Universitat Internacional de Catalunya
Facultat d'Odontologia

Tesis doctoral

Evaluacion de la eficacia de sistema digitales de toma de impresión de implantes dentales.

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EVALUACIÓN DE LA EFICACIA DE SISTEMAS DIGITALES DE TOMA DE IMPRESIÓN DE IMPLANTES DENTALES

TRABAJO DESTINADO A LA OBTENCIÓN DEL TÍTULO DE DOCTOR

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LA ODONTOLOGÍA,

Es una profesión que exige de los que a ella se dedican: el sentido estético de un artista, la destreza manual de un cirujano, los conocimientos científicos de un médico y la paciencia de un monje.

PIO XII

A mi familia:

A mis abuelos, por su ejemplo de Fe y vida

A mis padres, por darme alas y exigirme amorosamente siempre

A mis hermanos, mis dos estandartes de los que aprendo a diario

A Phil, mi mitad, por hacer que siempre quiera ser mejor

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JUSTIFICACIÓN

El ajuste de las estructuras protésicas es imprescindible para un buen funcionamiento clínico de las mismas. Este concepto, ya importante en la prótesis fija sobre dientes, parece serlo más cuando se trata de realizar prótesis sobre implantes. Recordemos que, a diferencia de los dientes, la ausencia de movilidad de los implantes dificulta su adaptación a los desajustes. Estos desajustes pueden ser responsables de tensiones mecánicas que causen alteraciones o fracturas de las estructuras, desatornillamiento, y posible pérdida de inserción de los implantes. Asimismo, pueden producirse filtraciones bacterianas que pudieran tener relación con procesos de mucositis y periimplantitis.

La constatación de este problema nos ha llevado a tratar de determinar en un primer estudio cómo las modificaciones en el diseño y longitud de los pilares de impresión convencionales pueden influir en la exactitud de las impresiones. Asimismo, dado que se están introduciendo en el mercado nuevos sistemas de toma de impresión por medio de escáneres ópticos, hemos tratado determinar en un mismo estudio la exactitud de diferentes técnicas de impresión convencionales (cubeta cerrada, cubeta abierta sin ferulizar los pilares de impresión y cubeta abierta ferulizando los pilares de impresión) y cuatro escáneres ópticos (Carestream 3600, CEREC Omnicam, TrueDefinition y TRIOS3).

Las impresiones con escáneres ópticos intraorales han dado excelentes resultados, con mayor exactitud que las impresiones convencionales, pero en casos de arcadas completas los resultados son más contradictorios. Por ese motivo creímos necesario llevar a cabo un ensayo clínico en vivo comparando el ajuste de prótesis fijas implantosoportadas de zirconio de arcada completa, una confeccionada a partir de una

impresión convencional (con sus correspondientes pruebas) y otra confeccionada a partir de un flujo totalmente digital. Los buenos resultados obtenidos por las prótesis derivadas del flujo digital nos llevaron a proponer una técnica clínica para un flujo totalmente digital en caso de carga inmediata de prótesis fija de arcada completa implantosoportada.

JUSTIFICATION

Accurate fit of prosthetic frameworks is essential for their good clinical behavior. If this was already important for teeth supported prostheses, it is even more important when dealing with implant supported dental prostheses. We need to remember that the lack of mobility of dental implants makes it more difficult for them to adapt to misfit. Misfit can be responsible for possible mechanical stress which can alter or fracture the framework, loosen screws and even cause implant insertion loss. It can also cause bacterial leakage, which could be related to mucositis and periimplantitis.

Before this problem, we designed a first study to try to determine how modifying length and design of the implant impression copings could affect impressions accuracy. Moreover, as many new intraoral optical scanners are being introduced in the dental market, we also prepared a similar study to determine the accuracy of three conventional impression techniques (closed tray, open tray not splinting the impression copings and open tray splinting the impression copings), and four intraoral scanners (Carestream 3600, CEREC Omnicam, TrueDefinition y TRIOS3).

Impressions from intraoral scanners have shown excellent results, more accurate than conventional impressions of one to few neighboring implants, but in complete arch cases results are not so clear. Attending that problem, we considered of interest to design a clinical trial comparing fit of complete arch implant supported zirconia prostheses, one produced from a conventional impression (including all regular steps) and another produced from a complete digital flow. The better results obtained by prostheses produced through complete digital flow led us to develop a clinical technique for a complete digital flow in immediate loading of complete arch implant supported prostheses.

OBJETIVOS

Objetivo general 1:

Analizar si un cambio en el diseño de los pilares de impresión puede mejorar la exactitud de las impresiones sobre implantes con elastómeros y cubeta cerrada.

Objetivos específicos:

1. Comparar la distancia entre los centros de la cabeza de los implantes en los modelos obtenidos con pilares de impresión largos y cortos con diseño nuevo y viejo y el modelo de trabajo original.
2. Comparar el cambio de angulación de los ejes de los implantes en los modelos obtenidos con pilares de impresión largos y cortos con diseño nuevo y viejo y el modelo de trabajo original.
3. Determinar si el modelo de trabajo sufría cambios dimensionales a lo largo del estudio.

Objetivo general 2:

Determinar si las impresiones digitales con nuevos sistemas de impresión óptica no son menos exactas que las impresiones convencionales con elastómeros.

Objetivos específicos:

1. Comparar el desplazamiento del centro de la cabeza de los implantes al tomar impresiones en un modelo de dos implantes contiguos con poliéter y cubeta abierta sin ferulizar los pilares, poliéter y cubeta abierta ferulizando los pilares, poliéter y cubeta cerrada, con Carestream 3600, con TRIOS3, con CEREC Omnicam y con TrueDefinition.

2. Comparar la distancia entre los centros de las cabezas de los implantes al tomar impresiones en un modelo de dos implantes contiguos con poliéter y cubeta abierta sin ferulizar, poliéter y abierta ferulizando, poliéter y cubeta cerrada, con Carestream 3600, con TRIOS3, con CEREC Omnicam y con TrueDefinition.
3. Comparar la rotación del eje de los implantes al tomar impresiones en un modelo de dos implantes contiguos con poliéter y cubeta abierta sin ferulizar, poliéter y abierta ferulizando, poliéter y cubeta cerrada, con Carestream 3600, con TRIOS3, con CEREC Omnicam y con TrueDefinition.
4. Comparar la exactitud de las impresiones en un modelo de dos implantes contiguos con poliéter y cubeta abierta sin ferulizar, poliéter y abierta ferulizando, poliéter y cubeta cerrada, con Carestream 3600, con TRIOS3, con CEREC Omnicam y con TrueDefinition.

Objetivo general 3:

Determinar si prótesis de circona implanto-soportadas de arcada completa fabricadas a partir de los modelos obtenidos por un escáner intraoral tienen un ajuste superior o al menos no inferior al de los obtenidos a partir de impresiones convencionales con elastómeros.

Objetivos específicos:

1. Comparar la percepción de ajuste de una prótesis de circona implanto-soportada de arcada completa fabricada a partir de un modelo obtenido por escáner intraoral con el de una idéntica fabricada a partir de un modelo convencional.

2. Comparar el ajuste táctil con sonda de una prótesis de circona implanto-soportada de arcada completa fabricada a partir de un modelo obtenido por escáner intraoral con el de una idéntica fabricada a partir de un modelo convencional.
3. Comparar el resultado de la prueba de Sheffield de una prótesis de circona implanto-soportada de arcada completa fabricada a partir de un modelo obtenido por escáner intraoral con el de una idéntica fabricada a partir de un modelo convencional.
4. Comparar el tipo de rampa del torque de inserción de una prótesis de circona implanto-soportada de arcada completa fabricada a partir de un modelo obtenido por escáner intraoral con el de una idéntica fabricada a partir de un modelo convencional.
5. Comparar el ajuste radiográfico de una prótesis de circona implanto-soportada de arcada completa fabricada a partir de un modelo obtenido por escáner intraoral con el de una idéntica fabricada a partir de un modelo convencional.
6. Determinar la preferencia de los evaluadores entre una prótesis de circona implantosoportada de arcada completa fabricada a partir de un escaneo intraoral con una idéntica fabricada a partir de un modelo convencional.

OBJECTIVES

General objective 1:

To analyse if changes in implant impression copings design can improve accuracy of implant impression with elastomers and closed tray.

Specific objectives:

1. To compare the distance between implants head centre in models obtained with long and short implant impression copings with a new and an old design, with that in the reference model.
2. To compare changes in implant axes angle in models obtained with long and short implant impression copings with a new and an old design, with that in the reference model.
3. To determine if the reference model had dimensional changes throughout the study.

General objective 2:

To determine whether digital impressions made with new intraoral impression scanners are less accurate than conventional impressions with elastomers or not.

Specific objectives:

1. To compare displacement of implants head centres in impressions of a model with two neighbouring implants, made with polyether and closed tray, polyether and open tray without splint impression copings, polyether and open tray splint impression copings, Carestream 3600, TRIOS3, CEREC Omnicam and TrueDefinition.

2. To compare the distance between implants head centres of a model with two neighbouring implants, made with polyether and closed tray, polyether and open tray without splint impression copings, polyether and open tray splint impression copings, Carestream 3600, TRIOS3, CEREC Omnicam and TrueDefinition.
3. To compare rotation angle of implants axes of a model with two neighbouring implants, made with polyether and closed tray, polyether and open tray without splint impression copings, polyether and open tray splint impression copings, Carestream 3600, TRIOS3, CEREC Omnicam and TrueDefinition.
4. To compare accuracy of impressions of a model with two neighbouring implants, made with polyether and closed tray, polyether and open tray without splint impression copings, polyether and open tray splint impression copings, Carestream 3600, TRIOS3, CEREC Omnicam and TrueDefinition.

General objective 3:

To determine whether a complete-arch implant supported zirconia framework obtained from an intraoral scanning are superior or not inferior to identical frameworks made from a conventional model from an elastomeric impression.

Specific goals:

1. To compare perception of fit of a zirconia complete-arch implant-supported framework made from an intraoral scanning with that of an identical one made from a conventional elastomeric impression.

