

**Bar and Ball Joint Overdentures Surface Roughness and Microbial Adherence**  
**NCT (not available)**  
**January 11, 2016**

**Research Ethics Review Committee  
GASTROVITAL**

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***Informed Consent Form***

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Informed Consent form for men and women who attend clinic Gastrovital, and who we are inviting to participate in research. The title of our research project is “**Bar and Ball Joint Overdentures Surface Roughness and Microbial Adherence**”

**Name of Principal Investigator** Rocío Violeta Valenzuela Narváez

**Name of Organization** Gastrovital

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form.

**PART I: Information Sheet**

**Introduction**

I am PhD Rocío Violeta Valenzuela Narváez, working for the Gastrovital Research Institute. We are doing research on bar and ball joint overdentures surface roughness and microbial adherence. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me

**Purpose of the research**

The purpose of the research was to compare the surface roughness (Ra) of bar overdentures compared to ball joint overdentures in relation to the adhesion of mold and yeast and mesophyll aerobe at 30 and 180 days of permanence in the oral cavity in order to establish if there are differences in surface roughness and which of these overdentures are characterized by their lower roughness and adherence of mold and yeast and mesophyll aerobe which is an important aspect to be considered in the rehabilitation of mandibular total edentulous patients with implants due to their influence on oral health.

### **Type of Research Intervention**

The working protocol for determining the bar overdenture (Ra) and ball joint overdenture (Ra) and the adhesion of molds and yeasts and mesophyll aerobics was carried out entirely by an investigator and the following working methodology was considered: Information to the patient of the research work to be performed. Obtainment of clinical data and patient informed consent. Patients were randomly assigned to group 1 and group 2. The saliva sample was obtained in each patient for the microbiological before the installation of the overdentures. Bar overdentures and ball joint overdentures were installed in each patient and according to each case. The bar overdenture and ball joint overdenture were removed at 30 days for surface roughness evaluation (Ra:µm) and the evaluation of the adhesion of mold and yeast and mesophyll aerobe (CFU/ml). For the study at 180 days the bar overdentures and the ball joint overdentures were installed in each patient. Bar overdentures and ball joint overdentures were removed after this time to proceed to the evaluation of surface roughness and adhesion of mold and yeast and mesophyll aerobe under the same parameters mentioned above.

### **Participant selection**

We are inviting all adults with total edentulous mandible from 50 to 60 years of age and absence of systemic conditions. The exclusion criteria for the study were: hyperplasia and history of periodontal disease, patients with local and/or systemic antimicrobial treatment within 72 hours prior to evaluation during the study and signs of severe oral parafunction

### **Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this clinic for your treatment, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

### **Information on the Trial**

For the manufacture of the overdentures in both groups will be made as material of choice Lucitone 199® (Dentsply International Inc. York, PA) and for the adaptation of the retention systems will be made Softreliner Tough Soft® Tocuyama Dental Corporation Inc., Japan. The overdentures were made for each group: Group 1: BOD: five systems titanium bar CARES® and synOcta® Straumann® Dental Implant System, Holding AG Inc., Basel, Switzerland (BOD). Group 2: BJOD: five systems ball joint Klockner® Implant System; Soadco Inc., Escaldes-Engordany, Andorra. We do not know of any known problems or risks associated with these materials to be used in the research.

### **Procedures and Protocol**

Because we do not know if the bar overdenture is better than the ball joint overdenture for treating in the rehabilitation of mandibular total edentulous patients with implants, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the bar overdentures while participants in the other group will be given the ball joint overdentures. It is important that neither you nor we know which of the two overdentures you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If there is anything you are concerned about or that is bothering you about the research please talk to me.

### **Description of the Process**

The study presents the results of a sample of ten patients randomly assigned to receive implant-retained overdentures and divided into two parallel groups of five participants in a single-blind trial at a follow-up period of 30 and 180 days permanence in the mouth. Five overdentures were made for each group: Group 1: bar overdentures: five systems titanium bar CARES® and synOcta® Straumann® Dental Implant System, Holding AG Inc., Basel, Switzerland (BOD). Group 2: ball joint overdentures: five systems ball joint Klockner® Implant System; Soadco Inc., Escaldes-Engordany, Andorra were used in two parallel groups of five participants.

The working protocol for determining the bar overdenture Ra and ball joint overdenture Ra and the adhesion of molds and yeasts and mesophyll aerobics was carried out entirely by an investigator and the following working methodology was considered: Information to the patient of the research work to be performed. Obtainment of clinical data and patient informed consent. Patients were randomly assigned to group 1 and group 2. The saliva sample was obtained in each patient for the microbiological before the installation of the overdentures. Bar overdentures and ball joint overdentures were installed in each patient and according to each case. The bar overdenture and ball joint overdenture were removed at 30 days for surface roughness evaluation (Ra:µm) and the evaluation of the adhesion of mold and yeast and mesophyll aerobe (CFU/ml). For the study at 180 days the bar overdentures and the ball joint overdentures were installed in each patient. Bar overdentures and ball joint overdentures were removed after this time to proceed to the evaluation of surface roughness and adhesion of mold and yeast and mesophyll aerobe under the same parameters mentioned above.

### **Duration**

The research takes place over 12 months in total. During that time, it will be necessary for you to come to the clinic. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 12 times to the clinic in 12 months. At the end of six months, the research will be finished.

### **Side Effects**

There are no known side effects. *However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.*

### **Benefits**

If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. Your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

### **Reimbursements**

We will give you 25 d. to pay for your travel to the clinic/parking and we will give you 50 d. for lost work time. You will not be given any other money or gifts to take part in this research.

### **Confidentiality**

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researcher will be able to see it. Any information about you will have a number on it instead of your name. Only the researcher will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except your clinician.

### **Sharing the Results**

The knowledge that we get from doing this research will be shared with you before it is made widely available to the public. Confidential information will not be shared. There will be small meetings and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

### **Right to Refuse or Withdraw.**

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment will not be affected in any way.

### **Who to Contact**

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: Rocío Valenzuela. Gastrovital. 511 961 563 122.

**This proposal has been reviewed and approved by Gastrovital, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the Gatsrovital, contact: Rocío Valenzuela. Gastrovital. 511 961 563 122.**

**PART II: Certificate of Consent**

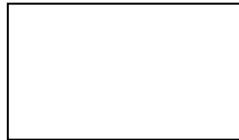
**I have read the foregoing information, and it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.**

**Print Name of Participant** \_\_\_\_\_

**Signature of Participant** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**

**AND Thumb print of participant**



**Statement by the researcher/person taking consent**

**I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done: compare the surface roughness (Ra) of the implant retained mandibular bar overdenture (BOD) and the implant retained mandibular ball joint overdenture (BJOD) in jaw and its relation with the adhesion of molds and yeasts and mesophyll aerobe, in time 30 to 180 days in mouth**

**I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.**

**A copy of this ICF has been provided to the participant.**

**Print Name of Researcher/person taking the consent: PhD DDS Rocío Violeta Valenzuela Narváez**

**Signature of Researcher /person taking the consent** \_\_\_\_\_

**Date** \_\_\_\_\_  
**Day/month/year**