Clinical Efficacy of Nobel Parallel CC Implants With on1 Abutment in Posterior Area Participants

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Study protocol

1. Study design and population

This study was approved by the ethics committee of the affiliated stomatology hospital of Zhejiang University medical college (No.2022-033), and then registered at clinicaltrials.gov under registration number (NCT05399589). The study was conducted according to the principles of Helsinki Declaration, following CONSORT guidelines for clinical trials.

Patients treated with Nobel Parallel CC implant in the posterior area without any bone augmentation in Zhejiang University Affiliated Stomatology Hospital during September 2021 and March 2022 were assigned into two groups by the primary stability: the two-piece abutment workflow (TAW) with a torque value of ≥35 Ncm, and the sealing screw with submerged healing workflow (SHW) with a torque value of <35 Ncm. The number of Hounsfield units (HU) was measured in preoperative CBCT scans in order to exclude the significant differences of bone mineral density (BMD) in two groups referring to previous study[28]. All patients received treatment from an experienced clinician (F.H.). Patients were informed and provided their signed consent and permission.

The inclusion criteria were as follows:

(1) At least eighteen years old without any medical contraindications, able to tolerate dental implant surgery;
(2) Planned to implant with Nobel Parallel CC in the maxillary or mandible posterior tooth regions with single-implant-prosthesis design;
(3) No requirement for further bone augmentation;
(4) Sufficient space to place the abutment and future prosthesis;
(5) Adhere to follow-up.

The exclusion criteria were as follows:

(1) Uncontrolled systematic diseases (blood pressure >180/100 mmHg, fasting blood glucose >8.88 mmol/L, myocardial infarction in six months, cardiac function class III to IV, third- or second-degree II atrioventricular block, and double bundle branch

block et al.);

(2) Using drugs such as bisphosphonates within three months;

(3) Heavy smoker (≥ 10 cigarettes per day), alcoholism, and drug abuse;

(4) Uncontrolled periodontitis;

(5) Implant site infection;

(6) Pregnancy or lactation;

(7) Severe malocclusion.

2 Sample size

The sample size was determined by referencing to previous study's data on MBL changes (mean and SD of two groups: 0.14mm ±0.27mm and 0.64mm ±0.64mm) [17], using G*Power 3.1 software with α=0.05 and 80% of power, which concluded that each group required 17 sample sizes. Ten percent additional patients were enrolled to compensate for possible dropouts.

3 Surgery procedure

After sterilization and local anesthesia, a full thickness flap was performed to fully expose the area. Nobel Parallel CC implants (4.3-5.0mm in diameter and 10-11.5mm in length) were placed within 0-2 mm below the alveolar crest according to the thickness of mucosa, 1.5mm away from adjacent teeth or implants, while maintaining a buccal bone thickness of at least 1.5mm. After implantation, the primary stability was assessed by a torque wrench in order to determine the grouping. In TAW group, a 1.75mm height Nobel Biocare® On-one base was chose to connect to the implant torqued to 35Ncm according to thickness of mucosa. Afterwards, an On-one healing cap was placed over it, and suture was performed with non-submerged healing. In SHW group, a sealing screw was connected to the implant with manual tightening and submerged healing.

4 Prosthesis procedure

Prosthetic procedures began 3 months after implantation with radiograph confirming

the osseointegration. In TAW group, the closed-tray silicone method with direct impression copings was used to record precise implant position and accurately replicate surrounding tissues shape. While in SHW group, an additional intervention (secondary operation) was necessary to replace the healing cap with the height of 5mm /7mm, and the impression should be made in two weeks for soft tissue healing. When the healing cap was removed, the connective tissue in TAW group maintained adhesion to the On-one base, while in SHW group it detached from adhesion. Then, the full zirconium crown (Wieland, Wielandent Dental Technology Co., Ltd, German) with definitive abutment (Esthetic abutment, Nobel, Nobel Biocare®, Sweden) were delivered and tightened to a torque of 35Ncm, according to the manufacturer's recommendations after an additional 2-3 weeks. Patients were recalled for clinical and radiograph assessment at 6 months and 12 months after implantation. The schematic diagrams of each step in two groups were shown.

5 Outcome measures

(1) Survival rate and complications: the implants/prosthesis that did not need to be replaced within a year were considered as achieving survival. Osseointegration failure, peri-implant mucositis, peri-implantitis, implant/screw/abutment fracture, and porcelain collapse of prosthesis were recorded.

