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Accuracy and stability of titanium dental implants placed with s-CAIS: an *in vitro* and *in vivo* pilot study

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Tesis Doctoral

Presentada por **Catarina Mendes Fonseca**

para optar al título Internacional de Doctor en Odontoestomatología

Salamanca, 2024

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Directores:

Prof. Doctor Javier Montero

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Salamanca, 2024

Dedication

I dedicate this work

To my parents,

To Ivo,

And to my eternal inspirations,

My grandmothers.

Thank you for always being with me.

Acknowledgments

My special appreciations to my thesis supervisors, Prof Dr Patrícia Fonseca, Prof Dr André Correia and Prof Dr Javier Montero, for all their help, professionalism, wisdom and motivation throughout this work. With their support and valuable guidance, it was possible to achieve all the established objectives.

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To my parents, it would be impossible to express in a single page the deep gratitude I feel for having you unconditionally by my side. You are a pillar for me, an example of love, kindness, humility, hard work and dedication, effort and resignation. Thank you for always "walking with me". I will continue to do everything in my power to ensure that your effort, dedication and all the investment you have made in me is rewarded. My love for you is infinite!

To my boyfriend, Ivo, thank you for your words of affection, motivation and understanding, for your constant companionship and for making "the far away closer". Thank you for your help during the preparation of this work. Thank you for making me feel unique and special!

To my two grandmothers, Gusta and Tininha, who, despite having left too soon, are for me two references who have unequivocally made me much of who I am today. They were examples of kindness, humility, generosity, altruism and, above all, courage in the face of the obstacles that life threw at them. They never stopped fighting or gave up and always put their family first. Thank you both for all the love you've given me. I hope I can continue to make you proud and I'm sure we'll meet again!

Thank you all so much!

RESUMEN

Introducción: Los nuevos diseños de implantes dentales, junto con los avances digitales en la planificación quirúrgica, han dado lugar a la actualización de protocolos y técnicas quirúrgicas. El concepto de mínima invasión con la cirugía guiada de implantes, ha generado gran atención entre los clínicos y científicos del sector. El objetivo principal es combinar las tecnologías y el conocimiento de los materiales, para crear nuevos flujos de trabajo digitales que proporcionen protocolos mejorados con el fin de ofrecer al paciente la mejor reabilitación protésica. Según la literatura, los implantes colocados con cirugía guiada estática mediante planificación digital ayudan a los clínicos a colocar los implantes según un plan preestablecido. Estas guías proporcionan una mayor precisión y previsibilidad en la colocación de los implantes, aunque siempre hay algunas desviaciones asociadas, principalmente a nivel del ápice.

Así, la cirugía de implantes guiada por la prótesis se ha convertido en un "*gold standard*" para mejorar el éxito de la reabilitación. La estabilidad primaria condicionará el momento de carga de los implantes y en última instancia el éxito y supervivência de los implantes dentales. El torque de inserción y el análisis de la frecuencia de resonancia son los métodos más utilizados para medir directa e indirectamente la estabilidade implantaria. En esta investigación se pretende determinar la precisión y la estabilidad de implantes dentales de titanio mediante una análisis *in vitro* y un estudio piloto *in vivo*.

Objetivos: El objetivo principal del estudio *in vitro* es determinar y comparar la estabilidad primaria de diferentes implantes de titanio, colocados mediante diferentes técnicas quirúrgicas, utilizando modelos de hueso artificial calibrados para 4 densidades óseas diferentes (D1-D4). Como objetivo secundario verificar se este diseño experimental con modelos de hueso artificial es válido para la análisis que se pretende efectuar en el objetivo principal.

El objetivo principal del estudio piloto *in vivo* es determinar y comparar las desviaciones lineales y angulares de implantes con diferentes macrogeometrías colocados con cirugía guiada en un grupo aleatorio de pacientes.

Materiales y Métodos: Este estudio se diseñó en dos aspectos: un estudio *in vitro* y un estudio piloto *in vivo*. El estudio *in vitro* incluyó 16 mini bloques de hueso (Bonemodels®, España), calibrados para los 4 tipos de densidad ósea (D1-D4). Se colocaron 3 tipos diferentes de implantes BL, BLT y BLX (Straumann®, Institut Straumann AG, Suiza) mediante procedimientos guiados por ordenador para permitir la evaluación de las desviaciones lineales y angulares. Los implantes se colocaron utilizando diferentes técnicas: parcialmente guiada con fresa aplanadora y totalmente guiada. Se utilizó

el *software* coDiagnostiX® (Institut Straumann AG, Suiza) para planificar virtualmente la posición de los implantes, diseñar las guías quirúrgicas y su herramienta "*Treatment evaluation*" para medir las desviaciones de los implantes tras un escaneado 3D final. También, tras la colocación de los implantes se llevó a cabo el análisis de frecuencia de resonancia (Osstell®, Suecia).
En el estudio *in vivo*, los datos pertinentes de los registros clínicos electrónicos de una clínica dental universitaria se transfirieron de forma segura/anonimizada al investigador principal. Se recogieron datos de la fase de planificación digital y del momento de la toma de impresiones con éscaner intra-oral. Se utilizó la herramienta "*Treatment evaluation*" para evaluar la precisión de los implantes colocados. El análisis estadístico se llevó a cabo, en ambas partes de este trabajo, utilizando el programa IBM *Statistical Package for the Social Sciences* (SPSS®, EEUU), versión 24. Se consideró estadísticamente significativo un nivel de significación de $p < 0.05$.

Resultados: De los 120 implantes colocados en el estudio *in vitro*, la mediana del torque de inserción fue de 51.9 Ncm, la mediana de los valores ISQ a nivel del implante fue de 69.8 para la orientación mesiodistal (MD) y de 69.9 para la orientación bucolingual (BL). A nivel del pilar, la mediana de los valores ISQ fue de 66.2 para MD y 67.0 para BL. La desviación angular mediana fue de 2.1º. Las desviaciones lineales medias en la base fueron de 0.13 mm para MD y 0.18 mm para BL, con valores ligeramente superiores en el ápice. Las variaciones en los valores de torque, así como en los valores ISQ entre los distintos tipos de hueso, fueron evidentes, siendo el tipo de hueso IV el que mostró la mayor dispersión. El tipo de implante influyó significativamente en las desviaciones angulares ($p=0.007$) y en las desviaciones BL en el ápice ($p=0.046$), siendo superior en los implantes tipo BLT. Las cirugías totalmente guiadas mostraron desviaciones angulares medias inferiores (1.75º) en comparación con las cirugías parcialmente guiadas. De los 53 implantes del estudio *in vivo*, la desviación angular mediana fue de 3.9º (4.1º para TLX y 3.7º para BLX). La desviación 3D mediana en el punto más coronal de los implantes fue de 1.04 mm (1.12 mm para TLX y 1.06 mm para BLX). En el ápice de los implantes, la desviación mediana fue de 1.56 mm (1.82 mm para TLX y 1.50 mm para BLX).

Conclusiones: Con esta investigación se puede concluir que en la cirugía estática guiada por ordenador se obtuvieron valores de desviación reducidos en la colocación de implantes dentales con diferentes macrogeometrías, siendo el BLT el que ha alcanzado peores resultados en comparación con los diseños BL y BLX (*in vitro*). Se necesitan más estudios para determinar si existen diferencias estadísticamente significativas en relación con la técnica parcialmente guiada. Factores como la densidad del hueso, el lugar de colocación del implante, el tipo de guía quirúrgica utilizada y la

macrogeometría del implante parecen influir en los valores de desviación. Herramientas informáticas como el "*Treatment evaluation*" permiten a los clínicos ser cada vez más exigentes con las técnicas quirúrgicas que eligen y los biomateriales que utilizan en determinado caso, ya que pueden evaluar la precisión de su propio trabajo.

Palabras-Clave: Implantes dentales, cirugía asistida por ordenador, informática dental, prostodoncia

ABSTRACT

Introduction: Dental implants have been used to re-establish mastication and aesthetics by the replacement of missing teeth. Titanium implants show a unique property among metals-osseointegration. The advent of new implants has resulted in updated surgical protocols and techniques. The notion of minimal invasiveness has attracted great attention within this current conception of implant success. Digital implant dentistry and guided surgery became allies by providing less invasive implant treatment alternatives. The main goal is to combine the technologies and the knowledge of the materials, to create new digital workflows that provide flawless protocols to offer the patient the best rehabilitation treatment. Prosthetically driven implant surgery has grown into a gold standard to improve short and long-term success. Implant success can also be predicted by primary stability and has been referenced as a requirement for osseointegration and long-term survival of dental implants. Insertion torque and resonance frequency analysis are the most extensively used methods to measure it. Computer-assisted implant surgery its part of digital workflow in implantology. According to the literature, implants placed using a guided approach show less deviation and more predictability.

Objectives: The main objective of the *in vitro* study is to determine and compare the primary stability of different titanium implants, placed using different surgery techniques, using artificial bone models calibrated to 4 different bone densities (D1, D2, D3, and D4). The main objective of the *in vivo* pilot study is to determine and compare the linear and angular deviations of implants placed with guided surgery in a group of patients.

Materials and Methods: This study was designed in two aspects: an *in vitro* study and an *in vivo* pilot study. The *in vitro* study included 16 mini bone blocks (Bonemodels®, Spain). They were calibrated to the 4 types of bone density (D1-D4). 3 different implant types BL, BLT, and BLX (Institut Straumann AG) were placed using computer-guided procedures to enable the assessment of linear and angular deviations. The implants were placed using different techniques: partially guided with milling cutter drill and fully guided. The software coDiagnostiX® (Institut Straumann AG) was used to virtually plan the position of the implants, to design the surgical guides and its “Treatment Evaluation” tool was used to measure implant deviations after a final 3D scan. After implant placement, the Resonance Frequency Analysis was carried out. In the *in vivo* study, pertinent data from the electronic health records of a university dental clinic were securely transferred to the lead researcher. All patients who underwent guided implant surgery gave informed consent and were subsequently enrolled in this study. Data was collected at the planning stage and at the time of dental impression making. The 'Treatment Evaluation' tool was used to evaluate the accuracy and precision of the implants placed. Statistical analysis was conducted, in both parts of this work, using IBM Statistical Package for the Social Sciences (SPSS), version 24. A significance level of $p < 0.05$ (two-tailed) was considered statistically significant.

Results: From the 120 implants placed in the *in vitro* study, the median insertion torque stood at 51.9 Ncm the median, ISQ values at the implant level were 69.8 for Mesiodistal (MD) orientation and 69.9 for Bucolingual (BL) orientation. At the abutment level, the median ISQ values were 66.2 for MD and 67.0 for BL. The median angular deviation was 2.10º. Median linear deviations at the base were 0.13 mm for MD and 0.18 mm for BL, with slightly higher values at the apex. Variations in torque values as well as in ISQ values across different bone types were evident with Bone type IV displaying the highest dispersion. The implant type significantly influenced angular deviations (p=0.007) and BL at apex deviations (p=0.046). Fully guided surgeries displayed lower median angular deviations (1.75º) compared to partially guided surgeries. From the 53 implants of the *in vivo* study, the median angular deviation was 3.90° (4.10º for TLX and 3.70º for BLX). The median 3D deviation of the most coronal point on the implants was 1.04 mm (1.12 mm for TLX and 1.06 mm for BLX). At the implants' apex, the median deviation was 1.56 mm (1.82 mm para TLX y 1.50 mm para BLX).

Conclusions: It can be concluded that static-guided surgery reduced deviation values obtained in the placement of dental implants with different macrogeometries, with BLT achieving worse results compared to BL and BLX designs (*in vitro*). Further studies are needed to determine whether statistically significant differences exist in relation to the partially guided technique. Factors such as bone density, implant placement site, type of surgical guide used and implant macrogeometry seem to influence the deviation values. Computer tools such as Treatment evaluation allow clinicians to be increasingly demanding with the surgical techniques they choose and the biomaterials they use in a given case, as they can evaluate the accuracy of their work.

Keywords: Dental implants, Computer Aided Surgery, Dental informatics, Prosthodontics

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LIST OF ABBREVIATIONS AND ACRONYMS

3D: Three Dimensional

BIC: Bone-to-Implant-Contact

BL: Bone Level implant

BLT: Bone Level Tapered implant

BLX: Bone Lever X implant

CAD/CAM: Computer-Aided Design and Computer-Aided Manufacturing

CAIS: Computed Assisted Implant Surgery

CBCT: Cone-Beam Computed Tomography

CRA: Cutting Torque Resistance Analysis

FDP: Fixed Dental Prosthesis

FG: Fully-guided

FOV: Field of View

HU: Hounsfield Unit

ISQ: Implant Stability Quotient

IT: Insertion Torque

ITI: International Team for Implantology

Mod-SLA: Modified Sandblasted, Large grit, Acid-etched

PG-MC: Pilot-Guided with Milling Cutter

PTV: PerioTest Value

RFA: Resonance Frequency Analysis

S-CAIS: Static-Computed Assisted Implant Surgery

SLA: Sandblasted, Large grit, Acid-etched

Ti: Titanium

1. INTRODUCTION

Dental implants have been used to re-establish mastication and, in some cases, aesthetics by the replacement of missing teeth. Clinical implant dentistry has grown significantly since the first description of the biologic processes leading to implant osseointegration and, currently, it is considered a predictable rehabilitation treatment modality.

In the first stages of implant development, the main goals were to improve and develop new implant designs and to modify its surface topography to improve osseointegration and, therefore, to maximize the chances of implant survival.

The advent of new implants has resulted in updated surgical protocols and techniques. The aesthetic outcomes and the long-term preservation of peri-implant tissues have conducted to the design of new macro- and micro- implant components. Therefore, the concept of implant success changed during this second stage of implant dentistry, while additional outcomes were integrated.

Nowadays, the notion of minimal invasiveness has attracted great attention from clinicians, companies, and patients within this current conception of implant success. The objective is to improve the patient's experience during implant treatment while reducing morbidity and enhancing tissue preservation. Digital implant dentistry, and associated with it, guided surgery, became allies by providing less invasive implant treatment alternatives.

The main goal of this actual stage of implant dentistry is to combine the technologies and the knowledge of the materials that we have, to create new digital workflows that give us flawless protocols to provide the patient with the best rehabilitation treatment.

1.1. Digital Implant Dentistry

1.1.1 Overview

Despite all the progress in dental implant materials, techniques, and technologies, there are still post-operatory complications due to improper planning of the cases and implant mispositioning.(1) Conventional approaches, such as freehand surgery, can result in critical implant placement which could produce biological and prosthetic complications.(1-3)

Clinicians have now many digital tools that allow the correct execution of their implant cases which inevitably depends on thorough planning. This tools also enable to improve the accuracy of implant placement and to reduce surgical and post-surgical risks.(4)

In what concerns of digital tools for implant dentistry and computer-aided implant surgery it is unavoidably to mention Cone-Beam Computed Tomography (CBCT), intraoral 3-dimensional (3D) scanners, 3D implant planning software, Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) and 3D printing.(1, 4) It is now difficult for clinicians to keep up and be aware of recent advances in digital implant dentistry. However, the application of these technologies, if possible together, in rehabilitations, allows an ideal, predictable, and correct positioning of dental implants placed.(2)

1.1.2 Digital Tools for Implant Planning

Nowadays, in cases where an implant-supported rehabilitation is recommended, the digital workflow should be the primary choice, and it is mostly designated as Computer-Aided Implant Surgery (CAIS).(5)

There are two types of CAIS placement techniques: **s**tatic navigation (S-CAIS) and **d**ynamic navigation. S-CAIS uses drill templates/surgical guides produced after preoperative planning,(6) while D-CAIS uses a device that allows to monitor, in 3D and in real-time, the position and progression of the drills and implants according to the preoperative plan.(7)

The first stage to perform CAIS is to do a preoperative CBCT.(5, 8) This radiographic exam is low-cost, low-dose, and provides valuable information for evaluation before starting to plan the dental implant(s).(5, 8) Then, a 3D intraoral scan should be performed in order to capture the full arches of the patient and its intermaxillary relation.(8)

After CBCT and 3D intraoral scan, a three-dimensional (3D) implant-planning software should be used to upload this collected data and superimpose the radiographic data with the data obtained from the scan which makes possible the implant planning stage.(4, 5) The purpose of using this software is to plan the placement of the implants in a prosthetically driven position. Sometimes, a digital diagnostic tooth setup can be added in this stage to assist with this task.(4, 5) Implants may be placed anywhere the bony anatomy permits, but in order to build a successful prosthesis, the correct planning must be done.(4) Nowadays, the majority of implant companies offer this software and, eventually, the possibility of fabricate the surgical guide.(5)

Implants are virtually positioned in cross-sectional images and three-dimensional surface models reconstructed from the CBCT, according to the prosthetic set-up and the anatomy of each patient.(4) In several software, there are alerts when the distances do not follow the recommendations: 3 mm between planned implants, 1-1.5mm between implant and tooth, and 2-5 mm between implant(s) and inferior alveolar nerve canal.(9) These parameters are configurable in the software definitions. Usually, the implant planning software allow the virtual placement of a variety of implant systems and enable to change implant type, length, height, diameter, rotation, and inclination as often as required.(4) The final selection of an implant and its position must be appropriately conferred in multiplane images.(4)

Once the implant is correctly positioned, a surgical guide can be designed upon the 3D model that results from the intraoral scan.[5] The guides can be then printed through CAD/CAM and placed in the patient's mouth in the surgery.[8] They can be supported by teeth, mucosa, or bone and help to position the implant in an optimal position – the prosthetically planned position.[10]