2. To compare tactile fit of a zirconia complete-arch implant-supported framework made from an intraoral scanning with that of an identical one made from a conventional elastomeric impression.
3. To compare the results of Sheffield test of a zirconia complete-arch implant-supported framework made from an intraoral scanning with that of an identical one made from a conventional elastomeric impression.
4. To compare radiographic fit of a zirconia complete-arch implant-supported framework made from an intraoral scanning with that of an identical one made from a conventional elastomeric impression.
5. To compare screwing torque of a zirconia complete-arch implant-supported framework made from an intraoral scanning with that of an identical one made from a conventional elastomeric impression.
6. To compare the overall performance of a zirconia complete-arch implant-supported framework made from an intraoral scanning with that of an identical one made from a conventional elastomeric impression.

HIPÓTESIS DE TRABAJO

HIPÓTESIS ALTERNATIVAS:

$H1_0$: La morfología del pilar de impresión influye en la exactitud del modelo obtenido con impresión mediante elastómeros.

$H2_0$: Los sistemas de impresión ópticos son tan exactos como los sistemas de impresión convencionales.

$H3_0$: Las prótesis de arcada completa implanto-soportadas en zirconio obtenidas por un flujo totalmente digital no son inferiores a las obtenidas a partir de impresiones convencionales.

HIPÓTESIS NULAS

$H1_0$: La morfología del pilar de impresión no influye en la exactitud del modelo obtenido con impresión mediante elastómeros.

$H2_0$: Los sistemas de impresión ópticos no son tan exactos como los sistemas de impresión convencionales.

$H3_0$: Las prótesis de arcada completa implanto-soportadas en zirconio obtenidas por un flujo totalmente digital son inferiores a las obtenidas a partir de impresiones convencionales.

WORK HYPOTHESIS

ALTERNATIVE HYPOTHESIS:

$H1_0$: The morphology of the implant impression coping influences the accuracy of the model obtained by elastomeric impression.

$H2_0$: Optical impression systems are as accurate as conventional impression systems.

$H3_0$: Accuracy of zirconia complete arch implanted-supported prostheses obtained by a fully digital flow is inferior to those obtained from conventional impressions.

NULL HYPOTHESIS

$H1_0$: The morphology of the implant impression coping does not affect the accuracy of the model obtained by elastomeric impressions.

$H2_0$: Optical impression systems are not as accurate as conventional impression systems.

$H3_0$: Accuracy of zirconia complete arch implanted-supported prostheses obtained by a fully digital flow is not inferior to those obtained from conventional impressions.

INTRODUCCIÓN

La exactitud en las impresiones dentales es un elemento esencial en la prótesis fija en general y en la prótesis sobre implantes en particular(1). Los elementos fabricados en el laboratorio deben tener un buen ajuste en boca, y para ello es necesario transferir con la mayor exactitud posible la realidad de la boca para permitir un buen trabajo al técnico de laboratorio.

Cuando trabajamos sobre dientes la presencia del ligamento periodontal dota de una cierta movilidad a los mismos, permitiendo una ligera adaptación a posibles inexactitudes en la prótesis fabricada. No se ha podido determinar científicamente cual es el nivel de inexactitud tolerable, pero algunos autores sugieren que la movilidad de los dientes sanos permite absorber sin problema desviaciones de hasta 100 μm. Cuando se trata de implantes, esa capacidad de absorción de inexactitud disminuye, dada la ausencia de ligamento periodontal en los implantes. Se ha cuantificado la capacidad de adaptación de los implantes a 10 μm (2). Pese a todo, existe una cierta tolerancia biológica al desajuste(3).

La consecuencia de la existencia de desajustes en las estructuras implanto-soportadas son diversas. El desajuste provoca tensiones, que pueden afectar tanto a la misma estructura protésica como a los implantes y tornillos de sujeción. Las tensiones, aun siendo pequeñas, pueden tener consecuencias mecánicas como fracturas por fatiga y desatornillamientos (4-6). Asimismo, esas tensiones pueden transmitirse en mayor o menor medida al hueso subyacente, pudiendo ser responsables de pérdida de soporte por pérdida de hueso(3). Por otra parte, el desajuste puede favorecer la colonización bacteriana de las interfases(7), lo cual pudiera ser a su vez causa de una posible afectación de los tejidos periimplantarios,

propiciando mucositis y periimplantitis. Si bien no se ha podido cuantificar el nivel de desajuste que puede dar lugar a esos efectos adversos mecánicos o biológicos(8), y aun cuando las consecuencias del desajuste son inciertas, es necesario tratar de conseguir el mejor ajuste posible. Como conseguir un ajuste perfecto parece inalcanzable(9), algunos autores han propuesto como tolerable un desajuste en el rango de las 30μm a las 100μm(6, 10-13).

Se ha propuesto el uso de diferentes materiales de impresión para conseguir la mayor exactitud posible, y en la actualidad parece existir consenso en la conveniencia de utilizar elastómeros de alta precisión como método de toma de impresiones sobre implantes, tanto silicona de adición como poliéter (14, 15). El proceso de reproducción de la situación de la boca debe además completarse con el vaciado en yeso de la impresión, incrementando el riesgo de errores de procedimiento. Es preciso que la proporción yeso-agua sea muy exacta y la mezcla debe realizarse al vacío para lograr minimizar los cambios dimensionales en el yeso(16). La toma de impresiones con estos materiales es por todo ello un proceso muy sensible a errores de técnica, engorroso para el clínico y molesto para el paciente (17-21).

Para intentar minimizar la falta de exactitud en impresiones con elastómeros, se ha tratado de implementar la utilización de diferentes técnicas de impresión, básicamente tres: cubeta cerrada, cubeta abierta y cubeta abierta con ferulización previa de las estructuras(2). Existe cierta controversia respecto la mejor técnica de impresión convencional, pues entra en conflicto no sólo la exactitud, sino también la facilidad de uso(22). Así, si bien la ferulización bien realizada parece mejorar algo la

exactitud(23), hace mucho más compleja y engorrosa la toma de impresión(24), lo que lleva a muchos clínicos a obviarla. Se ha tratado de intentar ofrecer mayor exactitud a través del uso de llaves de verificación pero se cuestiona tanto que mejoren el ajuste como el material para su confección(25). En el primer trabajo de esta tesis hemos tratado de determinar si la modificación de los pilares de impresión, en diseño y en longitud, podrían afectar a la exactitud de las impresiones con elastómeros en casos de dos implantes.

Para mejorar la exactitud de las impresiones convencionales, se ha tratado de implementar la utilización de sistemas alternativos o complementarios a los elastómeros. Destacan entre ellos la espectrofotogrametría (26-28) y tomografía computarizada de haz de cono, en inglés *cone beam computed tomography* (CBCT)(29). Si bien ambos sistemas mejoran significativamente la exactitud, adolecen de seguir requiriendo una impresión convencional, sobre la que luego se reajusta la posición de los implantes. Además, en el caso de la espectrofotogrametría, se requiere la utilización de un equipo de alto coste(4), mientras el CBCT obliga a someter al paciente a radiación(29).

En los últimos años se ha observado la introducción en el mercado de sistemas de toma de impresión intraoral por medio de escáneres ópticos, para tratar de mejorar la exactitud de las impresiones y la comodidad del dentista y del paciente(30). Estos dispositivos proporcionan ficheros con sistemas de datos, habitualmente en lenguaje de teselación estándar, en inglés *standard tesellation language* (STL). Esos ficheros permiten la reconstrucción digital de modelos virtuales.

La segunda parte de la Tesis, que dio lugar a un segundo artículo, trataba de establecer la exactitud de diferentes sistemas de impresión de implantes convencionales y digitales, en arcada parcial y en arcada completa. El trabajo en arcada parcial se realizó con un modelo de acrílico con dos implantes con un espacio edéntulo intermedio, evaluando tres tipos de impresiones convencionales (cubeta abierta, cubeta cerrada sin ferulizar los pilares y cubeta cerrada ferulizando los pilares) y cuatro sistemas de impresión óptica intraoral (Carestream 3600, Trios, Omnicam y Truedefinition), llegando a la conclusión de que las impresiones ópticas en un cuadrante eran más exactas que las impresiones convencionales. La segunda parte del trabajo, en arcada completa y con resultados similares, no se llegó a enviar a publicar por haberse publicado poco antes dos artículos muy semejantes que restaban novedad y relevancia a los resultados. Los resultados obtenidos y las conclusiones nos llevaron a pasar a una fase de evaluación clínica en boca, que dio lugar al tercer artículo.

Todos los trabajos deben tener como finalidad la aplicación en boca de los pacientes. Por ello, dado que nuestras conclusiones de laboratorio eran muy positivas con los sistemas de impresión óptica intraoral, decidimos comparar clínicamente la exactitud de los dos sistemas, convencional y digital. Para ello diseñamos un estudio en el que se fabricaron dos prótesis de óxido de circonio implanto-soportadas para arcada completa idénticas para cada participante, fabricadas una a partir de un escaneado intraoral y otra a partir de un modelo convencional obtenido de una impresión mediante elastómeros. Se compararon a

doble ciego ambas prótesis en boca para determinar la superioridad, o en su caso, la no inferioridad, de un tipo de prótesis respecto a otro.

Al desarrollar el protocolo del trabajo clínico, observamos la posibilidad de llevar a cabo una secuencia clínica particular que llevase a la realización de prótesis fija de arcada completa implanto-soportadas para carga inmediata siguiendo un flujo totalmente digital, y que ha sido publicado como técnica clínica en una revista indexada de primer cuartil JCR.

