Five years clinical and radiographic evaluation of dimensional changes in peri-implant tissues of Straumann® Roxolid® bone level implants

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ABSTRACT

Natural consequences of tooth extraction such as bone resorption and migration of the adjacent tooth create narrow mesio-distal edentulous spaces and mild Seibert Class I defects which can be challenging scenarios for clinicians.

The decision of placing narrow-diameter implants with a flapped or flapless surgical technique has not been closely examined in the literature.

Since NDIs have reduced contact areas with the bone in comparison with regular diameter implants, titanium alloys with higher tensile and yield strength have been used to manufacture NDIs. A titanium-zirconium (Ti-Zr) alloy has been developed (Roxolid®; Institut Straumann AG, Basel, Switzerland) from 83-87% titanium alloyed with 13-17% of zirconium. The combination of faster osseointegration with higher mechanical strength may allow implants made form Ti-Zr alloy be used in more daring clinical situations.

Aim: The primary objective of this non-interventional prospective study is the evaluation of the radiographic bone level changes of Straumann® Roxolid® ∅3.3 bone level implants from loading to 5 years of follow-up.

Secondary objectives include the determination of survival and success rate at 5 years of follow-up and assess, by quantitative 3D analysis, peri-implant soft tissue changes around reduced diameter TiZr Bone Level implants placed in crests with moderate facial resorption reconstructed using the roll flap technique 5 years after surgery.

Material and Methods: Twenty patients with unitary or multiple edentulous gaps in the upper and lower jaw without need for vertical augmentation procedures were recruited between October 2009 and May 2010. Implant placement surgery was performed to install Straumann® Roxolid Bone Level implants with 3.3mm diameter. Definitive cemented restorations were placed after a minimum transmucosal healing period of 6 weeks. Follow-up appointment was scheduled 5 years after surgery. Patients who had completed the main study were invited to participate in the follow-up study. Eligible patients were required to attend a routine follow-up appointment for standard oral hygiene procedures, clinical evaluation of the rehabilitation and periapical radiographic examination. Dental casts of ten patients with unitary edentulous gaps in the maxilla (FDI positions 15 to 25) with moderate horizontal facial resorption of the residual ridge and no need for vertical augmentation procedures were 3D examined.

Results: At 5 years, 17 of the 20 patients came in for the 5 years follow-up

appointment. With a total of 25 out of 29 implants, retrieving a recall rate of 85% at the patient level and 86.2% at the implant level. Mean age of the controlled patients was 48 years old. The overall mean bone level variation from loading to 5 years (mesial and distal) was -0.07 ± 0.78mm. No correlation could be established between bone level changes and labial profile variation.

Conclusions: Biomechanically the performance is excellent with survival rate of 100% which can be assigned to the mechanical properties of TiZr alloy associated with its biocompatibility. Narrow-diameter Ti-Zr implants performed well and without restrictions even in lower bone availability situations such as narrow crests over a 5-year period. Even though in our study no correlation could be established between bone level changes and labial profile, hard and soft tissues around reduced diameter TiZr Bone Level implants remained stable during the follow-up period of 5 years.

1 – INTRODUCTION

The rehabilitation of partially and edentulous patients with implant-supported prostheses has become a current practice in the last decades. (1)

Natural consequences of tooth extraction such as bone resorption and migration of the adjacent tooth create narrow mesio-distal edentulous spaces and mild Seibert Class I defects (2) which can be challenging scenarios for clinicians. Narrow bucco-lingual dimensions – less than 4mm in width - may not allow the placement of a standard diameter implant without the risk of implant thread exposure. (3) Although prior to implant installation, bone augmentation routines may provide the adequate bone volume, any additional surgical procedures represents increased risks, morbidity and costs, which could be overcome by the use of small diameter implants. The use of narrow diameter implants (NDI) would be valuable to reduce the number of augmentation procedures for implant insertion. (1, 4) The decision of placing narrow-diameter implants with a flapped or flapless surgical technique has not been closely examined in the literature. (5)

Advantages of flap elevation include enhanced surgical visibility and control (5) which may reduce the risk of occurrence of bone fenestrations and dehiscences.(6) The main disadvantages are the need of greater surgical access, the possible delay in tissue recovery and healing, increased bone loss (5) and the negative influence on esthetic outcomes, especially in the anterior maxilla. (6) It is indicated in cases of irregular alveolar bone; reshaping required; insufficient prosthetic volume requiring reduction of bone height (cases of overdentures) and direct visual access preferred. (5)

The concept of implant placement without flap elevation has long been used for some time with tooth extractions and site preservation, showing less morbidity. (6) Clinicians also consider a flapless approach for immediate implants in order to preserve the vascular supply and existing soft tissue contours. (6) Not damaging the periosteum layer grants a greater chance to preserve alveolar bone levels, improve blood supply to the implant region and reduce patient discomfort (swelling and pain). (5) Brodala (2009) in a review reported a statistically significant reduction in immediate postoperative discomfort, duration of discomfort, facial edema and the use of analgesics. Brodala also pointed a 98.6% survival rate for implants placed with a flapless technique (based on prospective cohort studies). (6) The roll flap technique is a modification of the flapless approach that could be applied in the presence of adequate width of keratinized mucosa (KM), but insufficient thickness. (7)

Soft tissue augmentation techniques such as Abhrams modified roll technique (8) (9) allows soft tissue augmentation of the buccal ridge deficiency in limited interdental spaces, while the pouch roll technique is indicated in single or multiple-implant sites with a wide interdental space. The final thickness depends on the thickness of the rolled flap. (10)

As major disadvantages, flapless access is more difficult due to the inability of the surgeon to directly visualize anatomical and vital structures; the learning curve is abrupt (5), requiring more experience and presurgical planning than was originally assumed. It is more challenging than the conventional surgical approach. It is not recommended as a “routine” procedure in daily practice(6); an inability to visualize the vertical endpoint of the implant placement (too shallow/too deep); decreased access to bony contours for alveoloplasty and inability to manipulate the soft tissues to ensure the ideal dimensions of keratinized mucosa around the implant. (6) The irregular and tortuous topography of the bone is a contraindication to this practice. (5)

Flapless surgery may minimize or eliminate crestal bone loss. It can be performed in the esthetic zone with favorable outcomes. This method gives the possibility of preserving almost all keratinized tissues, providing soft tissues for implant esthetics. (11)

The cumulative implant survival rate at the 3 - to 4- years follow-up examination is 98.7%, reflecting that minimally invasive flapless surgery has highly implant predictability with clinically insignificant crestal bone loss for up to 4 years. (12)

The main indications for the use of NDIs are small interdental or interimplant gaps usually found in the premolar or incisors region (4), reduced crestal width – narrow-ridges, reduced amount of interradicular space (13) and/or replacement of lateral maxillary and mandibular incisors (3).

