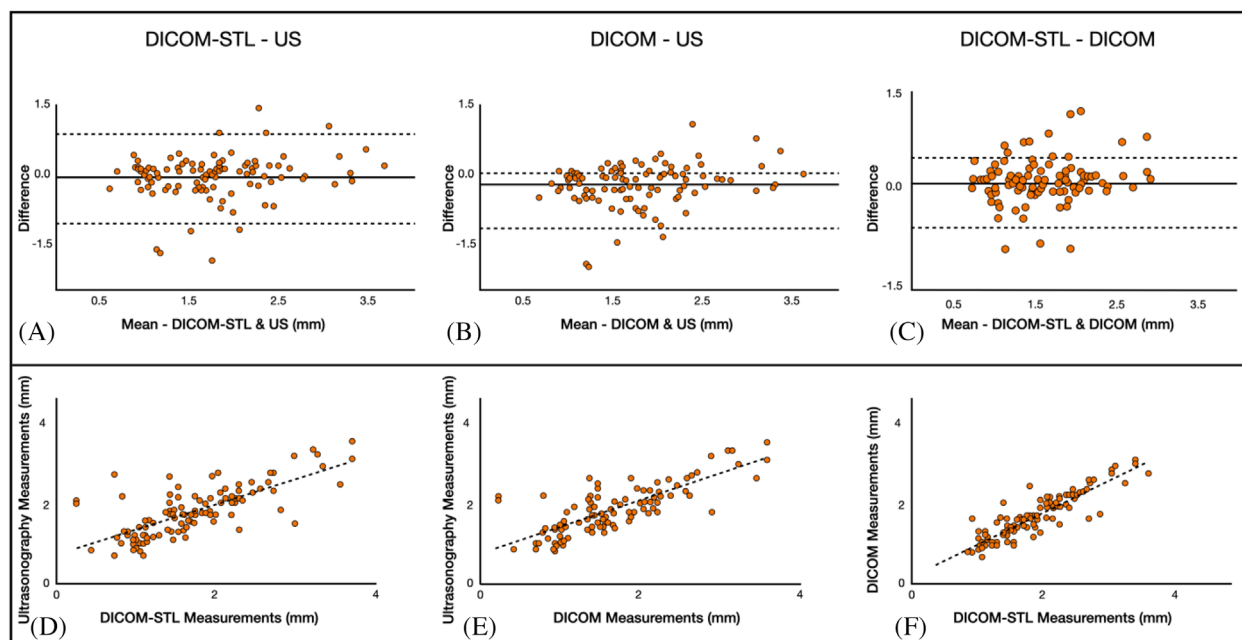
The excellent inter-rater reliability agreement between evaluators with the use of both CBCT-based assessment methods should be highlighted as one of the main observations of this study. This finding agrees with previous studies on this topic evaluating gingival thickness either utilizing superimposed CBCT and STL files<sup>17</sup> or CBCT files alone.<sup>14</sup> In a previous study, excellent inter-rater reliability agreement was demonstrated when the digital superimposition method was used.<sup>17</sup> Similarly, the study by Alves and collaborators reported excellent inter-rater reliability between examiners with the use of DICOM files alone.<sup>14</sup> Although both methods achieved excellent

**TABLE 1** Agreement between different modalities to assess peri-implant mucosal thickness.

N	Group	Mean difference $\pm$ SD (limits of agreement)	ICC	95% confidence interval		P value
				Lower	Upper	
100	DICOM-STL vs. US	$-0.13 \pm 0.50$ ( $-1.13$ to $0.86$ )	0.82	0.74	0.88	$<0.001^*$
100	DICOM vs. US	$-0.23 \pm 0.46$ ( $-1.12$ to $0.67$ )	0.81	0.73	0.87	$<0.001^*$
100	DICOM-STL vs. DICOM	$0.1 \pm 0.29$ ( $-0.47$ to $0.46$ )	0.94	0.91	0.96	$<0.0001^*$

Abbreviations: DICOM, Digital Imaging and Communication in Medicine; ICC, inter-class correlation coefficient; STL, stereolithography; US, ultrasound.

\*Indicates statistical significance ( $P < 0.005$ ).

**FIGURE 4** Bland-Altman and scatter plots depicting the level of agreement (A–C), and correlations (D–F) between different methods of assessment. DICOM, Digital Imaging and Communication in Medicine; STL, stereolithography; US, ultrasound.

reliability according to the mean ICC values in this study, the digital superimposition method rendered slightly superior agreement. This could be explained by the fact that the STL file is a detailed representation of the characteristics of scanned surfaces, which provides a clear outline reference to precisely assess gingival and peri-implant MT. Nevertheless, it must be highlighted that the CBCT scans included in this study for the assessment of FMT did not have the overlapping of soft tissue structures (i.e., lip, cheek), which would have made the assessment of the MT in the DICOM group virtually impossible. Second, the voxel size was set at 0.08 mm for all scans. It is well known that higher voxel sizes may potentially affect the accuracy of the digital assessment of the soft tissue compartment, and the effective digital superimposition of the STL file onto the corresponding CBCT-acquired DICOM file, when the software generates an inadequate alignment.<sup>38</sup> Finally,

it is important to emphasize that DICOM and STL files were adequately merged, and a meticulous calibration and assessment method was followed between the independent examiners prior to conducting the digital measurements. Nonetheless, it can be argued that one of the main limitations of the digital superimposition approach is that it requires time, training, and expertise. Additionally, this method is not exempt from some degree of error and could lead to an unreliable assessment of the soft tissue compartments.<sup>17</sup>

The assessment of the reliability between CBCT-based and non-ionizing US measurements demonstrated good agreement, with mean ICC values of 0.82 and 0.81, and mean differences of  $-0.13 \pm 0.50$  mm and  $-0.23 \pm 0.46$  mm, for the DICOM-STL and DICOM groups, respectively. These findings agree with a previous study by Chan and collaborators where the gingival thickness



values on teeth obtained by an ultrasound device and CBCT were  $0.3 \pm 0.1$  mm versus  $0.5 \pm 0.1$  mm, respectively,<sup>42</sup> and with a study by Tattan et al.<sup>21</sup> where the difference between ultrasound and CBCT was  $-0.213$  mm. Interestingly, a recent study by Ferry and collaborators evaluated the accuracy of transmucosal horizontal sounding with an endodontic file, DICOM files alone, and the superimposition of DICOM-STL files to measure gingival thickness compared to histologic measurements.<sup>18</sup> In that study the authors observed that the clinical assessment method overestimated soft tissue thickness by  $0.22 \pm 0.20$  mm, DICOM files alone underestimated soft tissue thickness by  $-0.23 \pm 0.19$  mm, whereas the digital superimposition approach was similar to the histology assessment, demonstrating a mean difference of  $-0.04 \pm 0.21$  mm.<sup>18</sup> Although other studies have shown good reliability between direct clinical measurements with DICOM-STL file superimposition<sup>19</sup> and ultrasound,<sup>20</sup> we believe that the current study is the first to compare peri-implant MT assessment utilizing the digital superimposition method, DICOM files alone, and an ultrasound device. Our study did not include direct transmucosal horizontal probing measurements to avoid any type of tissue invasiveness.

Analysis of the reliability between CBCT-based assessment methods showed an excellent agreement with a mean ICC value of 0.94, and a mean difference of  $0.1 \pm 0.29$  mm. To the best of our knowledge, no previous studies have compared the superimposition of DICOM-STL with DICOM files around dental implants. We believe that the assessment of periodontal and peri-implant phenotypes utilizing the digital superimposition method should be considered a core methodological component in dental research and could be utilized to evaluate the soft tissue phenotype (i.e., gingival/mucosal thickness) at different apico-coronal levels and soft tissue dimensional changes over time. Findings from this study can be also extrapolated across several clinical applications. Assessment using superimposed DICOM and STL files can be used in daily clinical practice as a non-invasive, reproducible, and reliable method for treatment planning or to assess the outcomes of therapy, among other applications.

This study is not exempt from limitations. First, two central maxillary implants presenting no peri-implant mucosal margin defects greater than 1 mm, and an adequate band of KMW, were included. Therefore, the findings of this study should be interpreted with caution in sites exhibiting peri-implant soft tissue deformities, reduced amount of KMW, or the presence of peri-implant mucositis or peri-implantitis. Second, time spent in the assessment of MT utilizing different assessment methods was not evaluated. This outcome should be included in future well-designed studies, incorporating reproducible

and reliable assessment methods. Third, data from this study cannot be extrapolated to posterior sites, and further studies evaluating the use of three-dimensional digital technologies compared to a non-ionizing US device should be performed in these intraoral locations. Fourth, a polyvinyl siloxane material was used to obtain the intraoral impression of the arch of interest. Although this could be considered a possible limitation, a previously published study concluded that there are no significant differences in terms of accuracy (i.e., precision and trueness) between conventional impressions and intraoral scans.<sup>43</sup> Fifth, although a periodontal probe was used to obtain the FMT at 3 mm apical to the zenith of the mucosal margin with the ultrasonic device, the use of an individual stent is indicated in future studies for better standardization between assessment methods. Sixth, no comparison with a direct method of assessment (i.e., transmucosal horizontal probing with an endodontic file) as a control group was included. Moreover, future studies with dental implants should evaluate the accuracy and precision of non-invasive assessment methods through comparison with direct clinical assessments. Finally, although the CBCT-based assessment groups showed excellent inter-rater reliability agreement, these methods, although not traumatizing for the tissues, have the disadvantage of ionizing radiation exposure and should be used according to the principle of as low as diagnostically acceptable (ALADA) according to the patient's needs.<sup>44</sup>

## 5 | CONCLUSION

Analysis of superimposed DICOM-STL files, DICOM files alone, and US are non-invasive, reliable, and similarly reproducible methods for the assessment of peri-implant MT in patients presenting adjacent implants in the anterior maxilla.

## AUTHOR CONTRIBUTIONS

Emilio Couso-Queiruga conceived and designed the idea. Emilio Couso-Queiruga, Clemens Raabe, Urs C. Belser, Daniel Buser, and Vivianne Chappuis contributed to data acquisition and analysis. Emilio Couso-Queiruga and Vivianne Chappuis led the writing. Gustavo Avila-Ortiz, and Diogo Moreira Rodrigues contributed to the analysis and interpretation of the data, and critically revised the manuscript. All authors gave final approval and agreed to be accountable for all aspects of the scientific work.

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