Al hablar impresiones es necesario tener presente el significado de conceptos como exactitud, veracidad y precisión. De acuerdo a la norma ISO 5725-1(31), utilizamos el término "exactitud" para describir la cercanía de una serie de mediciones al valor verdadero. Para que exista exactitud debe haber a su vez "precisión" y "veracidad". "Veracidad" es la cercanía de la media de un grupo de mediciones al valor verdadero, mientras que "precisión" es la cercanía de los diferentes resultados entre sí. Dentro del concepto precisión podemos englobar dos conceptos más, repetitividad y reproducibilidad. "Repetitividad" se refiere a la variación que se produce entre resultados obtenidos en una repetición de mediciones en las mismas condiciones y por el mismo operador. "Reproducibilidad" se refiere a la variación que se produce entre resultados obtenidos en una repetición de mediciones modificando los instrumentos y/o los operadores(31).

PUBLICACIONES:

Esta investigación ha tenido tres fases de trabajo, que han dado lugar a sendas publicaciones, y una cuarta parte adicional consistente en desarrollar una técnica clínica a partir de los aprendizajes del estudio, publicada también:

1. Impacto de la morfología y longitud de los pilares de impresión en los sistemas de impresión con elastómeros in vitro. Publicado en Journal of Clinical Experimental Dentistry, 2019, volumen 11, número 8, páginas 707 a 712. DOI: 10.4317/jecd.55888
2. Determinación in vitro de la exactitud de impresiones convencionales con dos tipos de toma de impresión por medio de elastómeros y diferentes escáneres intraorales. Publicado en PLOS ONE, 2020, volumen 15, número 2, páginas e0228266. DOI: 10.1371/journal.pone.0228266
3. Comparación clínica del ajuste de estructuras de zirconio de arcada completa implanto-soportadas obtenidas a partir de un flujo digital frente al de estructuras de idéntico diseño obtenidas a partir de un flujo convencional (con elastómeros). Publicado en The Journal of Prosthetic Dentistry, 2020, en prensa.
4. A partir de las conclusiones del estudio hemos desarrollado un protocolo clínico para la utilización del flujo digital en carga inmediata de arcadas completas. Publicado en The Journal of Prosthetic Dentistry, 2019, previsualizable online, en prensa. DOI: 10.1016/j.prosdent.2019.08.008

ARTICLE 1. Impact of design and length on the accuracy of closed tray transfer copings

Published in Journal of Clinical experimental Dentistry, 2019, volume 11, number 8, pages 707 to 712. DOI: 10.4317/jecd.55888

ARTÍCULO 1. Impacto del diseño y longitud en la exactitud de pilares de impresión de cubeta cerrada.

Publicado en Journal of Clinical Experimental Dentistry, 2019, volumen 11, número 8, páginas 707 a 712. DOI: 10.4317/jecd.55888

IMPACT OF DESIGN AND LENGTH ON THE ACCURACY OF CLOSED TRAY TRANSFER COPINGS

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RESUMEN

OBJETIVO: El propósito de este estudio fue evaluar la exactitud de dos pilares de impresión de implantes de cubeta cerrada (un nuevo diseño frente a un diseño antiguo) en dos diferentes longitudes (largo y corto). **MATERIAL Y MÉTODOS:** Se evaluaron cuatro grupos de pilares de impresión (NS – nuevo corto, NL – nuevo largo, OS – viejo corto y OL – viejo largo). Se preparó un modelo de resina epóxica con ausencia de los dientes 1.4, 1.5 and 1.6. Se colocaron dos análogos de implante Alpha-Bio en posición de los dientes 1.4 y 1.6, con una angulación de 10 grados. Dos operadores calibrados tomaron 10 impresiones de cubeta cerrada con poliéter en cubeta Rim-Lock a cada grupo. **RESULTADOS:** Tras medir y comparar las impresiones, se encontró una diferencia significativa entre los dos pilares nuevos y el pilar corto viejo. **CONCLUSIONES:** El diseño del nuevo pilar mejoraba significativamente la exactitud de la impresión. Un diseño adecuado del pilar de impresión para técnica de impresión de cubeta cerrada puede ayudar a obtener impresiones clinicamente aceptables para puentes implanto-soportados de dos unidades.

ABSTRACT

PURPOSE: The aim of this study was to evaluate the accuracy of two closed-tray transfer copings for implant impressions (a new design vs. an old design) in two different lengths (short and long). **MATERIALS AND METHODS:** Four groups of transfer copings (NS - new short, NL - new long, OS - old short and OL - old long) were tested. An epoxy resin model was prepared of missing teeth 1.4, 1.5 and 1.6. Two Alpha-Bio analogues were placed in

position of teeth 1.4 and 1.6, at a 10^{o} angulation. Two calibrated operators took 10 closed-tray impressions for each group with polyether in a Rim-Lock impression tray. **RESULTS:** After measuring and comparing impressions, a significant difference was found between the two new transfer copings and the old short transfer coping. **CONCLUSIONS:** The new transfer coping design significantly improved impression accuracy. An adequate transfer coping design for the closed-tray impression technique can help to achieve clinically acceptable impressions for two-unit implant supported bridges.

INTRODUCTION

One of the key factors for a successful prosthetic treatment is the accuracy of the implant impressions (1). To do this, the clinician must choose the optimum impression technique, transfer coping and material for each case.

There are two techniques for taking implant level impressions: the open tray technique and the closed tray technique. Taking impressions with the closed tray technique entails a clinical and a laboratory step. The clinical step consists of screwing the transfer coping into the implant, after which an impression is taken. The laboratory step involves the repositioning of the transfer coping in the impression and then pouring it to obtain a cast model. However, many factors intervene in these two steps that may slightly alter the position of the implant in the cast (2-4). Some studies have reported the number of variables involved in this process implies that a true passive fit of multi-implant-supported prostheses is unattainable (5). These variables include tolerance among the

components of the implant systems, changes in the materials, as well as the clinician´s skill at accurately repositioning the impression transfer copings and correctly connecting the components.

The imprecise fit of the prosthetic superstructure may subject these components to stress, consequently resulting in mechanical complications, including screw loosening, screw fracture, occlusal inaccuracies, implant fracture, as well as biologic consequences, such as increased plaque accumulation and tissue retraction, which often lead to peri-implant bone loss (6-8). In order to prevent possible complications, every effort must be taken to ensure an accurate impression and master model. Both open tray and closed tray impression techniques are widely used in clinical practice for transferring the position of the implant to the working cast, for which the choice of the transfer coping plays a decisive role.

Depending on the implant system, impression transfer copings come in different shapes, lengths, widths, retention systems and depths of indentations, all of which can affect the accuracy of final impression (5, 9). The shape and retention system are two factors that must be considered in the design of closed tray transfer copings. Shape refers to the conicity and to the presence of a flat surface, which provides not only the insertion path for the transfer coping in the impression but also prevents rotation. The retention system maintains the transfer coping in place in the vertical axis.

The present *in vitro* study compares the accuracy of closed tray impression transfer copings in two different geometries (Groups O and N). Group O consists of the old

design, which has a conical-trunk shape with two wide flat surfaces and two narrow ones. Group N consists of the new design, which is cylindrical shaped with a flat surface. The differences between these two groups according to the retention system are the oval-shaped tip in Group O, whereas Group N has two horizontal grooved notches. In addition, two different lengths (short and long) of transfer copings where tested for these two groups(IFigure 1).

The aim of the present study was to compare the accuracy of four different implant transfer copings for the closed-tray technique in a standardised *in vitro* setting.

HYPOTHESIS

Alternative (H1): There are differences among the four different closed tray transfer copings.

Null (H0): There are no differences among the four different closed tray transfer copings.

MATERIALS AND METHODS

1.1 Master model making

Epoxy resin was used to fabricate a master model of missing teeth 1.4, 1.5 and 1.6 with two internal conical standard connection Alpha-Bio analogues (Alpha-Bio, Israel) in position 1.4 and 1.6 with a 10^{o} angulation. A scan body was then screwed into each analogue, after which the model was scanned thrice with an industrial scanner

(Steinbichler COMET L3D, Zeiss, Germany). Each scan was exported as a Stereolithographic (STL) file and imported into Geomagic Control X software (3D systems, USA), with which a cylinder was drawn in accordance with the shape of each scan body. A plane was sketched on top of the cylinder and was then moved 10 mm apically along the length of the scan body(Figure 2). The intersection between the plane and the axis of the cylinder was identified as the centre of the analogue head, or centroid. The Best Fit method was used to compare the three STLs by aligning them in pairs. The mean difference between the centroids measured was acceptably precise (no more than 20 µm); therefore, the shortest file was selected as the STL reference file.

1.2 Closed tray impressions

Closed tray impressions of the master model were taken by two calibrated experienced operators (10) using four different types of transfer copings.

Four cycles of ten impressions were taken following the same protocol, in which the type of the transfer coping was randomly selected. After every 10 impressions, the master model was re-scanned and compared to assess possible alterations during the process.

For each impression, two closed-tray transfer copings were screwed into the analogues using a 10 Ncm torque, and the impressions were taken with polyether (Impregum Penta 3M ESPE, St. Paul, MN EEUU), in accordance with the manufacturer's instructions. A syringe was used to place the material around the transfer copings, and then a Rim-Lock tray was filled with the same material and placed on the master model. Once the

material had set, the impression was removed from the master model. Subsequently, the transfer copings were unscrewed from the master model and the implant analogues were inserted into them. The transfer copings were repositioned in the impression at magnification 3.8x under good lighting. At 30 minutes, CAD/CAM stone plaster (Ventura scan stone, Madespa, Spain) was mixed in a vacuum, according to the water/powder proportions recommended by the manufacturer and poured into the impression. Once the plaster had set, the impression tray was removed and the transfer copings were replaced by the scan bodies. As each scan body has six possible positions in the implant analogue, care was taken to place them in the same position as in the reference model. The model was then scanned using a dental desktop scanner (D200 3Shape, Copenhagen) and exported as an STL file.

1.3 Data Comparison

Geomagic Control X software was used to superimpose the STL reference file over the STL test files, then the STL scan bodies were aligned, using Best fit alignment, and exported as a single file.

Each centroid was established using the same procedure used for the reference model(Figure 3). The 3D distance between the two centroids was measured and the mean between the groups was compared using one-way analysis of variance (ANOVA).