Since NDIs have reduced contact areas with the bone in comparison with regular diameter implants, titanium alloys with higher tensile and yield strength have been used to manufacture NDIs such as Ti_6Al_4V. However, Altuna *et al*. reported on corrosion, toxicity and biocompatibility issues related to aluminium and vanadium, and reduced bone responses with this alloy. (13) This alloy is less biocompatible than commercially pure titanium (cpTi) in cell cultures and animal experiments. (4) The presence of ionized Al or V in the tissues may inhibit the differentiation of osteoblasts and hence the development of new bone. (14) In rats, implants from pure Titanium did not cause systemic toxicity or decrease immune activity, body weight, or the weight of any

individual organ. (15)

Therefore, to overcome the biocompatibility issue while retaining or improving the mechanical strength, a Titanium-zirconium (Ti-Zr) alloy has been created (Roxolid®; Institut Straumann AG, Basel, Switzerland). This implant material is made of 83-87% titanium alloyed with 13-17% of zirconium. (1, 13) The combination of faster osseointegration with higher mechanical strength may allow implants made form Ti-Zr alloy be used in more daring clinical situations. (16) Nowadays, Titanium-zirconium NDIs are recommended for the restoration of anterior and also posterior teeth, preventing possible fatigue failure of even when inserted in the high stress areas. (13, 17, 18) Regarding the safety of implant alloys, the possible release of ions and biocompatibility of Zirconium (Zr) is equivalent to Titanium (Ti); which presents neither local nor systemic toxicity. (15) Such alloy of Ti-Zr, with increased fatigue strength, has shown equally good osseointegration as pure Ti and allows the modification of the SLActive® Institut Straumann AG, Basel, Switzerland surface, which has been reported to enhance osseointegration in the early healing stages. (14)

The clinical performance of narrow-diameter TiZr implants has been studied in previous clinical trials showing high survival and success rates after short follow-up periods. (16)

For instance, Altuna *et al*. (2016) reports in a systematic review and meta-analysis the clinical evidence of titanium-zirconium dental implants including nine studies. The follow-up period varied from 3 – 36 months. The mean marginal bone loss after 1 year was 0.36 ± 0.06 mm and 0.41 ± 0.09mm after 2 years. (13) In the short term, narrow-diameter dental Ti-Zr implants show survival and success rates >95%, equivalent to regular diameter titanium implants. (13)

When compared with Ti Grade IV, Roxolid® implants achieved similar performance with regard to the change in marginal bone level, with one year of follow-up. (18)

Moreover, edentulous patients can benefit from mandibular overdentures of 2 interforaminal Roxolid® implants with safety and long term clinical evidence equivalent to titanium grade IV 3.3 diameter bone level implants, until 60 months. The marginal bone loss after 60 months was -0.60 ± 0.69 mm for the TiZr group and -0.61 ± 0.83 mm in the Ti Grade IV group. (19) Quirynen *et al.* presented 3-years results on this clinical setting showing similar outcomes of Ti-Zr and Ti Grade IV.(14) Al-Nawas *et al.* previously considered Roxolid implants performing as well as titanium Grade IV in patients with edentulous mandibles. (15)

However, there are few studies on the long-term clinical evidence of titanium-zirconium

narrow diameter implants. Results on this issue remain to be determined.

1.1 – OBJECTIVES

The primary objective of this non-interventional prospective study is the evaluation of the radiographic bone level changes of Straumann® Roxolid® ∅3.3 bone level implants from loading to 5 years of follow-up.

Secondary objectives include the determination of survival and success rate at 5 years of follow-up and assess, by quantitative 3D analysis, peri-implant soft tissue changes around reduced diameter TiZr Bone Level implants placed in crests with moderate facial resorption using the roll flap technique 5 years after surgery.

2 – MATERIALS AND METHODS

This study was designed as a prospective non-interventional study on dimensional changes of peri-implant tissues of twenty patients with a total of twenty-nine Straumann® Roxolid® bone level implants. Elected patients where previously enrolled in a three-year clinical prospective study (main study) and were contacted for a long-term follow-up appointment, 5 years after implant placement. Eligible patients were required to attend a routine follow-up appointment for standard oral hygiene procedures, clinical evaluation of the rehabilitation and periapical radiographic examination.

The project was approved by the Ethics Committee of the Faculty of Medicine of the University of Coimbra with the reference 129-CE-2015 (Annex 1 – Ethics Committee document)

2.1 – PATIENT SELECTION

Twenty patients with unitary or multiple edentulous gaps in the upper and lower jaw without need for vertical augmentation procedures were recruited between October 2009 and May 2010. Implant placement surgery was performed to install Straumann® Roxolid Bone Level implants with 3.3mm diameter. Definitive cemented restorations were placed after a minimum transmucosal healing period of 6 weeks. Follow-up appointment was scheduled 5 years after load. Patients who had completed the main study were invited to participate in the follow-up study. The inclusion criterias are: previous inclusion in the Straumann® Roxolid® non-interventional study; 3rd year evaluation completed; willing to participate after signature of informed and written consent.

All patients agreed to the planned procedure and signed an informed consent form (Annex 2 – Informed Consent)

2.2 - CONTROL VISIT PROTOCOL

The operator made a brief oral examination to assess patient's oral hygiene, soft tissues and the presence of any oral pathology.

2.2.1. Photographic collection

The equipment was as follows: a Canon EOS 70D camera, an EF 100mm F/2.8L Macro IS USM lens and a Macro Ring Lite MR-14EX. Photographs were taken using

JPEG and RAW file format.

Three intraoral photographs were essential to document each case: one oclusal and two orthogonal with the patient in maximum intercuspal position – one global and other detail of implant site. The settings employed are:

F/22

Shutter Speed – 1/160

ISO – 100

Flash 1/4

Magnification – 1:3

2.2.2. Cast collection

Impression only from rehabilitated arch was performed using alginate (Orthoprint®), standard trays and plaster of Paris as cast material.

2.2.3 Record of prosthetic complications

2.2.4 Execution of plaster study models

2.2.5 Radiographs

2.2.5.1 Periapical radiograph

Patients were subject to the risk of taking a periapical radiograph corresponding to an exhibition between 0.0003 – 0.022 mSv routine procedure for long-term monitoring of these patients.

2.3. - RADIOGRAPHIC READING AND DETERMINATION OF THE PROXIMAL BONE LEVELS

All the radiographs were taken using an acrylic customized x-ray positioning device to minimize variations in X-ray imaging geometry caused by different angulations between the central beam and the region of interest, preventing angular distortion and alignment errors. This standardized radiograph allows accurate linear evaluation of radiographic crestal bone changes.

Marginal bone level change was assessed at mesial and distal sites by a local investigator using standardized radiographs. Marginal bone levels at the mesial and distal sides of the implant were obtained by one investigator using ImageJ 1.44 (http://imagej.nih.gov/ij/) to measure the distance from the implant shoulder to the first visible bone contact (DIB).

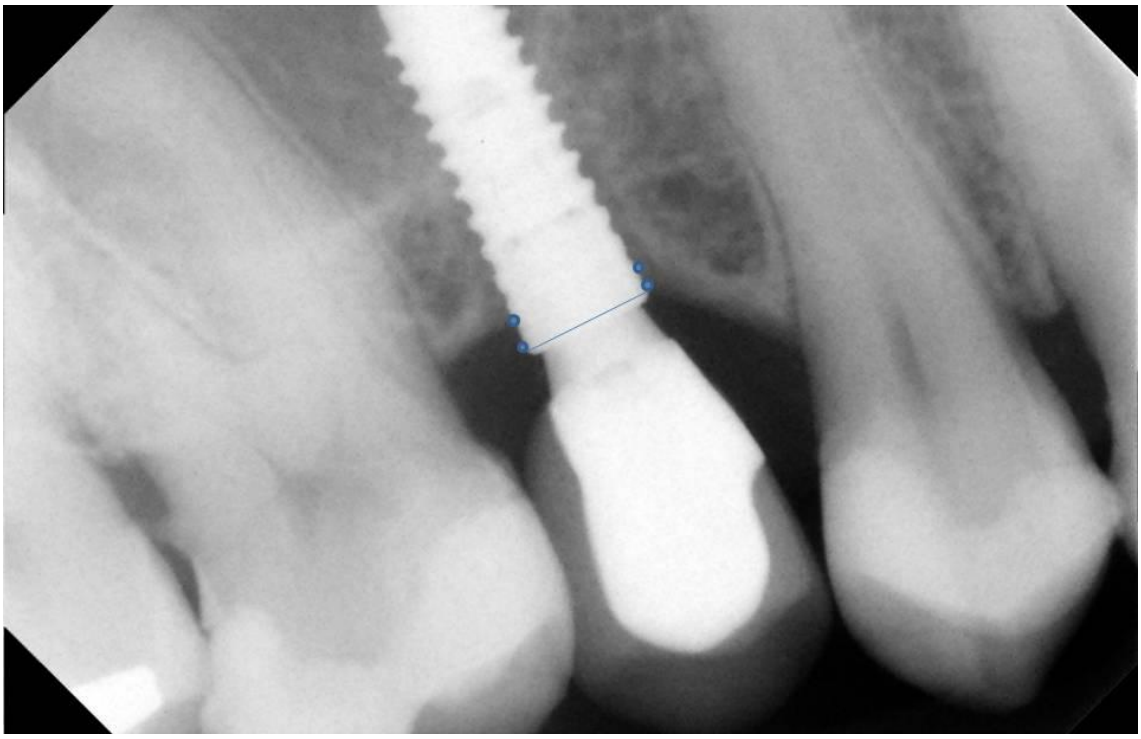


Fig.1 – Example of DIB measurement

2.4 - DIGITAL MEASUREMENT OF PLASTER MODELS USING A 3D SCANNER (INEOS X5, SIRONA) AND AN INSPECTION ENGINEER SOFTWARE (GEOMAGIC STUDIO ® AND GEOMAGIC QUALIFY®).