The benefits of S-CAIS are numerous: the patient's chair time is reduced, the implant's position is prosthetically driven, the surgery is more predictable and less stressful for the clinician, and the case difficulty is previously determined.[1]

As described above, S-CAIS surgery fully digital workflow includes seven steps in order: clinical diagnosis, CBCT scan, intraoral digitization (3D intraoral scan), digital diagnostic tooth setup, digital treatment planning, fabrication of surgical guide, and guided surgery.[5]

There is a learning curve of apprenticeship for this fully digital method. The clinician must keep in mind that the total amount of placement inaccuracy is determined by the sum of mistakes that occur during each step of the process.[1]

According to the literature, there is no perfect computer-guided surgical method at this moment.[1] Several studies have already indicated some degrees of angular, vertical and horizontal deviations from the positions digitally planned to the final positions after the surgery.[1-3, 11]

1.2. Implants and Primary Stability

In 1977, osseointegration was defined as a direct functional and structural connection between the bone and the surface of a loaded implant.[12] Histologically, when osseointegration occurs the presence of regenerated bone at the implant-bone interface can be identified. The adherence of cells to the surface of the biomaterial that constitutes the implant is a key factor for dental implant osseointegration.[12]During this period, the implant must remain immobile to allow osseointegration.[12] Primary stability is defined immediately following the insertion of an implant and is a consequence of the mechanical engagement of an implant with the contiguous bone.[13] This initial mechanical stability provided is critical for preventing micromovement of the implant, which could delay osseointegration.[12, 14]

1.2.1. Osseointegration and Primary Stability

The primary stability, defined immediately after implant placement, has been referenced as a requirement for osseointegration and long-term survival of dental implants.[15] Many factors like bone conditions (quantity/quality), implant design (diameter/length/microscopic and macroscopic morphology), and surgical protocol applied influence the primary stability outcome.[13]

During the early stages of healing and due to bone remodeling the primary stability decreases.[13] However, as new bone forms around the implant external surface, secondary stability is established. Secondary stability is the result of the osseointegration.[13]

The minimal displacement of the implant that can occur during the healing process is called micromotion and is not visible to the human eye.[16] According to the literature, the value of micromotion should not exceed a threshold value of 150 mm in order to not affect the osseointegration process.[16] Greater primary stability of the implant implies less micromovement between the implant surface and the bone apposition site. Other movements of greater range that can cause strain and stress can have a bad influence in bone remodeling process and osseointegration.[16] This type of movements may have a negative impact on the recruitment of new cells which can lead to the formation of fibrous tissues.[17]

As previously mentioned, the implant's 3-dimensional structural design influences primary stability. In fact, the design of the implant plays a vital role in attaining primary stability.[13] The area of the implant that contacts directly with the bone is termed Bone-to-Implant Contact (BIC).[18] Therefore, implants with threads offer a higher percentage of BIC in comparison to implants with cylindrical design.[18] More recently, the tapered design aims to provide a certain degree of compression of the cortical bone. However, many implant surface modifications have been developed in order to improve osseointegration and primary stability.[18]

Another factor that influences primary stability is surface topography and roughness.[18] Studies[18, 19] have shown that these factors increase the mechanical link to the surrounding tissues and consequently enhance primary stability. Also, acid-etched surfaces can accomplish a significantly higher BIC and primary stability in poor bone quality sites in comparison to implants with machined surface.[19] Schätzle and colleagues [20], in 2009, compared a standard sandblasted, large grit, acid-etched (SLA) surface with a chemically modified sandblasted/acid-etched titanium surface (modSLA) and achieved higher values at 12 weeks in the modSLA group versus SLA group.[20]

The quality and quantity of bone also has a direct impact on primary stability.[17] Its distribution and percentage (of both cortical and cancellous bone) in the implant site determine the insertion resistance during implant placement.[17] Some clinical studies[17, 21, 22] have stated that dental implants placed in the maxilla (especially the posterior region) have lower survival rates compared with those in the mandible. The desire is to always have a balance between cancellous and cortical bone.[23] According to Lekholm and Zarb's[24] classification, a type I cortical bone will result in high insertion torques with possible bone resorption while a type IV bone with no cortical bone provides minimal or no primary stability.[24] The lack of primary stability in turn may result in implant micromotion and osseointegration failure.[13]

Surgical techniques can also improve or optimize a high degree of implant stability.[17] Several implant bed preparation techniques and surgical protocols were developed over the years using osteotomes to laterally condense the bone, undersized drilling protocol, and counter-clockwise rotational surgical drills.[17, 25-28] The drilling of the implant bed is a crucial step of implant placement that causes mechanical damage to the bone and increases the temperature of the bone in close proximity to the implant surface.[17] E.g., if the temperature exceeds 47ºC for 1 minute, bone cell necrosis occurs.[29] Both mechanical and thermal damage to the neighboring tissue around the implant surface can have a critical effect on the initial state of the osteotomy.[13]

Primary stability is always desired. Even though, sometimes it may not be attainable either from operator-related factors (overpreparing) or from patient specific reasons (bone quality, for example).[15] Still some studies[15, 30-32] report that implants that lacked/had low primary stability exhibit comparable survival rates to those with high primary stability while others claim that although implant primary stability is not an absolute prerequisite to osseointegration it can significantly affect the implant survival rate.

1.2.2. Primary Stability Measurement

Primary stability has been extensively discussed in the literature, though there is no protocoled method to measure or quantify it.[18] Several techniques and methods were presented to measure implant stability, particularly primary stability. Non-invasive tests include visual inspection, percussion testing, insertion torque, and resonance frequency analysis.[16]

Friberg and colleagues developed, in 1995, the cutting torque resistance analysis (CRA).[13] The described technique consists of combining a torque gauge within the drilling unit to measure implant insertion torque in newton centimeter (Ncm) to be converted to joule per cubic millimeter (J/mm^3).[13] The required current needed in an electric motor to cut off a unit volume of bone during the low-speed threading of the implant osteotomy site is measured. The measurement of the energy identifies areas with cancellous bone.[13] This technique presents some limitations: it doesn't provide a clear lower-cutting torque threshold to indicate the risk of implant failure and doesn't provide any information on bone quality until the implant bed preparation is done.[33]

The Insertion Torque (IT) is the clinically most widely used tool to assess primary stability. The IT can only be verified at the time of implant placement and it is the value of the torque at which the implant is inserted.[13] This value can be verified on the implant motor. Any changes that occur after implant placement cannot be assessed.[13, 33]

Ottoni and collaborators [34] explored the correlation between insertion torque (IT) and the survival of single implants. This study suggested that to attain successful osseointegration, a minimum IT value of 20 Ncm and an optimal torque of 32 Ncm were recommended.[34] While a high IT value might indicate robust primary stability, it is crucial to note that maximum insertion torque can be misleading.[34] This is because direct pressure of the implant on the dense cortical bone, without sufficient BIC across the rest of the implant surface, can result in a falsely elevated IT value.[34]

Periotest (Siemens A, Benshein, Germany) was first developed by Schulte[35] to test tooth mobility using a metallic rod that applies an electronically controlled tapping force to the object.[33] The handpiece's sensor measures the response time to "controlled tapping," converting it into a value known as the periotest value (PTV). This value indicates the damping characteristics of the tissues surrounding the tooth or implant, ranging from -8 (low mobility) to +50 (high mobility).[33] According to Olive and colleagues[36], a typical PTV for an osseointegrated implant falls within a relatively narrow range of -5 to +5. However, other studies have suggested even narrower zones, such as -4 to -2 or -4 to +2.[13, 33] While many researchers initially believed that PTV precisely reflects the condition of BIC, criticism has been directed at its prognostic accuracy for implant stability due to poor sensitivity, challenges in application in the posterior region, and susceptibility to operator variables.[13]

The Resonance Frequency Analysis (RFA) consists of applying a transducer which provides the measurement regarding the axial stiffness of the BIC.[13] RFA suggested by Meredith[37] in 1998 has gained popularity in measuring both primary and secondary implant stability.[13] In this technique, an L-shaped transducer is inserted into the implant or abutment containing a vibrating element and a receptor. The vibrating element administers either a sinusoidal wave or an impact force wave, while the receptor gauges the resonance signal emanating from the implant-bone component, a measure proven to assess implant stability.[13] There are some devices available that allow us to perform this measurement like Osstell® (Osstell AB, Gothenburg, Sweden) and Penguin® (Citagenix Inc., North America). Osstell® device combines a transducer, computerized analysis, and vibration source into one single device and it is widely used.[33] Originally, Hertz was used as the measurement unit but then Implant Stability Quotient (ISQ) was developed. The ISQ value ranges from 0 to 100, of which the higher value refers to more implant stability.[33] According to the literature and due to its advantages, one of the gold standards for measuring primary stability *in vivo* is resonance frequency analysis.[13]

IT and RFA are nowadays the most extensively used methods. Their relationship has been equally analyzed and remains controversial.[13]

1.3. Guided Surgery

The demand to obtain the best functional and aesthetic results in implant rehabilitation implies that the clinicians position the dental implants correctly.[2] Therefore, diagnostic and treatment planning phases have a crucial role. Attention must be paid to prosthetic and anatomical constraints in the alveolar bone site.[2, 4]

There are two types of guided implant surgical protocols: static and dynamic.[6] Dynamic navigation provides guidance in a real-time drilling process.[38] The implant position is dynamically represented directly on a computed tomography data viewer and the drill location is also illustrated using an optical bur tracking system. Sensors are attached to both the patient and surgical handpiece.[38] These sensors transfer the positional information to a camera or detector. A computer can immediately calculate and display the position of the instruments at every moment of the surgery.[6] With this type of system, the clinician can modify the implant position during surgery but they remain expensive when compared to stereolithographic alternatives.[6] The static protocol refers to the use of a prefabricated surgical guide that leads the implant to the digitally preplanned position. It does not allow any intra-operative modification of the implant position and it’s still the most used approach.[2, 6]

According to the literature, both types, static and dynamic, have showed equal results in terms of accuracy.[6] Kaewsiri and colleagues[39] in their study with 60 patients found no statistical significance in terms of accuracy between S-CAIS group and D-CAIS. With a mean deviation at implant platform and implant apex in the static CAIS group of 0.97 ± 0.44 mm and 1.28 ± 0.46 mm and in the dynamic CAIS group of 1.05 ± 0.44 mm and 1.29 ± 0.50 mm. While angular deviation was 2.84 ± 1.71 degrees for the static-CAIS group and 3.06 ± 1.37 degrees for the dynamic group.[39] While, Hermann et al[40], concluded that static surgery is associated with fewer errors than dynamic navigation.[40] Nevertheless, other authors did not find statistically significant differences.[6, 38]

In S-CAIS, the use of implant planning software allows to process different parameters such as bone volume, bone quality, and anatomical restraints.[5] This virtual simulation of the positioning of the dental implant enables the design a three-dimensional model of the implant positioning guide.[5] Once printed, this guide can be used during the implant surgery. This kind of software as advantages like allowing to place the implants before surgery and to find the most suitable position not only in healed sites but also in post-extraction sites.[5] Furthermore, it allows to reduce or even exclude the use of bone grafts and substitute biomaterials and the placement of tilted dental implants avoiding important anatomical structures or with a cortical anchorage (in structures with dense cortical bone).[5]

S-CAIS includes different surgical techniques: pilot-guided surgery, partially-guided surgery and fully-guided surgery.[41] In pilot-guided technique the guide is only used to pass the pilot drill and then the surgical guide is removed and the remaining drilling protocol is performed without the guide, even the implant placement stage.[41] In the partially-guided technique, all the drilling protocol is done through the guide but the implant placement stage is performed without it. But the main advantageous protocol is the fully-guided one.[41] In this type of guided surgery, the surgical guide is settled at the beginning of the surgery and all drilling protocol is performed with the guide, even the final stage of the implant placement.[41]

Another advantage is the application of flapless-guided surgery, where no access flap is done before the drilling protocol. This type of surgery improves the post-operatory of the patient. However, enough keratinized tissue must be available. [41]

S-CAIS still has some disadvantages. The fracture of the guides is one of the common intraoperative complications according to a systematic review by Tahmaseb et al.[42] Thus, surgical guide fracture or sleeve displacement from the guide may be the consequence of improper force implementation on the guide.[1] The correct way to do it is to first insert the drill into the sleeve and then activate its rotation. Also, the drill should be used parallel to the internal wall of the sleeve and in a centric position.[43] A perceptible tolerance of surgical implant instruments within the metal sleeve, which is caused by the gap between the drill and the sleeve.[44] This allows the rotation of the drill in the sleeve. If the drill is not parallel to the sleeve unwanted lateral osteotomy may occur.[44] But if there is no tolerance, sleeve deformation or disintegration may occur in consequence of the friction created by mechanical components hindering the drilling process. In order to overcome these problems, new drilling systems are always being created and improved.[44] Numerous drilling systems incorporate drills with modified shanks. The shank portion of surgical instruments is used as a guiding element to restrict lateral drilling motion.[44] The drill's shank was widened to accommodate the guide sleeve, eliminating the necessity for an additional insertion of a metal guide spoon into the guide template. Incorporating depth control into the drills is a crucial aspect.[44] The introduction of a stopper serves to physically limit the depth of the osteotomy, permitting drill advancement only up to the level of the stopper. This depth control enhances safety by preventing drills from penetrating vital anatomical structures. This modification's goal was to improve the accuracy of implant positioning.[44, 45]

A critical factor that could influence the outcome of the guided surgery is the selection of the macrostructure of the implant.[2] Despite the tendency to use tapered implants, according to Ciabattoni's[46] study parallel-walled implants were used especially when the quality and quantity of the bone were good as they are easier to place by guided insertion. Implants with a more aggressive macrodesign, that takes advantage of the self-tapping capacity, should be preferred in cases where the density and effective residual bone volume are low, such as in extraction sites.[46]

Other intraoperative obstacles including maxillomandibular registration errors causing occlusal index maladjustment, insufficient mouth opening which causes difficulty in drilling through the guide, and bad adjustment of the guide are described in the literature.(1)

Besides this, guided implant surgery is more expensive than free-hand placement due to the cost of software, the digital setup of the case, the CBCT scan, the surgical guide, and the planning time.(1) Nonetheless, the whole workflow from the stage of the surgery to the insertion of the final prosthesis is less invasive, time-saving, and with minimal discomfort for the patient (if flapless surgery was performed).(1) Several studies published in the literature stated that patients prefer guided surgery and claimed that they could have undergone the same procedures again despite the costs.(1, 47)

Studies like Naeini et al. (48) with a 10 years follow up suggests that implant survival obtained rates showed high percentages with the use of guided implant surgery.

1.3.1. Surgical Guides

As previously described, the implant planning software enables to process and evaluate important factors like bone quality and volume and vital anatomical structures so that the implant can be planned based on anatomical limitations and restoration objectives which ultimately leads to the drawing of a guide that can be used during surgery.(1) Then, this virtual guide can be printed into a resin guide using a milling machine or a 3D printer.(8)

The types of surgical guides described in the literature, according to the supporting surfaces are:

- Tooth-supported, where the surgical guide is positioned on the teeth;
- Mucosa-supported, where the surgical guide is positioned on the mucosa;
- Bone-supported, where the surgical guide is placed directly on the bone after opening a mucoperiosteal flap.(10)

More recently, stackable surgical guides allow to use of different types of guides with different types of support in the same surgery.(49) These guides can be fitted just by friction or can use magnetics, and they are used most of the times for full arch implant placement. Usually, they have a base guide that the clinician should place and fixate at the beginning of the surgery, and then a sequence of other guides is used. The following guides are magnetically/or friction attached to the base one.(49) This allows to reduce the amount of errors that can occur from the process of change and place a new guide in the exact position of the previous one.(49)

Although surgical guides usually facilitate the implant placement surgery in full edentulous ridges its placement can be a challenge.(1) The correct seating of a surgical guide is always easier when the patient has teeth.(1) But in edentulous ridges the difficulty arises because of potential compression of the soft tissues and possible movement of the guide. The initial position of the guide on the soft tissue determines the position of the implants.(3) Studies suggest that the use of more than 3 anchor pins in this cases is recommended to improve guide stabilization and to obtain an accurate positioning of the guide.(50) However, if the guide was not initially positioned correctly, the fixating tools will perpetuate the error.(50) The comparison between the use of fixation pins with hand fixation was done by Kauffmann et al(51) in their study. The group that used fixation pins showed better results but the benefit was not significant.(51) Regardless this results, it is important to remember that guide fixation does not guarantee that the guide is in the correct 3D planned position but it reduces possible movements during surgery.(51) Some articles also recommend the placement of temporary micro/mini implants in some clinical cases where the anatomical references are scarce and in order to improve guide stabilization during surgery.(2)

The literature also recommends injecting anesthesia, especially on the palatal side (because of tissue deformation), after placement and fixation of the guide in order to decrease the risk of guide mispositioning.(52)

In cases where there are still clinically stable teeth or remaining roots (drilling through the root cases), that can provide adequate support to a guide and/or orientation in the implant placement, its extraction should be delayed to a stage after the implant placement.(53) After the first stage of implant placement, the remaining teeth or roots are extracted and the guide could be then fixed to the implants (placed in the first stage) and the remaining implants can be inserted maintaining the correct position of the guide. The secure anchoring of the surgical guide to the existing teeth is considered advantageous when this type of serial extraction protocol is applied.(53)

A systematic review based on “The Fifth ITI Consensus Conference” concluded that the bone-supported surgical guides showed the highest inaccuracy among all types of guides.(54) This can be justified by the distortions of the data registered by the CBCT which is then used to create the guide. As was previously mentioned, the placement of fixation pins after guide positioning can be beneficial to improve the outcomes.(54)

