Informed Consent Form

Project Title: Preoperative Differentiation of Jaw Cystic Lesions Based on Radiomics from Computed Tomography Images: A Multicenter, Prospective Machine Learning Study

Sponsor: Sun Yat-sen Memorial Hospital, Sun Yat-sen University

Principal Investigator:

Version Number: V2.0

Version Date: June 9, 2024

Informed Consent Form • Information Sheet

Dear Participant,

We invite you to voluntarily participate in the study titled "Preoperative Differentiation of Jaw Cystic Lesions Based on Radiomics from Computed Tomography: A Multicenter, Prospective Machine Learning Study." The principal investigator of this study is Dr. XXX from the Department of Oral and Maxillofacial Surgery at Sun Yat-sen Memorial Hospital, Sun Yat-sen University. This study has been approved by the Medical Ethics Committee of Sun Yat-sen Memorial Hospital.

Please read the following information carefully before deciding whether to participate in this study. If you understand the study in detail and decide to participate, you will need to sign this informed consent form.

1. Study Background

Jaw cystic lesions include odontogenic tumors and non-tumorous cystic lesions occurring within the jawbone. Ameloblastoma is the most common odontogenic tumor, while cystic lesions can be divided into odontogenic and non-odontogenic cysts. Currently, the treatment focus varies for different types of jaw cystic lesions. Ameloblastomas can recur and metastasize, often requiring surgical resection, whereas cystic lesions may be more amenable to curettage and marsupialization. Therefore, accurate preoperative differential diagnosis of various jaw lesions and the subsequent selection of appropriate treatment plans are crucial for achieving optimal treatment outcomes for patients. Inappropriate treatment choices may delay the disease or lead to overtreatment, affecting the patient's quality of life. At present, there is still a lack of an objective and accurate standard and differential diagnosis plan for the treatment of jaw cystic lesions. Establishing an objective and scientific preoperative diagnostic predictive model has important clinical significance. In previous research, we successfully developed an effective predictive diagnostic model by combining machine learning techniques with CT radiomics, achieving a maximum AUC value of >0.8, indicating good performance and clinical reference value in predictive diagnosis. In the current study, we aim to conduct a multicenter, prospective machine learning study to further enhance the predictive diagnostic performance of the model and assist clinical diagnosis and treatment.

2. Study Objectives

In previous studies, we have demonstrated the feasibility of developing an effective predictive diagnostic model using machine learning techniques combined with CT radiomics for the preoperative differentiation of various jaw cystic lesions. This study aims to utilize the existing diagnostic predictive model to further conduct a multicenter, prospective study to construct a preoperative diagnostic predictive model, providing more reliable scientific references for clinical diagnosis and treatment, while further optimizing and enhancing the performance of the predictive diagnostic model to better align with clinical practice and assist clinicians.

3. Introduction to the Clinical Research Project

1. **Study Design:** This is a non-interventional study. Our center will enroll a total of 25 participants. The main inclusion and exclusion criteria are:
    1. You must meet all of the following criteria to be eligible:
        - Complete medical records.
        - Patients with untreated jaw cystic lesions.
        - Preoperative maxillofacial CT examination with complete CT data, no artifact interference in the lesion area, and a lesion size with the longest diameter not less than 2 cm.

- Ability to tolerate surgical treatment, with specimens sent for routine pathological examination after surgery.

2. You will not be eligible to participate if you meet any of the following conditions:
   - Incomplete medical records, such as missing information on specialist examinations and therapeutic operations.
   - Patients who received therapeutic operations at an external hospital during the first visit, not completely cured or relapsed.
   - Patients who did not undergo CT examination preoperatively, with incomplete CT data, severe artifact interference in the lesion area, or lesion size not meeting requirements.
   - Inability to tolerate surgery due to local or systemic factors, or if the lesion was not sent for pathological examination during surgery, with no routine pathological examination.
   - Unclear postoperative pathological reports, or pathological diagnoses other than odontogenic cysts and non-solid ameloblastomas.

2. **Study Duration:** June 2024 - January 2026

4. Clinical Research Process

1. After signing the informed consent form, the research doctor will collect your clinical information (such as medical history, clinical examination, and symptoms), imaging data, and postoperative pathology results. Participation in this study will not interfere with your routine diagnosis and treatment, nor will it impose any additional economic or other burdens on your follow-up visits and necessary subsequent treatments.
2. **Sample Collection and Testing:** During this study, if necessary (e.g., for pathological consultation to confirm diagnosis), your doctor will, with your consent, collect pathological slides made from the corresponding lesion during routine diagnosis and treatment after surgery. Typically, your samples will be sent to the pathology department of our center and related diagnostic centers for definitive pathological diagnosis. The use of these samples will not affect your disease diagnosis and treatment, and the test results will be communicated to you. You will also authorize the research team to access your medical data and test results for scientific research purposes. Remaining samples will be stored at our research center.
3. **Follow-up Visits:** During the study, you will typically need to return to the hospital for follow-up one week after surgery and complete a follow-up visit. Based on pathology results, further treatment or the next follow-up visit will be scheduled. The research doctor will arrange the next follow-up visit time with you in advance during the follow-up visit (e.g., one month after surgery, dynamically adjusted based on each center and patient's actual situation). According to the protocol requirements, your doctor will arrange the following follow-up examination items:
   - Physical examination (including clinical examination and specialized tests)
   - Imaging examinations: panoramic dental X-ray, cone beam CT (CBCT), or maxillofacial spiral CT

