STUDY PROTOCOL, STATISTICAL ANALYSIS PLAN, AND INFORMED CONSENT FORM

Study Title

In-Vivo Diagnostic Accuracy and Repeatability of Root ZX3 for Working-Length Determination in Single-Rooted Teeth: Agreement with CBCT and Microscopic Validation

ClinicalTrials.gov Identifier

NCT07689838

Principal Investigator

Abier Fahad M. Alhekeir

Date

12 October 2026

Study Protocol

3.1 Study Design and Blinding

This mixed in vivo/in vitro diagnostic accuracy study evaluated the precision, accuracy, and agreement of the Root ZX3 EAL (J. Morita Corp., Tokyo, Japan) for WL determination in permanent teeth with different pulpal and periapical diagnoses scheduled for extraction. In the in vivo phase, WL was measured clinically using the Root ZX3 before extraction. Following extraction, the in vitro phase was conducted on the same teeth under controlled conditions. CBCT using the Axeos system (Dentsply Sirona, Bensheim, Germany) was used as a comparative 3D imaging method for WL estimation, and the actual WL was determined under a 3D digital microscope (Hirox MXG-5040RZ, Hirox Co., Tokyo, Japan) and considered the reference standard.

For standardization, reproducible coronal reference points and the AF were used consistently for measurements obtained by the three methods to allow direct comparison. In teeth with multiple foramina, the major AF corresponding to the main canal pathway was used as the reference apical point.

Repeated Root ZX3 measurements for assessment of intra-operator reliability were performed by the same operator without blinding, as the measurements were obtained during the same clinical session. A randomly selected subset of CBCT scans was independently re-evaluated by a second examiner to assess inter-observer reliability.

CBCT and digital microscopy measurements were performed independently by examiners blinded to the EAL results, pulpal and apical diagnoses, patient identifiers, and to the results obtained from the other measurement methods.

3.2 Ethical Considerations

The study was conducted following approval from the Institutional Review Board (IRB) of Riyadh Elm University (REU), Approval No. FPGRP/2025/930/1310/1207 (Appendix A). Additional approval was obtained from the Executive Department of Medical Devices Evaluation, Medical Devices Sector, Saudi Food and Drug Authority (SFDA), Application No. 2529, issued on 19 October 2025 (Appendix B). The study was conducted in accordance with the principles of the Declaration of Helsinki.

All participants were informed about the purpose, procedures, potential risks, and benefits of the study and provided written informed consent prior to participation (Appendix C). Participation was voluntary, and participants had the right to withdraw at any time without any impact on their planned treatment. Eligibility was confirmed through review of the participants' medical and dental history (Appendix D).

All data were coded using unique identifiers, securely stored, and handled with strict confidentiality. No personally identifiable information was included in any reports or publications.

3.3 Study Setting and Sampling

The study was conducted at REU Hospitals, Al-Namuthajiyah Campus, Riyadh, Saudi Arabia, between October 2025 and March 2026. A convenience sample of 41 patients requiring tooth extraction for clinical indications was included. Extractions were performed in the Oral and

Maxillofacial Surgery Department at REU Hospitals for reasons including orthodontic and prosthodontic treatment requirements. A formal a priori sample size calculation was not performed because the study used a convenience sample of teeth scheduled for extraction. All eligible cases available during the study period were included.

A total of 77 single-rooted teeth (one canal each) were included, with each tooth contributing one canal to the analysis. The tooth was considered the unit of analysis, and each included tooth contributed Root ZX3, CBCT, repeated Root ZX3, actual WL, and pulpal and apical diagnostic data for evaluation.

The study was divided into three phases: (1) a clinical phase involving pulpal and periapical status assessment and in vivo Root ZX3 measurements in the Oral and Maxillofacial Surgery Department; (2) a radiographic phase involving CBCT WL assessment in the radiology unit; and (3) a laboratory phase involving digital microscopy for actual WL determination serving as the reference standard.

3.4 Inclusion and Exclusion Criteria

3.4.1 Participant Selection Criteria

Participants were included if they were aged 18 years or older, classified as American Society of Anesthesiologists (ASA) physical status I or II based on medical history, and able to provide written informed consent.

Participants were excluded if they were under 18 years of age, classified as ASA physical status III or higher, unable to provide informed consent, or had any contraindication to tooth extraction or anticipated complications during the procedure, including teeth deemed difficult to extract or

at risk of intraoperative complications. Participants with known allergies to the materials used in the study were also excluded.