If the guided surgery protocols are strictly followed, if the correct type and design of surgical guide is chosen the results confirm that if the surgery is performed with caution, avoiding the displacement of the guide, it is possible to adapt the final prosthesis predictably.(10)

1.3.2. Accuracy of Guided Surgery

Prosthetically driven implant surgery has grown into a gold standard for improving short and long-term success.(1) Favorable aesthetic and prosthetic outcomes, long-term stability of peri-implant hard and soft tissues as a result of easier oral hygiene, and the potential to ensure optimal occlusal contacts and implant loading are dependent of a precise implant positioning. Furthermore, a correct 3D positioning of an implant will enable the fabrication of a retrievable screw-retained structure instead of cemented restorations that will avoid biological and mechanical complications.(1)

The “accuracy term” in implant position comprises precision and trueness.(52) Trueness refers to the deviation between the planned position of the implant and the actual final position after placement.(52) Precision refers to the deviation of repetitive test results. Usually, accuracy discussed in clinical studies refers to trueness. Both trueness and precision are involved in *in vitro* studies.(52)

The use of guided surgery can bring advantages for both patients and clinicians. Due to its relatively high level of accuracy, in this type of procedure, the risk of damage to important anatomical structures is diminished while maintaining and taking advantage of the residual bone volume.(42) Furthermore, the surgical chair time is reduced with less discomfort and fewer post-operative complications for the patient.(1)

Many factors can affect the accuracy of dental implant placement with S-CAIS: the data acquisition method, model matching to CBCT file, the guide manufacturing procedure, the tissue supporting type, the accurate seating of the guide, the fixation pins and guide sleeve tolerance and design, patient maximum opening, fully or partially-guided technique and operator experience.(1, 42)

Implants placed using a guided approach show less deviation and more predictability than conventional placement, even for experienced clinicians.(10)

Several studies and reviews have evaluated the accuracy of guided surgery.(10, 42-44, 51, 52) In a recent systematic review of the literature, the precision of guided surgery was emphasized, with an average error in the horizontal direction of 1.2 mm and in the vertical direction of 0.5 mm.(2)

According to the sixth ITI Consensus about the accuracy of S-CAIS that was based on 20 clinical trials, the mean angular deviation was 3.5 degrees and the 3D deviation at the most apical position was 1.5 mm.(55) This suggests that the apical regions are more susceptible to suffering deviation.(55)

Although on average, implant placement using static guided surgery is accurate, it is possible, due to CBCT discrepancy and/or incorrect placement of the guide, for gross deviations in position to occur.(1)

In cases of edentulous ridges, as was reported by Vasak *et al* an increase of mucosal thickness of 1 mm can result in an average increase in deviation of 0.41 mm.(56) The clinician should be alert of possible deviation consequent from compression of the soft tissue leading to unnoticed lifting of the guide. This lifting is sometimes difficult to distinguish and verify intraoperatively and may lead to a deviation in the final position of the implants.(1)

There is no standard evaluation for implant surgical accuracy but the most common indicators include angular deviation (°), coronal deviation (mm), apical deviation (mm), and depth deviation/vertical deviation (mm).[52] Nowadays, there are implant planning software available, with the before mentioned parameters incorporated, that through new tools allow the evaluation of implant positioning accuracy (e.g.: "Treatment Evaluation" tool from coDiagnostiX® (Institut Straumann AG, Switzerland)) .[57]

1.4. Justification

The placement of dental implants to replace lost teeth is one of the most common procedures performed, nowadays. The constant evolution of technology and dental implant designs/surfaces/materials requires new studies to understand which techniques are most predictable, which produce better long-term results and meet patients' expectations, and at the same time, which are the best materials to carry out these procedures.

The use of technology has allowed case planning to be done without the patient in the chair and through tools that allow to anticipate the surgical, anatomical, and prosthetic difficulties and solve them in advance.

Therefore, it is imperative to reinforce our knowledge and studies in the areas of digital dentistry, guided surgery, and its precision, and the latest materials available on the market.

Although there are many studies in the literature regarding guided surgery and primary stability, there are no studies that combine these types of titanium implants in relation to these topics and that compare them in preclinical and clinical terms.

1.5. Objectives

This study is divided in two parts: an *in vitro* study and an *in vivo* pilot study.

IN VITRO STUDY

The main objective of the *in vitro* study is to determine and compare the primary stability of different titanium implants, placed using different surgery techniques, using artificial bone models calibrated to 4 different bone densities (D1, D2, D3 and D4).

The secondary objectives of this study are:

1. To determine the influence of the bone densities on primary stability in different titanium dental implants;
2. To determine the influence of different titanium implant designs (shape and design of threads) for primary stability;
3. To determine the discrepancy between resonance frequency measurements taken directly on the implant *vs* on the abutment;
4. To determine the accuracy of implants placed using computer-guided surgery: to verify the impact of parameters, for instance, bone density, implant type, and surgery technique, have on the accuracy of implant placement by analyzing the data collected;

IN VIVO PILOT STUDY

The main objective of the *in vivo* pilot study is to determine and compare the linear and angular deviations of implants placed with guided surgery in a group of patients.

The secondary objectives of this pilot study are:

1. To determine the accuracy of implants placed using computer-guided surgery;
2. To compare the accuracy of pilot-guided surgery with fully-guided surgery;
3. To compare/cross the results of this *in vivo* pilot study with the *in vitro* part.

2. MATERIALS AND METHODS

The field of rehabilitation with implants is vast, and numerous studies have been published over the past years. With the evolution of digital dentistry, a new line of research has been created. Clinicians increasingly seek the best materials and greater predictability in their treatments. It was in this context that new lines of implants with new materials and designs, as well as planning software allowing the creation of surgical guides, were developed. Despite the existence of published literature on digital implantology, new studies with different implants and tools are necessary to better understand the biomechanical behavior and the reproducibility and predictability of new guided surgery protocols.

This study was designed in two aspects: an *in vitro* trial with four different implant lines, where a digital workflow was applied for their placement in four distinct bone types, and an *in vivo* trial with the application of the same type of workflow to establish comparisons between both trials.

2.1. *In vitro* study

An *in vitro* study was developed using the equipment and materials available in the Precision Dental Medicine Platform of the Center for Interdisciplinary Research in Health of the *Universidade Católica Portuguesa*, in Viseu, Portugal.

Eight artificial bone models (Figure 1) were used (Bonemodels®; Castellón; Spain). This models have four types of bone density (D1, D2, D3, D4), as per Lekholm and Zarb's(24) classification(58).

Each bone model full-sized was divided in 2 parts into mini bone blocks with 2 distinct bone densities in order to fit and respect the field of view (FOV) of the CBCT used (NewTom Go, NewTom | Cefla S.C.). A total of 16 mini bone blocks were obtained – as illustrated in Figure 2. These mini bone blocks were identified with a letter and a number (e.g.: D1 and D2 of the first bone block -A1 and D3 and D4 of the first bone block - A2) and subjected to a radiographic exam shown in Figure 3 and scanned with KaVo LS 3 (Nobel Biocare USA, LLC) for posterior digital implant planning.

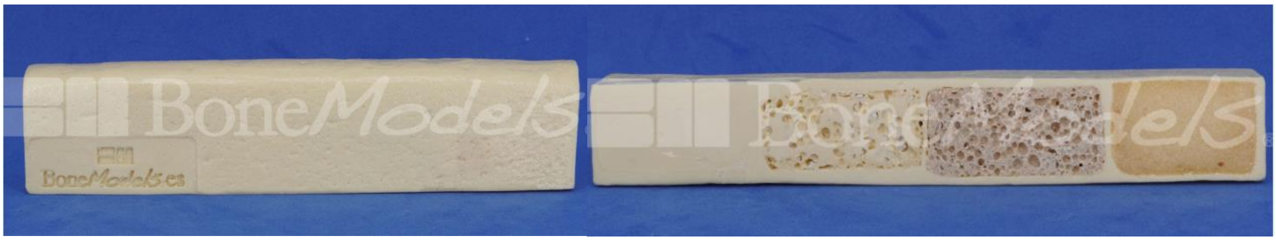


Figure 1- Artificial bone models (Bonemodels®; Castellón; Spain) with 4 types of bone densities (D1-D4).

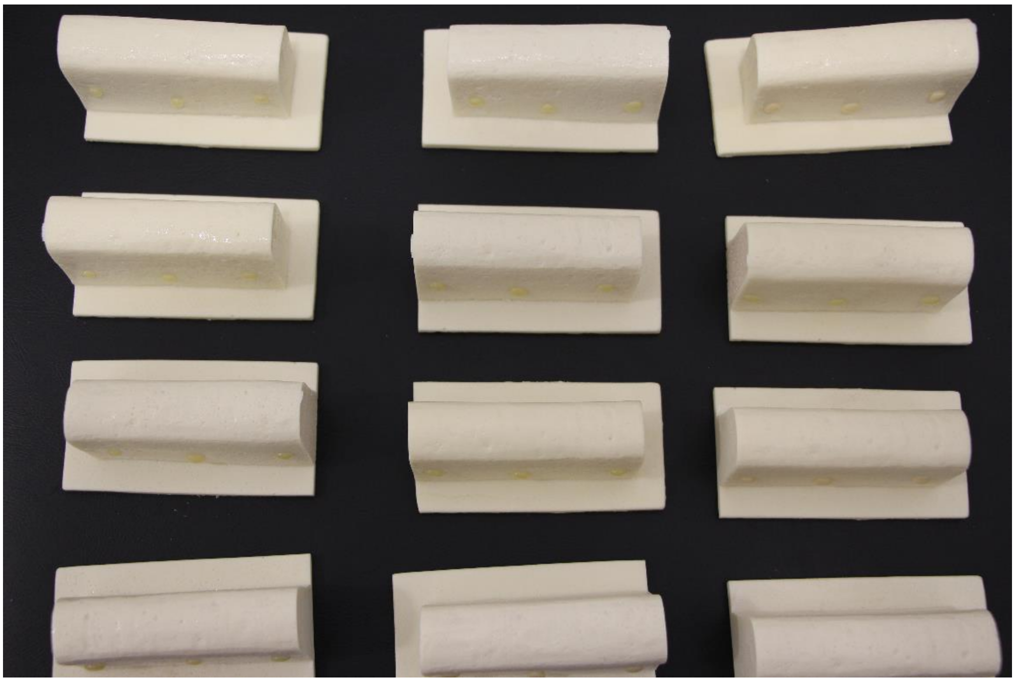


Figure 2 - Mini bone blocks (each with 2 different densities).

Figure 3 - bone blocks placed in the CBCT (NewTom Go, NewTom | Cefla S.C.).

A total of 120 implants were placed in the bone blocks, using computer-guided procedures to enable the assessment of linear and angular deviations (at the level of neck and apex).

The implants were placed using different techniques: partially guided with milling cutter drill (PG) and fully guided without the milling cutter (FG). The implant placement was performed by a Dentist ("expert") with long-time experience and training in all the surgical procedures needed including in digital dentistry. There were 3 different types of implants (described in Figure 4) that vary in macrogeometry. The *in vitro* study design is presented in Figure 5.

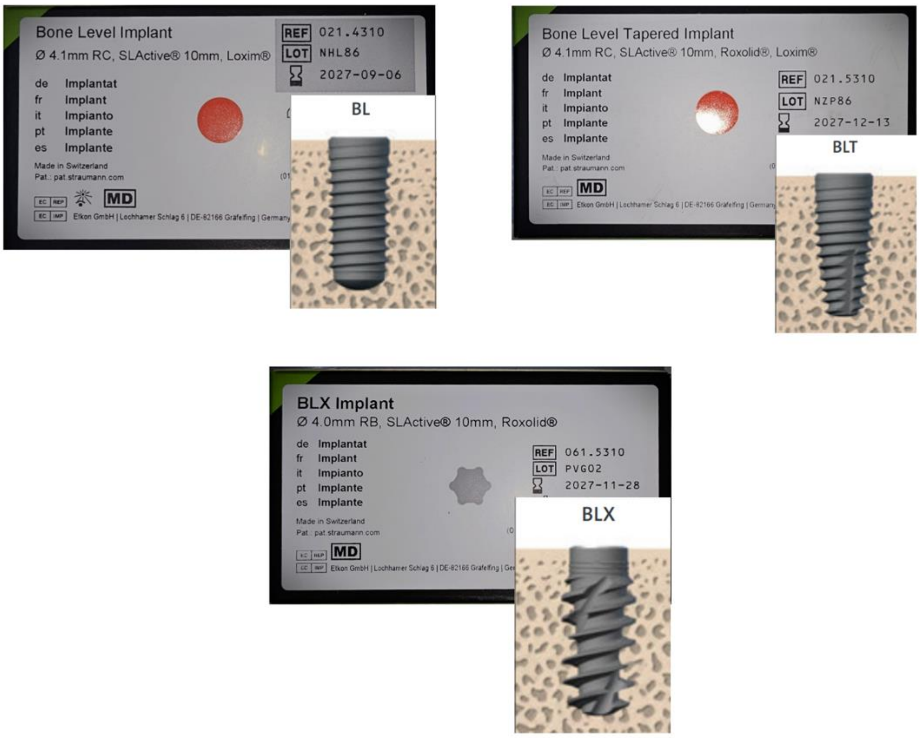
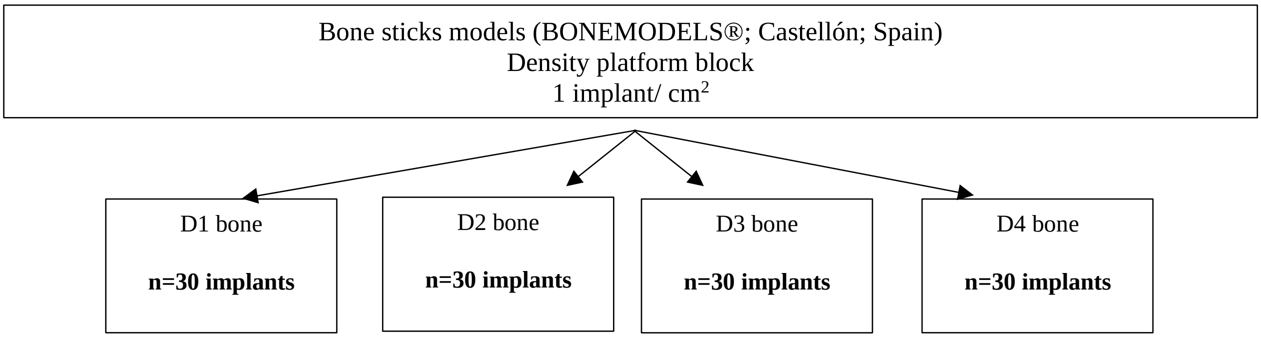


Figure 4 - Types of dental implants used in the study.

Figure source: Straumann® product catalogs - Catalogs (straumann.com).

The software coDiagnostiX® (Institut Straumann AG, Switzerland) was used to virtually plan the position of the implants placed with guided techniques and to design the surgical guides (Figure 5). The surgical guides were identified with the same letter and number of the correspondent mini bone block. Afterward, surgical guides were fabricated using a Phrozen Sonic Mini 8K printer (Phrozen Technology, Hsinchu City 30091, Taiwan) and resin material (ABS Like Resin Creamy White - Phrozen) – Figure 6. After post-processing, Ø 5 / 5 mm sleeves (T-sleeve; Institut Straumann AG, Switzerland) were manually press fit into the guides.

The implants were placed using the manufacturer's (Straumann®) surgical kits (according to each type of implant and shown in Figure 7) and the surgical motor used was iChiropro (Bien-Air, Bienne, Switzerland). The drilling protocols of the manufacturer were followed according to the type of implant and bone (soft, medium, hard). These protocols are described below (Table 1).



	BLT (Bone level tapered)	**BLX (Bone level X)**	**BL (Bone level)**
implant model	Roxolid® SLActive®	Roxolid® SLActive®	Roxolid® SLActive®
Platform type	RC (Regular CrossFit™)	RB (Regular TorcFit™)	RC (Regular CrossFit™)
Implant design	Conical	Conical	Cylindrical
Endosteal diameter (mm)	4.1	4.0	4.1
Length (mm)	10	10	10
Placement technique	Partially-guided with Milling Cutter drill and Fully-guided	Partially-guided with Milling Cutter drill and Fully-guided	Partially-guided with Milling Cutter drill and Fully-guided
Total implants (N)/density	5	5	5
Linear deviations (mm)	Mesio-Distal (MD) and Bucco-Lingual (BL) At Apex and Neck level		
Axial linear deviations (mm)	Apico-coronal (AC)		
Angular deviations (º)	Angle		

Figure 5 – Study design.