(2) Radiograph measurement: MBL measurement was conducted using panoramic radiograph (Panoramic dental X-ray machine, 85kV, 16mA). The images were saved and quantified using the CorelDraw 11.0 software referred to the previous study[4]. The implant length was used as calibration reference, and the calibration formula was as following:

$$MBL = \left(\left(C + D \right) * A \right) / \left(B * 2 \right)$$

(3) Clinical evaluation: probing depth (PD), bleeding on probing (BOP), modified plaque index(mPI), calculus index (CI), and gingival index (GI) were measured to assess the soft tissue and oral hygiene condition in T2 and T3. Briefly, plastic UNC 12 periodontal probe was used to measure the PD at mesial, middle, and distal sites of both

buccal and lingual surfaces. Bleeding status at each site was recorded after 30 seconds. mPI, CI, and GI were recorded based on the evaluation criteria.

(4) Patient satisfaction: patients were required to answer the Oral Health Impact Profile-14 (OHIP-14) at T0 and T2, which mainly includes 14 questions, with scores ranging from "0=never", "1=almost not", "2=occasionally", "3=often", to "4=always" meaning the frequency with each question within the past month[29]. Visual analogue scale (VAS) was used at prosthesis loading including the first 6 questions and T2 including the last 6 questions. Patients were instructed to indicate their perception experience by marking X on a 100mm horizontal line for each question. Participants' scores were obtained by measuring the distance between 0 and X (in millimeters, corresponding to 0-100 points, 0=completely unsatisfied, 100=fully satisfied[30]).

Statistical Analysis Plan

The statistical analysis was performed using SPSS 26.0 software. A Shapiro-Wilk test was performed to assess the normality of the data. The Friedman test was employed to identify differences in MBL between TAW group and SHW group at: T0, T1, T2, and T3, and the Mann-Whitney U test was utilized to identify disparities in the change of MBL(ΔMBL) between the two groups at the following time intervals: T0-T1, T0-T2, T0-T3, T1-T2, and T1-T3. Multivariate analyses in terms of these two workflows were conducted via generalized linear mixed model (GLMM) to adjust for potential confounding factors within inter-group differences. For soft tissue/oral hygiene indicators and patient satisfaction, Wilcoxon signed rank test or Mcnemar-Bowker test were used to evaluate the longitudinal alteration, and Mann-Whitney U test or Chi-square test were used to analyze the differences between groups. The criteria for significance were set at $p< 0.05$.

Informed Consent Form

Dear patient:

We sincerely invite you to participate in a clinical study on the clinical efficacy of implants using Nobel Parallel CC On1 abutment in the upper and lower posterior tooth areas. This study was conducted by the Department of Prosthetics (Dr. He Fuming). It has been reviewed and approved by the Ethics Committee of the Affiliated Stomatological Hospital of Zhejiang University School of Medicine.

Before deciding whether to participate in this study, please carefully read the following content. It can help you understand the study and why it was conducted, the procedure and duration of the study, and the potential benefits, risks, and inconveniences that participating in the study may bring to you.

The following is a detailed introduction to this study:

1. Research background

For patients with long-term tooth loss, implant surgery has become one of the most common methods. The soft tissue barrier formed around the implant after implantation is crucial for establishing and maintaining healthy tissue around the implant. However, in ordinary bone tissue level implants, the repeated connection and disconnection between the abutment and the implant simultaneously affect the stability of early and long-term soft tissue healing. Numerous literature studies have shown that multiple connections and disconnections between the abutment and the implant are significantly correlated with increased bone loss at the edge of the implant. Nobel Parallel TM CC has proposed the new concept of On1, and the On1 platform has been launched in China and can be put into clinical use. This concept is based on a two-stage abutment, where the On1 abutment is directly placed on the implant during surgery and will not be disconnected thereafter. The healing abutment placed on the On1 abutment during surgery can be easily replaced with a permanent abutment. Equivalent to bone level implantation and soft tissue level repair, it can protect and preserve the bone interface and connective tissue during all repair processes, while reducing patient discomfort

during treatment. At present, prospective clinical studies have found that the success rate, marginal bone resorption, and implant stability of Nobel Parallel TM CC implants combined with On1 abutment are good. However, there are relatively few clinical randomized controlled trials on Nobel Parallel TM CC implants combined with On1 abutment and conventional healing abutment.