3.4.2 Tooth Selection Criteria

Single-rooted permanent teeth with a single canal were included if they were indicated for extraction for reasons unrelated to the study and presented with fully developed apices. Teeth with minimal root curvature (<20°) were included (Schneider, 1971). Teeth in which a K-file could be advanced apically were included, and a stable “0.0” reading at the AF was subsequently confirmed using the Root ZX3 EAL. Teeth with conditions associated with alterations in canal morphology or apical anatomy affecting WL determination were excluded, including those with previous endodontic treatment, recent trauma, horizontal or vertical root fracture, hypercementosis, or root resorption. Teeth with root curvature ≥20° were excluded. Additionally, teeth with extensive restorations that could interfere with electronic measurements, obliterated canals, or cases where proper rubber dam isolation could not be achieved were excluded.

3.5 In Vivo Study Protocol

3.5.1 Device Description

The Root ZX3 EAL (J. Morita Corp., Tokyo, Japan), a Class II medical device approved by the U.S. Food and Drug Administration (Regulation No. 872.4920), was used in this study. The device uses impedance-based measurements at two frequencies to determine the position of the file relative to the AF for WL determination. It includes automatic calibration and a regulated current output. The device was used according to the manufacturer’s instructions.

3.5.2 Pre-operative Assessment

Participants were informed about the nature and purpose of the study, and written informed consent was obtained prior to enrollment. Medical and dental histories were reviewed to confirm eligibility (Appendix F).

Following patient enrollment, clinical examination was carried out to establish the pulpal and periapical diagnosis prior to WL measurement. This included sensibility testing using a cold test (Endo-Frost; Coltene/Whaledent), as well as percussion, palpation, and biting tests. Pulpal and apical diagnoses were based on clinical findings, supported by periapical radiographs where applicable Diagnoses were recorded according to the *Glossary of Endodontic Terms* (AAE, 2020) using a standardized data collection sheet (Appendix G).

3.5.3 Working Length Measurement Using Root ZX3

EAL measurements using the Root ZX3 were performed by a single calibrated operator. Following informed consent, local anesthesia (2% lidocaine with 1:100,000 epinephrine) was administered as required, and the tooth was isolated with a rubber dam. An access cavity was prepared using diamond burs and a high-speed handpiece to fully deroof the pulp chamber and locate the canal orifices. Orifice pre-flaring was performed using ProTaper SX (Dentsply Sirona, Ballaigues, Switzerland). Canal debridement and irrigation were carried out using 2.5% NaOCl, and excess irrigant was removed from the pulp chamber using cotton pellets prior to WL measurement (Dunlap et al., 1998; Figure 5).



Figure 5.
Instruments used for working length measurement with the Root ZX3.

A size 10–15 K-file that could passively negotiate the canal and be advanced apically without excessive resistance was selected. The lip clip was attached to the patient, and the file holder was connected to the K-file. Canal patency was confirmed by gently advancing the file slightly beyond the AF, as indicated by the Root ZX3 EAL, after which the file was withdrawn. The file was gradually advanced within the canal until a stable “0.0” reading, indicating the AF, was obtained and maintained for at least five seconds (Oliveira et al., 2017). If a stable electronic reading could not be achieved, or if apical patency was not confirmed, the tooth was excluded from the study.

The rubber stopper was adjusted to a stable coronal reference point at the incisal edge for anterior teeth and the buccal cusp tip for premolars. This reference point was maintained for all subsequent measurements, and the file was then withdrawn. The WL was measured from the rubber stopper to the file tip using a digital caliper with an accuracy of ±0.01 mm and recorded

in a data collection sheet (Appendix G). The measurement was then repeated under the same conditions using the same reference point and digital caliper. The repeated measurement was recorded for assessment of intra-operator reliability.

3.5.4 Risk Considerations

Operator calibration for EAL measurements was performed prior to the study through training and standardization of the measurement protocol under the supervision of a consultant endodontist during clinical procedures to ensure consistency of measurements. The Root ZX3 device was checked before each use, including verification of device functionality and battery status.

Risks to participants were minimal, as all included teeth were already indicated for extraction as part of routine clinical care. No additional invasive procedures were performed beyond standard treatment, and any inaccuracy in WL measurement did not influence the treatment plan or clinical decision-making.