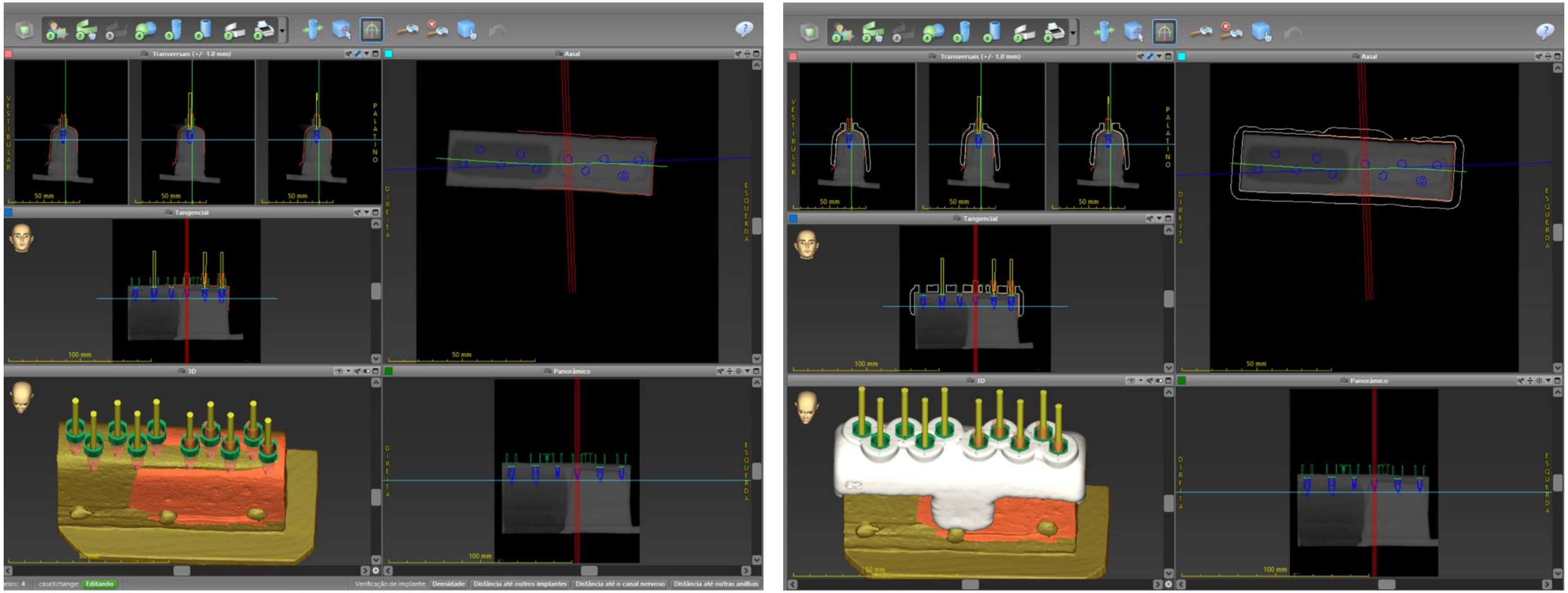


Figure 6 - Digital implant planning (top) and guide design (bottom) in coDiagnostiX® software.

Figure 7 - 3D printer and resin material used to print the surgical guides.

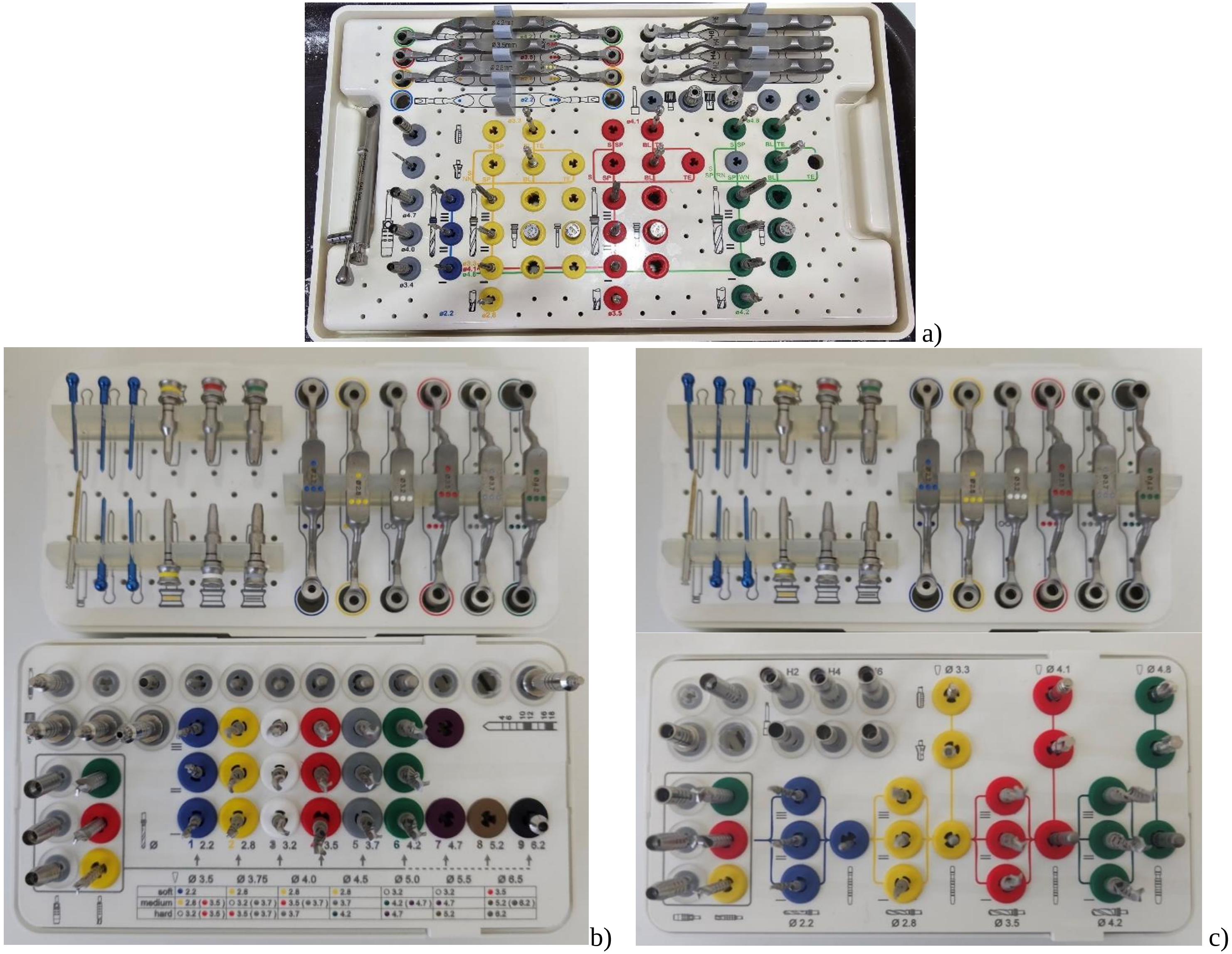


Figure 8 - Guided surgery kits used in the study: a) BL surgical kit; b) BLX surgical kit; c) BLT surgical kit.

Table 1 - Drilling protocols followed.

IMPLANT	ENDOSTEAL DIAMETER (MM)	LENGTH (MM)	DRILLING PROTOCOL X BONE TYPE		
			(Very) SOFT (D1)	MEDIUM (D2 and D3)	(Very) HARD (D4)
BLT Roxolid® SLActive® RC	4.1	10	1. Pilot drill Ø2.2mm (6 mm) (800 rpm) 2. Drill 2 Ø2.2mm (until final preparation depth) (800 rpm) 3. Drill 3 Ø2.8mm (600 rpm) 4. Implant placement (15 rpm)	1. Pilot drill Ø2.2mm (6 mm) (800 rpm) 2. Drill 2 Ø2.2mm (until final preparation depth) (800 rpm) 3. Drill 3 Ø2.8mm (600 rpm) 4. Drill 4 Ø3.5mm (500 rpm) 5. BLT Profile Drill Short Ø4.1 (300 rpm) 6. Implant placement (15 rpm)	1.Pilot drill Ø2.2mm (6 mm) (800 rpm) 2.Drill 2 Ø2.2mm (until final preparation depth) (800 rpm) 3.Drill 3 Ø2.8mm (600 rpm) 4.Drill 4 Ø3.5mm (500 rpm) 5.BLT Profile Drill Short Ø4.1 (300 rpm) 6.BLT Tap Ø4.1 (15 rpm) 7.Implant placement (15 rpm)
BLX Roxolid® SLActive® RB	4.0	10	1. Pilot Drill 1 Ø2.2 mm (800 rpm) 2. Drill 2 Ø2.8 mm (800 rpm) 3. Implant placement (15 rpm)	1. Pilot Drill 1 Ø2.2 mm (800 rpm) 2. Drill 2 Ø2.8 mm (800 rpm) 3. Drill 4 Ø3.5 mm (800 rpm) 4. Drill 5 Ø3.7 mm (preparation of cortical bone only: 6mm) (800 rpm) 5. Implant placement (15 rpm)	1.Pilot Drill 1 Ø2.2 mm (800 rpm) 2.Drill 2 Ø2.8 mm (800 rpm) 3.Drill 3 Ø3.2 mm (800 rpm) 4.Drill 5 Ø3.7 mm (800 rpm) 5.Implant placement (15 rpm)
BL Roxolid® SLActive® RC	4.1	10	1. Pilot drill Ø2.2mm (6 mm) (800 rpm) 2. Drill 2 Ø2.2mm (until final preparation depth) (800 rpm) 3. Drill 3 Ø2.8mm (600 rpm) 4. Implant placement (15 rpm)	1. Pilot drill Ø2.2mm (6 mm) (800 rpm) 2. Drill 2 Ø2.2mm (until final preparation depth) (800 rpm) 3. Drill 3 Ø2.8mm (600 rpm) 4. Drill 4 Ø3.5mm (500 rpm) 5. BL Profile Drill Short Ø4.1 (300 rpm) 6. Implant placement (15 rpm)	1.Pilot drill Ø2.2mm (6 mm) (800 rpm) 2.Drill 2 Ø2.2mm (until final preparation depth) (800 rpm) 3.Drill 3 Ø2.8mm (600 rpm) 4.Drill 4 Ø3.5mm (500 rpm) 5.BL Profile Drill Short Ø4.1 (300 rpm) 6.BL Tap Ø4.1 (15 rpm) 7.Implant placement (15 rpm)

After the placement, the RFA (Resonance Frequency Analysis) was measured with Osstell® (Osstell AB, Gothenburg, Sweden) device using its "SmartPegs", first directly in the implants (SmartPeg type 54 for BL and BLT implants; SmartPeg type 38 for BLX implant) and then in the abutments (SmartPeg type 25) (figure 8). The abutments used were RC Screw-retained abutment straight, Ø 4.6 mm, GH 2.5 mm (Institut Straumann AG) for BL and BLT implants, and RB/WB Screw-retained abutment straight, Ø 4.6 mm, GH 2.5 mm, TAN (Institut Straumann AG, Switzerland) for BLX implants. The procedure described was made for each implant placed to obtain the ISQ (Implant Stability Quotient) value. The measurements were repeated 3 times per implant and 3 times per abutment (described in Table 2) always following the manufacturer's instructions.

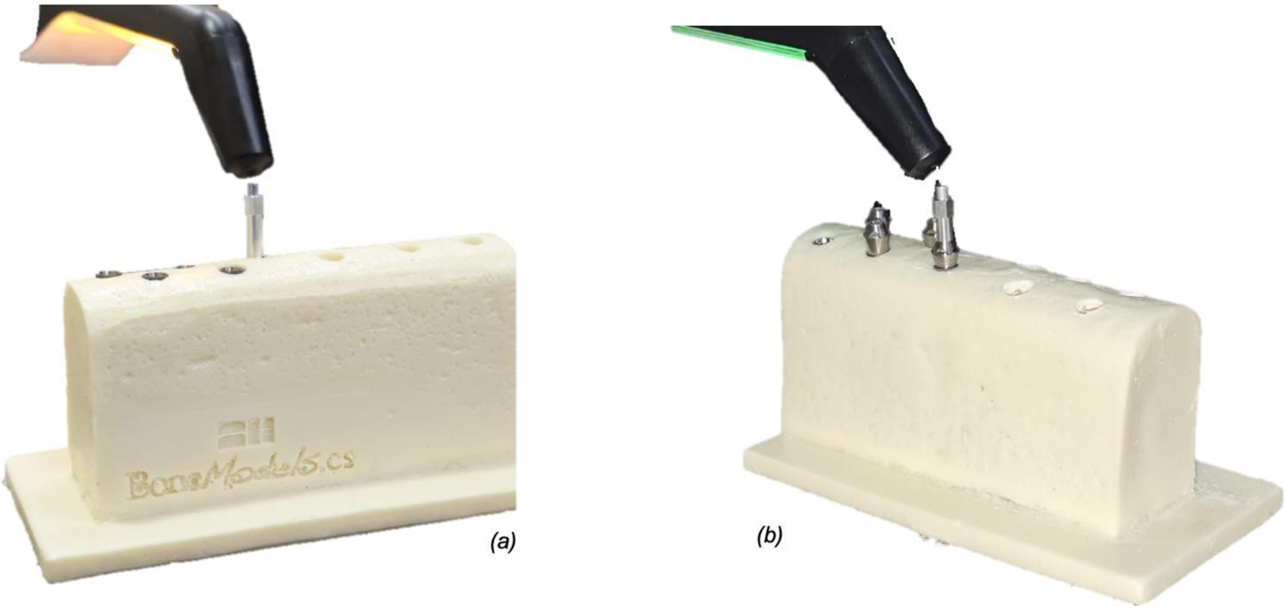


Figure 9 - Measurements with Osstell device: (a) implant level and (b) abutment level.

Table 2 - Schematic representation of the measurements done with Osstell device.

RFA	Measurement location	Number of measurements p/piece	Subtotal ISQ measurements (MD and VP/VL)	Total ISQ measurements
Osstell®	Implant	x6	120	480
	Abutment		120	
Penguin®	Implant	x6	120	
	Abutment		120	

Then, a final scan with scan bodies was performed with Trios v.4 (3Shape®, Sweden) to measure the deviations. The scan bodies used were CARES® RC Mono Scan body - D 4.1 mm, H 10 mm, PEEK, TAN (Institut Straumann AG) for BL and BLT implants and CARES® RB/WB Mono Scan body - Ø 3.8mm, H 10mm PEEK/TAN (Institut Straumann AG, Switzerland) for BLX implants.

The deviations between the virtually planned position and the final position were measured in the software coDiagnostiX® (Institut Straumann AG, Switzerland) through the add-on tool "Treatment Evaluation" and the parameters assessed were: the angle of the implant with respect to the axial axis, the 3D (mesio-distal and bucco-lingual) deviations at the most coronal area (crest), apico-coronal deviation at the most coronal area (crest), the 3D (mesio-distal and bucco-lingual) deviations at the most apical area (apex) of the implant and apico-coronal deviation at the apical area (apex) – Figure 9.

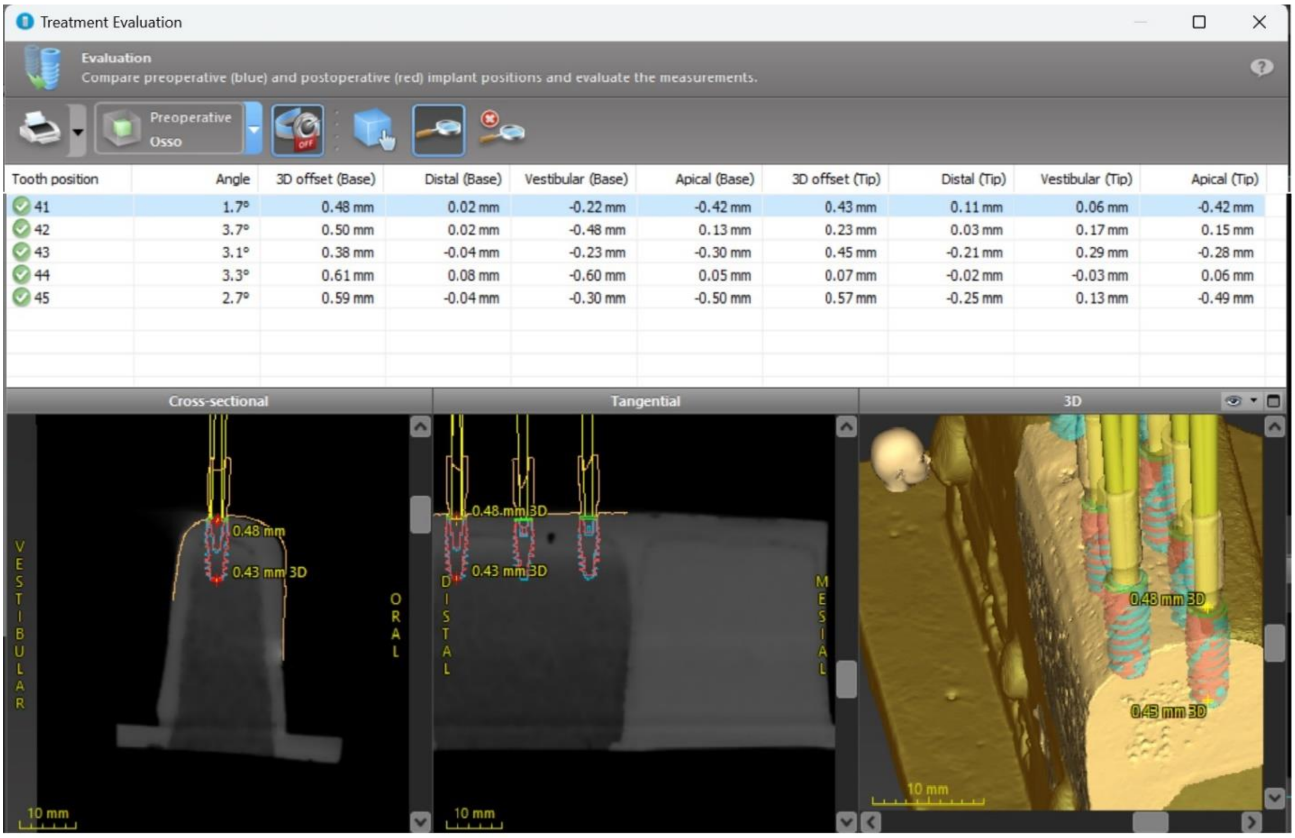


Figure 10 - "Treatment Evaluation" measurements from software coDiagnostiX®.