2. Research objectives

This study will investigate the application of Nobel Parallel in the upper and lower posterior tooth areas during a four-year follow-up period The clinical application effect of CC implant combined with On1 abutment, as the On1 abutment group (experimental group), and the simultaneous study of the application of Nobel Parallel in the upper and lower posterior tooth areasThe clinical application effect of CC implant combined with ordinary healing abutment as the control group. Study Nobel Parallel separately The therapeutic effect of using On1 abutment and ordinary healing abutment for CC implants in the maxillary posterior tooth area with sufficient bone mass without the need for bone grafting. Through long-term follow-up, periodontal indicators such as implant retention rate, restoration retention rate, implant edge bone level, keratinized gingival width, improved plaque index, improved gingival sulcus bleeding index, gingival index, peri implant probing depth, and patient satisfaction were measured in each group. Analyze Nobel Parallel The long-term clinical efficacy of CC implant system applied in the field of oral implantation.

3. What do you need to do if you participate in the research

1) Expected duration of participant participation in the trial

After you sign the informed consent form, we will conduct subsequent research according to the established research protocol. The expected duration of your participation in the trial is 5 years, including a 1-year dental implant treatment stage and a 4-year dental implant follow-up stage.

2) Grouping method and possibility of allocation to each group

According to the established research protocol, successfully enrolled subjects will be

randomly assigned to the experimental group (ono1 abutment) group and the control group (ordinary healing abutment) group using a random number table to generate a series of numbers, each corresponding to the patient's visit time. The grouping will be determined based on the parity of these numbers.

The probability of you being assigned to each group is equal.

3) Trial steps and obligations that subjects need to follow

If you are assigned to the experimental group, we will treat you using the Nobel PCC+On1 abutment.

If you are assigned to the control group, we will treat you using the Nobel PCC+conventional healing abutment.

During the follow-up stage, you need to receive follow-up according to the agreed time between the doctor and you. The doctor may inquire about your situation through phone calls or in person visits. Your follow-up data will provide reliable data for the study and serve as a basis for doctors to determine the effectiveness of the treatment you have received.

4. Possible benefits of participating in this study

1) Experimental content involved in the study and its potential benefits and risks

In this study, the implantation of Nobel Pcc on1 abutment was considered experimental. According to relevant research results, using ON1 abutment instead of conventional healing abutment in the upper part of Nobel Pcc implant restoration may have good clinical expected benefits. But we also remind you that any treatment may be ineffective, and there may be further development of the condition due to ineffective treatment or the combination of other diseases

2) Possible benefits of participant participation in the study

By participating in this study, you may gain a more comfortable oral treatment experience, understand your own oral health status, and acquire knowledge related to oral health protection. We will provide you with medical and health consultation.

In addition, your participation may be beneficial for future understanding and scientific diagnosis of the etiology, development, impact, and other aspects of such diseases. The

results of this study may be beneficial for providing more appropriate prevention, diagnosis, and treatment interventions for you and patients with similar diseases in the future.

5. Confidentiality of your personal information

Your medical records (including research medical records and physical and chemical examination reports, etc.) will be kept in the hospital according to regulations. Personnel unrelated to the study are not authorized to access your medical records without permission. Inspectors, auditors, ethics committees, and drug regulatory authorities may access your original medical records to verify the process and data of clinical trials, provided that confidentiality principles and relevant regulations are not violated. The public report of the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data within the permitted scope.

6. Termination of research participation

Whether to participate in this study depends entirely on your voluntary choice. You may refuse to participate in this study, or withdraw from the trial at any time and stage during the research process without discrimination or retaliation, and your medical treatment and rights will not be affected. We will inform you promptly of any new information that may affect your ability to continue participating in the experiment. In addition, your participation in this study may be terminated due to the following reasons:

1) You did not follow the instructions of the research doctor.

2) You have encountered a serious situation that may require treatment.

3) The research doctor believes that terminating the study is most beneficial for your health and well-being.

I confirm that I have read and understood the informed consent form for this study, voluntarily accept the treatment methods in this study, and agree to use my medical data for publication in this study.

Subject signature:

Contact information: Date:

Agent signature (if required):

Agent subject relationship:

Contact information: Date:

Witness signature (if required):

Contact information: Date:

I confirm that I have explained the detailed information of this study to the patient, including their rights, potential benefits, and risks, and provided them with a signed copy of the informed consent form.

Subject signature:

Contact information: Date: