

**Informed Consent**

**Study Number:** CIR-ECL-2016-03

**Protocol Version:** 1.2

**Version Date:** 07/06/2017

**Department:** Oral and Maxillofacial Surgery

**Research Line:** Oral Invalidity

**Research Title:** Evaluation of marginal bone loss in Straumann® BLT implants in patients with posterior partial edentulism. A randomized clinical study comparing direct implant connection vs. intermediate abutment.

**I, Mr./Ms.:**

- I have received verbal information about the study and have read the attached written information, of which I have received a copy.
- I understand what has been explained to me.
- I have had the opportunity to discuss the study and ask questions to the responsible professional.
- I give my consent to participate in the study and acknowledge that my participation is completely voluntary.
- I understand that I may withdraw at any time without affecting my future medical care.

By signing this informed consent form, I give my consent for my personal data to be used as described in this form, in compliance with **Organic Law 15/1999, of December 13, on the Protection of Personal Data.**

I understand that I will receive a copy of this informed consent form.

**Patient's Signature**  
**ID Number**

In Sant Cugat del Vallès (Barcelona), on the ..... of ..... of .....

PART II - Copy for the Investigator

### **Investigator's Statement**

The patient signing this consent form has received detailed oral and written information from the professional regarding the process and nature of this research study. The patient has had the opportunity to ask any questions concerning the nature, risks, and benefits of their participation in this study.

### **Investigator's Signature**

**Name:**

**Date of Signature**

In Sant Cugat del Vallès (Barcelona), on the ..... of ... of .....

### **PART II - Copy for the Investigator**

## **Objective**

To determine the influence of the prosthetic abutment height on marginal bone loss by comparing the volumetric changes in the soft and hard tissues around Straumann Bone Level Tapered (BLT) implants using different abutment heights in partially edentulous patients in the posterior area.

## **Cronogram**

### **SURGICAL STAGE**

#### **Pre-Operative**

- **2 weeks**
- **Evaluation for study inclusion**
  - Screening
  - Implantology Study (*CBCT 1*)
  - **Baseline 1**

#### **Surgery (*implant placement*)**

- **8 weeks**

#### **Second-stage surgery (*only for Control Group*)**

- **1-2 weeks**

### **PROSTHETIC STAGE**

#### **Provisional Crowns**

- **9 weeks**

#### **Impressions**

- **1 week**
- **10 weeks**

#### **Definitive Crowns**

- **Baseline 2**

### **FOLLOW-UP**

- **Control 1 → 3 months**

- **Control 2** → 6 months (*CBCT 3*)
- **Control 3** → 12 months
- **Control 4** → 24 months
- **Control 5** → 36 months

**PART II - Copy for the Investigator**

## Patient Scheduling for Implants

### 1. Required Documentation for Scheduling the Patient and Signing the Implant and Biomaterial Request:

- Signed informed consent from the patient and responsible guardians.
- Budget signed by the patient and responsible guardian.
- Approved clinical session document.
- Implant and biomaterial request signed by the tutor and validated by the Budget Department.
- Specific request for study implants (request from Isabel).
- Prosthetic attachment request signed by the tutor and validated by the Budget Department.

### 2. These documents must be submitted to the budget coordinators to schedule appointments and approve the material orders needed for the intervention.

**Morning shift:** Àngels Coll

**Afternoon shift:** Rosa Ma Castellano

### 3. Submission of Implant and Biomaterial Requests for the Intervention:

Signed implant and biomaterial requests must be submitted to Isabel or the CUO 4 coordinators.

**Morning shift:** Loli López

**Afternoon shift:** Cristina López

## IMPORTANT

Surgeries must be scheduled **15 days in advance**.

This study consists of several stages, requiring multiple work requests to the laboratory, referencing study **CIR-ECL-2016-03 (Odontècnic)**. The process will be supervised by **Mr. Josep Golano and Mrs. Alejandra Retamales**.

In the section "**Description of the prosthesis to be made,**" the specific request must be indicated. The stages requiring work requests include:

1. **Surgical Guide**
2. **Second Surgery** (only for the control group)
3. **Digital Impression** (for both provisional and final crowns)
4. **Metal Structures for Final Crowns**
5. **Biscuit of Final Crowns**

## 6. Glazing of Final Crowns

### Steps to be followed by students treating study patients (Includes a checklist for verification)

#### 1st Visit

- Intraoral and extraoral photographs (*CUO protocol*)
- OPG
- Periapical radiographs of the area
- Impressions (*for wax-up and then digital scanning*)
- Budget. Must include:
  - Implantology study
  - CIR-ECL-2016-03
  - CIR-ECL-2016-03 Second phase
  - CIR-ECL-2016-03 XENOGRAFT
  - CIR-ECL-2016-03 PONTIC CROWN (*only if necessary*)
  - Deposit

#### 2nd Visit

- CBCT
- The case must be presented in the Clinical Implant Session.