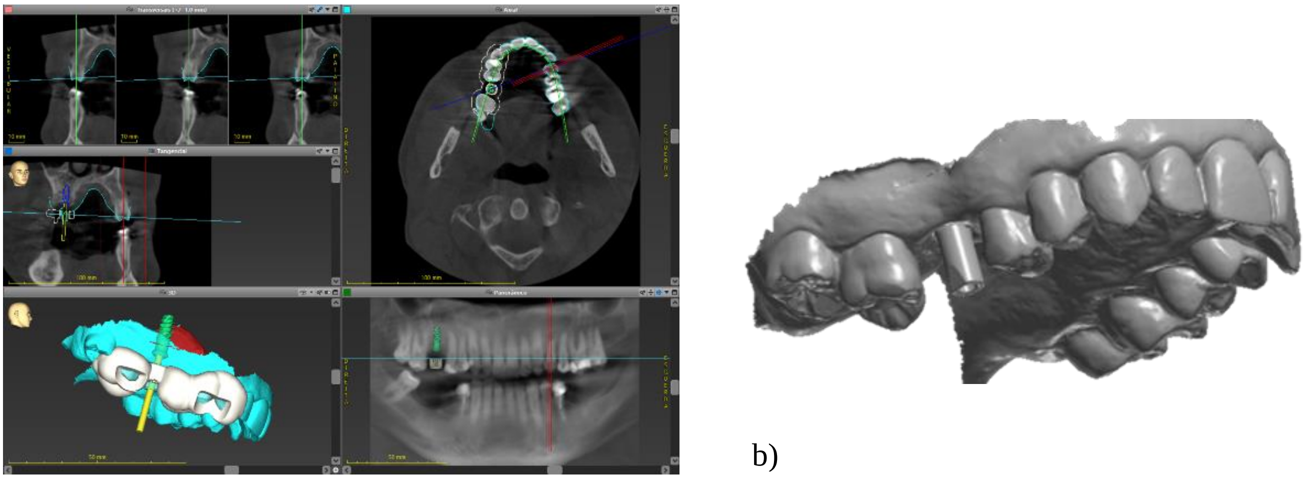
2.1.1. Statistical Analysis

Statistical analysis was conducted using IBM Statistical Package for the Social Sciences (SPSS, USA), version 24. A significance level of $p < 0.05$ (two-tailed) was considered statistically significant.

Categorical variables were expressed using absolute (n) and relative (%) frequencies. Continuous variables were presented as median (interquartile range) due to the non-normal distribution of the data, determined by the Kolmogorov-Smirnov test. Kruskal-Wallis (H) and Mann-Whitney (U) tests were employed to compare the distribution of linear deviations and torque concerning implant and bone types, as well as the use of tap and milling cutter drills. Spearman correlation coefficient and linear regressions were utilized to explore the relationship between implant and abutment deviations and torque values.

2.2. *In vivo* pilot study

To gather the necessary information, pertinent data from the electronic health records of the university dental clinic at the Faculty of Dental Medicine of the *Universidade Católica Portuguesa* (FMD-UCP) were securely transferred to the lead researcher. This data was made anonymous, and specifically, the data files generated by the coDiagnostiX® software were collected in two phases. Firstly, data was collected at the planning stage prior to the oral surgery (Figure 10 (a)), and secondly, data was collected at the time of dental impression making (Figure 10 (b)).



a) b)

Figure 11 - (a) Example of the implant and guide planning stage; (b) Dental impressions stage – a scanbody is attached to the implant placed.

The coDiagnostiX® software was also used to design the surgical guides. The TRIOS® 4 (3Shape, Copenhagen, Denmark) scanner was used to collect the data at the planning stage and at the time of the dental impressions. Surgical guides were printed using a Phrozen Sonic Mini 8K printer (Phrozen Technology, Hsinchu City 30091, Taiwan) and resin material (ABS Like Resin Creamy White - Phrozen). The time between data collection, planning, and the day of the surgery was at most 1 month for all patients involved.

Using the 'Treatment Evaluation' tool within coDiagnostiX® software (Straumann AG, Switzerland), a virtual plan for the implant position (highlighted in red - Figure 11) was superimposed with the scan body of the impression scan. This provided the final implant position (depicted in blue - Figure 11). Figure 11 illustrates this superimposition from the three different perspectives.

Subsequently, the software autonomously computed predefined parameters and presented them in a table, facilitating the assessment of implant location accuracy. This tool was used to evaluate the accuracy and precision of implant locations.

The parameters evaluated included the angle of the implant with respect to the axial axis, the 3D (mesio-distal and bucco-lingual) deviations at the most coronal area (crest), apico-coronal deviation at the most coronal area (crest), the 3D (mesio-distal and bucco-lingual) deviations at the most apical area (apex) of the implant and apico-coronal deviation at the apical area (apex).

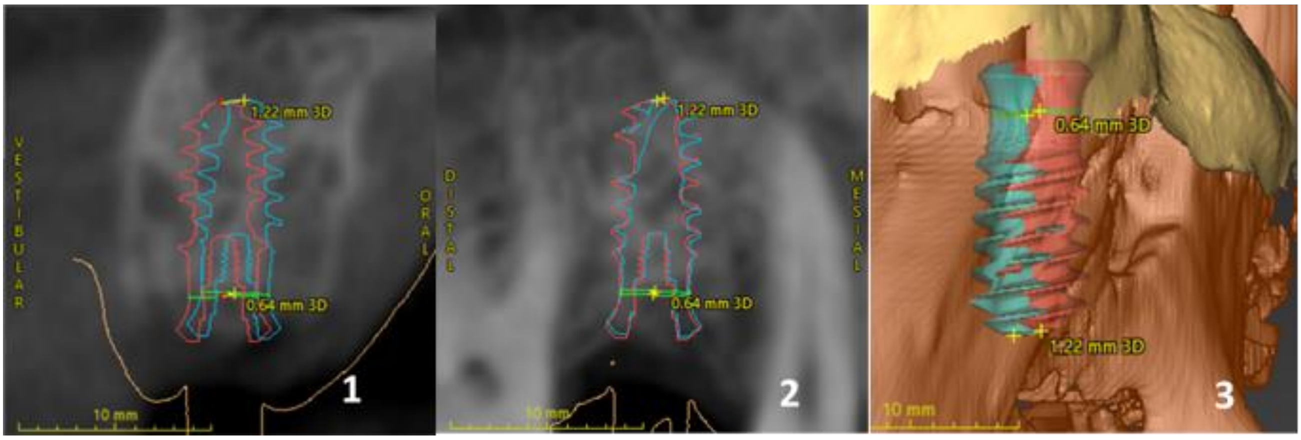


Figure 12 - “Treatment Evaluation” add-on from software coDiagnostiX®.

Angular deviations were reported in degrees and linear deviations in millimeters, both measured at the implant's most coronal point (crest/shoulder) and apex.

In addition, the study also recorded and analyzed the following variables:

- Type of surgical template: tooth-supported or tooth-tissue-supported with fixation pins.
- Guided surgery: fully-guided or pilot-guided approaches.
- Anatomical location of the implants: maxilla and mandible.

2.2.1. Ethics and Data Protection

The project received approval from the *Universidade Católica Portuguesa* Ethics Committee for Health (reference n.º 201, March 24th, 2022).

2.2.2. Statistical analysis

Continuous variables were reported as mean with standard deviation for normally distributed data, while the median (interquartile range) was used for data that did not exhibit a normal distribution. Categorical variables were summarized using absolute counts (n) and relative frequencies (%). To assess the normality of data distribution, the Shapiro-Wilk test was applied.

Statistical comparisons of linear and angular deviations based on the variables of interest were conducted using the T-test for independent samples (t) for normally distributed data and the Mann-Whitney (U) test for non-normally distributed data.

To explore the relationship between implant diameter, length, and deviations, the Spearman correlation coefficient (ρ) was calculated.

All statistical analyses were carried out using IBM Statistical Package for the Social Sciences (SPSS, USA), version 24. The null hypothesis, meaning the contrary of the hypothesis in the test, for each conducted test, posited the absence of a statistically significant difference or effect between the groups under investigation. The decision to reject the null hypothesis was made when the calculated p-value was less than 0.05, signifying a level of significance at which the observed results were deemed unlikely to occur by random chance alone.

3. RESULTS

The Results section of this study unveils critical insights into the efficacy and precision of implant placement techniques, specifically focusing on distinct types of implants. Through statistical analysis, we elucidate the comparative performance between pre-clinical and clinical outcomes associated with each implant variant.

Additionally, we explore the influence of factors, such as bone quality, and its impact on the pre-clinical outcomes. The data presented also offers a comprehensive evaluation of biomechanical stability.

Furthermore, the investigation focused on guided surgery methodologies, highlighting its impact on accuracy.

It is important to note that this analysis of the results from the data collected, due to the multiple parameters tested and the limited number of implants per surgical procedure, bone density, and type, prevented the carried out statistical analysis from individually detailing the influence of each parameter on the implant placement accuracy. The focus was to understand the general influence of each parameter, this meaning for e.g., that the influence of the bone type was assessed regardless of the surgery and implant types.

3.1. *In vitro* study

This study involved 120 implants distributed evenly across four bone types (types I to IV), three implant types (BLT: Bone Level Tapered; BLX: Bone Level X; BL: Bone Level), and two surgical approaches (fully guided and partially guided) – Table 3.

Table 3 - Descriptive statistics.

Variables, n (%)	**n (%)**
Implant type, (n=120)	
BL	40 (33,3)
BLT	40 (33,3)
BLX	40 (33,3)
Surgery type, (n=120)	
Fully guided	60 (50,0)
Partially guided	60 (50,0)
Profile drill*	50 (41,7)
Tap drill*	20 (16,7)
Milling Cutter Drill*	60 (50,0)
Torque, median (IQR)	51,9 (23,5)

IQR: Interquartile range; BL: Bone Level implant; BLT: Bone Level Tapered implant; BLX: Bone Level X implant.
* Used in specific implants according to manufacturer protocol.

The median insertion torque stood at 51.9 Ncm, with an interquartile range (IQR) of 23.5, indicating substantial torque variability across the sample.

Table 4 provides descriptive statistics for primary stability (ISQ) and absolute linear and angular deviation measurements, with most variables showing a non-normal distribution.

The median ISQ values at the implant level were 69.83 for Mesiodistal (MD) orientation and 69.93 for Buccolingual (BL) orientation. At the abutment level, the median ISQ values were 66.17 for MD and 67.00 for BL.

Table 4 also provides descriptive statistics for Treatment Evaluation measurements, median angular deviation was 2.10º, with interquartile range (IQR) ranging from 1.35 mm to 3.35 mm. Median linear deviations at the base were 0.13 mm for MD and 0.18 mm for BL, with slightly higher values at the apex (0.22 mm for MD and 0.29 mm for BL). The distribution linear deviations for apico-coronal (AC) measurements at the apex and base were very similar, with median values of 0.61 mm in both levels.

Table 4 - Descriptive statistics of primary stability and linear and angular deviation measurements.

Variables	Mean	SD	Minimum	Q1	Median	Q3	Maximum
Primary stability (ISQ)							
MD at implant	65.48	9.48	37.00	61.00	69.83	72.50	75.00
BL at implant	65.77	8.78	34.67	61.17	69.93	71.33	76.00
MD at abutment	63.35	10.65	23.00	59.67	66.17	70.00	77.00
BL at abutment	63.43	10.32	27.00	60.33	67.00	70.00	77.33
Treatment Evaluation							
Ang. Deviation (º)	2.48	1.57	0.10	1.35	2.10	3.35	8.10
3D at base (mm)	1.54	8.52	0.02	0.41	0.74	1.05	94.00
MD at base (mm)	0.36	1.04	0.00	0.07	0.13	0.35	11.00
BL at base (mm)	0.51	2.37	0.00	0.06	0.18	0.41	26.00
AC at base (mm)	0.72	0.88	0.00	0.31	0.61	0.92	9.00
3D at apex (mm)	1.96	8.80	0.07	0.56	0.83	1.20	94.00
MD at apex (mm)	0.43	0.91	0.01	0.10	0.22	0.42	9.00
BL at apex (mm)	0.63	2.46	0.00	0.12	0.29	0.56	27.00
AC at apex (mm)	0.74	0.90	0.00	0.31	0.61	0.94	9.00

AC: Apico-coronal; BL: Buccolingual; ISQ: implant stability quotient; MD: Mesiodistal.

Figure 13 illustrates scatter plots depicting strong positive correlations between torque values and primary stability measurements for both MD and BL orientations at implant and abutment levels (MD at implant: .720, BL at implant: .712, MD at abutment: .687, BL at abutment: .691).

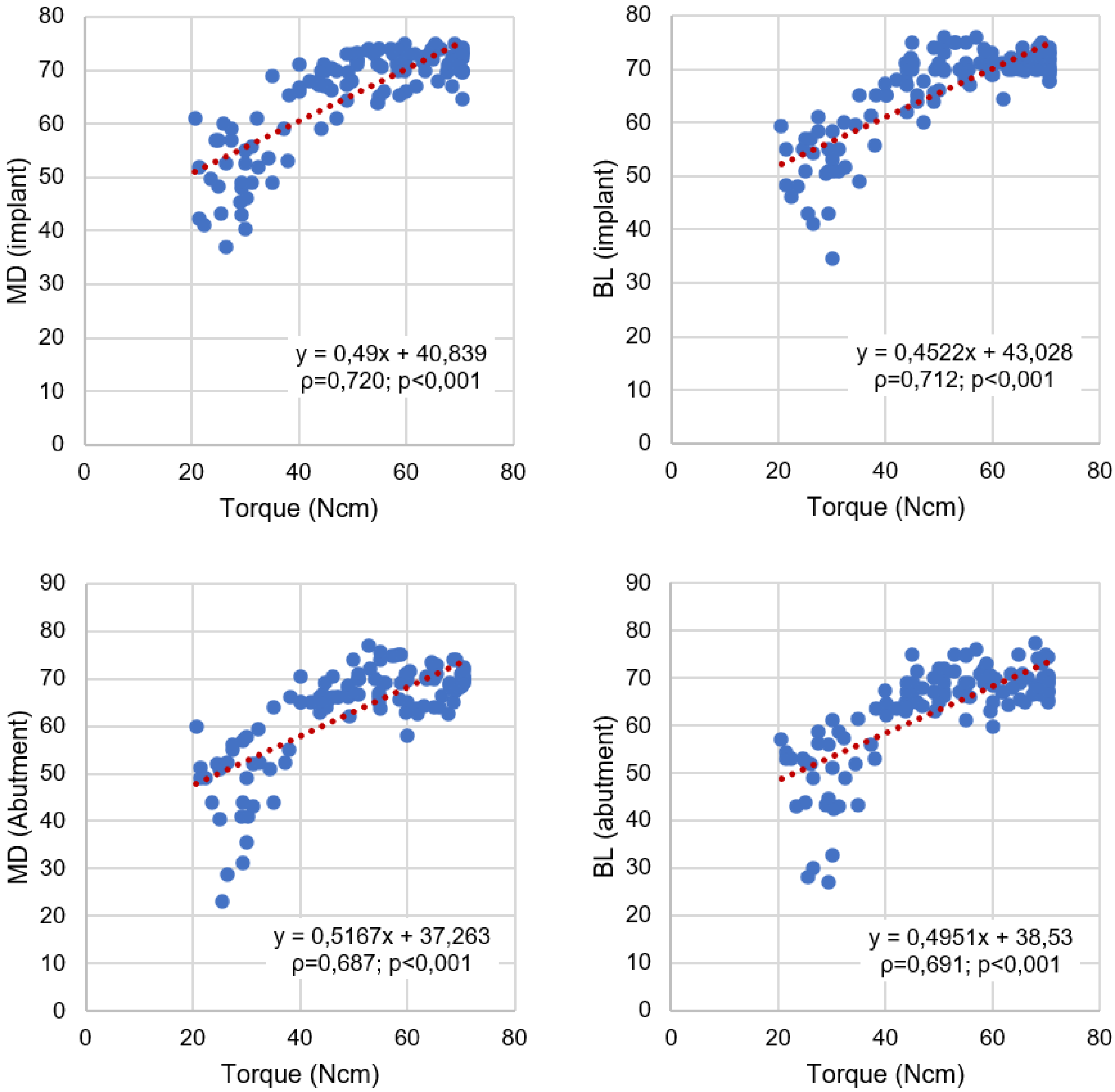


Figure 13 - Scatter plots between different torque values and primary stability measurements.

In Table 5, variations in torque values across different bone types were evident, with Bone type IV displaying the highest dispersion (IQR=6.30). Significant differences in torque values were observed among bone types (H=76.942, p<0.001), as well as in ISQ values for MD and BL orientations at implant and abutment levels (p<0.001).

Table 5 - Comparison of primary stability and torque values between bone types.

Variables	Bone type, median (IQR)				Kruskal-Wallis	
	I	II	III	IV	H	p-value
Torque (Ncm)	68.20 (15.70)	60.85 (15.60)	51.40 (15.00)	29.20 (6.30)	76.942	**<0.001**
MD at implant (ISQ)	71.00 (4.00)	71.83 (4.00)	70.50 (5.67)	52.00 (11.00)	68.526	**<0.001**
BL at implant (ISQ)	70.00 (3.00)	71.00 (5.00)	70.00 (3.00)	53.67 (8.00)	68.062	**<0.001**
MD at abutment (ISQ)	69.83 (3.00)	69.00 (6.00)	66.00 (6.00)	51.00 (9.33)	67.502	**<0.001**
BL at abutment (ISQ)	68.50 (3.00)	68.67 (4.67)	68.00 (6.33)	52.00 (12.67)	67.256	**<0.001**

BL: Buccolingual; MD: Mesiodistal; IQR: Interquartile range; ISQ: Implant stability quotient.

