Research Article

Data Mining-Based Clinical Study on the Effect of Oral Restoration Film in Guiding Oral Bone Regeneration and Dental Implantation

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Oral repair membrane guided oral bone regeneration, particularly in dental implants, is a guided regeneration technology for bone tissue. The principle is based on the characteristics of faster migration of epithelial cells and fibroblasts along with slower migration of osteoblasts. Materials are placed in the bone defect, creating a relatively closed environment which is conducive to the growth of bone tissue. In this paper, we have evaluated clinical effects of Hai’ao oral repair membrane as a barrier membrane to guide bone regeneration in implants. For this purpose, certain treatment data are collected through data mining and patient’s names with bone defects in the implantation area are selected. According to the randomness principles, these patients are divided into experimental and control groups and preoperative examinations along with basic periodontal treatments are performed on the selected cases. Furthermore, we have analyzed different effects by comparing treatment conditions. Experimental results, as a technical shielding film, verify that Hai’ao oral repair membrane meets requirements of safety and no immune rejection. It plays a role in promoting bone formation around the implant. Mid-to-long-term follow-up is satisfactory with no related complications. At the same time, it has the advantages of simple operation, reduced patient suffering, convenient transportation and storage, and longer validity period. Compared with the control group in terms of safety evaluation of postoperative vital signs, laboratory examinations, and incision healing, Hai’ao oral repair membrane has no significant difference. Postoperative osteogenesis effect is equivalent to that of the control group and meets requirements of superiority. Hai’ao oral repair membrane is used as a shielding membrane material in implant surgery technology to guide bone regeneration.

1. Introduction

Guided bone regeneration is a guided regeneration technology for bone tissue. Its principle is based on the characteristics of faster migration of epithelial cells and fibroblasts along with slower migration of osteoblasts. Placing the membrane material on the bone defect creates a relatively closed environment which is conducive to the growth of bone tissue. The oral barrier membrane establishes a mechanical biological barrier between soft tissue and bone tissue, which prevents fast-migrating heel connective tissue cells and epithelial cells from entering the bone defect area and allows osteoblasts with potential growth ability and slower migration speed priority access to the bone defect area, while protecting the blood clot, reducing the pressure of the covering tissue, forming a space for bone tissue growth under the shielding membrane and on the surface of the implant, and achieving the repair and regeneration of the bone tissue in the defect area. The barrier membrane plays a very important role in the process of guiding bone regeneration. Therefore, this technology is also called membrane guided technology or membrane guided bone regeneration technology [1]. In 1976, Melcher [2] first proposed the concept of guided tissue regeneration in the surgical
treatment of periodontal disease, using this technology to treat periodontal disease to obtain new periodontal attachment and regeneration of alveolar bone. Nyman et al. [3] and others first used nonabsorbable microporous membranes to treat periodontal disease and also obtained new periodontal attachment and alveolar bone regeneration. After entering the 1980s, with the widespread use of artificial dental implants, guided bone regeneration techniques have been gradually used in implant surgery. In 2015, the first animal experiment was conducted to guide bone regeneration using nonabsorbable membrane. The results showed that the effect of technology in promoting bone regeneration is very significant [4]. After applying this technology clinically, patients were followed up for ten years and it was found that all patients have achieved good repair effects [5]. Later, other scholars conducted more extensive and in-depth research on technology. At the end of the century, the technology was first introduced into dental implants to reconstruct the defective bone tissue. The results showed that the average bone defect height was reduced by 82%. As the technology matures, many scholars at home and abroad have used it in clinical dental implant surgery.

To address this challenging issue, clinical effects of Hai’ao oral repair membrane as a barrier membrane to guide bone regeneration in implants are evaluated in this paper. For this purpose, certain treatment data are collected through data mining and patient’s names with bone defects in the implantation area are selected. According to the randomness principles, these patients are divided into experimental and control groups and preoperative examinations along with basic periodontal treatments are performed on the selected cases. The major scientific contributions of this paper are as follows:

(i) To evaluate the effectiveness of the Hai’ao oral repair membrane, which is usually used as barrier membrane to guide bone regeneration in implants, in oral bone regeneration and dental implantation process carried out in hospitals.