#### 3rd Visit

☐ Budget validation. As a prerequisite, the following is required:

- Signature from the clinical session
- Signature of the Investigator's Declaration and the Informed Consent (dossier) by Dr. Ernest Lucas (*IS*)
- Signature of the Surgical Informed Consent (*by the patient*)
  - ☐ Scan models with and without wax-up using 3Shape and send them to the laboratory (*Odontenic*) to convert them to STL format for surgical guide planning (*send by email to Mr. Josep Golano, who is responsible for the Laboratory: jgolano@uic.es*). (*No patient or documentation needed.*)
  - ☐ The laboratory will then send the STL file to the student and Mr. Golano to proceed with planning the surgical guide.

- ☐ Guided surgery planning with the Straumann software (tool 18) and preparation of the laboratory request for the fabrication of the surgical guide (*signed by tutor and budget-validated*). Submit the request to Mr. Golano.
- ☐ Request for implants and biomaterial for surgery (*signed by tutor and budget-validated*). Submit the request to Mrs. Isabel López.

#### **4th Visit – Surgery Day**

- Implant placement
  - ☐ Fill in the Data Collection Notebook (dossier)
- Place the sticker with the material used.
- Request material for the second surgery (control group only) validated by Budgeting.
- Schedule the patient for the second surgery in 8 weeks (control group).
- Schedule patients for the 9-week mark for the placement of provisional crowns in both groups with the same students who referred the patient (PRIORITY AND MANDATORY APPOINTMENT).

#### **5th Visit – Day of the 2nd surgery (control group)**

- Placement of transepithelium and healing screws.
- Fill in the data in the Data Collection Notebook (folder).
- Place the sticker with the material used.
- Request material for taking impressions (signed by tutor and validated by Budgeting). Request from Isabel López.

#### **6th Visit – Take digital impressions in the mouth.**

- Impressions with scan bodies.
- Make a request to the laboratory for provisional crowns (validated by Budgeting).
- Send to the laboratory (Odontéctnic) from the 3Shape software (authorized by Mr. Golano).
- Fill in the data in the Data Collection Notebook (folder).

#### **7th Visit – Provisional crowns.**

- Placement of the provisional crowns.
- Fill in the data to be evaluated in the Data Collection Notebook (folder).



- Make a request to the laboratory to make the metal structures for the definitive crowns (signed by tutor and validated by Budgeting).

#### **8th Visit – Test of metal structures.**

- Verify the fit of the metal structures.
- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Make a request to the laboratory to perform biscuit baking (signed by tutor and validated by Budgeting).

#### **9h Visit – Test of metal structures.**

- Verify the fit, color, and occlusion of the biscuit.
- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Make a request to the laboratory to glaze the definitive crowns (validated by Budgeting).

#### **10th Visit – Definitive crowns.**

- Verify the fit, color, and occlusion of the definitive crowns.
- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Schedule a follow-up appointment within 3-4 months.

#### **11th Visit – Control 1 (3-4 months).**

- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Schedule the next control appointment.

#### **12th Visit –Control 2 (6 months).**

- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Schedule the next control appointment.

#### **13th Visit –Control 3 (12 months).**

- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Schedule the next control appointment.

#### **14th Visit –Control 4 (24 months).**

- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Schedule the next control appointment.

#### **15th Visit –Control 5 (36 months).**

- Fill in the data to be evaluated in the Data Collection Notebook (folder).
- Return the deposit.

\*\* Each step to be performed must be reported by one of the study researchers.