3.5.5 Extracted Teeth Handling

Following completion of the *in vivo* phase, the teeth were extracted in the Oral and Maxillofacial Surgery Department at REU Hospitals. The specimens were cleaned of visible debris and disinfected in 5.25% NaOCl for 15 minutes. After disinfection, the specimens were rinsed and stored in labeled containers containing saline solution at room temperature (Cury et al., 2021).

Each specimen was assigned a unique identification number to ensure accurate tracking of the corresponding clinical diagnoses and measurement data throughout the study.

A biological sample receipt and disposal form was completed for each specimen and submitted to the research supervisor and documented at the REU Research Center (Appendices E and F).

3.6 In Vitro Protocol

3.6.1 Working Length Measurement Using CBCT

The extracted teeth were mounted in a utility wax block during CBCT scanning without placement of an intracanal file, to avoid beam hardening and streaking artifacts that could obscure identification of the AF and compromise measurement accuracy (Figure 6). CBCT scanning was performed using the Axeos system (Dentsply Sirona, Bensheim, Germany) with a FOV of 5 × 5.5 cm. Imaging was carried out at 85 kVp (kilovoltage peak) and 6 mA (milliampere), with a voxel size of 0.3 mm, and an exposure time of 14.4 seconds (Figure 7).



Figure 6.
Extracted teeth mounted in a utility wax block for CBCT scanning.



Figure 7.
CBCT scanning setup using the Axeos system.

All CBCT measurements were performed using Sidexis 4 software in ENDO mode (Dentsply Sirona, Bensheim, Germany) by a single calibrated operator who was blinded to the Root ZX3 EAL and actual WL measurements. For each tooth, the image was adjusted to align the long axis of the root. The canal was examined in axial, coronal, and sagittal planes to ensure visualization of the entire canal path. WL was measured in the sagittal view from a reproducible coronal reference point to the AF, following the canal curvature (Izadi et al., 2024) (Figure 8).

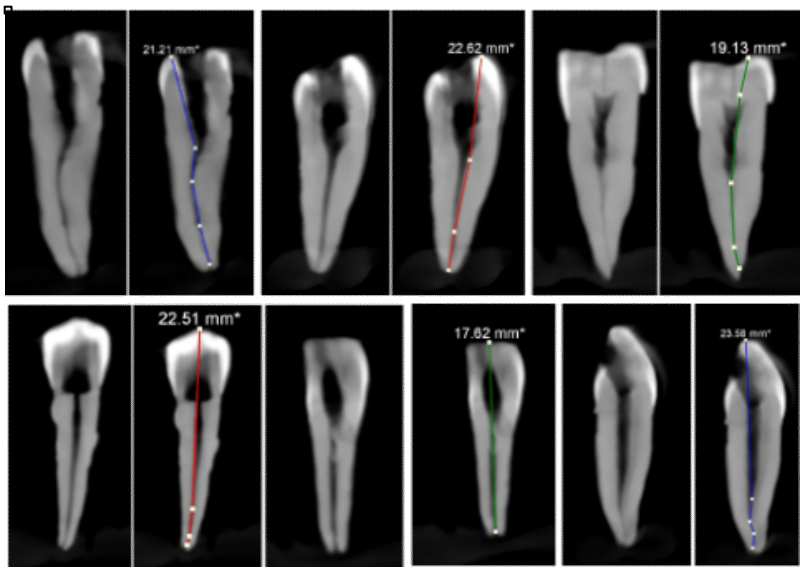


Figure 8.
CBCT working length measurement using ENDO mode in Sidexis 4 software.

Prior to measurement, the primary operator was calibrated under the supervision of a consultant endodontist. All measurements were performed using the same reference point and measurement approach for all teeth and recorded in a data collection sheet (Appendix G). A randomly selected subset of 20 CBCT images was re-evaluated by a consultant endodontist who was blinded to the initial CBCT and EAL results to assess inter-observer reliability.

.

3.6.2 Actual Working Length Determination

The AF was visualized under a Hirox MXG-5040RZ digital microscope at ×50 magnification (Figures 9 and 10). A size 10–15 K-file was advanced within the canal until the file tip was flush with the AF (Izadi et al., 2024) (Figure 11).

The rubber stopper was adjusted to the same coronal reference point, and the file was carefully withdrawn. The distance from the rubber stopper to the file tip was measured using a digital caliper with an accuracy of ±0.01 mm and recorded as the actual WL (Figure 12). Actual WL measurements were performed once by the primary operator, who was blinded to the EAL and CBCT measurements.