(ii) Selected patients are divided into control and experiment groups using a well-known procedure called randomness principles.

(iii) To perform extensive and thorough investigation on the selected cases, which are chosen based on required conditions. Furthermore, how the treatment process is effective on the recovery process of these groups and follow-up duration, specifically for the treatment of patients, for both groups is advised, which is based on experimental data values.

(iv) Finally, this article proposes using Hai’ao oral repair membrane as a shielding membrane material in implant surgery technology to guide bone regeneration.

The remainder of the article is planned according to the given guidelines.

In the subsequent section, that is, Section 2, a brief literature review is presented, which is followed by the proposed model’s experimental setup and procedures. In Section 4, experimental results are thoroughly examined, where various results are compared with the existing benchmark models available for the problem under consideration in this article. Finally, concluding remarks are given along with references.

1.1. Related Work. Domestic immediate implant research mainly focuses on the histological study of the effect of implant surface microstructure on osseointegration and other basic research and animal experiments on guided tissue regeneration technology and guided bone regeneration technology. There are fewer clinical trials, small sample size, and shorter research time, but the success rate is about the same as that of traditional implants. For example, Hoexter [5] chose Camlog implant system, Bio-Gide absorbable collagen membrane, and Bio-Oss artificial bone, and a total of 62 implants were implanted: 36 in the anterior area, 18 in the premolar area, and 8 molar implants in the area with an average follow-up observation of 28 months. As a result, 2 implants in the posterior region were loosened within 2–4 weeks after surgery. The remaining cases have a good clinical effect. The success rate is 95.2%. It is believed that the application of the membrane-guided regeneration technology in immediate dental implant surgery is reliable and can achieve good clinical results. Fedyaev et al. [6] reported that the combined application of Bio-Oss with the absorbable collagen membrane Bio-Gide can effectively promote the quantity and quality of immediate bone tissue regeneration around the implant and can promote the bone-implant bonding rate. In recent years, more and more implant doctors at home and abroad have conducted a large number of studies on the clinical effects of immediate implantation technology. The results show that immediate implantation combined with GBR technology can achieve a higher success rate. Although GBR technology has obtained satisfactory clinical results in the application of immediate implantation, there are still some problems in the application. Soft tissue valve dehiscence, membrane exposure, and infection are the most common problems in GBR immediate implantation. While GBR technology limits the growth of soft tissues, it also limits the blood supply and protection of soft tissues to the wound area. Therefore, after using a barrier film, there is often a risk of postoperative wound dehiscence. In the case of wound dehiscence, infection is not only guaranteed, but the osteogenesis effect cannot be guaranteed. It is also easy to cause planting failure. The incidence of soft tissue valve dehiscence and membrane exposure is related to the type of biofilm used. Because the nondegradable membrane has the characteristics of high strength and being not easy to form, it is more difficult to provide attachment and retention for the mucoperiosteal flap. Therefore, the dehiscence rate of the soft tissue flap is higher when the nonabsorbable membrane is used than when the absorbable membrane is used. In particular, the current domestic Qin membrane, without any pores in its structure, after application, in addition to restricting the entry of fibroblasts into the defect area, also restricts the entry of blood and even plasma. De Andrade et al. [7] reported that the wound
dehiscence rate of Bio-Gide membrane was 7.1%, while that of Qin membrane was 21.1%, and the self-healing condition of Bio-Gide collagen membrane after exposure was better than that of those using Qin membrane. In the clinical research of most scholars, membrane exposure infection has appeared, and the exposure rate is quite high. In 1994, Fotek et al. [8] reported 63 cases of implants using membrane materials, 14% had membrane exposure and infection, and 14% were exposed to the oral cavity without infection. AlGhamdi and Buhite [9] performed collagen membrane-guided tissue regeneration on 30 patients immediately after implantation. There was a case of membrane exposure after immediate implantation. Liu et al. [10] reported 25 cases of using e-PTFE membrane, and 14 cases of varying degrees of membrane exposure occurred 10–120 days after surgery. Research by Engelke WG, Diedederichs CG, and so forth [11] also found that those who used guided tissue regeneration surgery had a significantly higher proportion of membrane exposure and infection than those who did not. Although there are different reports on the membrane exposure rate, most scholars believe that the membrane exposure rate is 12%–16% [11, 12]. In recent years, there have been no reports of membrane exposure in the relevant literature on the application of frozen allogeneic dura mater, allogeneic periosteum, and autologous drill periosteal flaps. Therefore, how to avoid soft tissue valve dehiscence and membrane exposure is the key for GBR technology to guide bone regeneration failure. Regarding the reason for the exposure of the membrane, most scholars believe that this is due to the soft tissue gap in the heel after the tooth extraction. In order to seal the biofilm, the lip and buccal heel flap and the tongue heel flap must be sutured together to make the heel flap tension easy. Cracking occurs and exposure occurs. Gotfredsen et al. analyzed that the time of membrane exposure mostly occurred in 2–4 weeks after surgery and therefore believed that the membrane exposure was caused by the interference of the smooth surface of the biofilm and hindering the attachment of soft tissue flaps. Some scholars believe that the incidence of soft tissue valve dehiscence is related to the type of biofilm used. Nonabsorbable membranes are difficult to form due to their high strength and are difficult to provide attachment retention for mucoperiosteal flaps. Therefore, soft tissue valve cracks and opening rate are higher than those of the absorbable film. Some scholars have also suggested that e-PTFE membranes and stents containing power-increasing stents are easy to pierce the valve and cause the membrane to be exposed when the shape is not good. Goldman [13] also proposed exposure due to poor retention of biofilms. At present, the measures taken to solve the problems of membrane exposure and soft tissue flap infection mainly include the following categories:

2. Proposed Method

2.1. Research Objective. With 30 subjects enrolled, aged between 18 and 70 years, 16 cases in the test group were treated with oral repair membranes, 10 males and 6 females, with an average age of 37 years. In the control group, 14 cases were treated with medical collagen membrane, 12 males and 2 females, with an average age of 36.1 years.

2.1.1. Case Selection Criteria

(1) Subjects are 18–70 years old, and gender is not limited.
(2) Patients with dental implant indications and insufficient bone mass and need to apply technology for bone augmentation.
(3) Exclude systemic and local contraindications.

2.1.2. Case Exclusion Criteria

(1) Cases that do not meet the inclusion criteria.
(2) Unstable vital signs.
(3) People with severe heart disease, unstable angina pectoris, cardiac insufficiency, and myocardial infarction.
(4) Patients with chronic kidney disease or renal insufficiency.
(5) Patients with clear liver disease or liver insufficiency.
(6) Diabetic patients.
(7) Breast-feeding or pregnant women.
(8) People with a history of allergies to multiple drugs or patients with recent allergies, having used drugs known to cause damage to major organs within 4 weeks.
(9) Patients with mental illness.
(10) Specific allergies, especially those who are sensitive to collagen.

2.2. Method of Operation. Thirty patients with bone defects in the implantation area were selected. According to the principle of randomness, they were divided into 16 cases in the experimental group and 14 cases in the control group.
(i) Carry out preoperative examination and basic periodontal treatment for selected cases.

(ii) Carry out implant surgery, implant implants, and measure the “labial alveolar bone thickness of the implant before bone grafting” and the “alveolar bone thickness before bone grafting” using a ten-degree Vernier caliper.

(iii) Implant bone material as needed. The bone graft material used in the operation is “Tianbo Tegu” bone powder. The bone powder is soaked in normal saline by the surgical assistant according to the instructions and placed on the labial bone defect area of the implant to increase the amount of alveolar bone.

(iv) Use a tenth-degree Vernier caliper to measure the thickness of the alveolar bone on the labial side of the implant after bone grafting.

(v) Choose a suitable oral repair film. According to the shape and size of the wound, trim the “Hai’ao Oral Repair Film” and “Bot Medical Collagen Film” to the appropriate size and place them in the bone graft area of the test group and the control group. Cover 2-3 mm at the edge. After fully relaxing the soft tissue flap, 4-0 silk suture was interrupted to close the wound.