Table 6 highlights slight variations in median torque values among different implant types, but no statistically significant differences (H=1.917, p=0.383) were observed. Conversely, significant differences in ISQ values among implant types were noted for all measurements (p<0.002).

Table 6 - Comparison of primary stability and torque values between implant types.

Variables	Implant type, median (IQR)			Kruskal-Wallis	
	BLT	BL	BLX	H	p-value
Torque (Ncm)	55.25 (28.20)	51.95 (29.65)	48.00 (22.65)	1.917	**0.383**
MD at implant (ISQ)	71.00 (8.83)	70.50 (9.33)	66.00 (14.67)	19.243	**0.000**
BL at implant (ISQ)	70.67 (9.50)	70.50 (11.17)	66.50 (11.50)	19.411	**0.000**
MD at abutment (ISQ)	69.00 (12.33)	69.83 (10.00)	65.00 (13.50)	12.468	**0.002**
BL at abutment (ISQ)	68.83 (10.67)	67.17 (9.50)	65.00 (14.17)	13.072	**0.001**

BL: Buccolingual; MD: Mesiodistal; IQR: Interquartile range.

Tables 7 to 10 respectively demonstrate the distribution of linear and angular deviations concerning implant type, surgery type, bone type, and the utilization of the Milling Cutter Drill. The implant type significantly influenced angular deviations (p=0.007) and BL at apex deviations (p=0.046). BLT implants exhibited the highest median angular deviations (2.75º), while BL implants showed lower BL at apex deviations (0.23 mm). However, no significant differences were observed in 3D measurements or MD and AC deviations between the implant types. Surgery type revealed significant differences in angular deviations (p=0.012) and MD at base deviations (p=0.012). Fully guided surgeries displayed lower median angular deviations (1.75º) but higher MD at base deviations (0.19 mm) compared to partially guided surgeries. Other measurements, including 3D measurements and deviations at BL and AC at both base and apex, did not show significant differences. Variations in linear deviations according to the bone type differed only regarding the BL deviations at the apex (p=0.037), with bone type IV displaying the highest median BL deviation (0.46 mm) compared to other bone types. However, no significant differences were observed in other measurements, including MD and AC deviations at both base and apex.

Finally, the utilization of the Milling Cutter Drill resulted in significant differences (p=0.012) in angular deviations and MD at base deviations. Cases, where the Milling Cutter Drill was employed, showed higher angular deviations but lower MD at base deviations. However, no statistically significant differences were found in other measurements.

Table 7 - Distribution of linear and angular deviations according to the type of implant.

Variables (mm)	Implant type				
	BLT	**BL**	**BLX**	**Comparison statistics***	**p-value**
Ang. Deviation, median (IQR)	2.75 (2.30)	1.75 (1.80)	1.90 (1.90)	10.03	**0.007**
3D at base, median (IQR)	0.71 (0.61)	0.73 (0.54)	0.81 (0.74)	2.07	0.355
MD at base, median (IQR)	0.16 (0.61)	0.15 (0.18)	0.10 (0.20)	3.84	0.146
BL at base, median (IQR)	0.20 (0.64)	0.11 (0.22)	0.21 (0.38)	5.03	0.081
AC at base, median (IQR)	0.50 (0.64)	0.63 (0.51)	0.66 (0.85)	0.45	0.798
3D at apex, median (IQR)	0.90 (0.59)	0.83 (0.46)	0.77 (0.85)	3.74	0.154
MD at apex, median (IQR)	0.26 (0.40)	0.23 (0.32)	0.19 (0.20)	4.68	0.096
BL at apex, median (IQR)	0.36 (0.57)	0.23 (0.26)	0.33 (0.47)	6.14	**0.046**
AC at apex, median (IQR)	0.52 (0.55)	0.66 (0.54)	0.64 (0.89)	1.25	0.535

*Using the Kruskal-Wallis test.
AC: Apico-coronal; BL: Buccolingual; BL: Bone Level implant; BLX, Bone Level X implant; BLT: Bone Level Tapered implant; IQR, interquartile range; MD, Mesiodistal.

Table 8 - Distribution of linear and angular deviations according to the surgery type.

Variables (mm)	Surgery type			
	Fully guided	**Partially guided**	**Comparison statistics***	**p-value**
Ang. Deviation, median (IQR)	1.75 (1.70)	2.45 (2.55)	1323.50	**0.012**
3D at base, median (IQR)	0.73 (0.62)	0.74 (0.66)	1763.50	0.848
MD at base, median (IQR)	0.19 (0.29)	0.10 (0.23)	1324.00	**0.012**
BL at base, median (IQR)	0.21 (0.33)	0.10 (0.36)	1472.00	0.085
AC at base, median (IQR)	0.50 (0.61)	0.68 (0.64)	1798.00	0.992
3D at apex, median (IQR)	0.76 (0.63)	0.85 (0.58)	1568.00	0.223
MD at apex, median (IQR)	0.23 (0.38)	0.22 (0.29)	1664.00	0.475
BL at apex, median (IQR)	0.25 (0.29)	0.36 (0.50)	1549.50	0.188
AC at apex, median (IQR)	0.50 (0.62)	0.68 (0.65)	1632.00	0.378

Using the Mann-Whitney test.
AC: Apico-coronal; BL: Buccolingual; IQR, interquartil range; MD, Mesiodistal.

Table 9 *- Distribution of linear and angular deviations according to the bone type.*

Variables (mm)	Bone type					
	I	II	III	IV	Comparison statistics*	p-value
Ang. Deviation, median (IQR)	2.10 (1.80)	2.25 (1.90)	1.75 (2.20)	2.55 (2.30)	5.03	0.170
3D at base, median (IQR)	0.98 (0.48)	0.60 (0.59)	0.76 (0.66)	0.68 (0.54)	6.57	0.087
MD at base, median (IQR)	0.16 (0.34)	0.12 (0.36)	0.15 (0.19)	0.11 (0.20)	2.22	0.528
BL at base, median (IQR)	0.22 (0.34)	0.14 (0.41)	0.12 (0.25)	0.22 (0.24)	2.69	0.443
AC at base, median (IQR)	0.79 (0.67)	0.42 (0.58)	0.57 (0.49)	0.53 (0.53)	6.65	0.084
3D at apex, median (IQR)	0.94 (0.68)	0.66 (0.64)	0.80 (0.55)	0.96 (0.57)	4.48	0.214
MD at apex, median (IQR)	0.22 (0.27)	0.24 (0.13)	0.19 (0.39)	0.22 (0.36)	0.45	0.930
BL at apex, median (IQR)	0.25 (0.28)	0.30 (0.44)	0.23 (0.34)	0.46 (0.58)	8.51	**0.037**
AC at apex, median (IQR)	0.76 (0.76)	0.46 (0.54)	0.51 (0.53)	0.52 (0.59)	6.42	0.093

*Using the Kruskal-Wallis test.
AC: Apico-coronal; BL: Buccolingual; IQR: interquartil range; MD: Mesiodistal.

Table 10 - Distribution of linear and angular deviations according to the use of the Milling Cutter Drill.

Variables (mm)	Milling Cutter Drill			
	No	Yes	Comparison statistics*	p-value
Ang. Deviation, median (IQR)	1.75 (1.70)	2.45 (2.55)	1323.50	**0.012**
3D at base, median (IQR)	0.73 (0.62)	0.74 (0.66)	1763.50	0.848
MD at base, median (IQR)	0.19 (0.29)	0.10 (0.23)	1324.00	**0.012**
BL at base, median (IQR)	0.21 (0.33)	0.10 (0.36)	1472.00	0.085
AC at base, median (IQR)	0.50 (0.61)	0.68 (0.64)	1798.00	0.992
3D at apex, median (IQR)	0.76 (0.63)	0.85 (0.58)	1568.00	0.223
MD at apex, median (IQR)	0.23 (0.38)	0.22 (0.29)	1664.00	0.475
BL at apex, median (IQR)	0.25 (0.29)	0.36 (0.50)	1549.50	0.188
AC at apex, median (IQR)	0.50 (0.62)	0.68 (0.65)	1632.00	0.378

Using the Mann-Whitney test.
AC: Apico-coronal; BL: Buccolingual; IQR, interquartil range; MD, Mesiodistal.

3.2. *In vivo* pilot study

This study included a total of 53 implants from a sample of 30 patients (18 males and 12 females), with a median age of 52 years (interquartile range 19.0). Implants were predominantly placed in the maxilla (75.5%) and had a median diameter of 3.75mm. Tooth-supported templates were most used (83.0%) and fully guided surgery was most frequent (79.2%). The characteristics of all samples are shown in Table 11.

Table 11 - Sample's characteristics.

Gender	**% (n)**
Male	60.0 (18)
Female	40.0 (12)
Age (years), median (IQR)	52 (19.0)
Location	**% (n)**
Maxilla	75.5 (40)
Mandibula	24.5 (13)
Guide type	**% (n)**
Tooth-supported	83.0 (44)
Tooth-tissue-supported	17.0 (9)
Surgery type	**% (n)**
Pilot drill	20.8 (11)
Fully	79.2 (42)
Implant	**% (n)**
Straumann Tissue Level X	58.5 (31)
Straumann Bone Level X	41.5 (22)
Implant diameter (millimeters)	**% (n)**
3.5	24.5 (13)
3.75	50.9 (27)
4	5.7 (3)
4.5	15.1 (8)
5	3.7 (2)
Implant length (millimeters)	**% (n)**
5	3.7 (2)
8	7.5 (4)
10	28.3 (15)
12	52.8 (28)
14	5.7 (3)
16	1.9 (1)
Prosthodontic Diagnostic Index	**% (n)**
I	1.9 (1)
II	18.9 (12)
III	66.0 (35)
IV	7.5 (4)

IQR: interquartile range

Table 12 - Descriptive statistics and distribution of linear and angular deviations.

Variables	Descriptive statistics						Normality	
	MDN	Min	Max	IQR	$\bar{x}$	σ	S-W	p
Angular Deviation	3.90	0.90	12.00	3.60	4.36	2.21	0.938	**0.007**
3D deviation at crest	1.04	0.23	2.51	0.76	1.09	0.49	0.962	0.081
MD deviation at crest	-0.24	-2.25	0.91	0.70	-0.15	0.54	0.937	**0.006**
BL deviation at crest	0.42	-1.25	2.40	0.60	0.37	0.59	0.948	**0.020**
AC deviation at crest	-0.20	-1.91	2.14	1.08	-0.06	0.90	0.951	**0.026**
3D deviation at apex	1.56	0.19	3.61	0.87	1.68	0.74	0.966	0.117
MD deviation at apex	-0.65	-2.30	2.25	1.65	-0.36	1.02	0.962	0.078
BL deviation at apex	0.48	-3.09	2.78	1.17	0.68	1.05	0.941	**0.009**
AC deviation at apex	-0.19	-1.90	2.43	1.12	0.01	0.91	0.954	**0.035**

BL: Buccolingual; MD: Mesiodistal; AC: Apico-coronal; MDN: Median; Min: Minimum; Max: Maximum; IQR: Interquartile range; $\bar{x}$: Mean; σ: Standard deviation; S-W: Shapiro-wilk test; p: p-value; Angular deviation in degrees; All other deviations in mm.

Descriptive statistics and normality distribution analysis are shown in Table 12. The median angular deviation was 3.90°. The median 3D deviation of the most coronal point on the implants was 1.04 mm. At the implants' apex, the median deviation was 1.56 mm. With the exception of the 3D deviation at the implant's crest, apex, and the MD at apex, all the remaining linear and angular deviations exhibited a non-normal distribution.

Table 13 - Distribution of linear and angular deviations according to the type of implant.

Variables	TLX	BLX	Comparison statistics	p
Angular Deviation, median (IQR)	4.10 (3.50)	3.70 (3.40)	U=323.0	0.442
3D deviation at crest, mean (SD)	1.12 (0.58)	1.06 (0.34)	t=0.468	0.642
MD deviation at crest, median (IQR)	-0.24 (0.64)	-0.23 (0.77)	U=353.0	0.798
BL deviation at crest, median (IQR)	0.33 (0.71)	0.45 (0.60)	U=336.5	0.591
AC deviation at crest, median (IQR)	-0.23 (0.65)	0.03 (1.27)	U=346.5	0.714
3D deviation at apex, mean (SD)	1.82 (0.75)	1.50 (0.70)	t=1.633	0.108
MD deviation at apex, mean (SD)	-0.44 (1.09)	-0.26 (0.94)	t=-0.629	0.532
BL deviation at apex, median (IQR)	0.54 (1.17)	0.46 (1.33)	U=291.5	0.192
AC deviation at apex, median (IQR)	-0.21 (0.87)	-0.19 (1.33)	U=355.5	0.831

TLX: Straumann Tissue Level X implant; BLX: Straumann Bone Level X implant; MD: Mesiodistal; BL: Buccolingual; AC: Apico-coronal; p: p-value; IQR, interquartile range; SD: standard-deviation; t: T-test ; U: Mann-Whitney test; Angular deviation in degrees; All other deviations in mm.

Tables 13 to 16 compare the distribution of linear and angular deviations according to the type of implant, guide, location, and surgery, respectively. In fact, maxillary implants showed a smaller deviation compared to mandibular implants. The median MD at apex was also significantly lower in mandibular teeth (t=2.314; p=0.025). All remaining linear and angular deviations did not differ statistically in the inter-group analysis.

Finally, correlations between deviation variables and implant diameter and length are shown in Table 17. The 3D angle (ρ =-0.299; p=0.026) and the BL at the apex (ρ=-0.304; p=0.024) exhibited a weak albeit negative correlation with the implant length. No significant correlations were found for implant diameter.

Table 14 - Distribution of linear and angular deviations according to the type of guide.

Variables	Guide type			
	T-guides	**TT-guides**	**Comparison statistics**	**p**
Angular Deviation, median (IQR)	3.90 (3.60)	4.30 (3.20)	U=198.5	0.847
3D deviation at crest, mean (SD)	1.14 (0.50)	0.85 (0.39)	t=1.645	0.106
MD deviation at crest, median (IQR)	-0.24 (0.77)	0.03 (0.47)	U=179.0	0.524
BL deviation at crest, median (IQR)	0.46 (0.56)	0.20 (0.69)	U=163.5	0.322
AC deviation at crest, median (IQR)	-1.14 (1.22)	-0.50 (0.42)	U=151.0	0.203
3D deviation at apex, mean (SD)	1.73 (0.73)	1.44 (0.79)	t=1.068	0.291
MD deviation at apex, mean (SD)	-0.39 (1.05)	-0.21 (0.91)	t=-0.486	0.629
BL deviation at apex, median (IQR)	0.54 (1.09)	0.15 (1.64)	U=103.0	**0.018**
AC deviation at apex, median (IQR)	-0.13 (1.20)	-0.50 (0.40)	U=138.5	0.119

T-Guides: tooth-supported guides; TT-Guides: tooth-tissue-supported guides; BL: Buccolingual; MD: Mesiodistal; AC: Apico-coronal; IQR: Interquartile range; SD: Standard deviation; p: p-value; t: T-test; U: Mann-Whitney test; Angular deviation in degrees; All other deviations in mm.

Table 15 - Distribution of linear and angular deviations according to the location.

Variables	Location			
	Maxilla	**Mandibula**	**Comparison statistics**	**p**
Angular Deviation, median (IQR)	3.70 (3.30)	4.35 (4.10)	U=274.0	0.802
3D deviation at crest, mean (SD)	1.07 (0.46)	1.16 (0.58)	t=-0.597	0.553
MD deviation at crest, median (IQR)	-0.13 (0.77)	-0.32 (0.33)	U=215.0	0.164
BL deviation at crest, median (IQR)	0.45 (0.54)	0.31 (0.79)	U=270.5	0.750
AC deviation at crest, median (IQR)	-0.18 (1.07)	-0.32 (1.18)	U=274.5	0.809
3D deviation at apex, mean (SD)	1.60 (0.74)	1.95 (0.69)	t=-1.545	0.128
MD deviation at apex, mean (SD)	-0.19 (1.05)	-0.89 (0.74)	t=2.314	**0.025**
BL deviation at apex, median (IQR)	0.46 (1.13)	0.59 (1.51)	U=266.5	0.692
AC deviation at apex, median (IQR)	-0.17 (1.12)	-0.32 (1.23)	U=265.5	0.678

BL: Buccolingual; MD: Mesiodistal; AC: Apico-coronal; SD: Standard-deviation; IQR: Interquartile range p: p-value; t: T-test; U: Mann-Whitney test; Angular deviation in degrees; All other deviations in mm.

Table 16 - Distribution of linear and angular deviations according to the type of surgery.

Variables	Surgery type			
	Pilot drill	Fully guided	Comparison statistics	p
Angular Deviation, median (IQR)	3.75 (3.50)	3.90 (3.60)	U=241.5	0.736
3D deviation at crest, mean (SD)	1.01 (0.34)	1.12 (0.53)	t=-0.662	0.511
MD deviation at crest, median (IQR)	0.07 (0.63)	-0.29 (0.61)	U=241.0	0.083
BL deviation at crest, median (IQR)	0.27 (0.78)	0.46 (0.60)	U=241.5	0.457
AC deviation at crest, median (IQR)	-0.11 (1.00)	-0.20 (1.06)	U=241.0	0.354
3D deviation at apex, mean (SD)	1.42 (0.67)	1.76 (0.75)	t=-1.439	0.156
MD deviation at apex, mean (SD)	-0.30 (0.82)	-0.38 (1.08)	t=0.252	0.802
BL deviation at apex, median (IQR)	0.43 (0.15)	0.59 (1.20)	U=110.00	0.072
AC deviation at apex, median (IQR)	0.07 (1.03)	-0.22 (1.10)	U=241.5	0.541

BL: Buccolingual; MD: Mesiodistal; AC: Apico-coronal; IQR: Interquartile Range; SD: Standard-deviation; p: p-value; Angular deviation in degrees; All other deviations in mm.