RESULTS

Comparison of distance between points: The distance between the centroids, the centre of the implant heads, (point 1 and 2) in the STL reference file and STL test files were compared. No significant difference was found among Groups NS, NL and OL or between OS and OL. However, a significant difference was observed among Groups NS and OS as well as between NL and OS ($p > 0.05$)(Table 1). The Box-and-Whiskers plot shows the results obtained with the different transfer copings(Table 2).

Angular displacement: The two reference vectors (vector 1 and 2) compared using Best Fit showed no significant difference among any of the groups ($p > 0.05$). The comparison of all the transfer copings revealed a significant difference among the groups, the new transfer coping coming closer to the reference measurement of the model (Table 3).

DISCUSSION

No differences were found between the STL files of the master model taken after every ten impressions, indicating there were no changes in the model after the impressions.

The Best Fit method was used to superimpose the impression over the working model, locating a position between the two scan bodies simultaneously, thus distributing the discrepancy between points 1 and 2. This method is more clinically relevant, since this

is the accepted method for testing the accuracy of a superstructure over implants. The first scan body could also provide a reference in order to match point 1 in the STL reference file with point 1 in the STL test file, allowing all the differences to be measured in point 2.

Our results showed minimal changes in the position of the centroid in both implants 1 and 2. Group OS yielded a significantly poorer result than that of the NL and the NS did. No significant difference was observed between OL and OS. No significant difference was found among the OL and the NS and NL. The new design of the transfer coping appears to perform better than the old one, and the long transfer coping of the old design performs better that short one.

Some authors have claimed that the open tray impression technique is more accurate than the closed tray impression technique(11). Nevertheless, there is a preference for the closed tray technique for its easy handling, yet some studies argue that the open-tray technique is similarly accurate(12-14) and that the influence of the impression material and technique appears to be significant for highly non-axial implant angulations. Moreover, those differences are non-significant if the axial angulation remains small(15). Hence, we prepared a model with a 10^{o} axial angulation between two implants. Our results suggest that the overall difference was minor, and that the new design offered significantly improved results over the old one.

CONCLUSIONS

The new transfer coping design significantly improved impression accuracy. An adequate transfer coping design for the closed-tray impression technique can help to achieve clinically acceptable impressions for two-unit implant supported bridges.

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FIGURES AND TABLES

Figure 1. Main view of the two different implant transfers (green is the "old", silver is the “new”) in short and long lengths

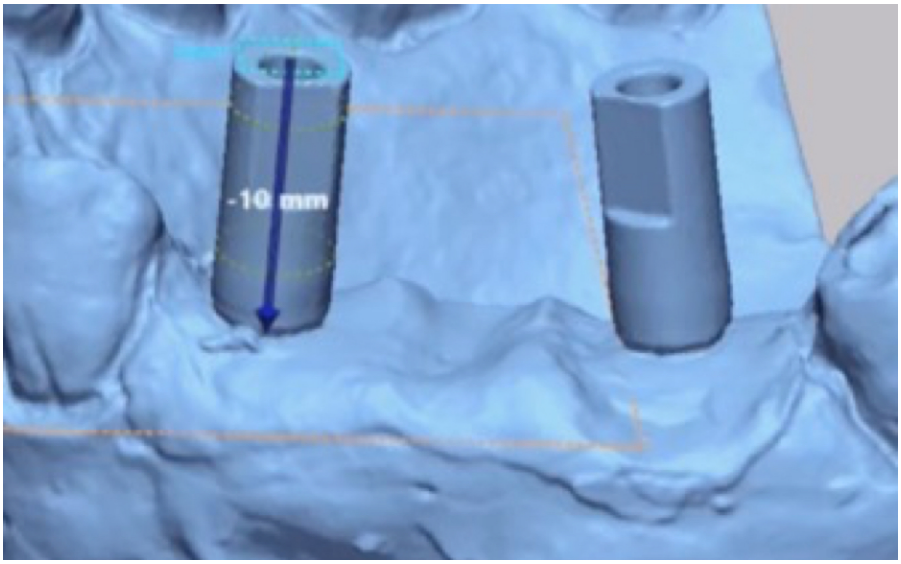

Figure 2. A plane was sketched on top of the cylinder and was then moved 10 mm apically along the length of the scan body. The centroid was determined by intersection of the apically moved plane and the axis of the scan body.

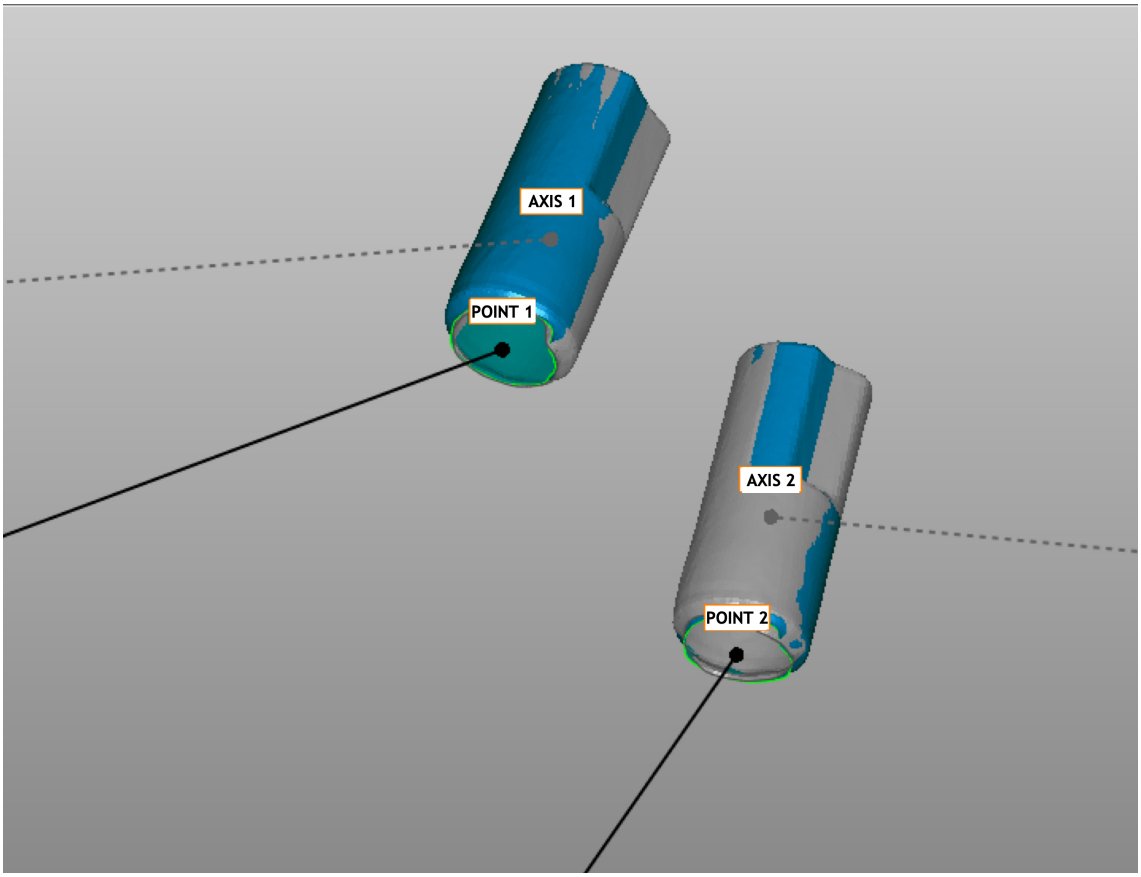

Figure 3. The center of the implant head and the axis of the scan body (which is the same as the implant axis) is determined.

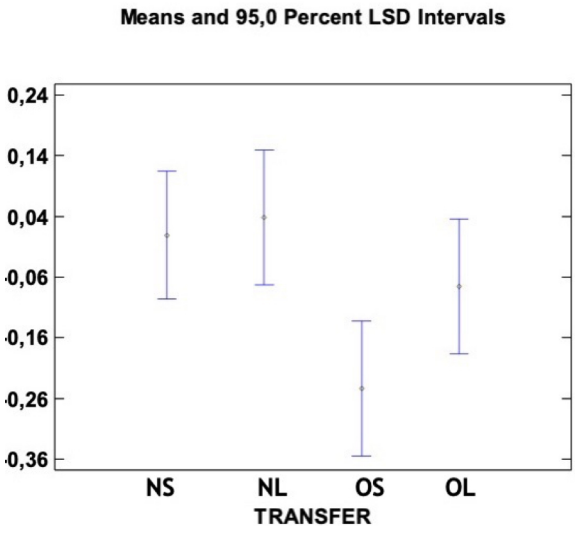

Table 1. Means and 95% LSD intervals for the difference between the center of the two implants in the test model and the difference between the center of the two implants in the reference model in the four transfer coping types. Value "0" corresponds to the reference value. There is significant difference between groups NS and OS and between groups NL and OL. There is not significant difference between the other groups.

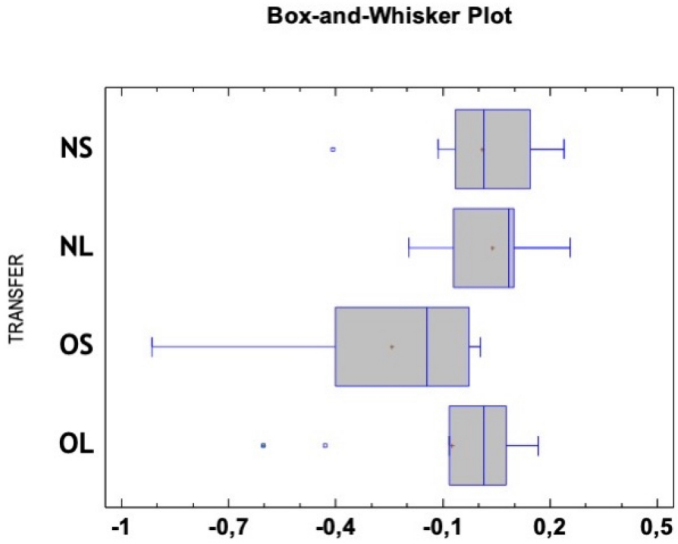

Table 2. Box-and-Whisker Plot showing the distance between the two implants centrE in all groups. Each value is the difference between the measurement in the test model and in the reference model. Value "0" corresponds to the reference value.