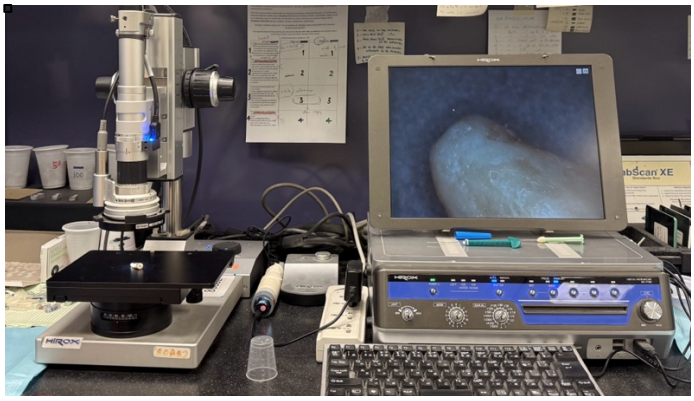


Figure 9.
Hirox digital microscope used for visualization of the apical foramen.



Figure 10.
Apical foramen visualized under digital microscopy at ×50 magnification.



Figure 11.
File tip positioned flush with the apical foramen under digital microscopy.



Figure 12.
Measurement of actual working length using a digital caliper.

3.7 Outcome Measures

The principal study variables included Root ZX3 WL, repeated Root ZX3 WL, CBCT WL, second-examiner CBCT WL, actual WL, and pulpal and apical diagnoses. All WL measurements were recorded in mm, and all variables were documented in the data collection sheet (Appendix G).

The actual WL determined under 3D digital microscopy served as the reference standard. Measurement error for Root ZX3 and CBCT measurements was calculated relative to the actual WL as:

$$Measurement\ error\ (mm) = Measured\ WL - Actual\ WL$$

The main error variables were signed and absolute measurement errors. Signed error was calculated as the difference between the method measurement and the actual WL, where negative values indicated underestimation and positive values indicated overestimation. Absolute error was calculated as the absolute value of this difference and was used to assess the magnitude of deviation regardless of direction.

The primary outcomes were the accuracy of WL measurements obtained using Root ZX3 and CBCT, expressed as signed and absolute measurement errors and as the proportion of measurements within ±0.5 mm and ±1.0 mm of the actual WL.

Secondary outcomes included intra-operator reliability of Root ZX3 measurements, agreement between Root ZX3 and CBCT measurements, inter-observer agreement of CBCT measurements, and the influence of pulpal and apical status on Root ZX3 measurement accuracy.

3.8 Data Management

Data were recorded on paper data collection sheets and subsequently entered into a Microsoft Excel spreadsheet (Appendix G). Each tooth was assigned a unique identification number, and no patient identifiers were included in the analysis dataset.

Teeth were included in the analysis if complete pulpal and apical diagnostic data and Root ZX3, CBCT, and actual WL measurements were available. Teeth with incomplete required measurements were excluded from the relevant analyses. Categorical variables, including tooth type and pulpal and apical diagnoses, were coded numerically for statistical analysis. Derived variables, including signed error, absolute error, and accuracy within ±0.5 mm and ±1.0 mm thresholds, were calculated as described in Section 3.7.

Statistical Analysis

All statistical analyses were performed using R version 4.6.0 (R Core Team, R Foundation for Statistical Computing, Vienna, Austria). The statistical analysis plan was structured according to the study objectives. Statistical significance was evaluated using a two-sided alpha level of 0.05.

3.9.1 Descriptive Analysis

Continuous variables were summarized using mean, standard deviation (SD), median, minimum, maximum, and interquartile range (IQR). Categorical variables were summarized using frequencies and percentages. These descriptive analyses were used to characterize demographic variables, tooth characteristics, extraction-related variables, pulpal and apical diagnoses, measurement distributions, and completeness of the dataset.

3.9.2 Normality Assessment

Normality of measurement error variables was assessed using the Shapiro–Wilk test. Although measurement error distributions deviated from normality, paired t-tests were used because they are considered robust to moderate departures from normality in paired samples of this size.

3.9.3 Paired Method Comparison

Paired t-tests were used to compare mean differences between Root ZX3 and actual WL, CBCT and actual WL, and Root ZX3 and CBCT.

