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Clinical evaluation of narrow diameter implants versus standard diameter implants with bone augmentation in posterior jaws:study protocol for a randomized controlled clinical trial

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Study protocol

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Abstract

Background: Nowadays, narrow diameter implants are being increasingly used in posterior regions with insufficient bone width to avoid invasive bone augmentation procedures. Recent studies have indicated that narrow implants with a diameter of 3.3 to 3.5mm showed comparable survival rate with standard diameter implants. However, there are no high-quality clinical trials comparing the clinical outcomes of narrow diameter implants to standard diameter implants with augmentation procedures in atrophic posterior region. The purpose of present study is to evaluate the clinical efficacy of narrow diameter implants in posterior jaws. Methods/Design: This study is designed as a prospective, single-center, 2-arm parallel, randomized controlled clinical trial. Patients in need of single implant crowns in posterior jaws will be included in the study according to clear defined inclusion-and-exclusion criteria. Randomized number table will be used to assign the patients into two groups: group 1: narrow diameter implant group (NDI); group 2: standard diameter implant with bone augmentation group (SDI). Implant survival rate, mechanical complications, marginal bone loss, peri-implant conditions and patients' satisfaction will be recorded. Clinical and radiological re-evaluations will be performed at 6, 12, 36, 60 months after the final crowns delivery. Discussion: Our findings will help evaluate the clinical efficacy of narrow implant in posterior region. If the results were favorable, narrow implants might be recommended as a viable alternative for posterior region with insufficient bone width. Trial registration: Clinicaltrials.gov identifier: ChiCTR1800020426 (registered on 29 December 2018)

Background

Implant-supported prostheses has been a highly predictable treatment to restore the function and esthetic of missing teeth in most clinical cases [1]. However, atrophic bony ridges with insufficient bone width remain a challenging situation for implant placement. A variety of lateral ridge augmentation techniques have been described in the literature to reconstruct deficient alveolar ridges, including guided bone regeneration, ridge splitting and block bone grafting. The survival rate of implants placed in narrow ridge where bone augmentation procedures are used is similar to the implant placed in pristine sites, with survival rates of 87%-95% and 99%-100% for the simultaneous and the staged approached respectively [2]. However, the lateral bone augmentation procedures have drawbacks in terms of patient morbidity, treatment time and total cost, thus making them less acceptable for patients, thus making them less acceptable by patients.

Narrow diameter implants are originally indicated in limited mesio-distal edentulous gap. Nowadays, NDI are increasingly used in sites with insufficient bone width to avoid invasive bone augmentation procedures. According to the modified classification at the 6th ITI Consensus Conference, NDI was divided into three categories [3]. NDI of category 3 with a diameter of 3.3 to 3.5mm showed survival rate comparable with SDI. Although the application of Category 3 NDI was not always clearly defined, it included the replacement of posterior teeth in both arches [4].

Our previous long-term retrospective study of NDI in the posterior jaws showed the overall implant survival rates were 96.9% at implant level and 97.0% at patient level. High patient satisfaction, acceptable complication rates and marginal bone resorption were achieved with at least 8-year follow-up [5]. A previous systematic review, based on the results of 5 studies with a control group, showed that NDI of 3.3 to 3.5mm are well documented in all indications including load-bearing posterior jaws [6]. According to a recent systematic review, it is reported that the mean survival rate of NDI placed in the posterior region was 98.6% with an observation period from 1 up to 12 years [7]. The authors hence concluded that NDIs might serve as an alternative to SDI in the posterior jaw.

Although previous studies have compared the clinical outcomes of NDI with SDI, there are no clinical trials with strict methodological designs comparing NDI without bone augmentation procedures to SDI with augmentation procedures. Therefore, we are designing this 5-year randomized clinical trial in order to evaluate the clinical parameters and patient-centered outcomes with NDI and SDI combined with lateral bone augmentation in atrophic posterior jaws.

