

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

<b>Submission date</b> 19/06/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/08/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> 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  
prof.guida@yahoo.it

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Andrea Guida

**ORCID ID**  
<http://orcid.org/0000-0002-1462-7205>

**Contact details**  
via Sartena 9  
Lido di Ostia (RM)  
Italy  
00122  
+39 (0)6 562 3973  
prof.guida@yahoo.it

## 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)

Italy

00122

**Study participating centre**

**Studio Dentistico Dr. Bacchiocchi**

Via Gaetano Donizetti 2

Castelfidardo (AN)

Italy

60022

## **Sponsor information**

**Organisation**

Studio Dentistico Dr Andrea Guida

**Sponsor details**

via Sartena 9

Lido di Ostia (RM)

Italy

00122

+39 (0)6 562 3973

ostia@sorridental.it

**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?
<a href="#">Results article</a>	results	01/05/2017		Yes	No