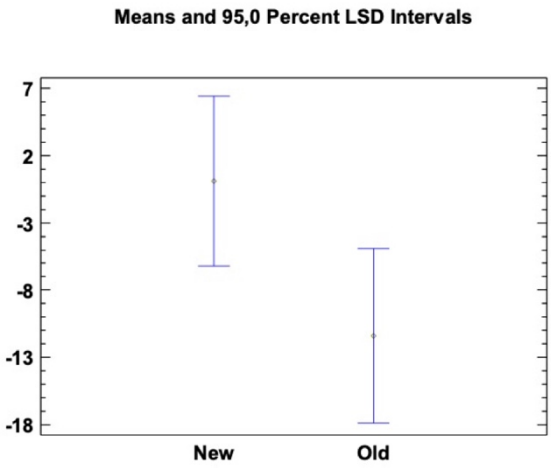

Table 3. Angle between the two implants axis in the reference model and in the test model. There is significant difference according to means and 95% LSD intervals. New and old transfer copings are grouped. Value "0" corresponds to the reference angle.

ARTICLE 2. In vitro comparison of the accuracy of four intraoral scanners and three conventional impression methods for two neighboring implants.

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ARTÍCULO 2. Comparación in vitro de la exactitud de cuatro escáneres intraorales y tres métodos de impresión convencional para dos implantes contiguos.

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IN VITRO COMPARISON OF THE ACCURACY OF FOUR INTRAORAL SCANNERS AND THREE CONVENTIONAL IMPRESSION METHODS FOR TWO NEIGHBORING IMPLANTS

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RESUMEN

Objetivo: Determinar si la exactitud de las impresiones de modelos de dos implantes tomadas con escáneres ópticos era inferior a la de las tomadas con materiales elastoméricos. **Materiales y Métodos:** Se tomaron impresiones de un modelo de referencia con dos implantes casi paralelos utilizando tres impresiones elastoméricas (técnica de cubeta cerrada, técnica de cubeta abierta sin ferulizar y técnica de cubeta abierta ferulizada) y se escaneó con cuatro escáneres ópticos ((CEREC Omnicam®, 3M™ True Definition Scanner®, 3Shape TRIOS3® and Carestream CS 3600®). Los STL obtenidos con los diferentes métodos se superpusieron y analizaron con un software de control (Geomagic® Control X™, 3D systems) para determinar la desviación media entre los escáneres. **Resultados:** Comparadas con las impresiones elastoméricas, las impresiones ópticas mostraron una precisión media significativamente mejorada. TRIOS3® y CS3600® mostraron una veracidad media significativamente mejor que las de la cubeta cerrada, CEREC Omnicam® y TrueDefinition®. Todos los métodos mostraron un cierto grado de rotación de los implantes sobre sus ejes, siendo significativamente mayor en las impresiones de cubeta cerrada y cubeta abierta no ferulizada. **Conclusiones:** Las impresiones ópticas, tomadas en las condiciones in vitro de este estudio, mostraron una exactitud mejor que las tomadas con elastómeros.

ABSTRACT

Purpose: To determine whether the accuracy of two-implant model impressions taken with optical scanners was inferior to that of those taken with elastomeric materials. **Materials and Methods:** Impressions of a resin reference model with two almost parallel implants were taken using three elastomeric impressions (closed tray technique, open tray nonsplinted technique and open tray splinted technique) and scanned with four optical scanners (CEREC Omnicam, 3M™ True Definition Scanner, 3Shape TRIOS3® and Carestream CS 3600). STL files of the different methods were superimposed and analyzed with control software (Geomagic® Control X™, 3D systems) to determine the mean deviation between scans. **Results:** Compared to elastomeric impressions, optical impressions showed a significantly improved mean precision. TRIOS3® and CS3600® showed a significantly improved mean trueness compared to that of closed tray, CEREC Omnicam and TrueDefinition®. All methods showed a certain degree of implant rotation over their axes, which was significantly higher in the closed tray and the open tray nonsplinted techniques. **Conclusions:** Optical impressions, taken under these in vitro conditions, showed improved accuracy compared with that of elastomeric impressions.

INTRODUCTION

Accuracy is crucial to the true passive fit of implant prostheses[1], which the existing clinical procedures and laboratory fabrication methods are unable to achieve. Without a true passive fit, also called misfit, the stresses in the implanted prostheses are directly

transferred to the mechanical components and surrounding bone[2]. Misfit may lead to bacterial microleakage, screw loosening or component stress and fracture[3-5].

Taking impressions using elastomeric materials to capture the position of the dental implant has become the most widely used technique and remains the gold standard. However, the elastomeric method has procedural shortcomings, and this technique is uncomfortable for the patient and inconvenient for the clinician[6-8].

To address these downsides and to maintain or improve the accuracy of elastomeric methods, several new optical impression systems have been introduced to the market[9]. These systems appear to improve patient experience[10-12] and reduce material costs and time[11, 13]. Some authors believe these optical impression systems have minimal distortion, which confers adequate clinical longevity to the prosthesis due to acceptably associated stress[14]; but these systems are, at present, unable to achieve a true “passive” fit. However, when used for short bridges or crowns, these systems fulfil the minimum requirements of accuracy[15]. A number of studies have reported that the inaccuracies associated with the systems used for implant impressions are too significant to be acceptable[16]. Although some studies claim that these systems provide sufficient accuracy in complete-arch impressions, scientific evidence on the intraoral scanning of complete-arches with teeth is lacking and outdated[17]. Elastomeric impressions of complete arches are significantly more accurate than those of optical arches[18] and the precision of intraoral scanners decreases as the distance between each scan body increases[19-21]. However, when only two implants are scanned, the accuracy of IOS improves[22]. In the case of IOS, in contrast to conventional impressions, the angulation of the implants does not affect the accuracy [23]. Digital

systems have gained wider acceptance in dentistry due to the emergence of more user-friendly and more accurate systems.

The verdict on digital impression accuracy remains inconclusive, and direct comparisons between implant impressions and digital alternatives are needed[24]. The present study aims to compare the accuracy of optical impressions recorded by several intraoral scanners with the accuracy of conventional impressions using elastomeric materials over implants in a partially edentulous model. To this end, we selected four optical systems: TrueDefinition (3M, USA), TRIOS3 (3Shape, Copenhagen, Denmark), CEREC Omnicam (Dentsply-Sirona, Bensheim, Germany), and CS3600 (Carestream, Atlanta, USA). The null hypothesis of the present study was that optical intraoral impressions were less accurate than conventional implant impressions were.

According to ISO 5725[24], the term “accuracy” refers to both trueness and precision. “Trueness” denotes the closeness of agreement between the arithmetic mean of a large number of test results and the “true” or accepted reference value. “Precision”, referring to the closeness of agreement between test results, is normally expressed in terms of standard deviations. To evaluate accuracy, both trueness and precision must be assessed.

The clinically acceptable degree of inaccuracy is difficult to determine because even minimal discrepancies seem to cause significant stress in the framework[4]. Some authors consider 30 µm to be acceptable[25], while other studies have proposed a limit of 150 µm to avoid long-term prosthetic problems[26].

However, the purpose of this study was not to determine the acceptable degree of inaccuracy but to establish whether optical impression systems were inferior to conventional impression systems in a two-implant model.

MATERIALS AND METHODS

Epoxy resin was used to fabricate a master model with teeth 1.4, 1.5 and 1.6 missing and restored with two internal connection implants at an almost parallel configuration (C1 MIS Implants, MIS-Implants Inc., Shlomi, Israel) in positions 1.4 and 1.6. A scan body (Scan Post CS-SP102, MIS implants) was screwed onto each implant, and the model was scanned three times with a desktop scanner (3Shape D810; 3Shape, Copenhagen, Denmark) (Figure 1). Three stereolithographic (STL) files obtained from the scanner were imported into Geomagic® Control X™ (3D Systems Inc., Rock Hill, SC, USA) and aligned by pairs using the best fit method. The axis of the scan body was established, after which a plane was constructed on its coronal flat surface (plane 1) and then moved 10 mm apically (offset 1). The intersection between the offset and the scan body axis was identified as the center of the implant analog head, or centroid (point 1) (Figure 2). The differences between the centroids in each STL file were measured. The STL file with the least differences was selected as the STL reference file.

Impressions of the model were taken using 4 intraoral optical scanners and 3 conventional impression techniques, and ten impressions were fabricated for each group.

Optical intraoral scanners

The scan bodies were screwed into the implants position closest to that in the reference model, with a 10 Ncm screwing torque. Two calibrated operators used each scanner to take five optical impressions of the model, and these scans were exported as STL files. The scanning protocol was started at the second right molar, the tooth distal to the distal implant, and subsequently the scanner was swept over the occlusal surface up to the first left molar. Returning to the second right molar, the operator rolled and wiggled the scanner to capture the buccal-palatal surfaces up to the second left molar. The following groups were studied:

1. **Group CS**. CS3600® 3.1 (Carestream, USA)
2. **Group TR**. TRIOS3® 1.18.2.10 (3Shape TRIOS®, Denmark)
3. **Group OC**. CEREC Omnicam SW4.6.1 (Dentsply Sirona, Germany)
4. **Group TD**. TrueDefinition® L51 V01.33 (3M™ True Definition, Germany). To facilitate scanning with this scanner, powder (3M High resolution scanning spray, 3M, Germany) was first sprayed onto the model surface.

Conventional impressions

5. **Group CT** - closed tray impression. After placing two closed tray impression copings (CS IC485, MIS implants) onto the dental implants of the master model, a polyether halfway (Impregum Penta; 3M ESPE, Germany) complete arch impression was taken following the manufacturer's instructions. Rim-Lock metal trays (Dentsply Sirona, Orange, USA) without polyether adhesive were used.