3.9.4 Diagnostic Accuracy Estimation

Clinical accuracy was calculated as the proportion of teeth with Root ZX3 or CBCT measurements within the predefined ±0.5 mm and ±1.0 mm thresholds from the actual WL. Accuracy was reported as counts and percentages. McNemar's test was used to compare paired accuracy classifications between Root ZX3 and CBCT.

3.9.5 Bland–Altman Analysis

Agreement between measurement methods was assessed using Bland–Altman analysis. For each paired comparison, the mean bias was calculated as the mean paired difference, and the 95% limits of agreement were calculated as the mean bias ± 1.96 × SD of the paired differences. Bland–Altman analysis was performed to evaluate agreement between Root ZX3 and actual WL, CBCT and actual WL, Root ZX3 and CBCT, repeated Root ZX3 measurements, and CBCT measurements between the two examiners. A stratified Bland–Altman plot was also generated for Root ZX3 and actual WL based on combined clinical status.

3.9.6 Concordance Analysis (Lin's CCC)

Lin’s concordance correlation coefficient (CCC) was used to assess concordance between continuous measurement methods by evaluating both precision and deviation from perfect agreement. Concordance analysis was performed for Root ZX3 versus actual WL, CBCT versus actual WL, and Root ZX3 versus CBCT.

3.9.7 Reliability Analysis

Intra-operator repeatability of Root ZX3 measurements was assessed using repeated Root ZX3 measurements. Reliability was evaluated using the intraclass correlation coefficient (ICC). In addition, repeated-measurement agreement was assessed using Bland–Altman analysis and the repeatability coefficient. The repeatability coefficient was calculated as 1.96 × SD of the paired differences and was used to estimate the expected range of variation between repeated measurements.

CBCT inter-observer agreement was evaluated using paired measurements obtained from a randomly selected subset of 20 teeth assessed by two CBCT examiners. Inter-observer reliability

was assessed using ICC, Bland–Altman analysis, and the repeatability coefficient. This analysis was restricted to teeth with complete paired CBCT examiner measurements.

3.9.8 Subgroup Analysis

Pulpal and apical diagnoses were recorded descriptively and categorized for statistical analysis as vital versus necrotic pulp and presence or absence of apical periodontitis. Subgroup analyses were therefore based on combined clinical status categories rather than isolated pulpal or apical conditions.

Subgroup analysis was performed to compare Root ZX3 measurement error across different pulpal and apical status categories. Signed and absolute Root ZX3 errors were summarized according to pulpal and apical status groups. Group comparisons were conducted using independent samples t-tests, and findings were interpreted with consideration of the observed data distribution.

3.9.9 Graphical Analysis

Graphical analysis was used to support data visualization and exploratory assessment. Accuracy plots were used to compare the proportion of measurements within clinical tolerance thresholds. Boxplots with individual data points were used to display absolute measurement error according to method and clinical status. Bland–Altman plots were used to assess systematic bias and limits of agreement between measurement methods. Density plots and individual-error plots were used to examine the distribution and clinical magnitude of signed Root ZX3 measurement errors.

3.9.10 Missing Data Handling

Missing data were evaluated before conducting the analyses. Complete-case analysis was used for each statistical procedure based on the variables required for that analysis. Accordingly, each analysis included only observations with the necessary paired measurements. No imputation was performed because the primary Root ZX3, CBCT, and actual WL variables required direct paired comparisons, and substitution of missing values was not considered appropriate for diagnostic accuracy or agreement analyses.

CBCT inter-observer agreement was analyzed separately because second-examiner CBCT measurements were available only for a subset of teeth. Therefore, this analysis was restricted to teeth with complete paired CBCT examiner measurements and was treated as a secondary subset analysis.

INFORMED CONSENT FORM

Appendix B
SDFA Approval Letter

جامعة رياض العلم
RIYADH ELM UNIVERSITY
مركز البحوث والابتكار
Research and Innovation Center

Informed Consent to Participate / نموذج موافقة للمشاركة

- You are invited to participate in this research study conducted at Riyadh Elm University Hospital.
- The purpose of this consent form is to explain the details of the study, the procedures involved, the potential risks and benefits, as well as your rights and responsibilities as a participant.

- ندعوك للمشاركة في هذه الدراسة البحثية التي تُجرى في جامعة رياض العلم.
- الغرض من هذا النموذج هو أن يوضح لك تفاصيل الدراسة، إجراءاتها، الفوائد والمخاطر المحتملة، بالإضافة إلى حقوقك وواجباتك كمشارك.