Ten patients with unitary edentulous gaps in the maxilla (FDI positions 15 to 25) with moderate horizontal facial resorption of the residual ridge and no need for vertical augmentation procedures were recruited.

Dental casts made prior to surgery, after implant placement and at 5-years follow-up were scanned with a 3D scanner (inEos X5, Sirona).

The .stl files were transferred to a digital shape sampling and processing software (Geomagic Studio®) to be transformed into an Exact Surface and then into CAD.

Basic Workflow

1 – Polygon Phase (Geomagic Studio®)

Each model was transferred to Geomagic Studio, cropped to the region of interest (implant and adjacent teeth) and “Mesh Doctor” was performed. The steps in the polygon phase walk through cleaning up the polygon object in preparation for moving to the surface phase.

2 – Exact Surface (Geomagic Studio®)

From the 3D scanner the point cloud was converted into polygon and then into exact surface, performed with AutoSurface.

3 – CAD → 3D Analysis

In Geomagic Qualify ® the initial model was set as the reference model. The goal of the test engineer is to perform an inspection process on an initial Test object and generate a report.

Internally, the Best Fit Alignment is performed in two steps. First 5000 random points on the Test are aligned and re-aligned to the Reference until the average deviation of the two objects match. Second step fine adjustments to the alignment are made using 25000 random points until average deviation is minimized.

The models were superimposed using the best fit alignment feature. Assessment of differences in the buccal aspect of the crest was made by measurement of the linear distance between the pre- and postsurgical models at 1 and 3mm apical to the gingival margin of the restoration with inspection software (Geomagic Qualify ®). Also measurement of the 5^{th} year model was performed in order to evaluate tissue evolution. Color-Coding Topological differences were used to generate “annotations” of the values we wanted to use statistically.

Success criteria

Routine clinical use of any implant system should be based on an evaluation of the outcome of that specific system in a long-term follow-up clinical investigation. In 1986 Albrektsson proposed as implant success criteria: 1- Individual, unattached implant is immobile when tested clinically; 2 – The radiograph doesn’t demonstrate any evidence of peri-implant radiolucency; 3 – Vertical bone loss be less than 0.2mm annually following the implant’s first year of load; 4 – Individual implant performance with absence of persistent and/or irreversible signs and symptoms: pain, infection, neuropathies, paresthesia or violation of the mandibular canal; 5 – In the above context, a successful rate of 85% at the end of a five-year observation and 80% at the end of a ten-year period be a minimum criterion for success. (20) Buser *et al.* proposed the follow criteria of success: 1- Absence of persistent subjective complaints, such as pain, foreign body sensation and/or dysaesthesia; 2- Absence of a recurrent peri-implant infection with suppuration; 3- Absence of mobility; 4- Absence of a continuous radiolucency around the implant and 5- Possibility for restoration. (21)

Success in implant dentistry should ideally evaluate a long-term primary outcome of an

implant-prosthetic complex as a whole. It appears clear that implant survival *per se* would no longer be enough to assess the clinical efficiency of contemporary implant prosthetic methodologies (22)

2.4 - STATISTICAL ANALYSIS

The main study population consisted of all patients who had completed the 3- and 5-year follow-up visit. The data were analyzed using frequencies for categories and mean values for continuous variables. Repeated measures ANOVA were used to determine statistical significant variations in BID over the course of the study. Paired-samples t-test was used to determine differences in marginal bone level changes between consecutive follow-up periods. Significance level was set as $\alpha = 0.05$.

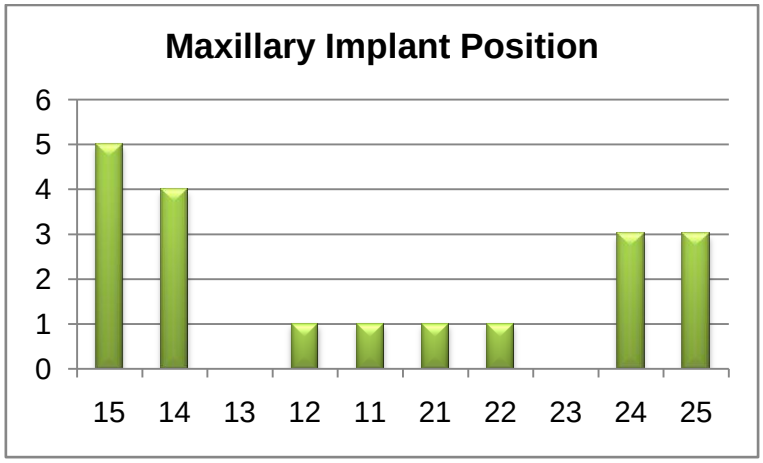
3 – RESULTS

Of the 20 patients that initially received Straumann® Roxolid® ∅3.3 bone level implants, 17 patients came in for the 5 years follow-up appointment, with a total of 25 out of 29 implants, retrieving a recall rate of 85% at the patient level and 86.2% at the implant level. Mean age of the controlled patients was 48 years old. The main demographic data are shown in table 1. All patients received only 3.3 mm Straumann® Roxolid® bone level implants. The rate of implants per patient was 1.47.

	Nr of patients	Nr of implants
Male	9	11
Female	8	14
	17	25

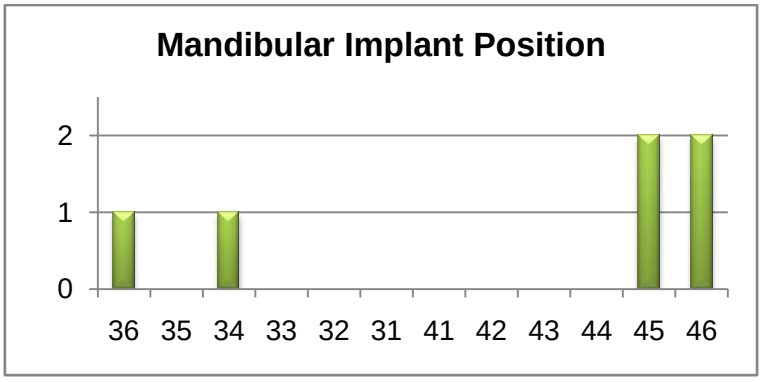
Table 1 – Demographic data

The maxillary implant positions ranged from 15 to 25 FDI positions (graphic 1) and the mandibular positions from 36 to 46 (graphic 2).



