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**Soft Tissue Measurement Method Using Radiopaque
Material on Cone-beam Computed Tomography:
An Ex Vivo Validation Study**

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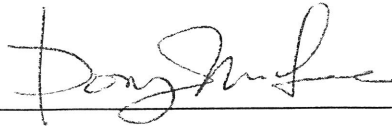
Directed by Professor Dong-Won Lee

The Doctoral Dissertation
submitted to the Department of Dentistry
and the Graduate School of Yonsei University
in partial fulfillment of the requirements for the degree of
Ph.D. in Dental Science

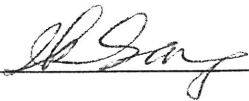
Hae Seok Lee

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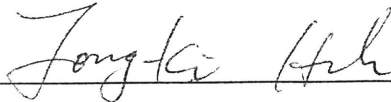
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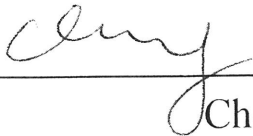
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Abstract

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An Ex Vivo Validation Study**

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Purpose: The Purpose of this study was to investigate the validity and reproducibility of a method based on cone-beam computerized tomography (CBCT) technology for the visualization and measurement of gingival soft tissue dimensions.

Methods: A total of 66 selected points in soft tissue of the ex vivo head of an adult pig were investigated in this study. For the measurement of radiographic thickness (RT), wet soft tissue surfaces were lightly covered with barium sulfate powder using a powder spray. CBCT was taken and DICOM files were assessed for soft tissue thickness measurement at reference points. A periodontal probe and rubber stop were used for the measurement of trans-gingival probing thickness (TPT). After flap elevation, actual thickness of soft tissue (actual thickness, AT) was measured. Correlation analysis and intraclass correlation

coefficients analysis (ICC) were performed for AT, TPT, and RT.

Results: All variables were distributed normally. Strong significant correlations of AT with RT and TPT values were found. The two ICC values between TPT vs. AT and RT vs. AT differed significantly.

Conclusion: Our results indicated that correlation of RT was stronger than that of TPT with AT. We concluded that soft tissue measurement with CBCT could be a reliable method, compared to the trans-gingival probing measurement method.

Keywords: Cone-beam computed tomography, Dimensional Measurement Accuracy, Imaging

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I. INTRODUCTION

Previously, a noninvasive method using a radiopaque material and periapical radiography to measure the vertical length of the interdental papilla in natural tooth and implant was proposed (Lee et al., 2005; Lee et al., 2006; Lee et al., 2009). By using radiopaque material, it was possible to demarcate soft tissue, without underexposing radiography. However, such two-dimensional information limits the assessment of the whole periodontium.

The metric assessment of soft tissue dimensions around teeth and implants is of great

clinical interest for the quantification and monitoring of gingival changes during therapies. Gingival soft tissue dimensions play significant roles in the assessment of whole treatment success, and thus should be monitored all through therapy. A lack of gingival thickness showed a tendency towards loss in attachment levels after traumatic, inflammatory, or surgical injuries (Claffey and Shanley, 1986). Likewise, orthodontic tooth movement may adversely affect the mucogingival complex, especially at sites in which the keratinized gingiva and underlying bone appeared thin (Foushee et al., 1985). Acceptable methods for the accurate quantification of tissue changes when assessing new treatment modalities and materials influencing soft tissues are thus needed (Ronay et al., 2011).

Cone-beam computed tomography (CBCT) is used routinely for imaging analyses of the maxillofacial region (Scarfe et al., 2006). This modality provides clinicians with high-quality diagnostic images and has become an important tool in dentistry. However, the inability of CBCT to distinguish overlapped soft tissues, such as mucogingival thickness on the buccal side of alveolar bone, has limited its application exclusively to the imaging of hard maxillofacial tissues (Guerrero et al., 2006).

Several studies reported using CBCT (Januario et al., 2008; Barriviera et al., 2009; Cao et al., 2015; Silva et al., 2017) for studying soft tissue thickness. Although validation process was not reported, these studies showed us a possibility to study delicate mucogingival soft tissue by retracting overlapped soft tissue. However, one validation study reported that soft tissues less than 0.5mm was not possible to be confirmed in spiral CT, thus making the application of spiral CT in very thin mucosa questionable (Ueno et al., 2011). In this study, we describe a method based on CBCT technology for the visualization and measurement of soft tissue dimensions, after demarcating the soft tissue with radiopaque material. The aim of this study was to investigate the validity and reproducibility of this method.