Study Title/ عنوان الدراسة

Precision of Root ZX3 Electronic Apex Locator for Working Length Estimation in Pulp and Apical Diseases Validated by Cone Beam Computed Tomography: *A Mixed In Vivo/In Vitro Diagnostic Accuracy Study*

دراسة دقة تشخيص جهاز *Root ZX3* لتحديد طول قناة الجذر في علاج مختلف أمراض اللب وذروة الجذر باستخدام التصوير المقطعي

Purpose of the Study

This study aims to evaluate the accuracy of the electronic apex locator in determining the working length of the root canal in various pulp and periapical diseases, and to assess whether the nature of these conditions affects the device's performance.

الغرض من الدراسة

تهدف هذه الدراسة إلى تقييم كفاءة جهاز قياس طول القناة العصبية في تحديد الطول العامل للقناة الجذرية في مختلف أمراض اللب وذروة الجذور، ودراسة ما إذا كانت طبيعة هذه الأمراض تؤثر على دقة الجهاز.

Participant Rights

- Your participation in this study is entirely voluntary. You have the right to refuse or withdraw from the study at any time, without affecting your treatment plan or the quality of care provided.
- You have the right to receive a full explanation of all details of the study, and any questions you have will be answered clearly.
- All your personal and medical information will be kept strictly confidential and will only be used for research purposes; it will not be shared with anyone outside the research team.
- You have the right to receive medical care for any complications that may arise from your participation.
- You may request to view the general results of the study after it is completed.
- There will be no financial cost to you for participating in this study.

حقوق المشارك

- مشاركتك في هذه الدراسة طوعية بالكامل، ولك الحق في رفض أو الانسحاب في أي وقت دون أي تأثير على خطتك العلاجية (الخلع) أو جودة الرعاية المقدمة.
- لك الحق في توضيح كامل لكافة تفاصيل الدراسة، وأي استفسار سيتم الإجابة عليه بوضوح.
- ستُعامل كافة معلوماتك الشخصية والطبية بسرية تامة ولن تُستخدم إلا لأغراض البحث و لن تُشارك مع أي شخص أو جهة خارج الفريق البحثي.
- لك الحق في الحصول على الرعاية الطبية لأي مضاعفات تنشأ بسبب مشاركتك.
- يمكنك طلب الاطلاع على النتائج العامة للدراسة بعد انتهائها.
- لن تتحمل أي تكاليف مالية مقابل المشاركة في هذه الدراسة.

Benefits

This study seeks to contribute to the improve the scientific understanding and provide evidence on the extent to which pulp and periapical diseases affect .the accuracy of electronic apex locators

الفوائد

تسعى هذه الدراسة إلى المساهمة في تطوير المعرفة العلمية حول مدى تأثير أمراض اللب وذروة الجذر على دقة أجهزة قياس طول القناة العصبية.

Appendix C
Informed Consent Form

جامعة رياض العلم
RIYADH ELM UNIVERSITY
مركز البحوث والابتكار
Research and Innovation Center

Potential Risks

- The procedures in this study will be performed on the tooth scheduled for extraction for therapeutic reasons, after obtaining your prior consent for its removal.
- You may experience mild discomfort during the procedure, similar to what is normally encountered during routine dental care. No known or expected complications are associated with this procedure.
- The study procedures will not affect the tooth extraction process in any way and will not increase the risks associated with the extraction itself.

Procedure

1. **Removal of the pulp tissue.**
2. **Determination of the root canal working length** using an Electronic Apex Locator.
3. **The tooth will be extracted** according to the approved treatment plan, and it will be preserved by the researcher for study purposes.

Note: These procedures will be performed prior to the planned extraction and will not affect, delay, or alter the extraction process.

If You Choose Not to Participate

- You will receive the planned medical treatment (tooth extraction) without any change.
- Your refusal will not affect the quality of medical care provided to you.

Termination of the Study

If it is not possible to take the measurement for any reason, or if the participant requests to withdraw, the patient's original treatment plan will proceed as scheduled, and the participant's involvement in the study will end immediately.

Consent

- I have read and understood the information provided in this consent form.
- I voluntarily agree to participate in this study.
- I have been provided with a copy of this document and a contact number in case I have any questions regarding the research.

Participant Name:
Participant Signature:

Researcher Name:
Researcher Signature:
Date:

المخاطر المحتملة

- ستُجرى الإجراءات في هذه الدراسة على السن المقرر خلعه لأسباب علاجية، بعد الحصول على موافقتك المسبقة على خلع السن.
- قد تشعر بانزعاج طفيف أثناء الإجراء، يشبه ما يحدث عادة أثناء الرعاية السنية الاعتيادية.
- لن تؤثر إجراءات الدراسة على عملية خلع السن بأي شكل، ولن تزيد من المخاطر المرتبطة بالخلع نفسه..

الإجراء

1. **إزالة نسيج اللب.**
2. **تحديد طول قناة الجذر** باستخدام الجهاز الإلكتروني لتحديد قمة الجذر.
3. **خلع السن** حسب الخطة العلاجية، مع الاحتفاظ بالسن مع الباحث لاستكمال البحث.

تنويه: ستتم هذه الإجراءات قبل الخلع المقرر، ولن تؤثر على عملية الخلع أو تؤخرها أو تغير من سيرها بأي شكل.

في حال رفض المشاركة

- ستتلقى العلاج الطبي المقرر لك مسبقًا (الخلع) دون أي تغيير.

الإنهاء من للدراسة

إذا تعذّر أخذ القياس لأي سبب أو طلب المشارك التوقف عن المشاركة، فسيتم متابعة خطة العلاج الأساسية للمريض كما هو مخطط لها، وتنتهي مشاركة المشارك في الدراسة فورًا.

الموافقة

- لقد قرأت وفهمت المعلومات الواردة في نموذج الموافقة هذا.
- أوافق طواعية على المشاركة في هذه الدراسة.
- قد تم تزويدي بنسخة من هذا المستند، ورقم للتواصل في حال وجود أي استفسار حول البحث.

اسم المشارك:
توقيع المشارك:

اسم الباحث:
توقيع الباحث:
تاريخ:

Appendix D
Medical and Dental History Form (English)

Patient Information

File number: Date of Birth: Gender:

Medical History

Check all that apply:

- ☐ Heart disease
- ☐ Hypertension
- ☐ Stroke
- ☐ Cardiac pacemaker
- ☐ Implantable cardiac defibrillator
- ☐ Cochlear implant
- ☐ Seizures
- ☐ Pregnancy
- ☐ Hepatitis (specify): A/B/C
- ☐ HIV/AIDS
- ☐ TB
- ☐ Diabetes
- ☐ Asthma
- ☐ Bleeding Disorders
- ☐ Kidney Disease
- ☐ Liver Disease
- ☐ Thyroid Problems
- ☐ Cancer (specify): _____
- ☐ Allergies (specify): _____
- ☐ Medications (specify): _____
- ☐ Hospitalizations/Surgeries
- ☐ (specify): _____
- ☐ Other:(specify): _____

Dental History

Check all that apply:

☐ Have you had any allergic reactions to dental anesthesia or other dental materials?

(specify): _____

Are you currently experiencing any of the following:

- ☐ Persistent toothache
- ☐ Sensitivity to hot or cold drinks/foods
- ☐ Pain during chewing
- ☐ Swelling or abscess
- ☐ Tooth discoloration
- ☐ Other:(specify): _____

Patient Declaration and Signature:

I confirm that the information provided above is accurate and complete to the best of my knowledge. I understand that this information is important for my care and will be treated confidentially.

Patient Name: _____ SIGNATURE: _____

DATE: _____

Appendix D
Medical and Dental History
Form (Arabic)

معلومات المريض

رقم الملف: تاريخ الميلاد: الجنس:

السجل الطبي

يرجى تحديد على ما ينطبق

- ☐ أمراض القلب
- ☐ ارتفاع ضغط الدم
- ☐ السكتة الدماغية
- ☐ جهاز تنظيم ضربات القلب
- ☐ مزيل الرجفان القلبي القابل للزرع
- ☐ زراعة القوقعة
- ☐ السكري
- ☐ الربو
- ☐ أمراض الدم
- ☐ أمراض الكلى
- ☐ أمراض الكبد
- ☐ مشاكل الغدة الدرقية
- ☐ نوبات الصرع
- ☐ الحمل
- ☐ التهاب الكبد (حدد: أ/ب/ج)
- ☐ فيروس نقص المناعة البشرية / الإيدز
- ☐ السل

- ☐ السرطان (حدد):_____
- ☐ الحساسية (حدد):_____
- ☐ الأدوية (حدد):_____
- ☐ العمليات الجراحية أو الدخول للمستشفى (حدد):_____
- ☐ أخرى (حدد):_____