Total = 19

Graphic 1 –Maxillary implant sites



Total = 6

Graphic 2 – Mandibular implant sites

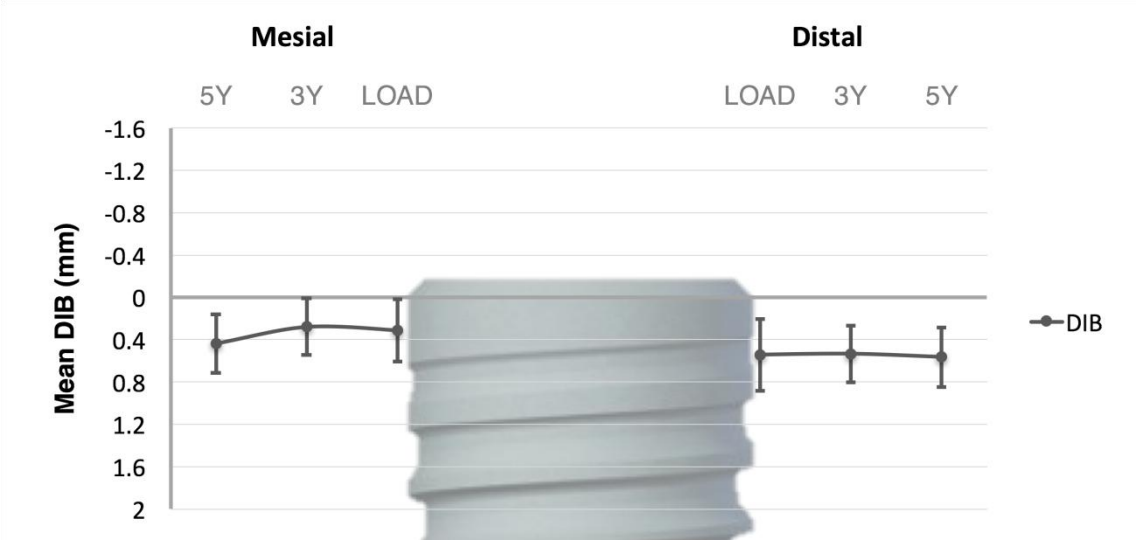
Only 2 implants were not placed in healed sites. The surgery approach was flapless with roll-flap technique in the majority of cases (15 implants), full thickness flap and flapless were performed in 4 implants each and immediate implant placement was executed in 2 (table 2). Transmucosal healing was performed in all cases. Definitive loading was performed after a minimum transmucosal healing period of 6 weeks with unitary cemented restorations.

Surgical Approach	Max.	Man.	Total
Flapless	2	2	4
Flapless with Roll-flap technique	15	0	15
Full-thickness flap	0	4	4
Immediate implant placement	2	0	2
			25

Table 2 – Surgical Approach

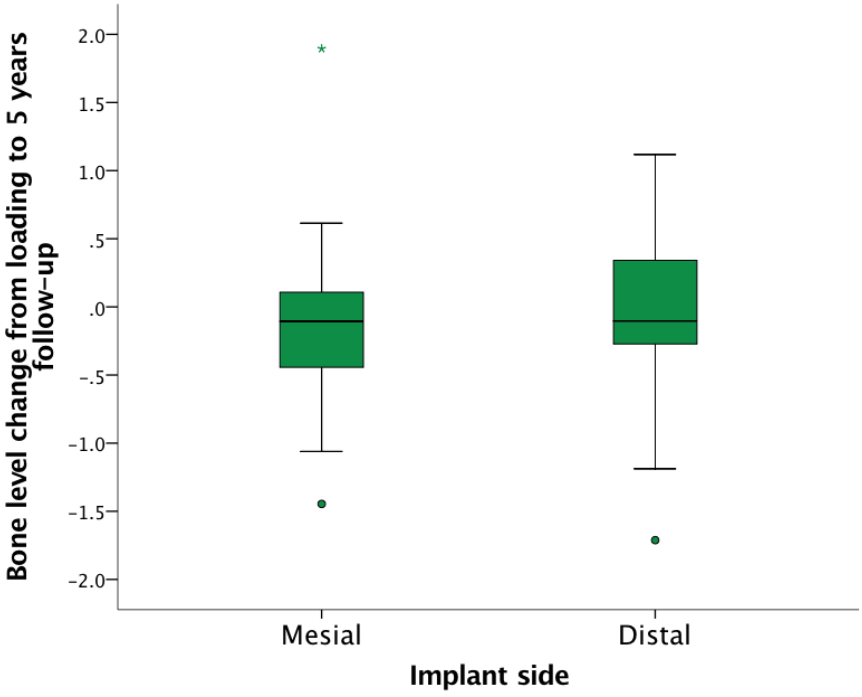
Only four cases presented minor prosthetic complications related to chipping of the ceramic veneering of the crown. No other complications were detected from loading onwards.

Mesial and distal bone levels presented similar evolution over time (p=0.651 for the repeated measures ANOVA with Greenhouse-Geiser correction), as demonstrated by the graphic 3 illustrating the mean linear distance from implant shoulder to the first implant-bone contact from loading to the 3 years and 5 years follow-up.



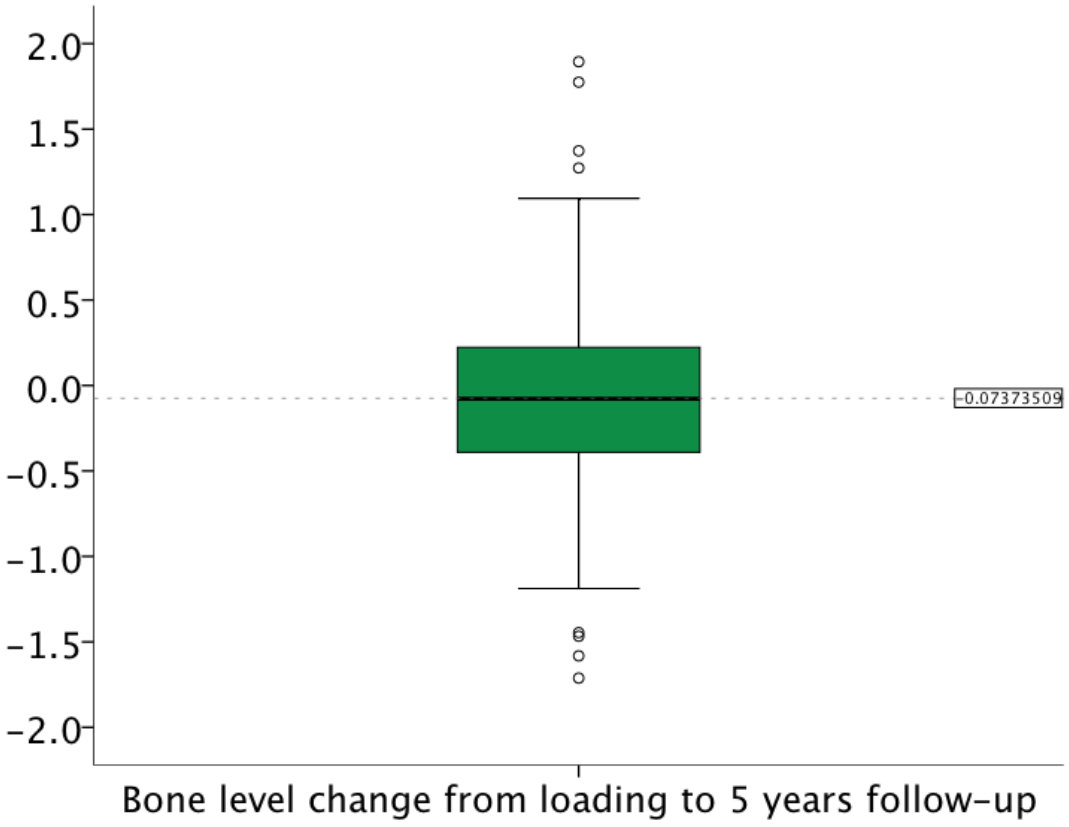
Graphic 3 – Mean linear Distance from Implant shoulder to the first implant-Bone contact (DIB)

From loading to 3 years, there was a slight recovery of bone level at the mesial side (0.03 ± 0.46 mm) and at the distal side 0.01 ± 0.73 mm. On the contrary, from loading to 5 years, the mean mesial bone level change was -0.13 ± 0.71 mm and the mean distal bone level change was -0.02 ± 0.86 mm. Even though from 3 years to 5 years the mean bone level change was non-significant (p=0.103 for paired samples t-test), there was a bone loss of -0.09 ± 0.40 mm, meaning that the greatest variation occurred in this period.



