CLINICAL STUDY PROTOCOL

TITLE:

Post Market Clinical Follow up Study (PMCF) of CeraRoot Ceramic Implants One-piece: 3 Years Follow up (Period: 2020- 2023)

ID:200806
NCT: 04598776

Written and Approved:
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1.Description of study

1.1. Brief Summary:

The main objective is to evaluate the survival / failure rate of CeraRoot ceramic implants (one piece) during a three year follow up.

1.2. Detailed Description:

Traditionally the material of choice for dental implants has been titanium.
The success of such material has been unquestionable for the last decades.
However a number of issues arise lately regarding the biocompatibility or cytotoxicity or allergies regarding the degradation or oxidation particles within the bone or gum. Esthetics has been a concern as well, especially in patients with thin biotypes where the metal may produce a greyish look of the mucosa. For this reason the dental community and patients have raised much interest in ceramic dental implants as a tooth colored and metal free alternative for dental implants.

2.Objectives

Since 2006 CeraRoot ceramic implants have been available in the market. The main goals for designing this PMCF is to evaluate the long term success of CeraRoot ceramic implants.
To achieve those objectives an observational study of patients that have received such implants is designed with implant survival as the main outcome measure.

3.Design

3.1. H_0 (Null Hypothesis)

There are no significant differences between the failure rate in this study and the failures rates in literature regarding this dental implant.

3.2. H_1 (Alt.Hypothesis)

There are significant differences between the failure rate in this study and the failures rate in the literature.

3.3. Study Type:

Observational [Patient Registry]

3.4. Observational Study Model:

Cohort

3.5. Time Perspective:

Prospective

3.6. Biospecimen Retention:

None Retained

3.7. Biospecimen Description:

3.8. Enrollment:
200 [Anticipated/ predicted]
175 real participants enrolled in the study.

3.9. Number of Groups/Cohorts:
1

3.10. Target Follow-Up Duration:
3 Years

3.11. Groups and Interventions
no interventional

3.12. Outcome Measures

Primary Outcome Measure:
1. Implant Survival (Implant without pain, without mobility and in function.) [Time Frame: Baseline until 3 years]

Secondary Outcome Measure:
2. Surgical complications (SC)
Any complications, as bleeding, infection, no primary stability, early loss.... that may appear will be collected [Time Frame: Baseline to 7 days]
3. Before loading implants Complications (BLIC)
Any complications before the prosthesis is delivered (implant mobility, implant infection, implant loss...) will be collected [Time Frame: 7 days post operative to delivery of prosthesis]
4. After loading implants Complications (ALIC)
Any complications after the prosthesis is delivered (implant loss, bone loss, implant mobility...) that may appear will be recorded. [Time Frame: Baseline to 3 years]
5. Prosthetic Complications (PC)
Any difficulty during the confection of the crown, complications such as decementation, chipping, etc... will be registered. [Time Frame: Baseline to 3 years]
6. Implant Success
Implant survival in addition to not having bone loss around it.(. [Time Frame: Baseline to 3 years]

Definition of success:
A "successful implant" is an implant where all of the following success criteria (according to Buser et al., 1992) apply:
- Absence of persisting subjective discomfort such as pain, foreign body perception and/or dysesthesia (painful sensation);
- Absence of recurrent peri-implant infection with suppuration;
- Absence of tactile implant mobility;
- Absence of a continuous peri-implant radiolucency.

Definition of Survival:
Any implant present in the mouth at the moment of evaluation.

3.13. Eligibility

Study Population:

Patients that needed a tooth replacement that fulfilled the eligibility criteria.

Sampling Method:

Non-Probability Sample

Minimum Age:

18 Years

Maximum Age:

80 Years

Sex:

All

Gender Based:

No

Accepts Healthy Volunteers:

Yes

Criteria:

Inclusion Criteria:

• Patients that have received the studied ceramic implant after 27 August 2020.
• Patients of CeraRoot Clinic (Barcelona)
• Age >18
• Single or multiple missing or hopeless teeth

Exclusion Criteria:

• Smokers.
• The patient is taking medications or having treatments which have an effect on healing in general (e.g. steroids, large doses of anti-inflammatory drugs).
• Untreated periodontal conditions

3.14. Contacts/Locations

Study Officials: Dr. Josep Oliva-Ochoa , Dr. Xavi Oliva-Ochoa
Locations: CeraRoot CLINIC. Les Franqueses del Vallès, Barcelona, Spain, 08520

4.Materials and Methods

4.1. Main product used:

CeraRoot ceramic implant

4.2. Secondary products used:

CeraRoot rotary instruments

CeraRoot accessories surgical
CeraRoot accessories prosthetics

4.3. Method

A patient history revision of dental charts is done by searching in the database patients with CeraRoot implants placed during the period of this study at CeraRoot CLINIC.
An excel sheet database is done with the patients that are compatible with the inclusion criteria.
The statistical analysis is performed with the database.

4.4. Sample Size Calculation

The sample size calculation has been performed with the assumption that the results of this study will be similar to those obtained in scientific literature with the same device which is around 98% (Oliva 2010).
The chosen statistical test and sample size equation for this clinical study is:

Formula:
$$n = P * (1 - P) * \left(\frac{Z_{1-\alpha} + Z_{1-\beta/2}}{\lvert P - P_0 \rvert - \delta}\right)^2$$
Source: The-Medical-Device-Sample-Size-Cookbook.pdf Z values taken from this source.

The inputs required for this calculation are defined below

VARIABLE	VALUE	CLARIFICATION
n	?	the sample size
P	2% (0,02)	This is called the True Proportion, i.e. the proportion to be tested. We assume that 2% of implants will fail to integrate.
P0	3% (0,03)	This is called the Null Hypothesis Proportion. It's the reference value (gold standard) we are testing up against, and thus not assumed but originating from the literature
P - P0	1% (0,01)	The minimum clinically meaningful effect, i.e. the difference between the two proportions - which makes it interesting to test for equivalence.interesting to test.
δ (Delta)	8% (0,08)	The testing margin, if the difference in failures is 6% or more, it's not considered equivalent from a clinical perspective.
H_0 (Null Hypothesis)	$\lvert P - P_0 \rvert \geq \delta$	The difference between the two proportions is 6% or higher. This would mean that it's not equivalent.

H_1 (Alt.Hypothesis)	$\| P - P_0 \| < \delta$	The difference between the two proportions is less than 6%, and thus equivalent.
α (Alpha)	5% (0,05)	The recommended minimum standard (can be lower)
Power (1 - β)	80% (β = 0,20)	The recommended minimum standard (can be higher)

The inputs in the formula are:
$n = 0,02 * (1 - 0,02) * ((1,645 + 1,282) / ((0,02-0,03)-0,08))^2 = 20,729 >> 21$

This is, that we would need at least 21 subjects to illustrate equivalence of results of this clinical study versus the previous CeraRoot study (PMCF #191220). For this reason the estimated sample size of 200 patients for the present study PMCF 200806 is more than sufficient based on this statistical calculation.

5.Scientific Background

5.1. References:

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