(vi) After 5 days of postoperative anti-inflammatory treatment and 10 days later, follow-up and suture removal were done.

(vii) A follow-up visit was one month after the operation, and clinical examination and line film were to observe the condition of the alveolar bone and the osseointegration of the implant.

(viii) Two-stage implant surgery was performed 3 months after surgery, the mucosa was reopened, the osseointegration of the implant was observed and the amount of new bone tissue was measured and evaluated, and the thickness of the alveolar bone on the labial side of the implant was measured, according to clinical standards; evaluate osteogenesis, and calculate osteogenesis thickness.

(ix) Calculate the bone growth effect and the average growth effect according to the bone growth effect = osteogenesis thickness/bone graft thickness*100%.

(x) Complete the restoration of implant denture, as well as clinical inspection of the restoration effect.

(xi) Follow up every 6 months and take X-rays to observe bone resorption.

(xii) In order to reduce system errors, all data are measured by the same staff under the same conditions.

3. Experimental Results and Observations

In this section, we have described how the experimental setup was created and how many patients were selected, what their selection criteria are and how the results are obtained, and, finally, how the proposed model is realized in actual environmental setting of the traditional hospital.

3.1. Experiment Procedure. Connect frozen physiological saline to the planting machine, turn on the foot switch, connect the planting mobile phone to the planting machine, and finally turn on the power. The test patient rinsed with hydrogen peroxide for a minute before the operation, initially disinfected the oral cavity, and then rinsed with normal saline. The iodophor solution used by the assistant physician disinfects the patient's implantation area and oral cavity face. The subject's chair position is suitable. When the upper collar teeth are planted, the upper collar is approximately 45 degrees Celsius with the ground; when the lower collar teeth are planted, the lower collar is approximately 30 degrees Celsius with the ground, and the mouthpiece is placed, and sterile towels and surgical drapes are placed. Adopt azure articaine epinephrine injection to perform local infiltration anesthesia in the planned implantation area. For some patients who are sensitive to pain, use painless injection instrument for local infiltration anesthesia. The cutting design is fan-shaped, and both sides reach the membrane. A round blade is used to cut the mucosa and mucoperiosteal to the bone surface in turn, and use a periosteal dissector to open the mucoperiosteal flap to completely reveal the alveolar bone. According to 31 implantation operation requirements, prepare holes and implant implants in the planned implantation area step by step. Artificial bone material is implanted in the labial bone defect area as needed. Soak the bone meal with normal saline and place it on the bone defect area to increase the amount of alveolar bone. During the operation, the bone graft materials used in the experimental group and the control group were “Tianbo Tegu” bone powder. Use ten-degree Vernier caliper to measure the thickness of the bone graft. Choose a suitable oral repair film, according to the shape and size of the wound, trim the “Zhenghai Oral Repair Film” and the “Bot Medical Collagen Film” to the appropriate size, and place them in the bone graft area of the test group and the control group. We repaired the edge of the film to cover the defect area to 2.0-3.0 mm, completely relaxed the teeth and filled the soft tissue flap, and then sutured the wound with 0-4 mm silk thread. Put sterile cotton rolls in the intraoral surgery area to stop bleeding, take out the sterile cotton rolls after 30 minutes, and observe the condition of the serum after the incision. After the operation, oral scalp and metronidazole anti-inflammatory treatment was given for 5 days, while gargling with medical mouthwash for 1 week. After 10 days, follow up and remove the stitches, conduct a clinical evaluation of the incision healing, perform a physical examination on the patient, and record the examination results. After 1, 3, and 6 months and every 6 months' follow-up, clinical examination and radiographs were performed to observe the condition of alveolar bone and implant osseointegration. Follow up 3 months after surgery, perform physical examination and laboratory examination, and record the results of the examination. Perform implant secondary surgery, reopen the
membrane, observe the osseointegration of the implant and measure and evaluate the amount of new bone tissue, measure the thickness of the labial alveolar bone of the implant, evaluate the osteogenesis according to clinical standards, and calculate the result of bone thickness. According to the bone growth effect = osteogenesis thickness/bone graft thickness × 100%, calculate the bone growth effect and the average growth effect.

3.2. Record Measurement Data. This test mainly qualitatively studies the effect of different shielding membrane materials in guiding bone regeneration. The indicators to be observed and recorded are as follows: During the first-stage operation: before bone graft, alveolar bone thickness D1; before bone graft, labial alveolar bone thickness D2; after bone graft, the thickness of the labial alveolar bone is D3; the thickness of the bone graft is \( A = D_3 - D_2 \); and during the second stage operation: the thickness of the alveolar bone is D4. The thickness of osteogenesis = D4 – D1.

3.3. Clinical Evaluation Criteria

3.3.1. Effectiveness Evaluation. Main efficacy indicators: bone growth effect (%)

(1) Bone growth effect (%) = (osteoogenesis thickness (B)/ bone graft thickness (A)) × 100%.

(2) Superior effect: bone growth effect ≥95%.

(3) Marked effect: 80% ≤ bone growth effect <95%.

(4) Invalid: bone growth effect <80%.

(5) Superior effect and marked effect are counted as effective.

3.3.2. Secondary Indicators. Incision Healing.

3.3.3. Safety Evaluation Criteria. Analyze the relationship between laboratory abnormalities, abnormal signs, and adverse events and applied materials.

3.4. Data Management

3.4.1. Data Collection

(1) The researcher must ensure that the data is true, complete, and accurate.

(2) All items in the research record must be filled out. “No blanks or missing items can only be crossed when making any corrections.” Note the revised data. The initials of the name of the researcher must be signed and dated. The original records must not be erased or overwritten.

(3) Laboratory inspection items are complete. After the trial cases are observed, the research records and other materials will be submitted to the person in charge of clinical trials for review and preservation for final statistics. Data monitoring: the clinical trial supervisors review a record sheet for each original study to confirm that the clinical trial data records are timely, accurate, standardized, and complete.

3.5. Statistical Processing. Record the required data, input all into the computer, and use the software to analyze the data. Use frequency, median, mean, composition ratio, and so forth to describe quantitative and qualitative data. Before the formal analysis of the quantitative data, the normality test of the data distribution is first performed; for the data that meets the normal distribution, the two-independent-sample \( t \)-test or the paired \( t \)-test is used to test the two sets of indicators or the indicators before and after the operation. Data conformed to the normal distribution, using non-parametric test to test the two groups of indicators or indicators before and after the operation. When analyzing qualitative data, use the Pearson chi-square test or the exact probability method to test. In the effect analysis, non-inferiority test is used, and other statistical tests are two-sided tests. \( p \) less than 0.05 is considered to be statistically significant. Covariance analysis was used to compare the data between groups to eliminate the possible effects of baseline data.

4. Results and Analysis

In this experiment, GBR technology was used to repair the bone defect around the implant, and the effect of different membrane materials to guide bone regeneration was analyzed qualitatively and quantitatively.

4.1. Qualitative Research Indicators

(1) Incision healing.

(2) Evaluation of implant osseointegration.

(3) Evaluation of the effect of occlusal reconstruction.

(4) Safety evaluation.

4.2. Quantitative Research Indicators

(1) Basic information of the patient.

(2) Changes in physical examination and laboratory examination data before and after implantation.

(3) Comparison of intraoperative bone graft thickness.

(4) Comparison of bone formation thickness during the second-stage operation.

(5) Comparison of bone growth effects.

4.3. Clinical Trial Results

4.3.1. Qualitative Research Indicators. A total of 30 subjects were enrolled in this trial: 16 in the experimental group and 14 in the control group. The incision healing rates of the experimental group and the control group were 100%, both of which were Grade A healing. Implant osseointegration is good, all repair is completed, and the patient’s occlusal
function is restored. In terms of safety, one patient in the control group had an adverse event of swelling in the operation area 3 days after the operation. No adverse event was found in the test group during the entire trial.

4.3.2. Quantitative Research Indicators. The age composition, gender composition, various vital signs, and laboratory test results of the preoperative test group and the control group are similar. The thickness of the unilateral bone graft in the two groups during the operation is the same. The vital signs of the postoperative test group and the control group are the same. The index and the laboratory examination index are the same; there is no significant difference in the effect of the two components of the bone. Adverse events and side effects found in clinical trials and their treatment are as follows: one patient in the control group developed facial swelling. After symptomatic treatment, the swelling disappeared.

4.4. Analysis of Clinical Trial Results. Under random sampling conditions, using relevant statistical analysis, the results show the basic information of the test group and the control group (including gender, age, medical history, etc.), preoperative vital signs, laboratory biochemical examinations, and intraoperative unilateral bone grafting; there is no significant difference in thickness. There was no statistically significant change in the vital signs at the time of postoperative suture removal and when the teeth were shaped. There was no statistically significant change in the laboratory indexes during the postoperative heel shaping compared with the preoperative indexes. The basic situation comparison of the selected cases in the experimental group and the control group is shown in Table 1.

A normality test was performed on the age data of the test group and the control group, and the data was found to conform to a normal distribution. Therefore, an independent-sample test was used. The results showed that the difference in age between the test group and the control group was not statistically significant (p > 0.05). The difference in age has no effect on the final result, which is shown in Table 2.

Chi-square test was used to compare the sex composition of the two groups. The results showed that there was no statistically significant difference in sex composition between the test group and the control group (p > 0.05). The difference in gender composition between the two groups has no effect on the final results, which is shown in Figure 1.

Three days after surgery, there was a case of facial swelling in the control group. The swelling disappeared after anti-inflammatory and symptomatic treatment. There were no adverse events such as infection in other cases in the test group and the control group, indicating that the safety of Zhenghai biofilm is equivalent to that of the control group material, and it does not increase the risk of patient infection and other adverse events, which is shown in Figure 2.

It can be seen from the figure that the incision healing of all patients in the two groups was Grade A, and the incision healing rate was 100%, which is shown in Figure 3.

Since the effective rate of bone growth in the two groups is 100%, noninferiority methods cannot be used for testing. The specific advantages and composition of the two groups are shown in Figure 4.

The comparison found that the experimental group and the control group had basic demographic information, case treatment history, unilateral bone graft thickness, preoperative and postoperative vital signs and laboratory examinations, and occurrence of adverse events, incision healing, bone growth effect, and so forth. The difference was not statistically significant. As a shielding film for planting technology, Zhenghai biofilm in the experimental group has
no significant difference in safety and functional effects compared with the control material. The safety and effects of the two are equivalent.

In summary, in oral implants, GBR technology is used to increase the formation of new bone around the implant and promote the repair of bone defects. Therefore, the postoperative osteogenesis rate is used as the main observation index for the effectiveness evaluation of this clinical trial. Through the 6-month follow-up observation of subjects, the effective rate of bone growth in both the control group and the test group is 100%. In conclusion, in the process of guiding bone regeneration as a dental implant barrier, the use of Zhenghai biofilm can meet the requirements of promoting osteogenesis around the implant.

5. Conclusion and Future Work

As a technical shielding film, Hai’ao oral repair membrane meets the requirements of safety and no immune rejection. It can promote the formation of bone around the implant. It is satisfactory in the medium- and long-term follow-up. It has no related complications and is easy to operate and reduces patient suffering, with convenient transportation and storage, longer validity period, and other advantages. Compared with the control group in terms of safety evaluation of postoperative vital signs, laboratory examinations, and incision healing, Hai’ao oral repair membrane has no significant difference. The postoperative osteogenesis effect is equivalent to that of the control group. It meets the requirements of superiority and obvious effect. Hai’ao oral repair membrane can be used as a shielding membrane material in implant surgery technology to guide bone regeneration.

In the future, we will examine how effective the proposed model would be in various patients if selection criteria were changed and how the proposed system can be converted into a doctors-assisting tool.

Data Availability

The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

Authors’ Contributions

Qingjie Lin conceived and designed the study. Yong Zhang and Yanguo Liu provided administrative support. Qingjie
Lin provided the study materials or patients. All the authors collected and assembled the data: Bo Wu performed data analysis and interpretation. All the authors wrote the manuscript. All the authors approved the manuscript.

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