II. MATERIALS AND METHODS

For this study, the ex vivo head of an adult pig was used. The test sites were confined to the soft tissue around the posterior teeth. Radiographic markers made of radiopaque flowable composite (EsthetXflow A3; Dentsply, Milford, DE, USA) were applied to the enamel cusps of each tooth and light cured (EliparFreeLight 2; 3M ESPE, St. Paul, MN, USA). A total of 22 markers were obtained (Fig. 1). To align CBCT section and actual measurement as close as possible, CBCT cross section contained two composite markers. Actual measurement and trans gingival probing were performed on the imaginary line connecting two composite markers. For the measurement of soft tissue thickness, we chose 9, 12, and 15 mm apical to the flowable composite markers. Thus, a total of 66 selected points in soft tissue were investigated in this study.

1. Testing intra-observer variability

The measurements were done by a single operator. Prior to taking part in the present investigation, intra-observer variability was tested under the supervision of the director. 3 parameters were tested. Thus, 40 arbitrary selected sites on pig mandible were measured with 1) DICOM viewer (Simplant®; Materialise NV, Leuven, Belgium) after CBCT (Voxel size 0.08 mm, Pax-Zenith 3D; Vatech, Seoul, Korea) taking, 2) trans-gingival probing and measuring with caliper, 3) actual soft tissue thickness measurement.

2. Comparison of measuring techniques

1) Experimental group 1

For the measurement of radiographic thickness (RT), wet soft tissue surfaces were covered with barium sulfate powder (SoloTop; Taejoon, Seoul, Korea, Fig. 2), a radiopaque material used as a gastrointestinal contrast medium, using a powder sprayer (Cerec Propellant; VITA Zahnfabrik, Bad Säckingen, Germany). Images were acquired with a CBCT scanner. Scanning parameters were 110 kVp, 24 seconds, 5.7 mA, a voxel size of 0.08 mm, and a field of view of 5cm×5 cm. DICOM files were then assessed on viewer as follows. First, concentric circles of 9, 12 and 15mm diameter were drawn from composite markers. Then, soft tissue thicknesses were measured at the intersection points between circle and soft tissue surface (Fig. 3). All gingival thicknesses were determined at the 0.01 mm level by the software.

2) Experimental group 2

A probes and rubber stop were used for the measurement of transgingival probing thickness (TPT). A periodontal probe (Williams PW, Hu-Friedy, Chicago, IL.) was inserted vertically into the soft tissue surface until resistance of the bone was felt. A rubber stop was placed in contact with the surface to facilitate the measurement of tissue thickness (Wara-aswapati et al., 2001). TPT was measured with digital calipers (Mitutuyo, Tokyo, Japan). All measurements were rounded to the nearest 0.01 mm.

3) Control group

For the measurement of actual thickness (AT), an incision was made onto each marked area. After flap elevation, actual soft tissue thickness was measured using the same method that was used for TPT. All measurements were rounded to the nearest 0.01 mm.

3. Statistical analysis

Statistical analysis was consulted to independent statistician. SAS version 9.2 (SAS Institute, Cary, NC, USA) and MedCalc (MedCalc Software, Ostend, Belgium) version 12.7.0 were used for data analyses. The Kolmogorov–Smirnov test was used to determine whether variables were distributed normally. Correlations of RT and TPT values with AT values were examined using Pearson correlation coefficients. The distributions of variables were examined using dot plots. For reliability analysis, intra-class correlation coefficients (ICC) were calculated (Shrout and Fleiss, 1979) for AT, TPT, and RT. ICC values > 0.75 were considered to have excellent reliability (Fleiss, 1986). To graphically examine the degree of agreement between radiographic and actual measurements, a Bland–Altman plot was constructed, and limits of agreement were calculated for the outcome measure (Bland and Altman, 1999). P-values < 0.05 were considered to be statistically significant.

III. RESULTS

1. Intra-observer variability

The paired t-test revealed no significant difference between the first and second readings. Also, correlation of the two measurements was significant (Pearson correlation coefficient on parameter 1 = 0.99; $P < 0.01$, parameter 2 = 0.96; $P < 0.01$, parameter 3 = 0.97; $P < 0.01$). The intra-observer variability and correlation coefficient were comparable to previous studies (Webber et al., 1990).