Graphic 4 – Functional bone loss from loading to 5 years follow-up

Notwithstanding this, the overall mean bone level variation from loading to 5 years (mesial and distal) was very stable at -0.07 ± 0.78 mm, with the exception of four cases with bone loss superior to 1.5 mm (graphic 5), yet within the parameter of Albrektsson for implant success (1.5 mm in the first year followed by 0.2 mm per additional year in function).



Graphic 5 – Functional bone loss from loading to 5 years follow-up

At the 5th year evaluation all 10 implants were successful with no visual evidence exposure of the abutment or a grey gingival collar. Standardized radiographs revealed that bone level kept stable at the implant shoulder. For these cases, mean bone level changes from definitive restoration to the 5th year was 0.16 ± 0.52 mm, ranging from 1.37 mm loss to 0.54 mm gain.

From the initial situation to 5 years, 1 mm apical to the gingival margin of the restoration there was a mean increase of 0.31 ± 0.42 mm in the labial profile. At 3 mm, the labial profile variation was 0.52 ± 0.57 mm and was positive in 8 of the cases, reflecting volume gain. The measurements at 1 and 3 mm were correlated (r=0.833, p≤0.001). Most of soft tissue gain at 3 mm occurred after crown insertion (0.40 ± 0.47 mm), reflecting tissue maturation.

No correlation could be established between bone level changes and labial profile variation.

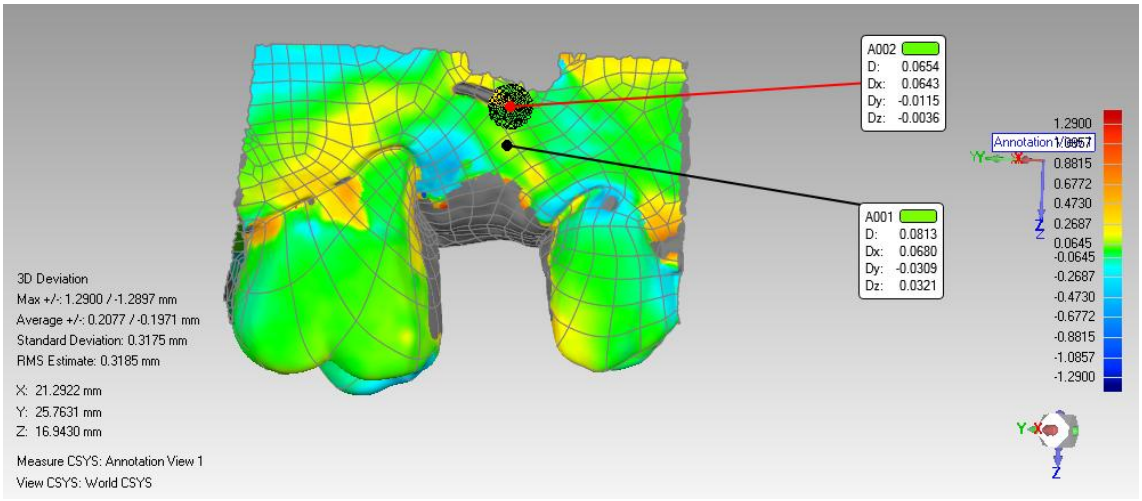


Fig. 1 – Example of a 3D Deviation from initial model to 5th year model

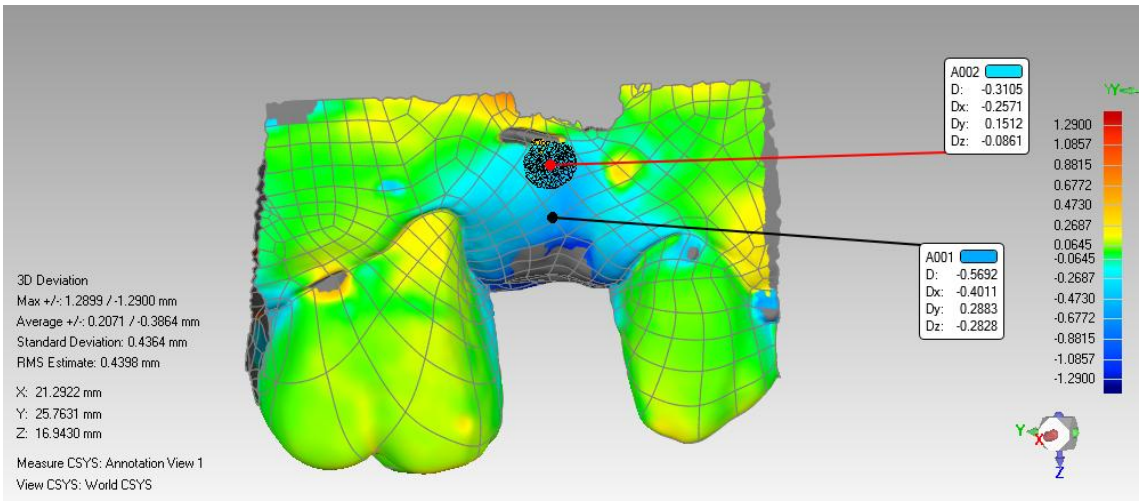


Fig.2 – Example of a 3D deviation from initial model to crown model

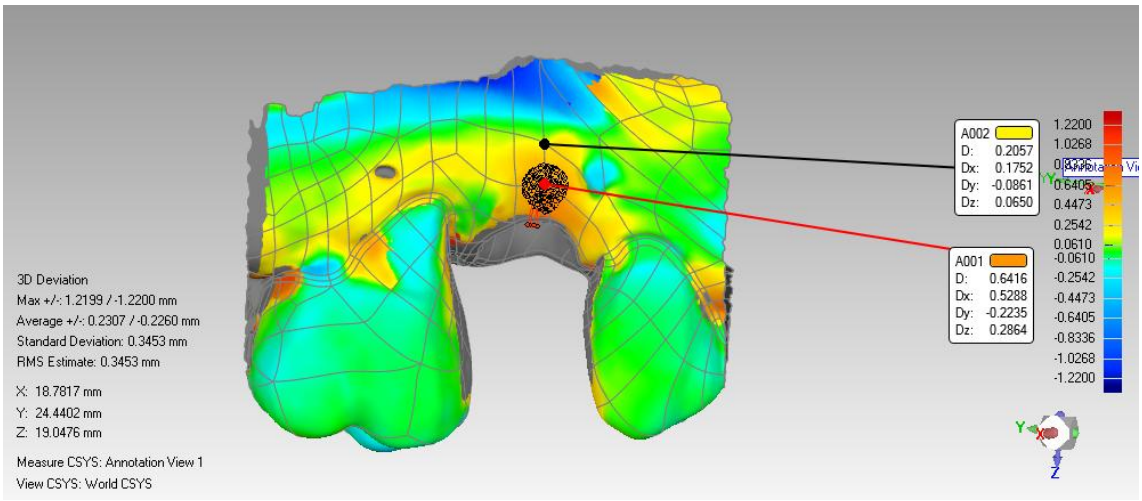


Fig. 3 – Example of a 3D deviation from crown model to 5 years model

4 - DISCUSSION

The purposes of this study were to assess marginal bone levels of Roxolid® implants and to assess clinical outcomes regarding peri-implant tissue changes around narrow-diameter implants placed in narrow crests using roll-flap technique as first-stage surgery.