OBJECTIVES AND HYPOTHESIS

The purpose of present study is to evaluate the clinical efficacy of narrow diameter implants in posterior jaws. Implant survival rate, mechanical complications, marginal bone loss, peri-implant conditions and patient-centered outcomes will be recorded. Clinical and radiological re-evaluations will be performed at 6, 12, 36, 60 months after the final crowns delivery. The null hypothesis is that there is no significant difference regarding survival rate between two groups.

Methods

Overview

The proposed study is designed as a prospective, single-center, 2-arm parallel, randomized controlled clinical trial. The study flow chart is presented in Fig.1. We plan to enroll 132 adult patients who are in need of single implant crown treatment in the posterior jaws. The study has been approved by the Ethics Committee of Shanghai Ninth Peoples Hospital, China. In addition, the study has been registered in Clinical-Trials.gov and the identifier number is ChiCTR1800020426. The clinical component of the study will be initiated in February 2019 at the Department of Oral Implantology, Shanghai Ninth People's Hospital, Shanghai Jiao Tong University, China. The trial schedule is shown in Fig.2 and the SPIRIT Checklist is reported in Additional file 1.

All patients received oral hygiene instruction and periodontal treatment before implant surgery. Basic information including the age, gender, physical health of all participants will be recorded and they should meet the following inclusion criteria. Panoramic and peri-apical radiographs with paralleling technique

will be performed to assess the available bone height and bone width. Cone-bone CT will be taken if needed.

Inclusion criteria

1. ≥18 years old and in good health;
2. presence of single premolar or molar site to receive implant-supported single crown; available bone width ranging from 5 to 6mm to allow the placement of an implant with 3.5 mm diameter without concurrent bone augmentation
3. available bone height ≥10mmsufficient mesio-distal distance of edentulous gap with at least 1.5mm the distance between implant and neighbouring teeth
4. sound antagonist teeth and neighbouring teeth;
5. absence of systemic and local condition incompatible with implant placement
6. willing to provide informed consent and capable of complying the study protocol

Exclusion criteria

1. uncontrolled diabetes mellitus or other systemic disorders;
2. untreated periodontal disease;
3. Heavy smokers (≥10 cigarettes/day);
4. insufficient bone quality to achieve implant stability
5. previous implant installation or bone grafting at the implant site.
6. Unwilling to participate in the present study.
7. extensive bone augmentation needed during surgery

Recruitment

Participants will be recruited in the Department of Oral Implantology, Shanghai Ninth People's Hospital. Eligible patients will receive the study information and any patients who do not sign the consent forms will not be included in the study.

Allocation and blinding

All patients eligible for the study will be assigned into two groups according to a according to a computer-generated randomization list: group 1: narrow diameter implant group (NDI); group 2: standard diameter implant with bone augmentation group (SDI). A permuted-block randomization with block sizes of 4 and allocation ratio of 1:1 was applied to avoid possible bias in the allocation of subjects. The assignment will be concealed to the clinical operators until the beginning of implant placement to prevent selective bias. The assignment will be kept unknown to the outcome examiners and patients.

Surgery procedure

For all the patients, the NobelReplace Conical Connection implants system (Nobel Biocare AG, Gothenburg, Sweden) will be used. The surgery will be performed under local anesthesia. Following a mid-crestal incision, a full-thickness flap will be elevated. The following surgical steps will be dependent on randomization allocation. In group 1, implant with a diameter of 3.5mm will be inserted according to the instruction of manufactures. In group 2, implant with a diameter of 4.3mm will be inserted in the same protocol with group1. Lateral bone augmentation will be performed with bone substites(Geistlich Bio-Oss®; Geistlich Pharma AG, Wolhusen, Switzerland) and colleagen membranes(Geistlich Bio-Guide®; Geistlich Pharma AG, Wolhusen, Switzerland). Implants in both groups were left to heal non-submerged. Implants lacking primary stability at the time of insertion were excluded from the study. Medical prescription including anti-inflammatory amoxicillin (Xinya Co., Shanghai, China, 500 mg, three times a day for 7 days) and metronidazole (Xinyi Wanxiang, Shanghai, China,400 mg, three times a day for 7 days) will be given to patients. Besides, 0.12% chlorhexidine oral rinse will be prescribed for 60 s two times a day for 14 days. A one-stage protocol will be performed. After a healing period of 6months, an impression will be taken at the implant level. Nobel titanium abutment will be screwed into the implants. Porcelain fused to metal crown will be delivered.