2. Comparison of measuring techniques

All variables were distributed normally. Mean AT was 1.568 ± 0.64 mm, mean TPT was 1.759 ± 0.74 mm, and mean RT was 1.654 ± 0.664 mm (Table 1). Coefficients of correlation between TPT and AT, and between RT and AT, were 0.810 and 0.892, respectively (Table 2).

The ICC for TPT vs. AT was 0.87 (95% confidence interval [CI], 0.79–0.92; $p < 0.0001$), and that for RT vs. AT was 0.939 (95% CI, 0.9–0.963; $p < 0.0001$). The two ICC values differed significantly (Table 3).

Figure 4 is a Bland–Altman plot illustrating the degree of agreement between AT and RT values. The mean discrepancy between thicknesses was -0.09 mm. The 95% limit of agreement for thickness was 0.51 to -0.68 mm.

IV. DISCUSSION

The purpose of the present study was to validate a simple and noninvasive method of assessing the dimensions of soft tissues by CBCT. Strong significant correlations of AT with RT and TPT values were found, indicating that both of methods are valid for the assessment of mucogingival soft tissue thickness. However, statistically significant difference was noted comparing coefficient values, indicating that correlation of RT and AT was stronger than that of TPT and AT. Although mean difference between RT and TPT might be minimal (mean difference 0.1 mm) significant difference in correlation with AT suggests that RT might reflect AT better than TPT.

The radiographic measurement method showed good reliability, as indicated by the ICC. This result indicates that measurement error is small compared with the variability between AT and RT values. Comparable results were obtained for TPT. However, the significant difference between ICC values suggests that the radiographic measurements reflect actual gingival thickness than trans gingival probing, which is known to be the gold standard method. The narrow limit of agreement showed that the agreement of RT values was good.

Easy measurements performed with a periodontal probe, e.g., measurement of recession of gingiva, are fast and commonly part of routine diagnostic examination, but they provide limited three-dimensional information. The same applies to the ultrasonic method of soft tissue thickness measurement, which does not provide an overview of the periodontal structures or relationship (Eger et al., 1996).

For the measurement of soft tissue dimensions, trans-gingival probing is commonly used method (Lee et al., 2005). However, this technique must be performed under local anesthesia, which might cause inadvertent volume change and discomfort to the patients. The use of radiopaque material enables the noninvasive measurement of soft tissue width and thickness, thereby allowing more accurate determination of the clinical prognosis. In addition, this method makes it possible to demarcate overlapped tissue area, such as buccal gingiva and cheek. However, possible drawbacks of using radiopaque material exists, such as additional cost for using radiopaque material, blurring of the image, and allergic reaction. These drawbacks should be dealt in depth for the possible routine clinical usage.

A previous study proposed a novel method based on CBCT technology called soft tissue CBCT to determine the relationship of the structures of the dento-gingival unit (Januario et

al., 2008). This method is a more suitable tool for the acquisition of an anatomic overview, and a more painless method to obtain images of the teeth and surrounding periodontal structures, compared with trans-gingival probing. However, verification of the method was not reported, and soft tissue dimensions can be underestimated considerably, depending on scan settings and tissue thickness (Ronay et al., 2011). Nevertheless, CBCT is part of the standard protocol for diagnosis and treatment planning in difficult cases with special questions. As correlation between bone and soft tissue is becoming important topic, this technique could play an increasingly significant role in dentistry as it is developed further.

In this study, we verified a method that utilizes the advantages of CBCT while overcoming disadvantages of this modality for the metric assessment of soft tissue dimensions around teeth and implants. Although additional research is needed to determine the proper concentration of contrast medium, the findings of this study suggest an opportunity to increase the usefulness for CBCT.

V. CONCLUSION

In conclusion, the results of the present study suggest that soft tissue measurement with CBCT and radiopaque material could be a reliable method, compared to the trans-gingival probing measurement method, with good validity and reproducibility.

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TABLES

Table 1. Mean value and standard deviation for clinical measurements (mm) (n = 66).

Variables	Mean \pm SD
Actual Thickness	1.568 \pm 0.64
Transgingival probing Thickness	1.759 \pm 0.74
Radiographic Thickness	1.654 \pm 0.664

SD: standard deviation.

Table 2. Correlation coefficients with Actual thickness and Correlation comparison.

	TPT:AT	RT:AT	Correlation comparison (<i>P</i> -value)
<i>r</i>	0.80951	0.89217	0.0103

TPT: Transgingival probing Thickness; AT: Actual Thickness; RT: Radiographic Thickness;
r: Pearson's correlation coefficient.

Table 3. The intraclass correlation (ICC) with Actual thickness and ICC comparison

Variables	TPT		RT		ICC comparison (<i>P</i> -value)
	ICC (95% CI)	<i>P</i> -value	ICC (95% CI)	<i>P</i> -value	
ICC	0.87(0.788-0.92)	<.0001	0.939(0.9-0.963)	<.0001	0.0249

CI: confidence interval.

TPT: Transgingival probing Thickness; AT: Actual Thickness; RT: Radiographic Thickness;
r: Pearson's correlation coefficient.

FIGURES

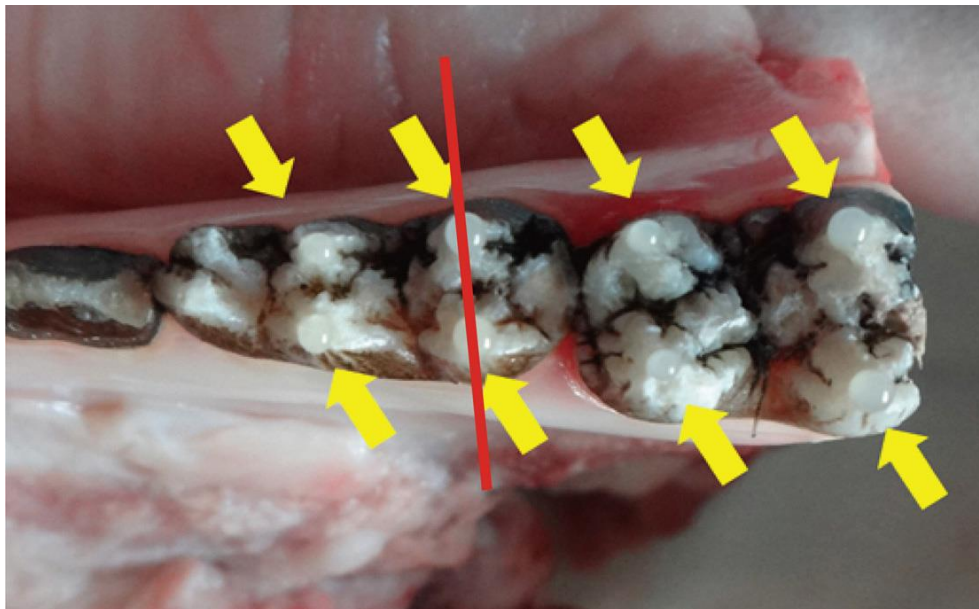


Figure 1. Radiopaque flowable composite markers were attached to the enamel (yellow arrows). Red line indicates imaginary line connecting two composite markers. These line will be the CBCT cross section and AT and TPT will be performed.



Figure 2. Barium sulfate powder was sprayed on soft tissue surface.