سجل صحة الأسنان

يرجى تحديد على ما ينطبق

☐ حساسية من مواد أو تخدير الأسنان؟

رجى التحديد: _____

- ☐ ألم مستمر في الأسنان
- ☐ حساسية للمشروبات/الأطعمة الساخنة أو الباردة
- ☐ ألم أثناء المضغ
- ☐ تورم أو خراج
- ☐ تغير في لون الأسنان
- ☐ أخرى (يرجى التحديد): _____

اقرار المريض

أُقر بأن المعلومات المذكورة أعلاه صحيحة وكاملة حسب علمي، وأفهم أن تقديم هذه المعلومات ضروري لتقديم الرعاية الطبية المناسبة، وسيتم التعامل معها بسرية.

اسم المريض: _____ التوقيع: _____

التاريخ: _____

Appendix E
Biological Sample Receipt Form

Biological Sample Receipt Form – For research purposes only

- Biological Sample Storage Facility Name: _____
- Place/Campus: _____
- Date of Receipt: ____ / ____ / _____

Details of the Investigator

Name: _____

Department: _____

Professional Status: Undergraduate Student/ Postgraduate Student/Faculty

Contact Number: _____

Email Address: _____

Details of the Research Project:

Project Title: _____

_____

_____

Project IRB Number: _____

Project SFDA Number: _____

Funding Source (if applicable): _____

Supervisor/Principal Investigator: _____

Appendix E
Biological Sample Receipt Form

Details of the Sample

File number: _____

Type of Sample: _____

Quantity of sample: _____

Storage Conditions: _____

Expiry date: _____

Attach full list if more samples are received.

Purpose of Sample Collection

☐ Laboratory analysis

☐ Molecular testing (e.g., DNA/RNA extraction)

☐ Cell culture

☐ Educational/demonstration purposes

☐ Clinical correlation

☐ Other (please specify): _____

Clarification/Justification for use of the sample:

_____

_____

_____

_____

_____

_____

Appendix E
Biological Sample Receipt Form

Declaration by the Receiving Investigator

I, _____(name of the receiver of the biological sample) hereby confirm the receipt of the biological samples with details mentioned as above. I agree to undertake the handling of the biological samples in accordance to the Riyadh Elm University, institutional biosafety, infection control and ethical procedures and guidelines.

I confirm that the biological samples received as per the description above will be used solely for the IRB and/ SFDA approved research project as per the ethical policies and guidelines.

Sample Receiving Investigator Signature: _____

Date: ____ / ____ / _____

Details of the Storage Facility Authorization

Name of the Storage facility Authorizer (for release of biological sample):_____

_____

Position: _____

Signature: _____

Date of Release: ____ / ____ / _____

Appendix F
Biological Sample Disposal Form

Biological Sample Disposal Form – For research purposes only

- Biological Sample Collection Facility Name in REU: _____

  _____

- Place/Campus: _____
- Date of Receipt: ____ / ____ / _____

Details of the Investigator

Name: _____

Department: _____

Professional Status: Undergraduate Student/ Postgraduate Student/Faculty

Contact Number: _____

Email Address: _____

Details of the Research Project:

Project Title: _____

_____

_____

Project IRB Number: _____

Project SFDA Number: _____

Supervisor/Principal Investigator: _____

Appendix F
Biological Sample Disposal Form

Details of the Sample

File number: _____

Type of Sample: _____

Quantity of sample: _____

Storage Conditions: _____

Date Received:_____

Expiry date: _____

Attach full list if more samples are received.

Reason for Disposal

☐ Completion of Research

☐ Sample Expiry

☐ Contamination

☐ No Longer Needed

☐ Other (please specify): _____

Disposal Method

☐ Autoclaving

☐ Incineration

☐ Chemical Disinfection

☐ Other (please specify): _____

Appendix F
Biological Sample Disposal Form

Declaration by the Investigator

I, _____(name of the investigator who handled the biological sample) hereby confirm that the biological samples with details mentioned as above of the IRB and/ SFDA approved research project were handled in accordance to the Riyadh Elm University, institutional biosafety, infection control and ethical procedures and guidelines.

Sample Disposing Investigator Signature: _____

Date: ____ / ____ / _____

Details of the Disposal Facility Authorization

Name of the disposal facility Authorizer (for disposal of biological sample):_____

_____

Position: _____

Signature: _____

Date of Acceptance of the sample for disposal: ____ / ____ / _____