Outcomes

Baseline assessment

A panoramic and a peri-apical radiograph will be taken post-operatively. Resonance frequency analysis measurement using the Osstell ISQ (Osstell AB, Gothenburg, Sweden) will be performed. Treatment time and patient-reported outcome will also be recorded. Treatment time will be calculated from the moment incision is made to wound closure with suturing. A 100-mm visual analogue scale(VAS) will be used to record patients' answers regarding intra-operative and post-operative discomfort and satisfaction with function, esthetic and oral hygiene maintenance of the implant-supported prostheses after loading.

Follow-up assessment

All the included patients will be recalled for clinical and radiological re-evaluations at 6, 12, 36 and 60months after the insertion of final crown. Implant survival rate, mechanical complications, marginal bone loss, peri-implant conditions and patients' satisfaction will be recorded.

Implant survival rate. Survival rate is defined as the percentage of implants that remain in place with or without complications.

Mechanical complications. Ceramic chipping, framework fracture, abutments or implants fracture, abutment screw loosening or fracture and loss of retention will be recorded during the follow-up.

Marginal bone loss. Peri-apical radiographs will be performed using paralleling technique on the day of crown delivery and during each recall after loading. The digital imagines will be analyzed in a software program(SIDEXIS 1.12, Sirona Dental System GmbH, Bensheim, Germany). The distance between implant platform and the most coronal level of implant-bone contact will be recorded using implant length as a calibration reference. The distance at the mesial and distal sites will be averaged to get the final result. Marginal bone loss is defined as the change of the distance between baseline and follow-up visit.

Peri-implant conditions. The following parameters of peri-implant conditions will be recorded both on the day of crown delivery and each recall after loading, including modified plaque index (mPI), pocket probing depth (PD) and bleeding on probing (BOP).

Patient-center outcomes. All patients will be asked to fill out VAS(1-100) forms at the day of surgery, 2 weeks post-operative, crown delivery and 6, 12, 36 and 60 months after the insertion of crown. VAS rating for the day of surgery will include the perception regarding intra-operative pain and general discomfort. Two weeks after surgery, VAS form will be completed regarding the patients' perception towards post-operative complications(bleeding, pain, swelling and bruising).VAS score recorded during each follow-up visit will cover patients' satisfaction of function, esthetic and oral hygiene maintenance of the implant-supported protheses after loading.

Sample size

Sample size estimation of this study is based on non-inferiority test

The implant survival rate is chosen as the primary outcome. A previous study [8] showed that the 5-year implant survival rate was 95.4% in standard diameter implants with bone augmentation (P=0.954). The implant survival rate of test group is considered not inferior to control group if $P_t - P_c \leq -0.1$. The calculation of sample size is as follows:

$n = 2\times(U_\alpha+U_\beta)^2\times P(1-P)/\delta^2$

$\alpha=0.05, U_\alpha=1.6449, \beta=0.2, U_\beta=0.845\ \pi=0.954\ \delta=0.1$

$n=2\times0.954\times(1-0.954)\times\{(1.6449+0.845)/0.1\}^2\approx55$

Considering possible dropout of patients, the final sample size is 55×120%≈66 for each group. Thus, the total sample size is 66×2=132.

Statistical analysis

SPSS Software (SPSS 17.0, SPSS Inc., Chicago, IL, USA) will be used for data management and data analysis. Mean and standard deviations (SD) will be calculated for descriptive statistics of quantitative data consistent with the normal distribution. Two sample t test will be used to compare the between-groups mean levels if the quantitative data was consistent with the normal distribution. Percentage will be used for descriptive statistics of categorical variables and the 95% confidence interval (CI) will be calculated to describe and compare the implant survival rate. If the 95% CI of overall 5-year between-group survival rate difference accords with $-\delta<C_l$ then it will conclude that implant survival rates of the test group is not inferior to the control group. In addition, Chi-square test will be used to compare the proportion of mechanical complications of two groups. Nonparametric test will be performed if the quantitative data was inconsistent with the normal distribution. P value of less than 0.05 will be considered to indicate statistical significance.

Missing data

First, an increase of 20% patients were added to each group during sample size estimation process to assurance the power of statistical test due to the possible loss to follow-up of patients. Moreover, the dropout and loss to follow-up patients will not be excluded during data analysis using the intention-to-treat principle. The baseline and the previous follow-up information of dropout or loss to follow-up patients will be evaluated. The missing data of primary outcome in test group will be assigned to failed case. In the control group, the primary outcome of the most similar patient will be added to the missing data of the patient.

Ethical considerations

Ethical approval

Approval by the Ethics Committee of Shanghai Ninth People's Hospital, China (SH9H-2018-T69-2) has been obtained. All eligible patients will receive the study information and consent forms. No patients will be included if the patients do not sign the consent.

Withdraw

All of the participants will be informed that they have the right to withdraw at any period of time during the study, regardless of whether they complete the program or withdraw early, the treatment requested by the patient will be provided.

Dissemination of results

The study findings will be published in an international peer-reviewed journal. A summary of the study findings will also be saved at Clinicaltrials.gov to allow public access to study results.

Discussion

Narrow bone ridges in posterior jaws is often difficult for the placement of standard-diameter implant due to the insufficient bone width and limited operative field. There are two main approaches to reconstruct deficient alveolar bone width: guided bone regeneration or bone blocks grafting. Both treatment options can lead to high survival and success rates(≥95%)of implants placed on the regenerated bone [9]. On the other hand, previous studies reported predictable results of NDI placed in posterior jaws to circumvent the trauma and costs associated with the lateral bone augmentation procedures [10, 11]. Therefore, it is of great significance to perform a comparison of the long-term treatment outcomes between NDI alone and SDI combined with lateral bone augmentation.

The study findings will support better decision-making for implant treatment in narrow bone ridges in posterior jaws. If the results are favorable, the use of the narrow diameter implant may avoid adjunct procedures associated with the placement of SDI, which is problematic in terms of patient morbidity, treatment time and costs.

Trial Status

The trial (Version number 20181206) was registered at Clinicaltrials.org.cn. The recruitment started at 1st February 2019 and will completed at 31st December 2020.

Abbreviations

NDI: narrow diameter implant group; SDI: standard diameter implant with bone augmentation group; mPI: modified plaque index ; PD: pocket probing depth;BOP bleeding on probing; VAS: visual analogue scale

Declarations

Ethics approval and consent to participate

The study (SH9H-2018-T69-2) has been approved by the Ethics Committee of Shanghai Ninth People's Hospital, China. In addition, the study has been registered in Clinical-Trials.gov and the identifier number is ChiCTR1800020426. Informed consent will be obtained from eligible participants.

Competing interests

The authors declare that no competing interests exist.

Availability of data and materials

Not applicable.

Consent for publication

Not applicable.

Authors' contributions

SJQ and JJM conceived and design the study. SJQ and SCQ prepared the study protocol and wrote the manuscript. JJM contributed to the conception of the surgical part of the study and critically revised the manuscript for important intellectual content. XZ performed the data analyses and contributed to the writing of the manuscript. YZ participated in data acquisition and interpretation and critically revised the manuscript. All authors read and approved the final manuscript.

