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The ball welding bar: a new solution for the immediate loading of screw-retained, mandibular fixed full arch prostheses

Submission date
19/06/2017

Recruitment status
No longer recruiting

Registration date
27/06/2017

Overall study status
Completed

Last Edited
25/08/2017

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Complete mandibular edentulism is the condition where all of the lower teeth are missing. It is a difficult condition for patients because complete removable dental prostheses (dentures) are extremely difficult to wear, move during chewing, lack stability and cause pain/discomfort when eating. A possible solution to stabilize the complete prostheses is to place dental implants in the mandible (lower jaw). Dental implants are titanium fixtures that can be placed in the bone to support the prosthesis and stabilize it, preventing movement and discomfort when eating. In order to obtain better stability of the prosthesis over the implants, the implants can be splinted by means of a bar to support the prosthesis. Conventionally, making a bar to support the prosthesis is a procedure that involves different laboratory steps, with a longer treatment time and higher costs for the patients. As an alternative, and in order to reduce the laboratory steps and time for this treatment, different welding techniques have been proposed for creating the bar inside the mouth of the patients. These techniques can be highly successful. In this study, a new technique for the making a mandibular bar is tested, the ball welding bar. The ball welding bar consists of smooth prosthetic cylinders, interconnected by titanium bars which are adjustable in terms of distance from the ball terminals and inserted into the rotating rings of the cylinders. All the components are welded and self-posing.

Who can participate?
Patients with complete mandibular edentulism and problems related to their complete, removable conventional dentures (i.e. lack of stability, discomfort during eating and aesthetic embarrassment)

What does the study involve?
All participants are treated using the new ball welding bar technique and are followed for a 2-year period in order to assess the survival of the implants and the success of this technique.

What are the possible benefits and risks of participating?
The ball welding bar technique can simplify the creation of mandibular bars, reducing time and costs, with clear benefits for the patients. For the dentists, the main advantages of this method

are that it makes it easy to centre the bars over the bone crest, allows for fine regulation, and makes it easy to solder the framework without distortions. Finally, the procedure is very rapid and can be managed by a single operator, both of which allow for reduced rehabilitation costs.

Where is the study run from?
1. Studio Dentistico Guida (Italy)
2. Studio Dentistico Dr. Bacchiocchi (Italy)

When is the study starting and how long is it expected to run for?
January 2010 to December 2015

Who is funding the study?
Studio Dentistico Dr Andrea Guida (Italy)

Who is the main contact?
Prof. Andrea Guida
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
0001

Study information

Scientific Title
The ball welding bar: a new solution for the immediate loading of screw-retained, mandibular fixed full arch prostheses

Acronym
BWB

Study objectives
The purpose of this study was to present a new intraoral welding technique, and in particular a new method for the fabrication of a bar (the ball welding bar) that can be used to support screw-retained, mandibular fixed full arch prostheses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Fundacao Universitaria Vida Crista (FUNVIC) Institutional Board, 25/01/2010

Study design
Non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Implant prosthodontics

Interventions
In the period between January 2010 and December 2013, all patients with complete mandibular edentulism or irreparably compromised mandibular dentition, who were referred to two different private dental centres patients for restoration of the masticatory function with a fixed mandibular prosthesis supported by dental implants, were treated with the new ball welding bar technique. The patients were then followed for a 2-year period, in order to evaluate the survival of the implants and the success of this technique.

Intervention Type
Procedure/Surgery

Primary outcome measure
Implant survival, i.e. the clinical condition in which the implants are still in function in the patients' mouth, at the end of the 2-year follow-up period

Secondary outcome measures
Prosthetic success, i.e. the clinical condition in which no adverse events or complications (such as fractures/alterations of the resin superstructure and of the intraorally welded titanium framework) occur at the prosthesis level, assessed at the end of the 2-year follow-up period

Overall study start date
01/01/2010

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Complete mandibular edentulism, with functional and aesthetic problems related to the presence of a complete, removable conventional denture (i.e. lack of stability of the complete denture, discomfort during function and aesthetic embarrassment)
2. Irreparably compromised mandibular dentition, due to advanced periodontal disease or destructive/massive tooth decay, that made the residual dental elements unrestorable
3. Sufficient bone volume (bone height x width) to allow for the placement of implants of at least 8 mm in length and 3.0 mm in diameter
4. Will to restore the masticatory function with a fixed mandibular prosthesis supported by dental implants
5. Ability to understand and sign an informed consent form for implant treatment.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40-50

Key exclusion criteria
1. General medical conditions/systemic diseases that represented an absolute contraindication to surgical and implant treatment, such as severely immunocompromised patients or severely uncompensated diabetics, patients receiving radiotherapy to the head and neck area or chemotherapy, patients receiving amino-bisphosphonates intravenously and/or orally
2. Psychiatric disorders
3. Addicted to alcohol or drugs
4. Needed bone augmentation procedures with autogenous bone or other bone substitutes, to allow for proper implant insertion

5. Previously undergone major regenerative bone surgery, preliminary to the placement of dental implants

Date of first enrolment
01/01/2010

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Italy

Study participating centre
Studio Dentistico Guida
via Sartena 9
Lido di Ostia (Roma)
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Study participating centre
Studio Dentistico Dr. Bacchiocchi
Via Gaetano Donizetti 2
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Studio Dentistico Dr Andrea Guida

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/07/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Andrea Guida (prof.guida@outlook.it).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No