## PART II - Copy for the Investigator

### (Case Report Form)

PATIEN CODE		
AGE		
SURGICAL DATE		
SURGICAL STUDENT		
PROSTHODONTIC TUTOR		
PROSTHODONTIC STUDENT		
GROUP		

#### MESIAL

#### DISTAL

Pre-operative		Position		Pre-operative		Position	
		Lengt				Lengt	
		Width				Width	
		Bone Qua ity				Bone Qua ity	
S u r g e r y		Insertion		u r g e r y		Insertion	
		Torque				Torque	
		MBL M C D				MBL M D	
		So Tissue				So Tissue	
P r o v i s i				P r o v i s i		PPD	
		BOP				BOP	

o n a			
Impres		MBL (M/C/D)	
De initive Crowns	PPD		
	BOP		
	KM		
	MBL M C D		
Contro 1 (3 months)	PPD		
	BOP		
	KM		
	MBL (M		
	Soft Tissue		
Contro 2 (6 months)	PPD		
	BOP		
	KM		
	MBL M C D		
	Soft Tissue		
Contro 3 (12 months)	PPD		
	BOP		
	KM		
	MBL M C D		
	So t Tissue		
Control 4 (24 months)	PPD		
	BOP		
	KM		
	MBL M C D		
	Soft Tissue		
Contro 5 (32 months)	PPD		
	BOP		
	KM		

o n a			
Impres		MBL (M/C/D)	
De initive Crown s			
	BOP		
	KM		
	MBL M C D		
Contro 1 (3 months)	PPD		
	BOP		
	KM		
	MBL (M C D)		
	Soft Tissue		
Contro 2 (6 months)	PPD		
	BOP		
	KM		
	MBL M C D		
	Soft Tissue		
Contro 3 (12 months)	PPD		
	BOP		
	KM		
	MBL (M C D)		
	So Tissue		
Contro 4 (24 months)	PPD		
	BOP		
	KM		
	MBL M C D		
	So Tissue		
Contro 5 (32 months)	PPD		
	BOP		
	KM		

	MBL M C D				MBL M C D	
	So Tissue				So t Tissue	

## PART II - Copy for the Investigator

Pre operatory		Photography. Periapicals Xray. Digital impression. <u>CBCT(I)</u> . Surgical splint.
Surgery		Photography. Periapicals Xray. CBCT
Second surgery (8 Weeks) <u>ONLY CONTROL</u> <u>GRUOP</u>		Photography. Peri apic als Xra y. Hea ling cap.
Provisional (9 Weeks)		Photography. Periapica ls Xray. Provisio nals.

Impresion (10 Weeks)		Photography. Periapicals Xray. Digital Impression. Sent to the laborato
Metal test	C]	Photography. Periapicals Xray. Interoclusal registre to calibrate orcelain.
Biscuit test (2 Weeks after)		(Photography, ] Periapicals Xray. ( Evaluate color, interproximal and occlusal contacts. ]
Definitive crowns		(Photography. ] Periapicals Xray. ( Digital Impression. ] VAS (1). ( Probing pocket depht. ] Bleeding on probing. Keratinized measure.
Control I (3 Months)		(P ] h o t o g r a p h y . P e r i a p i c a l s X r a y .

Control 2 (6 Months)	Photography. Periapicals Xray. Digital Impression. CBCT (3) Probing pocket depht. Bleeding on probing. Keratinized measure.
Control 3 (12 Months)	Photography. Periapicals Xray. VAS Probing pocket depht. Bleeding on probing. Keratinized measure.
Control 4 (24 Months)	Photography. Periapicals Xray. VAS (3). Probing pocket depht, Bleeding on probing. Keratinized measure.
Control 5 (36 Months)	Photography. Periapicals Xray. VAS (4) Probing pocket depht. Bleeding on probing. Keratinized measure.

**Contact** For screening, you can request an appointment in the student-researcher's agenda (underlined). Ask the CUO coordinators: Mrs. Mónica Pariente (mornings) or Mrs. Eva Anglés (afternoons).

Dr. Jordi Gargallo—Albiol (Principal Investigator)  
Email: iqarqallo@uic.es  
Department of Oral and Maxillofacial Surgery  
Universitat Internacional de Catalunya

Dr. Ernest Lucas Taulé (Secondary Investigator)  
Email: ernest.lucas@uic.es  
Phone: 675947204  
Department of Oral and Maxillofacial Surgery  
Universitat Internacional de Catalunya

Daniel Paternostro (IMOS)  
Email: dani.pater@uic.es  
Department of Oral and Maxillofacial Surgery  
Universitat Internacional de Catalunya

Rafael Rodríguez  
Department of Oral and Maxillofacial Surgery  
Universitat Internacional de Catalunya

Dr. Jose Espona R. (Prosthetics Coordinator)  
Email: joseespona@uic.es  
Department of Restorative and Aesthetic Dentistry  
Universitat Internacional de Catalunya

Dr. Andrés Aliaga Martínez (Dental Research Manager CUO)  
Email: aliaga@uic.es  
Phone: 93 042 018 (ext. 5927)  
Universitat Internacional de Catalunya Dental Clinic