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Figures

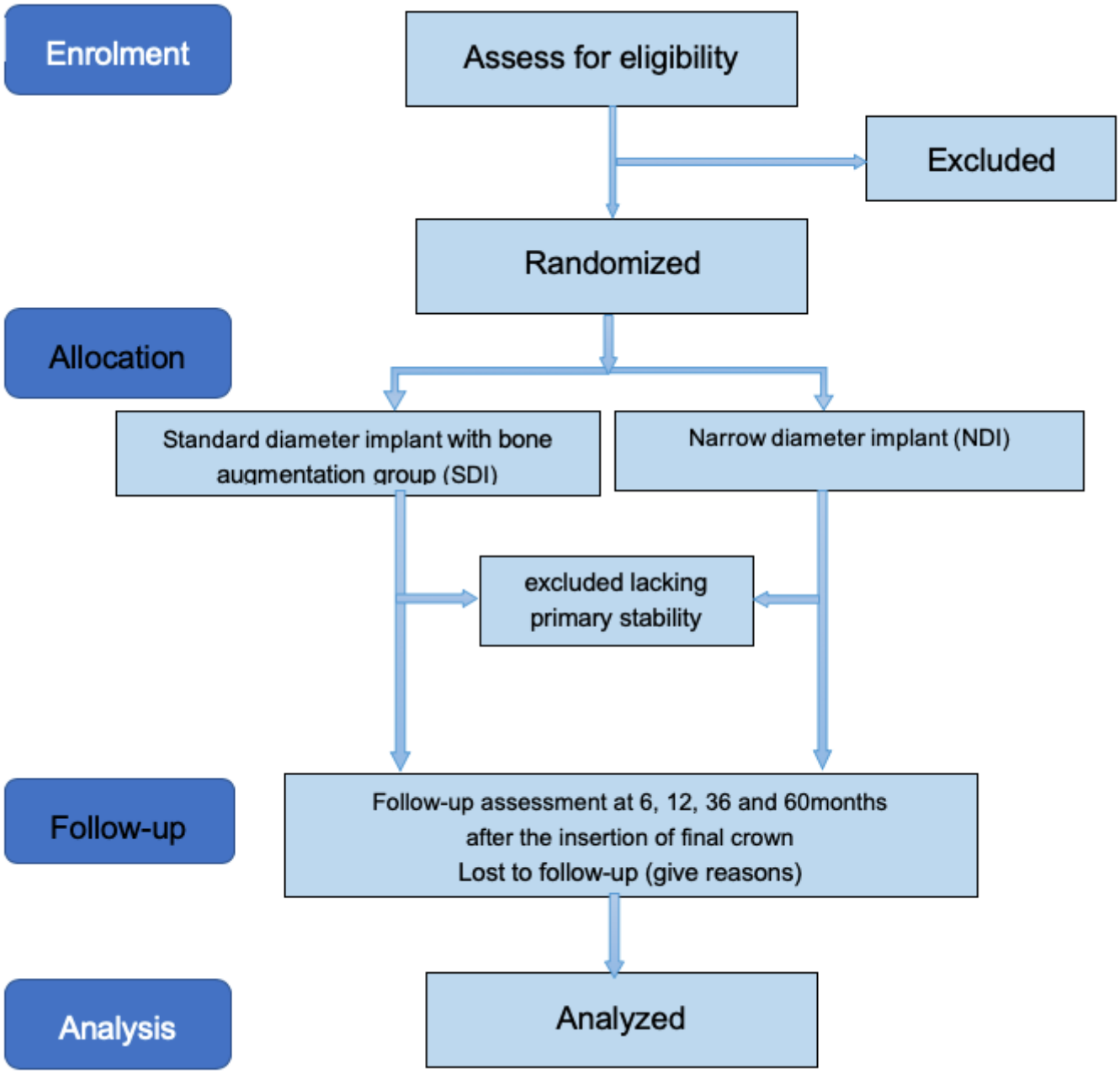

Figure 1

The Trial flowchart.

	STUDY PERIOD									
	Enrollment	Allocation	Treatment				Follow-up			
TIMEPOINT	-1	0	1	2	3	4	5	6	7	8
ENROLLMENT										
Eligibility screen	X									
Informed consent	X									
Allocation		X								
INTERVENTIONS										
NDI			X	X	X	X				
SDI			X	X	X	X				
ASSESSMENTS										
Oral examination			X	X	X	X	X	X	X	X
Peri-apical radiograph				X	X	X	X	X	X	X
Peri-implant conditions				X	X	X	X	X	X	X
VAS			X	X		X	X	X	X	X
Adverse event			X	X	X	X	X	X	X	X

Figure 2

Schedule of enrollment, interventions, and assessments (NDI: narrow diameter implant group; SDI: standard diameter implant with bone augmentation group).

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- supplement1.doc