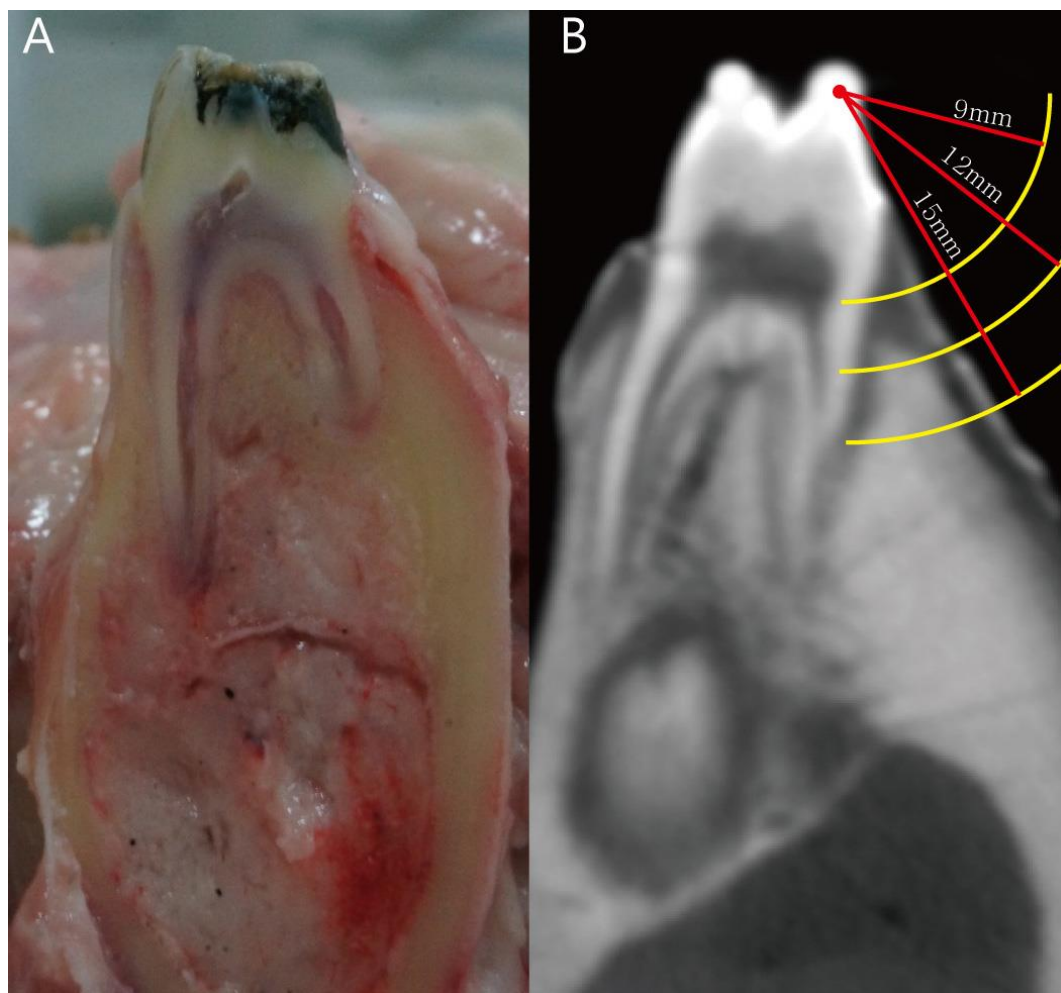


Figure 3. Actual cross section of pig mandible (A) and CBCT image (B). Measurements were done 9 mm, 12 mm, 15 mm apical from the markers.

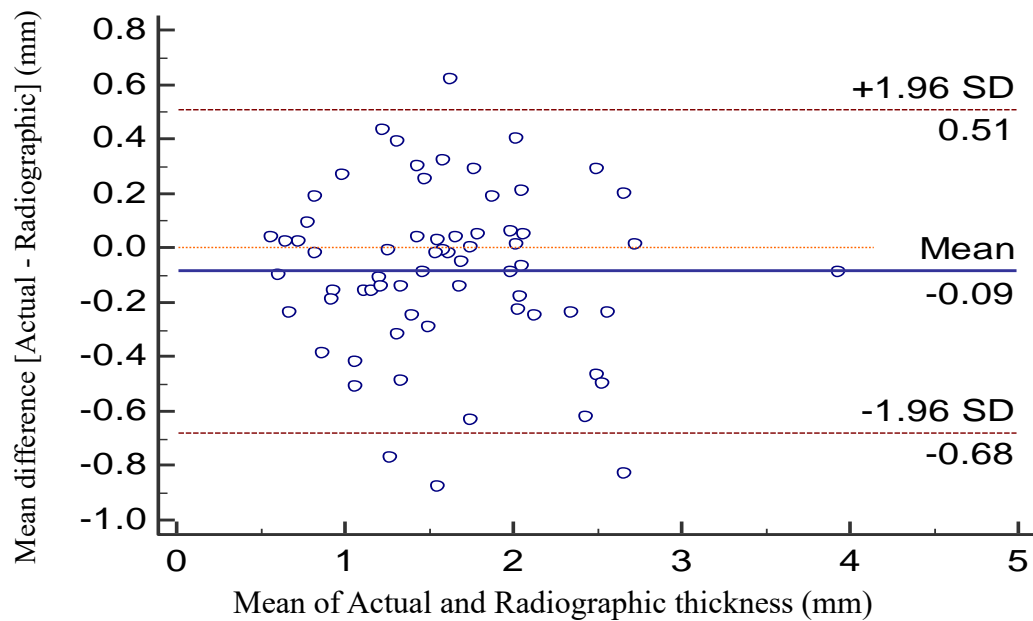


Figure 4. Bland-Altman plots portraying the agreement between Actual and Radiographic measurements for soft tissue thickness. The solid line indicates the mean difference between actual and radiographic measurements; dashed line shows the 95% limits of agreement.