Table 17 - Correlation between linear and angular deviations and implant diameter and length.

Variables	Implant diameter		Implant length	
	ρ	p	ρ	p
Angular deviation	-0.018	0.894	0.030	0.828
3D deviation at crest	0.005	0.972	-0.177	0.196
MD deviation at crest	0.132	0.336	0.257	0.058
BL deviation at crest	0.136	0.323	-0.024	0.862
AC deviation at crest	-0.085	0.536	-0.040	0.770
3D deviation at apex	-0.037	0.788	-0.299	**0.026**
MD deviation at apex	-0.073	0.594	0.256	0.059
BL deviation at apex	-0.060	0.666	-0.304	**0.024**
AC deviation at apex	-0.056	0.684	0.047	0.732

BL: Buccolingual; MD: Mesiodistal; AC: Apico-coronal; ρ: Spearman correlation coefficient; p: p-value; Angular deviation in degrees; All other deviations in mm.

4. DISCUSSION

This study was divided into 2 parts: an *in vitro*/pre-clinical part and an *in vivo*/clinical part. The aim of the first part of this study, *in vitro*, was to determine and compare the primary stability of different types of implants, using different surgical techniques, in 4 types of artificial bone with different densities. To achieve this objective, 3 types of implants were used (BL, BLT, and BLX), the Osstell® device was used to measure the primary stability of the implants placed, 2 surgical techniques were applied (fully-guided and partially-guided surgery) and blocks of artificial bone with 4 different densities (Type I to IV according to Zarb's classification [26]) were used to place the implants.

The aim of the second part of this *in vivo* study was to determine and compare angular and linear deviations of implants placed in patients. To do this, patients who had undergone surgery (fully-guided and pilot-guided surgery) to place implants (BLX and TLX) were selected and the digitally planned position was compared with the final placement position using an implant planning software tool.

In addition to these main objectives, other secondary objectives were defined for both parts of the study, with the aim of crossing the results between the two.

The discussion section presented below answers the different questions raised for both parts of the study, highlights the most relevant results and relates them to the existing literature. It also opens up perspectives for further research.

4.1. *In vitro* study

4.1.1. Bone density and primary stability

In this study, 120 implants were placed, 40 of each type and 10 in each of the 4 bone types. Insertion torque values were registered for all implants placed and primary stability values were measured at both implant and abutment levels. The resin bone blocks used in this study represent an excellent biosimulator for mimicking the behavior of implants *in vitro* in terms of parameters related to primary stability. This material has been used in several studies[59-63] related to dental implants and for investigation of mechanical and fatigue behavior of implants and is capable of simulating the mechanical response in different densities of human bone due to linear elastic properties and is easy to work with. According to published literature[64], it is known that insertion torque is a value that can only be recorded when the implant is placed. Stability, on the other hand, can be measured at different times, with primary stability being recorded immediately after implant placement and secondary stability during the healing period.[64] Although it is not possible to measure secondary stability in this type of study, it is known that the stability value can be a predictor of implant loss.[64] The relationship between these two factors is controversial in the literature.[33, 64, 65] After analyzing the results, it was possible to note that the highest torque values were recorded for bone type I and the lowest for bone type IV which is in line with the literature.[66-69] Furthermore, this validates the use of these bone models to assess primary stability. The same was observed for the ISQ values. The lowest ISQ readings were recorded in bone type IV. There was no great discrepancy between the ISQ values recorded in type I and type II densities, either at implant or abutment level. In addition to these results, a positive correlation was established between torque values and initial primary stability. This positive correlation indicates that an implant with a higher insertion torque value will also have higher primary stability.

The existing literature supports these results.[13, 16, 64, 65] Articles such as Ferreira et al.[64] and Souza et al.[65] describe a relationship between the primary stability of an implant and the insertion torque. Insertion torque is a strictly mechanical measure of the rotational friction of an implant and, as described in the literature, provides information on bone density at the time of implant placement.[64] Primary stability, measured by resonance frequency, measures the rigidity and deflection of the implant in the bone and is necessarily influenced by the density of the bone.[70] However, other factors need to be assessed, such as the length, diameter and macrogeometry of the implant.[71]

4.1.2. Implant macrogeometry and primary stability

As described in the literature, factors such as the diameter, length, and macrogeometry/design of the implant influence its primary stability.[71] In this study, one of the objectives was to determine the influence of implant design (shape and design of the threads) on primary stability. To achieve this, the implants used all had the same diameter and length but varied in the shape and design of the threads. While the BL implant has a cylindrical design with a shorter and less aggressive thread pitch, the BLT and BLX implants have a more conical design. Comparing the BLT and BLX thread designs, the latter has a wider thread pitch, with wider and sharper threads.

Looking at the results obtained in the study, no statistically significant differences were found between torque values and the different implant types. However, higher torque values were recorded for BL and BLT implants compared to BLX.

Statistically significant differences were found in the ISQ values recorded between the different implant types. The BLX implants showed the lowest ISQ readings.

In other words, higher torque values are associated with the cylindrical shape of the implant (BL) and with shorter threads (BLT) due to the greater contact area of the interface with the surrounding bone walls. As for the primary stability factor, the values recorded for the BLX implant did not correspond to what would be expected for an implant that is associated with the concept of "immediacy". Although this result is not entirely in line with the literature[72, 73], it is known that conical geometry with a wider thread pitch and thinner threads results in a lower percentage of BIC compared to more conservative designs.[74]

However, previous studies have also reported similar results, with implants similar in design to BLT showing better ISQ results compared to implants similar in design to BLX.[75] However, these results should be interpreted with caution as artificial bone was used which does not fully mimic what happens in human bone. Nevertheless, these results are in line with the existing literature, supporting the hypothesis that differences in implant macrogeometry can translate into visible effects at a clinical level.[70, 75]

4.1.3. Resonance frequency measurement: implant vs abutment

In this study, after the placement of each implant, the resonance frequency (RFA) was measured with the Osstell® device (Osstell AB, Gothenburg, Sweden) both at the implant level and at the level of a 2.5 mm high abutment. The RFA unit is the ISQ, which can vary between 1 and 100 (maximum stability). Three readings were always recorded in both the mesio-distal (MD) and bucco-lingual (BL) directions in an attempt to minimize the error factors associated with the measurement made by the operator. RFA makes it possible to objectively assess implant stability at any stage of treatment in a reproducible manner.[71] As mentioned above, RFA measures the stability of an implant according to the rigidity of the implant/bone interface and, consequently, the micromobility of an implant in its bed. As described in the literature, these micromovements are important since, above 150 µm, there is a high risk of fibrointegration on the implant surface.[71]

In this study, higher ISQ values were recorded when the transducer of the measuring device was screwed in at the implant level. However, the ratio was maintained when comparing ISQ values measured on different types of implants or on implants placed in different types of bone. In other words, when the ISQ value measured at the implant level increased, it also increased when measured at the abutment level.

In the existing literature, several factors are pointed out as having an influence on the ISQ value, such as implant length, distance from the transducer to the marginal bone (the further the transducer is from the bone, the lower the reading value), type of bone density, transducer tightening torque, presence of soft tissue between the implant and the transducer and the amount of bone in contact with the implant.[64, 70] The concept of "one-abutment-one-time" was developed to minimize soft tissue trauma and be less invasive. Several experimental studies have described some of the phenomena that can occur when a prosthetic abutment is loosened and tightened several times.[71, 76, 77] In some cases, this can lead to soft tissue damage and consequent recession or even marginal bone loss. With these consequences being reported in the literature[76], transducers applied to the abutments rather than directly to the implant have been created. This new application avoids removing the abutments, making it easier to measure stability. On the other hand, as already mentioned, the fact that the transducer is screwed to the abutment increases its distance from the bone, which affects the ISQ value recorded, which will be lower.[76, 77] This study confirms this assumption and is in line with existing literature.

4.1.4. Implant accuracy and implant type

After the placement of all the implants, which were digitally planned, a final scan was carried out with a scan body in order to use the "Treatment Evaluation" tool of the coDiagnostiX® software (Straumann AG) to study the angular and linear deviations of the implants placed through both fully-guided and partially-guided surgery.

Statistically significant differences in relation to the type of implant placed and the deviations were recorded for the angular deviation parameter and the bucco-lingual (BL) deviation parameter at the apex level. With regard to angular deviation, higher values were recorded for BLT implants, followed by BLX and lastly BL. With regard to BL deviation at the apex, higher deviation values were recorded for BLT implants, followed by BLX and, lastly, BL. These results do not seem to be in line with studies such as that by Kholy et al.[78] which indicate that the macrogeometry of the implants may influence the deviations, with cylindrical implants showing the highest values of angular and linear deviations at the apex. However, in this study, there was no variation in bone density where the implants were placed. Other recent studies such as the one by Min Wey et al.[79] show that there is still no consensus on which of the implants, straight or tapered, is better in terms of deviations and primary stability.

Considering the existing literature on deviations of implants placed through s-CAIS, it is known that these can be due to various factors, such as the type of drills used to prepare the implant bed, the type of surgical guide used, friction between the sleeve of the surgical guide, the handle and the drill, the type of surgical technique used and the density of the bone.[78, 80, 81] BL drills are straight twist drills, while the BLT drills, except the pilot drill, are vertically fluted tapered drills. Tapered implant drills create a narrower osteotomy at the apex, while for cylindrical implants the osteotomy walls are practically parallel.[74] Thus, when BL implants are placed, they immediately come into contact with all the prepared walls, whereas tapered implants only come into contact with the bone walls when their apical 5 mm are already in a subcrestal position. In addition, other studies point to drill vibration as a factor influencing implant accuracy.[74] When a drill rotates, it creates a certain vibration. These vibrations can often alter the dimensional accuracy of the drilling process, changing the bed and geometry of the hole. These dimensional inaccuracies of the osteotomy can later be translated into inaccuracies in the final position of the implant. [74] The Straumann® Velodrill™ drills used to place BLX implants have a higher vibration rate, due to a higher speed of operation (maximum: 800 rpm) compared to Twist Drills™ (maximum: 500 rpm), which may partly explain the deviations associated with this type of implant.

Therefore, these results regarding general implant deviations should be interpreted with caution, since other variables such as the type of drills used, the type of surgical protocol used, and the type of bone are not being compared. More detailed studies on implant macrogeometry and the associated deviations should be carried out in the future, as the literature is scarce in this field.

4.1.5. Implant accuracy and guided surgery type

Two different types of guided surgery were applied: fully-guided and partially-guided. 60 implants were placed through fully-guided surgery and another 60 through partially-guided surgery. As described in the introduction section of this work, guided surgery procedures are currently being more used because, in addition to their predictability, they allow for prosthetically guided rehabilitation planning, minimizing operator errors. A fully-guided protocol presupposes that all stages of drilling and implant placement are carried out using a surgical guide. The partially-guided protocol presupposes that the entire drilling process is carried out using the surgical guide, although the implant placement stage is done freehand.[82] This latter surgical technique is a type of universal solution, which provides the maximum guidance achievable with any implant system that does not have a fully guided kit. As the implant planning was carried out digitally using the coDiagnostiX® software (Straumann AG), the entire drill sequence was automatically obtained in the form of a protocol following the manufacturer's recommendations. In addition, the motor used to place the implants communicates directly with the planning software, indicating the entire sequence of drills to be used. The offset (the length of the metal sleeves determines the distance between the neck of the implant and the occlusal surface of the sleeves) was always the same. All the protocols obtained for implant placement indicated the use of medium-sized drills. In cases where fully-guided surgery was used, the limit height for implant placement was always the same, marked by the 1st dash (H2) on the implant transporter.

According to the results of this study, higher angular deviation values were recorded in the partially-guided protocol (2.45º) compared to the fully-guided protocol (1.75º). This result is in line with several articles already published, as well as with the ITI Consensus on Accuracy of s-CAIS.

Although all the other linear deviation parameters analyzed were not statistically significant except for the mesio-distal (MD) deviation at the base, higher deviation values were recorded for the partially-guided protocol, which is in line with the literature.[83, 84] There are studies in the literature[80, 85, 86] which indicate that the differences between fully-guided and partially-guided are not statistically significant. However, for the MD at base parameter, the deviation value was higher for the fully-guided protocol. This difference may have been due to the use of the Milling Cutter drill at the start of the partially-guided protocol. This drill is indicated by the manufacturer for flattening the alveolar crest, as it prevents the following drills and the implant itself from slipping. This drill was only used for the partially-guided protocol and not for the fully-guided protocol. These results point to a possible influence of this drill in reducing the deviations obtained at the base of the implant. However, nothing can be concluded with certainty since it would be necessary to carry out the same surgical procedure (partially-guided) but this time without the use of this drill in order to establish a reliable comparison.

Overall, the results of this study are in line with previously published studies such as Varga Jr. et al.[87] who concluded that there was no statistically significant difference between these guided surgery protocols.

4.1.6. Implant accuracy and bone type

The assessment of the quality and quantity of bone available is usually carried out before implant surgery. CBCT provides precise anatomical information on bone condition.[88] In real cases, bone density can also be determined by Hounsfield units (HU). However, in this study, we used bone blocks with 4 different types of density (type I - IV) or from D1 to D4 according to Lekholm and Zarb's classification [24].

According to the results obtained in this study, higher angular deviation values were recorded in type IV bone (2.55º). In addition, variations were recorded in the linear deviation parameters such as the BL at the apex ($p = 0.037$), with type IV bone displaying the highest median BL deviation (0.46 mm) compared to other bone types.

Although it has been discussed previously, and in the literature[88], that bone density is a factor that affects implant accuracy, this study has underlined these findings.[70] The region most affected by bone density was the apex region.

4.2. *In vivo* study

4.2.1. Implant accuracy and s-CAIS

The implants were meticulously planned and positioned with the assistance of tooth-supported or tooth-tissue-supported templates. While this sample size is notable, it remains small, which may impact the statistical analyses. Nevertheless, this research contributes to the existing scientific evidence on this subject which is of substantial interest.

Through the dental informatics tool, it was possible to compare the digitally planned position with the final position of the implants after surgery. According to the literature [42, 44, 89-95] guided surgery generally leads to more accurate and precise implant placement. However, certain factors can influence outcomes and potentially lead to deviations. These factors include though may not be limited to operator expertise and the inherent degree of freedom of movement observed between the sleeves of the templates and the surgical twist drills [44]. After the analysis of the results, it appears evident that the apical region of implants is most susceptible to 3-D deviations. Additionally, an angular deviation of 3.90 degrees was recorded. These findings align with prior studies in the literature, highlighting that despite numerous advantages, guided surgery still exhibits a degree of variability concerning implant position [42, 44, 89-92, 94-96].

Regarding the type of implants used in this study (Straumann TLX and BLX), no significant differences were found in relation to the values of the deviations registered. No prior studies comparing the accuracy of TLX implants with BLX implants were identified.

Regarding the type of surgical template, in this sample, only 9 implants were positioned using a tooth-tissue-supported guide with fixation pins. All of these implants were positioned in patients with Kennedy class I in the posterior/molar region, where tooth contact alone was not feasible. An increase in the general values of deviations in surgeries performed with tooth-supported with pins guides can be observed in this study. According to the results, the BL deviation at the apex was significantly different between the types of templates used. However, this result must be interpreted with caution because only 9 out of 53 implants were placed with tooth-tissue-supported templates with fixation pins and because the results may be associated with treatment difficulty rather than choice of template.

Regarding the anatomical location of implant placement, whether in the maxilla or mandible, the findings suggest better outcomes for implants positioned in the maxilla. This seems contradictory to the prevailing opinion, which typically suggests higher deviation values in maxillary implants. This is attributed to factors such as the lower bone density in the maxilla, trabecular bone structure, and the curved ridge shape compared to the more favorable anatomy of the mandible [96, 97]. However, maxillary templates utilizing tissues may exhibit improved support and stability, promoted by a palatal “major connector” when compared to mandible templates where the presence/movement of the tongue may reduce template support and stability, particularly in most posterior regions.

Concerning surgery type, pilot or fully guided, it was not possible to establish a correlation because a significant majority of the procedures involved fully guided surgery. According to existing literature, fully guided surgery generally yields superior outcomes, compared to pilot-guided, in terms of accuracy and precision [98]. Deviation values reported in this study appear to align with this prevailing assumption.

According to the results, the diameter of the implants used did not impact deviations, although deviations were noted based on implant length. Implants of greater length are more likely to present 3D and BL deviations at the apex level. There are studies suggesting that this phenomenon might be influenced by challenges in angulating longer drills, particularly in cases where patients have limited mouth opening, or in cases where the template-crest distance is higher and the planned implant is longer [99, 100].

In addition, in this research only one kit or guided surgery system was used. This may have an influence on the values of deviations but was not a variable considered in this study. Different drill designs might have an impact on implant placement accuracy.[45] Future studies should compare different guided surgery systems, surgical protocols, and drill sequences.

4.2.2. *In vitro* vs *in vivo*

As mentioned above, this study was divided into 2 parts: an *in vitro* study and an *in vivo* study.

In the *in vitro* study, as already described, different types of implants were used with 2 different designs: cylindrical and tapered. Variables such as primary stability, insertion torque, type of guided surgery, and bone type were also analyzed. In the *in vivo* pilot study, 2 different types of implants were used (TLX and BLX) but with the same tapered design. In addition, these implants varied in diameter and length, unlike the *in vitro* study.