5. Costs Related to the Study

For patients enrolled in this study, from admission for treatment to subsequent regular follow-ups, all related examinations and tests, including panoramic dental X-ray, cone beam CT (CBCT), or

maxillofacial spiral CT, as well as other corresponding examination and test items (such as pathological diagnosis fees, blood routine, biochemistry, coagulation routine, etc.), are routine examinations required for the clinical treatment of jaw cystic lesions. Unless necessary, no additional specialized examination items will be added. Therefore, participating in this study will not impose any additional economic burden on you. The costs of examinations and tests related to the treatment of jaw cystic lesions will need to be borne by you.

6. Possible Benefits

This is a non-interventional study, and its results may not directly be used for your diagnosis and treatment. However, analyzing your samples or medical data will contribute to further research and understanding of such diseases in medicine, with the hope of improving diagnosis and treatment levels in the future.

7. Possible Risks

This is a non-interventional study and will not affect or interfere with your routine diagnosis and treatment, thus not posing any additional risks. If you have any questions during the study, you can consult the research doctor or the ethics committee. Additionally, our center will desensitize and strictly implement confidentiality measures when using your imaging data and related materials during treatment, minimizing the risk of data leakage.

8. Confidentiality Measures

The results of this clinical study are for scientific research purposes only. Your participation in the study and your personal data will be kept confidential and protected by law, and your name and identity will not be disclosed. Your name will not appear in any study reports or publications. Government regulatory agencies, hospital ethics committees, and researchers have the right to access all your study data, including clinical observation forms and trial data, as required by their work.

9. Rights

This study has been reviewed and approved by the Medical Ethics Committee of Sun Yat-sen Memorial Hospital, and the protocol design meets ethical requirements, ensuring that your rights are not violated in this study. Your participation in this clinical study is entirely voluntary, and you may refuse to participate or withdraw at any time without facing discrimination or retaliation, and your medical treatment and rights will not be affected. If the doctor believes that you are not suitable to continue participating during the study, they have the right to terminate your participation to protect your interests. Additionally, during the study, you can access information related to the study at any time. If we learn of any new information about this study, we will promptly inform you, allowing you to decide whether to continue participating.

10. Detailed Contact Information

If you have any concerns or questions about participating in this study, or if you experience any abnormal reactions during the study, or in case of an emergency, you should contact:

Doctor: [Doctor's Name]

Contact Phone: [Doctor's Phone Number]

If you have any complaints, concerns, or questions about the conduct of the research by the study physician, or about your rights as a research participant, you can contact the Medical Ethics Committee of our center:

Email: sysyxllwyh@163.com

Contact Phone: 020-81332587

Informed Consent Form • Consent Signature Page

Participant Declaration

1. I have carefully read this informed consent form, and the research personnel have explained it to me in detail and answered my related questions. I fully understand the following:

(1) As a participant, I will comply with the requirements of the participant's instructions, voluntarily participate in this study, and fully cooperate with the research personnel, truthfully and objectively providing my health status and related information before participating in this study.

(2) I agree to allow Sun Yat-sen Memorial Hospital to access my medical data and research results for scientific research purposes. I understand that the results of this clinical study are for scientific research purposes only, and except for government regulatory agencies, ethics committees, and researchers, my participation in the study and personal data will be kept confidential and protected by law.

(3) My participation in this study is entirely voluntary, and I can refuse to participate or withdraw from the study at any time without facing discrimination or retaliation, and my medical treatment and rights will not be affected.

I also declare:

(1) I am willing to comply with the research process;

(2) I have received this informed consent form.

Participant Signature: [Participant's Signature]

Contact Information: [Participant's Contact Information]

Date: [Year] [Month] [Day]

Participant Guardian Signature (if necessary): [Guardian's Signature]

Relationship to Participant: [Relationship]

Contact Information: [Guardian's Contact Information]

Date: [Year] [Month] [Day]

Witness Signature (if necessary): [Witness's Signature]

Contact Information: [Witness's Contact Information]

Date: [Year] [Month] [Day]

Researcher Declaration

2. I have fully explained and described the purpose, research methods, operational procedures, and potential risks and benefits of participating in this study to the participant and have satisfactorily answered all their related questions.

Researcher (Informing the Participant) Signature: [Researcher's Signature]

Contact Information: [Researcher's Contact Information]

Date: [Year] [Month] [Day]