There were no implant failures during the 5-year follow-up period. Our study determined a mean functional bone loss from loading to 5 years (mesial and distal) of -0.07 ± 0.78 mm

These results are in accordance with the data reported in previous studies about Ti-Zr ∅3.3 implants. In a recent randomized controlled clinical study, Ioannidis *et al.* (2015) compared 3.3 mm diameter Ti and TiZr implants. Twenty patients received one Ti and twenty received one TiZr implant in the anterior or pre-molar region. At 3 years, 32 of 40 patients attended the follow-up examinations, rendering a recall rate of 80%. With respect to implant survival no implant failures were recorded, yielding a 3-year implant survival rate of 100% for both the Ti and TiZr groups. From the 1-year to the 3-year examination, the median change in mean marginal bone level (MBL) measured -0.01 mm for the Ti implants and -0.04 mm for the TiZr implants. The difference between the groups was not statistically significant. (23)

In a pilot study (Barter *et al.* 2012), 22 patients received 3.3 mm diameter titanium-zirconium implants splinted to a 4.8 mm standard Grade IV titanium regular neck implant with a fixed dental prosthesis and the mean change in bone level 2 years after loading was -0.33 mm. The survival rate of the Ti-Zr implants reached 95.2%. (24)

Another study evaluated the use of narrow-diameter implants made of titanium-zirconium placed in the posterior regions of the jaw to support single crowns (Tolentino et al. 2014). It compared the survival and success of narrow diameter implants made of titanium-zirconium alloy to implants made of pure titanium installed in the posterior region with 1 year of follow-up after loading. Both groups achieved 95.2% survival and success at 1-year follow-up, showing a high survival rate of narrow diameter implants installed in the posterior region of the jaws. No implant fractures or prosthesis failures of the titanium-zirconium implants were observed in this study. However, due to short term follow-up of this study no implant fractures or prosthesis failures could be observed. Possible differences on material resistance between the two implants may be shown after several years of loading. (25)

Regarding the use of TiZr narrow diameter implants in the rehabilitation of unilateral

atrophic mandibular distal extensions with 3-units ceramo-metal fixed partial dentures with 1 year of follow-up, El-Sheikh *et al.* (2014) reported that the survival rate of the implants was 100%. No implant fractures were recorded and the overall mean marginal bone loss after 1 year was less than 1 mm which encourages this approach to the rehabilitation of atrophic mandibular distal extensions. (26)

One more study showed a 1-year implant survival of 97.3% for edentulous patients receiving 2 maxillary implants as overdenture support. (27)

In conformity with our results, Al-Nawas et al. (2015) presented a survival and success rates after 2 years in daily dental practice of 97.6% and 97.4%, respectively, which compares positively with the survival rates of narrow-diameter implants in strict randomized controlled clinical trials. (16)

Respecting to the molar region, Tolentino *et al*. (2016) analyzed narrow-diameter implants made of TiZr in comparison with commercially pure titanium (cpTi) in the molar region of the mandible with 1 year of follow-up. Survival and success rates were 100% for both groups, showing a high success and survival rates for NDIs installed in mandibular molar sites. The mean MBL at 1-year follow-up was 0.32 ± 0.27 mm for TiZr NDIs while for cpTi was 0.35 ± 0.24mm, with no statistically significant differences between the NDIs studied. These findings are limited to a 1-year loading period. (28)

Even though results are promising, studies with stricter methodological designs, including clinical and radiographic examinations to assess cpTi and TiZr NDIs placed in the posterior region of the mouth are still lacking in the literature. (28)

When considering regular diameter implants placed in areas of adequate bone volume, Rocha *et al.* (2016) analyzed a total of 135 implants and reported a mean bone gain from load to 36 months of the of 0.16 ± 0.53 mm for platform switching implants. In line with the previous study, Moergel *et al.* (2016) studied 52 implants showing a mean bone level change at the implant shoulder from loading to 12-month follow-up of 0.12 ± 0.42 mm. In the present study a marginal bone loss from loading to 5 years was slightly higher than observed in regular diameter implants probably due to the anatomical characteristics of the crests, with limited bone for implant placement and due to the more risky surgical approach. Flapless surgery, or with modified roll technique used in the majority of the cases could difficult the 3D positioning of the implant leading to increased narrowing of the buccal plate and consequently higher bone resorption. The radiographic bone level also induces the need to deepen the implant in order to achieve the buccal level, which places the implant deeper than the proximal levels

leading to more radiographic resorption. (29) (30) Different radiographic readers can also influence the results.

Nonetheless, biomechanically the performance is excellent with survival rate of 100% which can be assigned to the mechanical properties of TiZr alloy associated with its biocompatibility.

In this context, several preclinical trials found similar or even stronger bone tissue responses than Ti implants regarding osseointegration and change in MBL between Ti-Zr and Ti implants. (31) (32) (33) (34)

The current study evaluated a treatment in daily practice in a prospective non-interventional manner without the risk of bias toward more favorable outcomes that can appear in formal randomized controlled trials. The inclusion of all type of patients and different clinical needs shows the external validity of the study proving that narrow-diameter Ti-Zr implants work without restrictions even in situations of low bone availability such as narrow crests.

More clinical long-term investigations are needed reporting survival and success of narrow-diameter implants.

Tooth loss often leads to alveolar bone loss and a consecutive reduction of the alveolar process width. (35) From a morphologic standpoint, Seibert groups ridge deformities into three classes according to the vertical and horizontal defect components. Class I is described as present a buccolingual loss of tissue, with normal ridge height in apicocoronal dimension. With respect to severity Allen classified as mild when in the presence of <3mm alveolar deformity. The prognosis is better in cases of horizontal defects (36) (2). In the treatment of mild or moderate horizontal ridge defects soft tissue reconstruction seems sufficient. (37) The roll procedure is indicated in cases of small to moderate Class I defects. (36)

Even though in our study no correlation could be established between bone level changes and labial profile, hard and soft tissues around reduced diameter TiZr bone level implants remained stable during the follow-up period of 5 years.

Our results are in line with other study, Man, Y. *et al.* (2013) studied 12 cases with respect to the efficacy of a roll palatal roll envelope technique with the intention of reconstructing the convex profile on the buccal aspect. The convex feature was significantly improved and clinically appreciable. At 3 and 6-months volume changes were insignificant, denoting a stable condition. This study has a 6 months follow-up

period which is less than our study. (38)

The Modified Roll Flap (MRF), first described by Abrams in 1980 for correction of mild to moderate soft tissue horizontal defects, was adapted by Hurzeler *et al.* (2010) to the peri-implant tissues with the purpose of management of mild soft tissue defects around implants in the esthetic zone. (39) Using the gingival tissues over the covering screw to augment the thin buccal gingival tissues K. Barakat *et al*. (2013) evaluate the efficacy of the MRF in increasing the gingival thickness around the implants in the esthetic zone. The study population was 14 patients and MRF was performed as second-stage surgery after 4 months healing period. MRF was effective in increasing the soft tissue thickness from (1.2±0.2) to (3.0±0.5). A short follow-up period (6 months) and the small sample size might affect the external validity of the study. (40)

Regarding stage-two surgeries, Tunkel et al (2013) observed, after 1 year, a mean gain in tissue thickness of 2.41mm in the Roll Flap (RF) group. The gain in tissue thickness with the RF was perfectly stable after a 12-month healing period. The results demonstrate that in cases of missing tissue thickness a RF should be performed. (35)

In line with the previous described studies, a mean increase of 0.31 ± 0.42 mm in the labial profile at 1mm apical to the gingival margin of the restoration was observed in this study from the initial situation to 5 years. At 3 mm, the labial profile variation was 0.51 ± 0.57 mm and was positive in 8 of the cases, reflecting volume gain. Although the modified roll flap technique is simple it provides stable volumes of soft tissue. In this cases it provided low quantity of soft tissue because of the low quantity of dislocated tissue. However, the volume gain cannot be justified just due to the soft tissue or to the bone remodeling when placing an implant.