Once the material had set, the impression was removed from the model. Subsequently, the transfer copings were unscrewed from the master model, and the implant analogs were repositioned under 3.8x magnification and good lighting into the transfer copings. One hour later, CAD/CAM type IV stone plaster (Ventura scan stone, Madespa, Spain) was vacuum-mixed, in accordance with the water/powder proportions (20 ml, 100 g) recommended by the manufacturer, and poured into the impression. According to the manufacturer, expansion at 2 h is 0.08%. After 2 h, the impression tray was removed, and the transfer copings were replaced with the scan bodies. Given that each scan body has six possible positions in the implant analog, utmost care was taken to place the two scan bodies in the same position as that in the reference model. Subsequently, the model was scanned using a desktop scanner (D810; 3Shape®, Copenhagen, Denmark), and an STL file was obtained.

6. **Group OS** - open tray splinted impression. Two open tray implant impression copings (CS IO485, MIS implants) were placed on the dental implant, where they were splinted and unified with a clear colorless Triad gel light cure material (Dentsply International, York, PA), which was polymerized for at least 60 seconds in each section. After polymerization, the resin structure was cut using a 0.8 diamond disk approximately halfway between the implants. Twenty-four hours later, the structure was resplinted with tiny amounts of the same gel to reduce the shrinkage of the resin. A plastic tray (Impression Tray, 3M ESPE) was perforated with two holes corresponding to the positions of the transfer copings to allow the placement and removal of the screws. An impression was taken with polyether, in accordance with the manufacturer's instructions. Once the

impression material had set, the impression was removed by unscrewing the transfer copings. Implant analogs were then screwed into the transfer copings fixed to the impression. The impression was then poured, as in group CT.

7. **Group ON** - open tray non-splinted impression. Two open tray transfer impression copings (CS IO485, MIS implants) were screwed into the dental implants. Two perforations were made in a plastic tray (Impression Tray, 3M ESPE) according to the positions of the transfer copings to allow the placement and removal of the screws. The impressions were then taken and poured, as in the OS group.

Two calibrated operators took the impressions using the scanners that they had been trained to use following the same scanning protocol. As differences between operators have been shown, operators completed a one-hour session on how to take elastomeric impressions[27].

Different measurements were taken to assess accuracy:

3D displacement of the centroids

Geomagic® Control X™ was used to superimpose the STL test files over the STL reference files. The STL scan bodies were then aligned using the reference alignment and the best fit alignment and exported as a single file.

After determining a point at the center of each implant head, also called the centroid[29], each scan body axis was established. This procedure provided data on the three-dimensional axes (x, y and z-axes) as the coordinate values that are transformed

into linear and angular data. Then, the distances between the reference files and the test centroids were analyzed (Figure 3). The reference and best fit superimposition methods were used. In the reference method, the test STL and the reference STL were aligned with the first implant using a scan body, while for the best fit method, all the scan bodies were aligned with the implants at the same time. The best fit method distributes the differences among all implants, while the reference method shows the maximum possible differences.

Distance between the two implant centers

The distance between the centers of each implant head was measured and subtracted from the distance in the reference (Figure 4).

Rotation of the implants over their axes

After constructing a plane on a wall parallel to the axis of each scan body, the angle between the two planes was determined (Figure 5). The deviation was then calculated by subtracting the angle of the reference model.

Precision

Precision was analyzed by comparing each set of STL files with all STL files taken with the same scanning system. The root mean square (RMS) error obtained was used to assess precision[30].

Levene's test and the Shapiro-Wilk test ($p<0.05$) were used to determine normality of variance and distribution. One-way analysis of variance (ANOVA) with Fisher's least significant difference (LSD) post hoc test was used to compare means between groups

(p<0.05). Statgraphics centurion XVII software (Statgraphics Technologies, Virginia, USA) was used to analyze the results.

RESULTS

3D displacement of the centroids

Significant differences (p<0.05) were observed with one-way analysis of variance (ANOVA). As significant differences were found (p<0.05), the LSD post hoc test was used to identify homogeneous groups. Group means were compared in pairs to ensure homogeneity (Table 1). The results of Carestream 3600 and TRIOS3 were significantly inferior to those of the closed tray technique, open tray technique, CEREC Omnicam and True Definition scanning systems.

Multiple Range Test for Point by System

	POINT 1		POINT 2	
System	Mean (mm)	Homogeneous Groups	Mean (mm)	Homogeneous Groups
CS3600®	0.012	X	0.018	X
Master model	0.018	X X	0.020	X
Trios3®	0.019	X	0.024	X X
Close tray	0.034	X	0.047	X
Open tray non-splinted	0.047	X	0.056	X
Open tray splinted	0.059	X	0.060	X X
CEREC Omnicam	0.225	X	0.063	X X
TrueDefinition®	0.235	X	0.078	X

Method: 95,0 percent LSD

Within each columm, the levels containing X's form a group of means within there are no statistically significant differences.

Table 1. Comparison of the mean distance between each implant head center in the STL test file and the STL reference file. As significant differences were found ($p<0.05$), the LSD post hoc test

Distance between the two implant centers

Figure 6 shows the distances between the two centroids of the test model and the reference model. The distances of the optical impression groups did not appear to be inferior to those of the conventional groups.

Rotation of the implants over their axes

All systems used showed a certain degree of rotation. The differences in the angle between the two flat horizontal surfaces of the two implants in the test and the reference models are shown in Figure 7. The nonsplinted elastomeric impressions

revealed significantly inferior results than those of the optical impressions. No significant differences were found between the open splinted elastomeric impressions and any of the other 6 impression systems analyzed or between the closed impression and any of the other six impression systems (Table 2).

Multiple Range Test for Angle by System

System	Mean (Degree of rotation)	Homogeneous Groups
Open tray non-splinted	86.040	X
CEREC Omnicam	87.568	X X
CS3600®	88.259	X X X
Open tray splinted	88.939	X X X X
Close tray	90.296	X X X
Trios3®	90.579	X X
TrueDefinition®	92.153	X

Method: 95,0 percent LSD

Within each columm, the levels containing X's form a group of means within there are no statistically significant differences.

Table 2. Comparison of the implant rotation over their axes for each group.

Precision

No significant differences were observed between the optical impressions. In addition, these impressions were significantly more precise than the elastomeric impressions ($p<0.05$) (Table 3). No significant difference was found between the two open tray methods, although both methods were significantly more precise than the closed tray method ($p<0.05$) (Figure 8).

Multiple Range Test for Precision by System

System	Mean (mm.)	Homogeneous Groups
TrueDefinition®	0.027	X
Trios3®	0.029	X
CEREC Omnicam	0.034	X
CS3600®	0.042	X
Open tray non-splinted	0.113	X
Open tray splinted	0.121	X
Close tray	0.227	X

Method: 95,0 percent LSD

Within each columm, the levels containing X's form a group of means within there are no statistically significant differences.

Table 3. Comparison of the precision among systems.

DISCUSSION

Two samples (CEREC Omnicam and CS3600) were discarded because they could not be aligned with less than 20 µm of misfit, despite the calibration of the operators. Both discarded files revealed evident defects in the impressions. Following the same protocol as that for conventional impressions, the clinician must carefully check optical impressions for defects before delivering them to the technician. If a defect is identified, then a new optical impression must be taken.

Regarding the precision of conventional impressions, in the conditions of our in vitro study, conventional impressions are significantly less precise than optical impressions are. It is important to highlight the high variability in different studies on linear and 3D distortion values, which range between 2 µm and 180 µm [30-33]. According to Baig

[34], there is currently no evidence to support the splinting of impression copings to improve implant impression accuracy. Nevertheless, our results with respect to conventional impressions are similar to those of Izadi et al., who also found that open tray impressions were better than closed tray impressions [35]. The type of implant used might also contribute to differences in accuracy. Osman et al. also concluded that open tray impressions were more accurate than closed tray impressions, although in some implants, there was no difference [23]. Osman et al showed that the accuracy values were low, but these authors only measured the horizontal discrepancy in micrometers, whereas in the case of vertical discrepancy, a qualitative assessment of the presence or absence of discrepancy was performed. In our case, overall 3D discrepancy was measured[23]. Additionally, the type of gypsum might explain the differences between the studies, although some authors consider that the type of gypsum used is not important[36], while other authors claim better accuracy for certain types of gypsum [37]. The morphology and length of the impression copying can also determine differences between different studies[38].

Both the test and the reference STL files were aligned using Geomagic reference fit and best fit options. The reference fit option superimposes the first scan body and then calculates the difference between the centroid of the first and the second scan body[39]. Nevertheless, as superimposition is never perfect[39], the error is magnified in the subsequent scan body. Therefore, we discarded the models based on the first implant references and used the best fit option, which aligns the two scan bodies simultaneously. When screwing the bridge on several implants, the clinician never screws on each implant individually but alternates between the implants. Once all screw joints have been

tightened, the final torque is applied. This procedure compensates for any inaccuracies. The final result we obtained was the maximum difference in every implant, instead of the increasing difference in every next implant.

As the impression-taking process in all the groups took almost two months, we had to scan the master model every week to ensure its stability and to check whether any possible variations in the position and rotation of the implants occurred in the master model. A mean deviation below 6 μm indicated that the model was stable and that there were no changes in the implant position over time[40].

According to our results, under in vitro conditions, optical scanners are not inferior to conventional techniques for taking impressions of two almost parallel implants between teeth. Nevertheless, the results of the present study do not necessarily correspond to the clinical results. In the case of optical impressions, the presence of humidity and the mobility of the soft tissues surrounding the scan bodies can significantly affect the scanning process and the impression accuracy. In the case of elastomeric impressions, humidity can also alter the accuracy of the results. Closed tray impressions were significantly less accurate in terms of 3D displacement than were splinted open tray impressions. No significant difference was found between closed tray and nonsplinted open tray impressions or between splinted and nonsplinted open tray impressions.