국문요약

콘빔 전산화 단층촬영에서의 방사선불투과성 물질을 이용한 연조직 계측 방법: 유효성 연구

<지도교수 이 동 원>

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이 해 석

과거, 방사선 불투과성 물질과 치근단 사진을 이용하여 자연 치아 및 임플란트에서 치간유두의 수직 길이를 측정하는 방법이 제안되었다. 방사선 불투과성 물질을 사용함으로써, 연조직의 경계를 측정하는 것이 가능했지만 전체 치주조직의 이차원적 평가라는 한계가 존재하였다.

치아와 임플란트 주변의 연조직에 대한 양적 평가는 치료 중 치주조직 변화의 정량화 및 모니터링에 있어서 큰 임상적 관심사이다. 치주 연조직 크기는 전체 치료 성공의 평가에 중요한 역할을 하며, 따라서 치료 기간동안 항상 모니터링해야 한다. 치주 조직 두께의 부족은 외상, 염증 또는 외과적 상해 이후에 부착수준의 감소의 결과를 나타내는 경향이 있다. 마찬가지로, 치아의 교정 이동이 치주 점막복합체에 악영향을 줄 수 있으며 이는 부착지은과 치조골 사이가 얇은 부위에서 도드라지게 나타난다. 따라서 연조직에 영향을 주는 새로운 치료 방법과 물질을 평가할 때 연조직 변화의 정확한 정량화를 위한 허용가능한 방법이 필요하다.

콘빔 전산화 단층촬영은 악안면 영역의 시각적 분석에 일반적으로 사용된다. 이것은 임상 의에게 고품질의 진단 이미지를 제공하였고 치과에서 중요한

도구가 되었다. 하지만 연조직의 중첩을 구별하는데 있어서 한계가 있었고 이는 주로 악안면부 경조직의 진단에만 사용하게 되는 이유가 되었다.

연조직 두께를 측정하기 위한 많은 연구가 있었고 이러한 연구 들에서 중첩된 연조직을 배제하여 세밀한 치주 연조직을 측정할 수 있는 가능성을 보여주었다. 그러나 한 유효성 검사 연구에서 0.5mm 미만의 연조직이 나선형 전산화 단층촬영에서 확인할 수 없다는 것을 보고하였기 때문에 매우 얇은 점막에서 나선형 전산화 단층촬영의 적용을 의심하게 한다. 이 연구에서는 방사선 불투과성 물질로 연조직을 구분한 뒤 연조직 크기의 시각화 및 측정을 위한 콘빔 전산화 단층촬영 기술을 기반으로 하는 방법을 제안한다. 이 연구의 목적은 이 방법의 타당성과 재현성을 조사하는 것이다.

죽은 성인 돼지 머리의 치주 연조직에서 총 66 개의 기준점을 선택해 조사하였다. 방사선학적 두께의 측정을 위해 연조직 표면은 황산염 분말을 스프레이를 이용하여 가볍게 도포하였다. 콘빔 전산화 단층촬영을 하고 DICOM 파일을 평가하여 각각의 기준점에서의 연조직 두께를 측정하였다. 그리고, 치주 탐침을 이용하여 각각의 기준점에서 연조직 탐침 깊이를 측정하였다. 마지막으로 피판을 거상하여 실제 연조직의 두께를 측정하였다. 이 세가지 측정값에 대하여 상관 관계 분석과 급내 상관 계수 분석을 수행하였다.

모든 측정값은 정상적으로 분포되었고 유의한 상관관계가 나타났다. 탐침 깊이 측정값과 방사선학적 측정값의 급내 상관 계수는 유의할 만한 차이를 보여주었다.

이 결과는 방사선학적 측정값이 전통적인 탐침 깊이 측정값보다 강한 상관 관계를 보여준다. 우리는 콘빔 전산화 단층 촬영을 이용한 연조직 측정방법이

치주 탐침 깊이 측정 방법에 비하여 신뢰할 만한 방법이 될 수 있다고 결론을 내렸다.

핵심되는 말: 콘빔 전산화 단층 촬영, 부피 계측 정확도, 시각화