This *in vivo* pilot study also used 2 surgical techniques: the fully-guided technique (similar to the *in vitro* study) and the pilot-guided technique (unlike the *in vitro* study). In this patient study, other variables were analyzed, such as the type of guide used, the region of the oral cavity where the implant was placed, and the diameter and length of the implant, in order to try to understand their impact on the angular and linear deviations of the implants. The same protocol for analyzing deviations and the same parameters were used in both parts of this study.

Although it is not statistically possible to establish any correlation between the 2 studies because the conditions were different in both, it is possible to make some comparisons regarding the type of implant and the deviations recorded. The area most susceptible to deviation is the apical region of the implants in both parts of the study, both in implants placed in artificial bone and in implants placed in patients. In the *in vitro* study, with regard to 3D deviation at the apex level, BLT implants had a higher deviation value than BLX. In the *in vivo* study, the TLX implants showed a higher deviation value than the BLX. This last observation should be carefully interpreted since the number of TLX implants placed exceeds those of BLX. Higher deviation values were recorded for all parameters in the *in vivo* test compared to the *in vitro* test. This can be explained by the difference in the elasticity of the artificial models compared to living bone especially regarding the homogeneity of the bone, the less difficulty of access to the implant placement area (*in vitro* study), and the different operators involved (*in vitro* and *in vivo*).

Variations in the distance from the sleeve to the bone and in the drill lengths used, which were variable for the *in vivo* pilot study, may also have influenced the increase in these values compared to those recorded in the *in vitro* trial where these variables were always standardized.

4.3. Study limitations and future perspectives

4.3.1. Study limitations

Some limitations and difficulties can be pointed out regarding the execution of this study. With regard to the *in vitro* part, bone blocks (Bonemodels®; Castellón; Spain) were used to place the implants. In order to plan the implants to be placed, it was necessary to perform a CBCT and a 3D scan of the blocks. To carry out the CBCT scan, the blocks had to be cut because the FOV (Field of View) of the X-ray machine was not large enough to give an image of a complete block. This meant that the number of CBCTs performed had to be doubled. In addition, these blocks had a very smooth and shiny surface, which in turn prevented an initial scan with an intraoral scanner. It was necessary to use a laboratory scanner to initially scan the blocks. Even to scan the blocks on the laboratory scanner, they had to be sprayed with powder so that the scanner could read the entire surface of the blocks. When performing the final scan with the scan bodies, there were difficulties reading with the intraoral scanner. Some of the final scans had to be repeated in order to have enough reference points to perform the superimposition in the "Treatment Evaluation" tool. As so, these artificial models presented limitations and therefore hindered the digital workflow that was planned for this part of the study.

Also, for the *in vitro* part of the study, the Milling Cutter drill was used in the partially-guided protocol, as it was indicated in the manufacturer's protocols. The indication for this drill is the flattening of the alveolar ridge. When comparing the fully-guided and partially-guided procedures, it was found that the implant deviation at base results was lower for the partially-guided procedure. It is believed that this result can be explained by the use of this drill. However, no firm conclusions can be drawn since it would be necessary to repeat the partially-guided procedure without using the drill described, which did not happen. Future research will be done on this issue.

As far as the *in vivo* study is concerned, the main limitation was the sample size, which was still too small to carry out a more detailed statistical analysis. However, this is a study carried out with post-graduation patients at a university dental clinic. Hence, the investigation is always dependent on the number of patients who appear and agree to undergo this type of treatment. In addition, only those who underwent a digital workflow for their rehabilitation could be selected as cases for this study.

This study recorded 2 types of surgical protocols: fully-guided and pilot-guided. Two types of surgical guides tooth-supported and muco-tooth-supported were used. However, the number of pilot-guided procedures and procedures using muco-tooth-supported guides should be increased in order to obtain a more balanced sample. The same was true for the number of BLX vs TLX implants.

In this *in vivo* study, only variables such as the type of surgery, the type of implant placed, and at the end, the deviation values were recorded. Other variables such as measuring stability, recording the insertion torque, and recording the type of bone were not recorded, which is a limitation of this part of the study that subsequently made it impossible to compare these variables with the *in vitro* study. In addition to all these factors, it should be borne in mind that, unlike the *in vitro* part of this study, all the procedures carried out had different operators, all of them post-graduation students, with more or less experience. This may also have some influence on the deviation values obtained.

In addition to the above described, there were some difficulties with the statistics for both parts of the study. In the *in vitro* part there were many variables, so it was difficult to identify objectives and isolate variables in order to proceed with a statistical analysis and, consequently, obtain results. In the *in vivo* part, the size of the sample prevented some conclusions from being statistically valid.

4.3.2. Future perspectives

This work, both *in vitro* and *in vivo*, leaves some questions that could open the way for further research. This is the case with the use of the Milling Cutter drill in guided surgery protocols. No articles were found in the literature that refer to the use of this specific drill and that study its impact on this type of protocol and implant-related deviations.

It is known that the type of drills used, the distance of the sleeves from the bone, and the friction generated between the handles and the sleeves of the surgical guides are all factors that can have an impact on the deviation values associated with implant placement. New surgical kits that have already been developed now have the stops on the implant bed preparation drills themselves, avoiding the use of handles to minimize the friction generated and with a possible impact on deviations. Further research varying these factors could bring new results that allow guided surgery protocols to be optimized.

Every year, new implants are launched onto the market with new designs and new properties. The macrogeometry of implants and their impact is still a subject that is not fully clarified in the literature. New studies with other implants, varying their designs and properties, are needed to understand which types are best suited to each of the different clinical situations.

Regarding the *in vivo* study, while it emphasizes the reliability of guided surgery as a viable option, it is suggested to expand the sample size, guide, and surgery types, to promote a more robust statistical analysis and reach more conclusions. Additionally, in future studies, the bone density of each patient could be assessed in order to analyze it’s impact on the implant accuracy and stability. Furthermore, this will allow the comparison with data available from *in vitro* studies. This may help to achieve better surgical and prosthetic results.

5. CONCLUSION

The term “prosthetically driven” emerged some time ago in the field of Oral Rehabilitation and presupposes an approach that prioritizes the functional design of the prosthesis and the aesthetic result. To achieve this goal, the digital workflow in implantology makes it possible to guarantee more precise implant placement. This digital workflow concept can involve tools such as 3D design and printing and CAD-CAM techniques that make it possible to create, for example, customized surgical guides for each case and customized crowns/prostheses that consider the patient's soft tissues and provide increasingly natural aesthetic results.

As mentioned above, guided surgery is a crucial step in this workflow. Static-guided surgery involves the use of computer-generated surgical guides that help clinicians place implants according to a pre-executed plan. These guides provide greater precision and predictability in the placement of implants, although there are always some deviations associated. In addition, this type of protocol minimizes surgical complications, reduces chair time, and reduces post-surgical recovery time. Although different techniques within guided surgery have been applied in this study, it can be concluded that fully guided surgery reduces deviations associated with implant placement. Further studies are needed to determine whether there are statistically significant differences in relation to the partially guided technique.

In addition to the different techniques that can be applied within guided surgery, other factors can interfere with the results of an implant's placement accuracy. As we can see from this study, factors such as the density of the bone, the implant placement site, the type of surgical guide used, and the macrogeometry of the implant seem to have an impact on the deviation values. Tools such as Treatment Evaluation allow clinicians to be increasingly demanding with the surgical techniques they choose and the biomaterials they use in a given case, as they are able to assess the accuracy of their own work.

Increasingly, rehabilitation cases must be prepared in advance and all patient factors must be carefully examined. CBCT is an excellent tool for assessing anatomical conditions and bone density. We know, also according to this study, that a bone with a low density implies more deviations, insertion torque, and more critical primary stability values. Therefore, this knowledge on the part of a clinician allows them to choose a more predictable technique or an implant with more favorable macrocharacteristics beforehand.

This study has provided a comprehensive analysis of the primary stability and accuracy of different implant types using various surgical techniques in both *in vitro* and *in vivo*. The findings underscore the impact of bone density and implant design on deviation values, particularly in the apical region of implants, aligning with existing literature that emphasizes the role of bone quality in implant outcomes.

The *in vitro* component revealed significant insights into how different bone densities and surgical techniques influence implant stability. Notably, type IV bone exhibited higher angular deviations, reinforcing the notion that lower bone density poses greater challenges for implant accuracy. The use of the Milling Cutter drill in partially-guided protocols highlighted potential advantages in reducing base deviations, although further research is necessary to confirm these results without the drill's involvement.

The *in vivo* study supported the reliability of guided surgery but also highlighted the need for larger sample sizes and more varied surgical protocols to enhance statistical robustness. The variability in operator expertise and the digital workflow's dependence on patient availability were noted as limitations. Additionally, the study's exclusion of variables such as stability measurements, insertion torque, and bone type in the *in vivo* phase limited direct comparisons with *in vitro* results.

Future research directions include exploring the impact of different drill types and surgical guides on implant deviations, assessing new implant designs, and increasing sample sizes for more detailed statistical analysis. Further investigations into bone density assessments for patients and their correlation with implant accuracy and stability are also recommended to optimize guided surgery protocols.

The development of *in vitro* and *in vivo* studies in this area serves several purposes. *In vitro* studies allow predictive models to be validated, i.e. in controlled laboratory environments it is possible to test the precision and reliability of procedures carried out using s-CAIS by comparing planned positions with final implant positions using specific software and assessing the level of precision achieved. They also allow biomechanical tests to be carried out, such as evaluating the resonance frequency and insertion torques by varying various parameters and simulating various factors. *In vivo* studies make it possible to evaluate other types of factors, under other conditions, such as biological responses and healing, which helps to assess the success and biocompatibility of the materials used and the surgical protocols applied. The combination of *in vitro* and *in vivo* studies is an attempt to bridge the gap between laboratory results and clinical practice. Cross-referencing the results obtained in both is essential for optimizing surgical protocols and increasing treatment success rates. This work and the cross-referencing of these studies provide scientific information that is intended to guide the clinical practice of clinicians who are increasingly looking for evidence-based practice. Studies like this, both *in vitro* and *in vivo*, are essential for validating the precision, efficacy, and safety of guided implant surgery techniques, for assessing the primary stability of the implant, and for paving the way for new research in this area that can ultimately translate the results of research into clinical practice.

In conclusion, while this study has contributed valuable data to the field, addressing its limitations through continued research will be crucial in refining implant placement techniques and improving patient outcomes.

6. CONCLUSIÓN

El término *"prosthetically driven"* surgió hace algún tiempo en el campo de la Rehabilitación Oral y presupone un enfoque que da prioridad al diseño funcional de la prótesis y al resultado estético. Para lograr este objetivo, el flujo de trabajo digital en implantología permite garantizar una colocación más precisa de los implantes. Este concepto de flujo de trabajo digital puede implicar herramientas como el diseño y la impresión en 3D y las técnicas CAD-CAM que permiten crear, por ejemplo, guías quirúrgicas personalizadas para cada caso y coronas/prótesis personalizadas que tienen en cuenta los tejidos blandos del paciente y proporcionan resultados estéticos cada vez más naturales.

Como ya se ha mencionado, la cirugía guiada es un paso importante y crucial en este flujo de trabajo. La cirugía guiada estática implica el uso de guías quirúrgicas generadas por ordenador que ayudan a los clínicos a colocar los implantes según un plan preestablecido. Estas guías proporcionan una mayor precisión y previsibilidad en la colocación de los implantes, aunque siempre hay algunas desviaciones asociadas. Además, este tipo de protocolo minimiza las complicaciones quirúrgicas, reduce el tiempo de sillón y reduce el tiempo de recuperación postoperatoria. Aunque en este estudio se han aplicado diferentes técnicas dentro de la cirugía guiada, se puede concluir que la cirugía totalmente guiada reduce las desviaciones asociadas a la colocación de implantes. Se necesitan más estudios para determinar si existen diferencias estadísticamente significativas en relación con la técnica parcialmente guiada.

Además de las diferentes técnicas que pueden aplicarse dentro de la cirugía guiada, otros factores pueden interferir en los resultados de la precisión de colocación de un implante. Como se desprende de este estudio, factores como la densidad del hueso, el lugar de colocación del implante, el tipo de guía quirúrgica utilizada y la macrogeometría del implante parecen influir en los valores de desviación. Herramientas como *"Treatment evaluation"* permiten a los clínicos ser cada vez más exigentes con las técnicas quirúrgicas que eligen y los biomateriales que utilizan en un caso determinado, ya que pueden evaluar la precisión de su propio trabajo.

Cada vez más, los casos de rehabilitación deben prepararse con antelación y todos los factores del paciente deben examinarse cuidadosamente. La CBCT es una herramienta excelente para evaluar las condiciones anatómicas y la densidad ósea. Sabemos, también según este estudio, que un hueso con baja densidad implica más desviaciones, torque de inserción y valores de estabilidad primaria más críticos. Por lo tanto, este conocimiento por parte del clínico le permite elegir de antemano una técnica más predecible o un implante con macrocaracterísticas más favorables.

Este estudio ha proporcionado un análisis exhaustivo de la estabilidad primaria y la precisión de distintos tipos de implantes utilizando diversas técnicas quirúrgicas tanto *in vitro* como *in vivo*. Los hallazgos subrayan el impacto de la densidad ósea y el diseño del implante en los valores de desviación, especialmente en la región apical de los implantes, en consonancia con la literatura existente que hace hincapié en el papel de la calidad ósea en los resultados de los implantes.

El componente *in vitro* reveló datos significativos sobre cómo influyen las distintas densidades óseas y técnicas quirúrgicas en la estabilidad de los implantes. En particular, el hueso de tipo IV mostró mayores desviaciones angulares, lo que refuerza la idea de que una menor densidad ósea plantea mayores retos para la precisión de los implantes. El uso de la fresa en protocolos parcialmente guiados puso de manifiesto posibles ventajas en la reducción de las desviaciones de la base, aunque se necesitan más investigaciones para confirmar estos resultados sin la participación de la fresa.

El estudio *in vivo* corroboró la fiabilidad de la cirugía guiada, pero también puso de manifiesto la necesidad de contar con muestras de mayor tamaño y protocolos quirúrgicos más variados para mejorar la solidez estadística. Se señalaron como limitaciones la variabilidad de la experiencia del operador y la dependencia del flujo de trabajo digital de la disponibilidad del paciente. Además, la exclusión en el estudio de variables como las mediciones de estabilidad, el par de inserción y el tipo de hueso en la fase *in vivo* limitó las comparaciones directas con los resultados *in vitro*.

Las futuras líneas de investigación incluyen la exploración del impacto de diferentes tipos de fresas y guías quirúrgicas en las desviaciones de los implantes, la evaluación de nuevos diseños de implantes y el aumento del tamaño de las muestras para un análisis estadístico más detallado. También se recomiendan nuevas investigaciones sobre la evaluación de la densidad ósea de los pacientes y su correlación con la precisión y estabilidad de los implantes, con el fin de optimizar los protocolos de cirugía guiada.

El desarrollo de estudios *in vitro* e *in vivo* en este ámbito tiene varias finalidades. Los estudios *in vitro* permiten validar los modelos predictivos, es decir, en entornos de laboratorio controlados es posible comprobar la precisión y fiabilidad de los procedimientos realizados mediante s-CAIS comparando las posiciones planificadas con las posiciones finales de los implantes mediante software específico y evaluando el nivel de precisión alcanzado. También permiten realizar pruebas biomecánicas, como evaluar la frecuencia de resonancia y los pares de inserción variando diversos parámetros y simulando distintos factores. Los estudios *in vivo* permiten evaluar otro tipo de factores, en otras condiciones, como las respuestas biológicas y la cicatrización, lo que ayuda a evaluar el éxito y la biocompatibilidad de los materiales utilizados y los protocolos quirúrgicos aplicados. La combinación de estudios *in vitro* e *in vivo* es un intento de salvar la distancia entre los resultados de laboratorio y la práctica clínica.

Cruzar los resultados obtenidos en ambos es esencial para optimizar los protocolos quirúrgicos y aumentar las tasas de éxito del tratamiento. Este trabajo y el cruce de estos estudios aportan información científica destinada a orientar la práctica clínica de los clínicos, que buscan cada vez más una práctica basada en la evidencia. Estudios como éste, tanto *in vitro* como *in vivo*, son esenciales para validar la precisión, eficacia y seguridad de las técnicas de cirugía implantológica guiada, para evaluar la estabilidad primaria del implante y para allanar el camino a nuevas investigaciones en este campo que, en última instancia, puedan trasladar los resultados de la investigación a la práctica clínica.

En conclusión, aunque este estudio ha aportado datos valiosos al campo, abordar sus limitaciones mediante la investigación continuada será crucial para perfeccionar las técnicas de colocación de implantes y mejorar los resultados en los pacientes.

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8. APPENDICES

APPENDICE I

Publication Certificate

JOMI The International Journal of Oral & Maxillofacial Implants

Editor-in-Chief
Clark M. Stanford, DDS, PhD

To whom it may concern,

This letter hereby confirms that authors Catarina Mendes Fonseca, Patrícia Alexandra Barroso da Fonseca, Margarida Martins Quezada, Tiago Marques, Javier Montero Martín, Dean Morton, and André Correia have had their article "Analyzing Linear and Angular Deviations After Guided Surgery for Dental Implant Placement: A Preliminary Study" accepted for publication in a future issue of *The International Journal of Oral & Maxillofacial Implants*. While awaiting formal publication, the article has been published as an online, ahead-of-print version available on the JOMI website.

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Sincerely,

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