Given that some studies have claimed polyether to be more accurate than polyvinyl siloxane impression material, we chose polyether for conventional impressions[41]. Knowing that time can affect impression accuracy, we waited one hour before pouring the impression[7]. Water to powder proportions were followed according to the manufacturer's instructions. Although some authors have claimed that conventional

impressions are more accurate than optical impressions for two consecutive implants[16], our results did not show an inferior performance of the optical impression techniques when compared to conventional impressions. These findings could be because the many steps involved (impression making stages, master cast, resin verification jig, waxing, investing, casting, veneer addition and finishing) can distort the final outcome[1]. The optical devices yielded a result in the range of 50-60 μm, suggesting these devices could be used for clinical impressions.

No significant difference was found between splinted and nonsplinted open tray impressions in the present study. This finding is in accordance with studies claiming that when highly rigid impression material (such as polyether) is used, the splinting of pick-up impression copings with acrylic resin is not useful to improve precision[42].

One possible issue regarding precision is the rotation of the implant analog, which might clinically affect the model. Implant analog rotation over the axis was determined by the angle between the two vertical flat surfaces of the scan body. Unlike elastomeric impressions, optical impressions appeared to reduce the risk of implant analog rotation. However, elastomeric impressions with splinted abutments rotated less than the nonsplinted abutments. When splinted frameworks with nonengaging connections are required, no rotation occurs, but the use of engaging connections might compromise the clinical result. In open tray impressions, extreme care was taken when placing the implant analogs in the impression transfer copings. All procedures were performed under magnification and good lighting.

The implants used in the model were placed almost parallel to each other, and the distance between them was the ideal for placing a molar and a premolar on top with a premolar pontic between them. According to Chia et al.[43], placing the implants angulated would probably lead to worse results for conventional impressions, while optical results would have probably been less affected. The distance between the implants was relatively wide (one pontic in between), which is not the best scenario for implant impressions[22, 44], but this scenario does not seem to affect conventional impressions[21]. Nevertheless, the results for the optical impressions did not seem to be affected.

A possible limitation of this study is the use of a desktop scanner to evaluate conventional models because it is not as accurate as a probe[22]. Nevertheless, we preferred the use of a desktop scanner because it is still highly accurate[38] and, moreover, a desktop scanner is commonly used by lab technicians to capture conventional models to proceed with their prosthodontic designs.

Another possible limitation is the continuous changes in the device software. Although accuracy should be improved, it could also become worse [22], so continuous assessment of the new software versions is needed.

From a clinical perspective, intraoral scanners have advantages and drawbacks. Patients generally have an overall better perception of IO scanning than of conventional impressions[45]. Optical scanning seems to be a more didactic and preclinical instruction; however, this method requires a rapid increase with multiple practice attempts [46].

CONCLUSIONS

Our findings suggest that optical impressions are superior to elastomeric impressions for placing two implants in one quadrant. Closed tray impression accuracy was significantly lower than that of open tray impressions for placing two implants in one quadrant.

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FIGURE LEGENDS

Figure 1. STL model obtained by scanning the model with the scan bodies screwed onto the implant analogs.

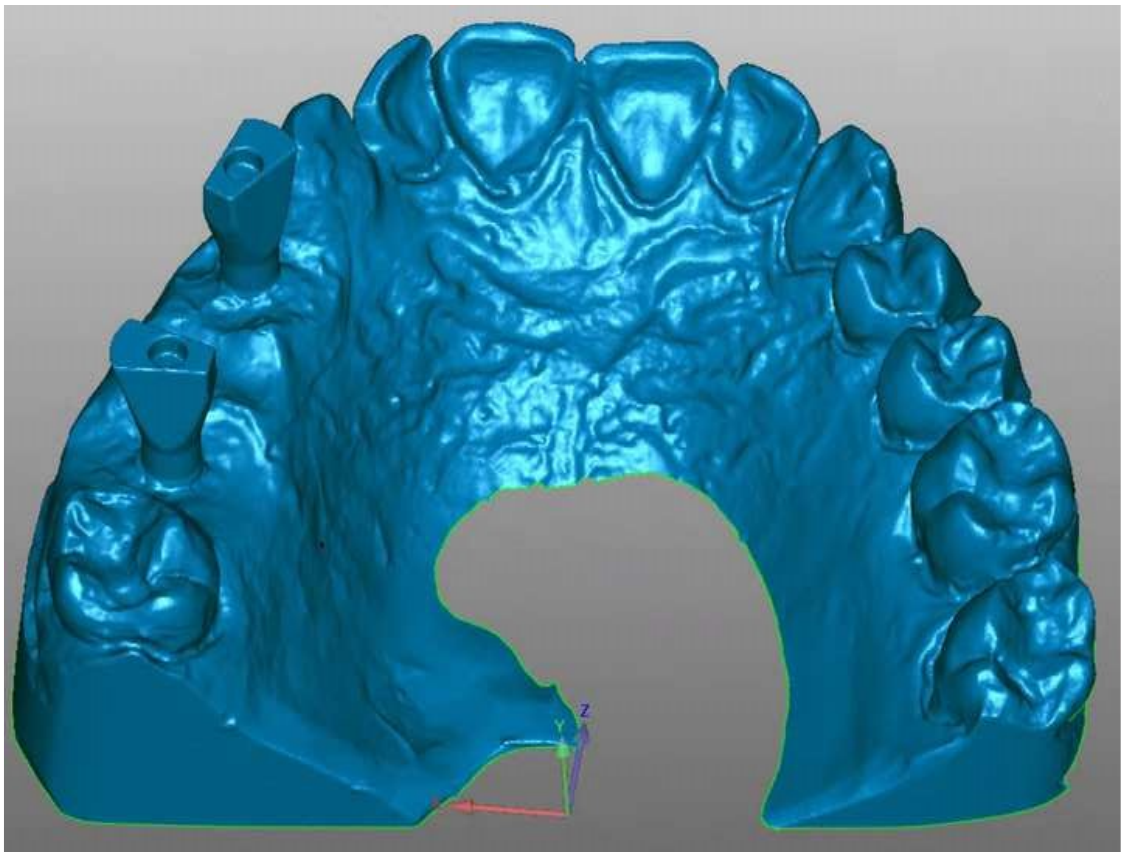


Figure 2. A plane was constructed on top of the scan body (plane 1). An offset plane was obtained by a -10 mm reduction apically (offset 1). A cylinder was constructed based on the shape and the axis (axis 1) of the scan body (cylinder 1). The intersection of offset 1 and axis 1 was considered the center of the implant head, or centroid (Point 1)

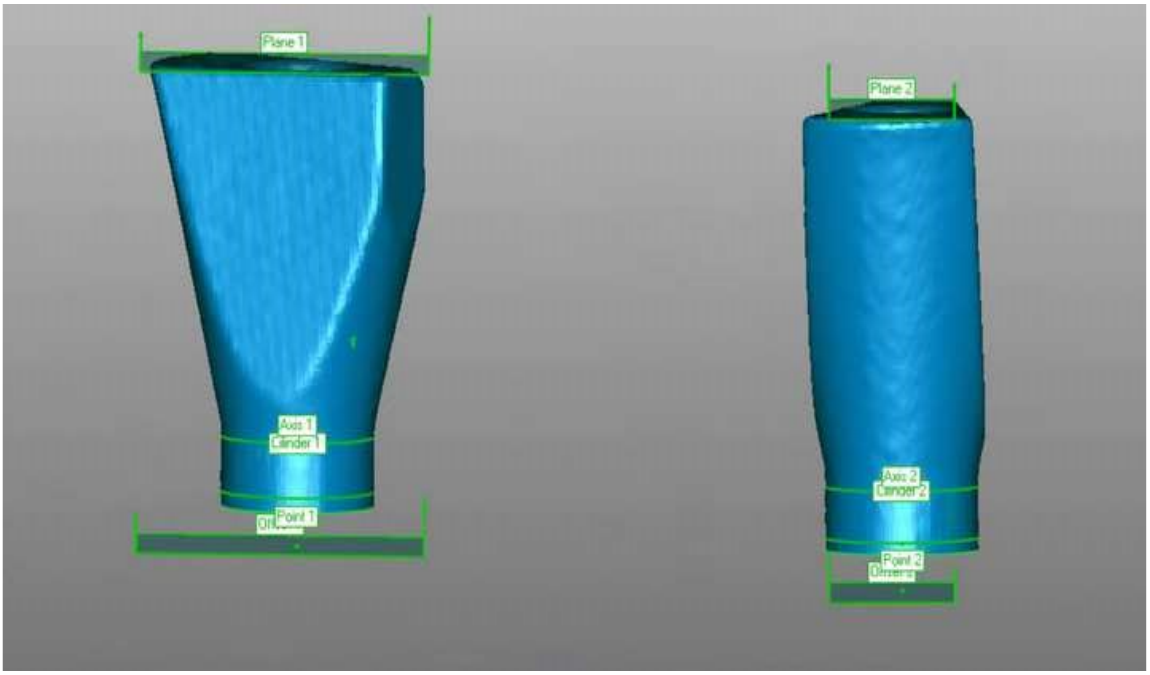


Figure 3. The best fit alignment was used to measure the distance between the two points.