5 – CONCLUSION

In conclusion, narrow diameter Ti-Zr dental implants show high survival rates and marginal bone level changes that are comparable to those of regular diameter titanium implants in the short term. Our outcomes are in line with the first results of the 5-years outcomes showing the excellent clinical performance of Ti-Zr after a longer period of follow-up. Biomechanically the performance is excellent with survival rate of 100% which can be assigned to the mechanical properties of TiZr alloy associated with its biocompatibility. Narrow-diameter Ti-Zr implants performed well and without restrictions even in lower bone availability situations such as narrow crests over a 5-year period. Even though in our study no correlation could be established between bone level changes and labial profile, hard and soft tissues around reduced diameter TiZr Bone Level implants remained stable during the follow-up period of 5 years.

The modified roll flap technique produces a stable increase of soft tissues. Although it is not correlated with protection of bone resorption, this technique contributes to the health of tissues.

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7 - SCIENTIFIC PRODUCTION

Peri-implant tissue stability around bone level implants placed in narrow crests with roll flap technique: a case series with 5 years of follow-up – 25th EAO congress poster; Paris; September 2016; Accepted for presentation

II. ANNEXES

Annex 1 – Ethics Committee document

FMUC FACULDADE DE MEDICINA
UNIVERSIDADE DE COIMBRA

COMISSÃO DE ÉTICA DA FMUC

Of. Refª **129-CE-2015**
Data 21/12/**2015**

C/C aos Exmos. Senhores
Investigadores e co-investigadores

Exmo Senhor
Prof. Doutor Duarte Nuno Vieira
Director da Faculdade de Medicina de
Universidade de Coimbra

Assunto: Pedido de parecer à Comissão de Ética - Projecto de Investigação autónomo (refª CE-133/2015).

Investigador(a) Principal: João Paulo dos Santos Tondela

Co-Investigador(es): Adriana Margarida Lopes Oliveira e Ana Lúcia de Pereira Neves Messias

Título do Projecto: ***"Estudo não intervencional para documentação clínica e radiográfica de alterações dimensionais peri-implantares em implantes Straumann® Roxolid® após 5 anos de função".***

A Comissão de Ética da Faculdade de Medicina, após análise do projecto de investigação supra identificado, decidiu emitir o parecer que a seguir se transcreve: ***"Parecer Favorável".***

Queira aceitar os meus melhores cumprimentos.

O Presidente,

Prof. Doutor João Manuel Pedroso de Lima

GC

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Annex 2 – Informed consent

FMUC FACULDADE DE MEDICINA
UNIVERSIDADE DE COIMBRA

FORMULÁRIO DE INFORMAÇÃO E CONSENTIMENTO INFORMADO

TÍTULO DO PROJECTO DE INVESTIGAÇÃO:
Five years clinical and radiographic evaluation of dimensional changes in peri-implant tissues of Straumann® Roxolid® bone level implants
Avaliação clínica e radiográfica de alterações dimensionais peri-implantares em implantes Straumann® Roxolid® bone level após 5 anos de função

INVESTIGADOR COORDENADOR	João Paulo dos Santos Tondela
CENTRO DE ESTUDO	Mestrado Integrado em Medicina Dentária
INVESTIGADOR PRINCIPAL	João Paulo dos Santos Tondela
MORADA	Departamento de Medicina Dentária, Estomatologia e Cirurgia Maxilo-Facial Av.ª Bissaya Barreto, 3000-075 Coimbra
CONTACTO TELEFÓNICO	+351917585253

NOME DO DOENTE

(LETRA DE IMPRENSA) _____

É convidado(a) a participar voluntariamente neste estudo porque pretendemos efectuar uma consulta de controlo ao fim de 5 anos da reabilitação protética realizada

no âmbito da sua participação no estudo observacional sobre o desempenho clínico de implantes Straumann® Roxolid®.

Este procedimento é chamado consentimento informado e descreve a finalidade do estudo, os procedimentos, os possíveis benefícios e riscos. A sua participação poderá contribuir para melhorar o conhecimento sobre o desempenho clínico dos implantes Straumann® Roxolid® na actividade diária da consulta de medicina dentária.

Receberá uma cópia deste Consentimento Informado para rever e solicitar aconselhamento de familiares e amigos. O Investigador ou outro membro da sua equipa irá esclarecer qualquer dúvida que tenha sobre o termo de consentimento e também alguma palavra ou informação que possa não entender.

Depois de compreender o estudo e de não ter qualquer dúvida acerca do mesmo, deverá tomar a decisão de participar ou não. Caso queira participar, ser-lhe-á solicitado que assine e date este formulário. Após a sua assinatura e a do Investigador, ser-lhe-á entregue uma cópia. Caso não queira participar, não haverá qualquer penalização nos cuidados que irá receber.

1. INFORMAÇÃO GERAL E OBJECTIVOS DO ESTUDO

Este estudo irá decorrer no departamento de Medicina Dentária, Estomatologia e Cirurgia Maxilo-Facial, com o objectivo de documentar as alterações clínicas e radiográficas dos implantes Straumanm® Roxolid® na prática diária de medicina dentária.

Trata-se de um estudo observacional pelo que a consulta e registos efectuados são em tudo semelhantes a uma consulta de rotina de qualquer paciente reabilitado com implantes dentários.

Este estudo foi aprovado pela Comissão de Ética da Faculdade Medicina da Universidade de Coimbra (FMUC) de modo a garantir a protecção dos direitos, segurança e bem-estar de todos os doentes ou outros participantes incluídos e garantir prova pública dessa protecção.

Como participante neste estudo beneficiará da vigilância e apoio do seu médico, garantindo assim a sua segurança.

Serão incluídos 20 doentes que concluíram previamente o estudo observacional de 3

anos aos mesmos implantes.

2. PROCEDIMENTOS E CONDUÇÃO DO ESTUDO

2.1. Procedimentos

A consulta e registos efetuados no âmbito deste estudo são em tudo semelhantes a uma consulta de rotina de qualquer paciente reabilitado com implantes dentários pelo que apenas serão feitos os seguintes procedimentos:

- Observação oral
- Registo fotográfico
- Execução de impressão da arcada reabilitada
- Avaliação radiológica
- Protocolo de higienização

2.2. Calendário das visitas/ Duração

Este estudo consiste numa visita única com duração de cerca de 90 minutos.

Descrição dos Procedimento:

Serão realizados os seguintes procedimentos:

- Observação oral
- Registo fotográfico
- Impressão da arcada reabilitada
- Avaliação radiológica
- Protocolo de higienização

3. RISCOS E POTENCIAIS INCONVENIENTES PARA O DOENTE

Os procedimentos de determinação das condições intra-orais e periodontais, bem como a técnica radiográfica apresentada, são utilizados há anos de uma forma eficaz e segura, pelo que não existem riscos associados a este estudo. Estará sujeito a um risco de exposição de uma radiografia periapical correspondendo a um risco de exposição entre 0.0003-0.022 mSv. Assim, sendo este um estudo sem riscos, não haverá, para os participantes compensações nem médicas nem financeiras.

4. POTENCIAIS BENEFÍCIOS

A participação neste estudo oferece-lhe a possibilidade de receber tratamento de manutenção adequados à sua reabilitação protética e ao seu estado de saúde oral. A informação recolhida irá contribuir para uma melhor informação dos médicos dentistas de forma a melhorar os cuidados clínicos a prestar aos doentes com situações idênticas à sua.

5. NOVAS INFORMAÇÕES

Ser-lhe-á dado conhecimento de qualquer nova informação que possa ser relevante para a sua condição ou que possa influenciar a sua vontade de continuar a participar no estudo.

6. TRATAMENTOS ALTERNATIVOS

7. SEGURANÇA

Não se espere que devido à sua participação venha a sofrer problemas de saúde.

