Informed consent

Dear patients:

You will be invited to participate in a study led by Dr. Kaining Liu in the Department of Periodontology at Peking University School and Hospital of Stomatology. This study will observe the regenerative effect of modified minimally invasive surgical technique (M-MIST) combined with Bio-Oss® Collagen for isolated interdental intrabony defects. The study will last 12 months. The total number of patients is 40. Since you meet the inclusion criteria, you are invited to join this study.

This informed consent form provides you with important information to help you decide whether to participate in this study. Your participation in this study is voluntary. This study has been reviewed and approved by Ethics Committee of Peking University School and Hospital of Stomatology. If you agree to join this research, please read the following instructions:

Please read it carefully. If you have any questions, please consult the researcher in charge of the study.

Background:

A modified minimally invasive surgical technique (M-MIST) was proposed to be used in the periodontal regeneration therapy for isolated interdental intrabony defects in 2009. It has been used for more than 10 years, and there have been more than 100 cases reported in the literatures. This technique only elevates the buccal flap to ensure adequate blood supply, tighter primary wound closure and lower risk of bacterial infection. In addition, Bio-Oss® Collagen is similar to human cancellous bone, with the ability to promote bone formation. Bio-Oss® Collagen, with outstanding plasticity and spatial stability, is suitable for the small field of vision resulting from

M-MIST.

Recently, the combination of different materials and techniques has become a research hotspot. By combining the advantages of regeneration technology and materials, better regenerative results can be achieved. Therefore, we plan to research the therapeutic effect of M-MIST combined with Bio-Oss® Collagen and the use of M-MIST exclusively for periodontal tissue regeneration of isolated interdental intrabony defects.

Research plan:

You will be randomly assigned to one of the two groups. Test group: M-MIST combined with Bio-Oss® Collagen. Control group: M-MIST. All surgical operations will be performed by an experienced therapist. Before surgery, you will receive a periodontal clinical examination and have periapical radiographs and cone beam computed tomography taken. You will receive a phone-call for re-examinations at 1 week and 1, 3, 6, 9, and 12 months post-surgery. Periapical films and cone beam computed tomography of the defect associated site will be taken 6 and 12 months post-surgery. In addition, you will finish a VAS to evaluate the discomfort after 1 week of treatment.

All patients are randomly grouped according to the random sequence, and you will have an equal chance of being assigned to each group. Neither you nor the therapist can choose your treatment group.

The following criteria should be met:

(1) age 18 to 75 years;

(2) both genders will be considered for selection in the study;

(3) patients with stage III or IV periodontitis at least two months after periodontal initial

therapy;

(4) good compliance;

(5) good oral hygiene;

(6) full-mouth plaque score and full-mouth bleeding score each less than 30%;

(7) systemically healthy.

Your responsibilities:

The study will last for 12 months. You will receive a phone-call for re-examinations at 1 week and 1, 3, 6, 9, and 12 months post-surgery.

During the follow-up period, you also need to maintain good oral hygiene. The above items will not increase the number and time of your visits. Periodontal treatment has the characteristics of lasting life, so after the study, periodontal maintenance treatment will be offered for you.

The impact of participating in the study on your life:

You may feel that these visits and examinations are inconvenient. In addition, some examinations may make you feel uncomfortable. If you have any questions about the examinations and procedures in the study, you can consult the researchers.

During the entire study period, you can no longer participate in any other clinical trials related to drugs or medical devices.

Risks and adverse effects of participating in this study:

During the study, you may experience common discomfort after periodontal surgery (see the informed consent form for periodontal surgery for details). We will monitor all patients in the study for any adverse reactions. If you have any adverse reactions during the research process, please call your doctor for consultation in time, and we will perform treatment accordingly.

You need to tell your family or friends close to you that you are participating in a clinical study and they can pay attention to the events described above. If they have questions about your participation in the study, you can tell them how to contact your doctor.

Are there any other treatment options:

Although there is already evidence that the M-MIST is effective for treating isolated interdental intrabony defects, it is not guaranteed to be effective for you. The M-MIST + Bio-Oss® Collagen used in this study is not the only way to treat isolated interdental intrabony defects. You can also ask your doctor about other treatments you might get.

Expenses, compensation and remuneration for participating in this research association:

There is no compensation for this study. All examination and treatment costs are borne by the yourself.

We will arrange supportive periodontal therapy for you, as well as oral hygiene guidance and related consultations.

Confidentiality of your personal information:

If you decide to participate in this study, your participation in the experiment and your personal information in the experiment are confidential. Your name, ID number, address, phone number, or any information that can directly identify you in the research records will not be leaked outside the Peking University School and Hospital of Stomatology. We will use a unique number to represent your research information that is sent outside the Peking University School and Hospital of Stomatology. The coded information will be properly stored in Peking University School and Hospital of Stomatology.

At any time during the study, you can request access to your personal information (such as your

name and address), and modify this information if necessary.

withdraw

You can quit the research at any time. The withdrawal will not influence you further treatment in the Department of Periodontology.

Contact information

If you have any questions related to this research, or if you have any discomfort or injury during the research process, or have questions about the rights of participants in this research, you can contact Dr. Haidong Zhang, Office Tel: 010- 82195367; mobile phone: 13426305500. Or contact the Ethics Committee of Peking University School and Hospital of Stomatology, Tel: 010-82195759, Email: keyanchuethics@163.com

Competing interests

None

Subject's agreement statement:

I have read the above introduction about this research and fully understand the possible risks and benefits of participating in this research. I have voluntarily agreed to participate in the clinical research described in this article.

Name of the subject:_____

Signature date:_____ Phone number:_____

Researcher's statement:

I confirm that I have explained the details of this study to the patient, especially the possible risks and benefits of participating in this study.

Name of the researcher:_____

Signature date:_____ Phone number:_____