8. PARTICIPAÇÃO/ ABANDONO VOLUNTÁRIO

É inteiramente livre de aceitar ou recusar participar neste estudo. Pode retirar o seu consentimento em qualquer altura sem qualquer consequência para si, sem precisar de explicar as razões, sem qualquer penalidade ou perda de benefícios e sem comprometer a sua relação com o Investigador que lhe propõe a participação neste estudo. Ser-lhe-á pedido para informar o Investigador se decidir retirar o seu consentimento.

9. CONFIDENCIALIDADE

Sem violar as normas de confidencialidade, serão atribuídos a auditores e autoridades reguladoras acesso aos registos médicos para verificação dos procedimentos realizados e informação obtida no estudo, de acordo com as leis e regulamentos aplicáveis. Os seus registos manter-se-ão confidenciais e anonimizados de acordo com os regulamentos e leis aplicáveis. Se os resultados deste estudo forem publicados a sua identidade manter-se-á confidencial.

Ao assinar este Consentimento Informado autoriza este acesso condicionado e restrito. As equipas de trabalho do patrocinador, Institut Straumann AG, Basileia, Suiça (ou os seus representantes) podem comprovar o desenvolvimento do estudo como parte de uma observação do seu desenvolvimento ou de uma auditoria. Estas pessoas, assim como as autoridades competentes, podem consultar os seus dados de

paciente durante estas inspecções. O comité de ética do cantão de Berna também pode, de igual modo, ver os seus dados de paciente. De qualquer modo, tanto no estudo como nas inspecções é mantida a confidencialidade absoluta dos seus dados.

Ao assinar este termo de consentimento informado, permite que as suas informações médicas neste estudo sejam verificadas, processadas e relatadas conforme for necessário para finalidades científicas legítimas.

Confidencialidade e tratamento de dados pessoais

Os dados pessoais dos participantes no estudo, incluindo a informação médica ou de saúde recolhida ou criada como parte do estudo, (tais como registos médicos ou resultados de testes), serão utilizados para condução do estudo, designadamente para fins de investigação científica.

Ao dar o seu consentimento à participação no estudo, a informação a si respeitante, designadamente a informação clínica, será utilizada da seguinte forma:

1. O promotor, os investigadores e as outras pessoas envolvidas no estudo recolherão e utilizarão os seus dados pessoais para as finalidades acima descritas.
2. Os dados do estudo, associados às suas iniciais ou a outro código que não o (a) identifica directamente (e não ao seu nome) serão comunicados pelos investigadores e outras pessoas envolvidas no estudo ao promotor do estudo, que os utilizará para as finalidades acima descritas.
3. Os dados do estudo, associados às suas iniciais ou a outro código que não permita identificá-lo(a) directamente, poderão ser comunicados a autoridades de saúde nacionais e internacionais.
4. A sua identidade não será revelada em quaisquer relatórios ou publicações resultantes deste estudo.
5. Todas as pessoas ou entidades com acesso aos seus dados pessoais estão sujeitas a sigilo profissional.
6. Ao dar o seu consentimento para participar no estudo autoriza o promotor ou empresas de monitorização de estudos/estudos especificamente contratadas para o efeito e seus colaboradores e/ou autoridades de saúde, a aceder aos dados constantes do seu processo clínico, para conferir a informação recolhida e registada pelos investigadores, designadamente para assegurar o rigor dos dados que lhe dizem respeito e para garantir que o estudo se encontra a ser desenvolvido correctamente e que os dados obtidos são fiáveis.

7. Nos termos da lei, tem o direito de, através de um dos médicos envolvidos no estudo/estudo, solicitar o acesso aos dados que lhe digam respeito, bem como de solicitar a rectificação dos seus dados de identificação.
8. Tem ainda o direito de retirar este consentimento em qualquer altura através da notificação ao investigador, o que implicará que deixe de participar no estudo/estudo. No entanto, os dados recolhidos ou criados como parte do estudo até essa altura que não o(a) identifiquem poderão continuar a ser utilizados para o propósito de estudo/estudo, nomeadamente para manter a integridade científica do estudo, e a sua informação médica não será removida do arquivo do estudo.
9. Se não der o seu consentimento, assinando este documento, não poderá participar neste estudo. Se o consentimento agora prestado não for retirado e até que o faça, este será válido e manter-se-á em vigor.

10. COMPENSAÇÃO

Este estudo é da iniciativa do investigador e, por isso, se solicita a sua participação sem uma compensação financeira para a sua execução, tal como também acontece com os investigadores e o Centro de Estudo.

11. CONTACTOS

Se tiver perguntas relativas aos seus direitos como participante deste estudo, deve contactar:

Presidente da Comissão de Ética da FMUC,
Azinhaga de Santa Comba, Celas – 3000-548 Coimbra
Telefone: 239 857 707
e-mail: comissaoetica@fmed.uc.pt

Se tiver questões sobre este estudo deve contactar:

Investigador: João Paulo dos Santos Tondela

Direcção: Departamento de Medicina Dentária, Estomatologia e Cirurgia Maxilo-Facial
Av.ª Bissaya Barreto, 3000-075 Coimbra
Telefone: +351917585253
E-mail: jtondela@fmed.uc.pt

NÃO ASSINE ESTE FORMULÁRIO DE CONSENTIMENTO INFORMADO A MENOS QUE TENHA TIDO A OPORTUNIDADE DE PERGUNTAR E TER RECEBIDO

RESPOSTAS SATISFATÓRIAS A TODAS AS SUAS PERGUNTAS.

CONSENTIMENTO INFORMADO

De acordo com a Declaração de Helsínquia da Associação Médica Mundial e suas actualizações:

1. Declaro ter lido este formulário e aceito de forma voluntária participar neste estudo.
2. Fui devidamente informado(a) da natureza, objectivos, riscos, duração provável do estudo, bem como do que é esperado da minha parte.
3. Tive a oportunidade de fazer perguntas sobre o estudo e percebi as respostas e as informações que me foram dadas.

   A qualquer momento posso fazer mais perguntas ao médico responsável do estudo. Durante o estudo e sempre que quiser, posso receber informação sobre o seu desenvolvimento. O médico responsável dará toda a informação importante que surja durante o estudo que possa alterar a minha vontade de continuar a participar.
4. Aceito que utilizem a informação relativa à minha história clínica e os meus tratamentos no estrito respeito do segredo médico e anonimato. Os meus dados serão mantidos estritamente confidenciais. Autorizo a consulta dos meus dados apenas por pessoas designadas pelo promotor e por representantes das autoridades reguladoras.
5. Aceito seguir todas as instruções que me forem dadas durante o estudo. Aceito em colaborar com o médico e informá-lo(a) imediatamente das alterações do meu estado de saúde e bem-estar e de todos os sintomas inesperados e não usuais que ocorram.
6. Autorizo o uso dos resultados do estudo para fins exclusivamente científicos e, em particular, aceito que esses resultados sejam divulgados às autoridades sanitárias competentes.
7. Aceito que os dados gerados durante o estudo sejam informatizados pelo promotor ou outrem por si designado.

   Eu posso exercer o meu direito de rectificação e/ ou oposição.
8. Tenho conhecimento que sou livre de desistir do estudo a qualquer momento, sem ter de justificar a minha decisão e sem comprometer a qualidade dos meus cuidados médicos. Eu tenho conhecimento que o médico tem o direito de decidir sobre a minha saída prematura do estudo e que me informará da causa da mesma.
9. Fui informado que o estudo pode ser interrompido por decisão do investigador, do promotor ou das autoridades reguladoras.

Nome do Participante:_____

Assinatura : _____

Data:_____/_____/____

Nome de Testemunha / Representante legal:_____

Assinatura: _____

Data:_____/_____/____

Confirmo que expliquei ao participante acima mencionado a natureza, os objectivos e os potenciais riscos do Estudo acima mencionado.

Nome do Investigador:_____

Assinatura: _____

Data:_____/_____/____

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