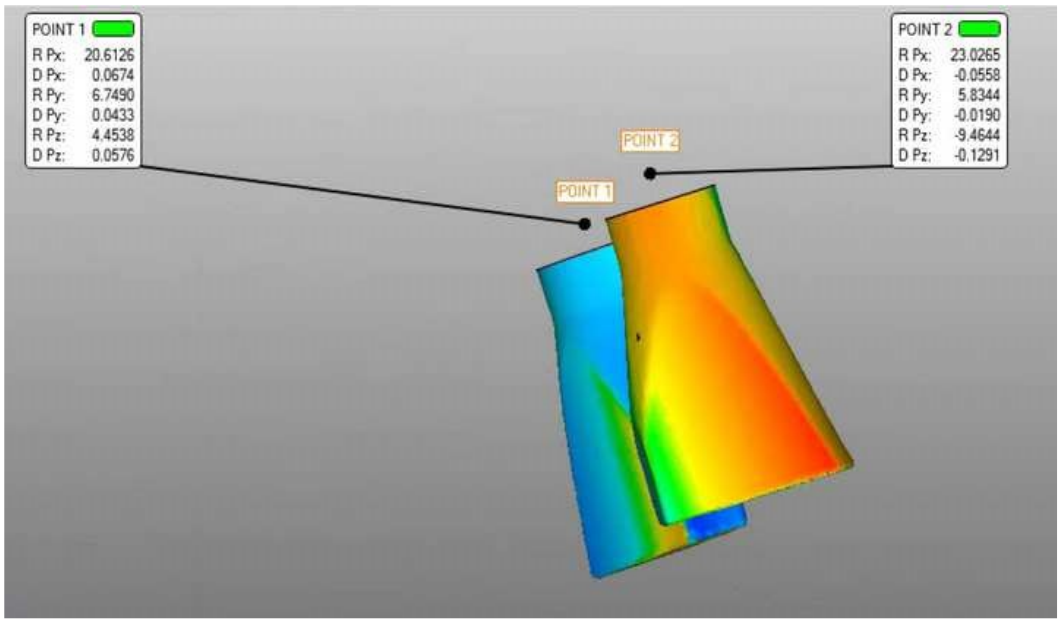


Figure 4. Measuring the distance between the centroids of the two implant heads.

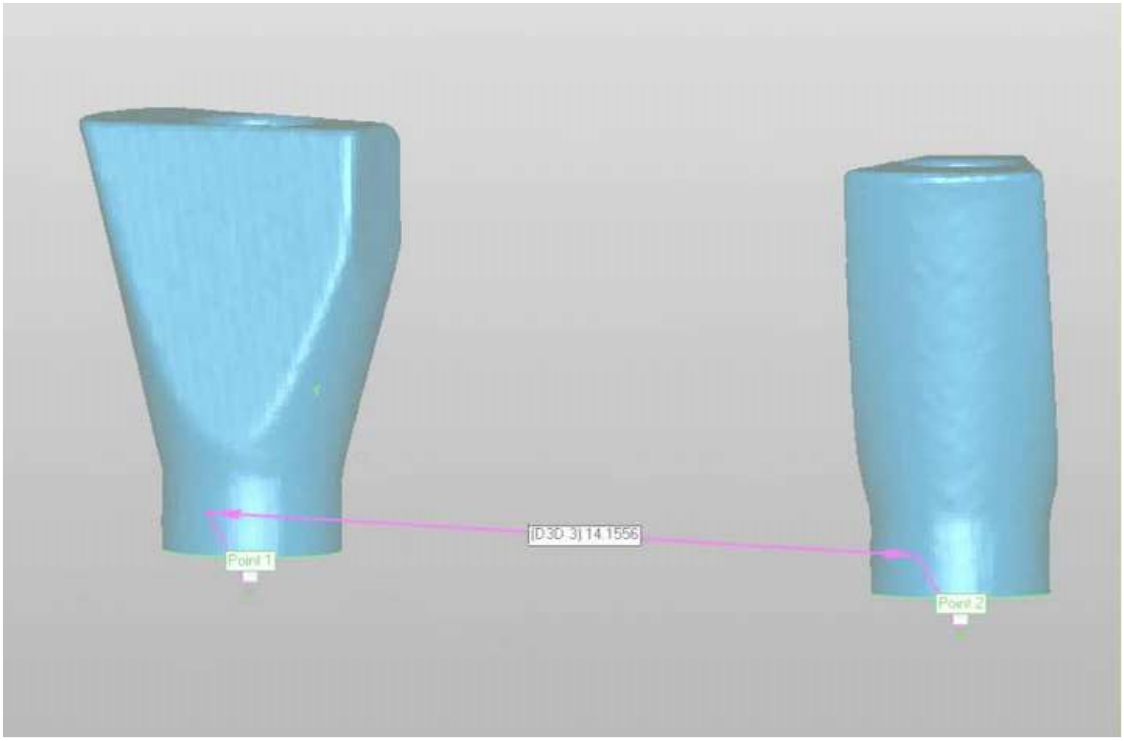


Figure 5. Two planes were constructed on a wall parallel to the implant axis of each scan body, and the angle between them was determined.

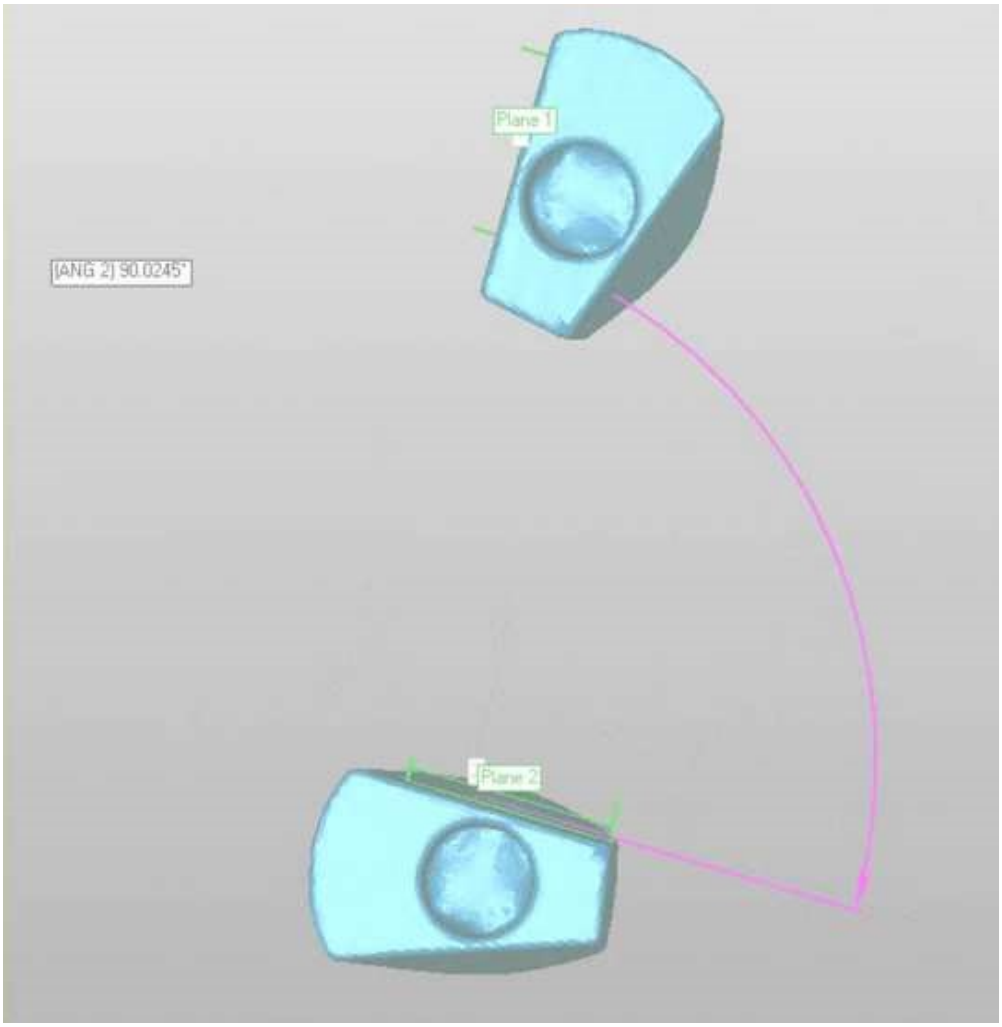


Figure 6. Differences between the distance of the two centroids of the test model and the reference model.

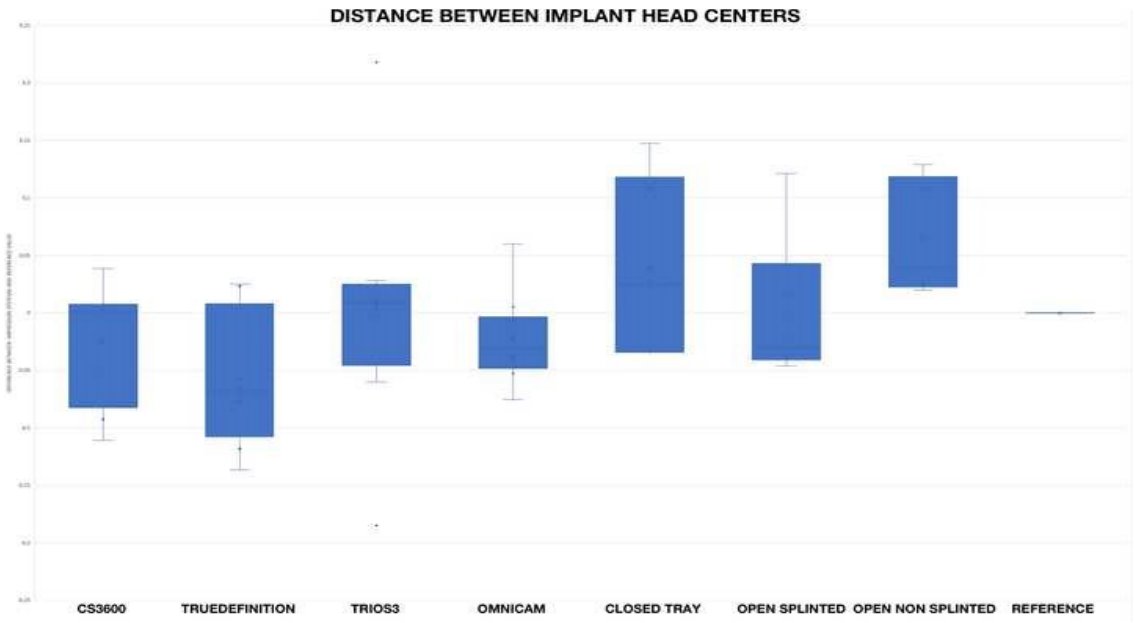


Figure 7. The differences in the angle between the two flat horizontal surfaces of the two implants in the test and the reference models.

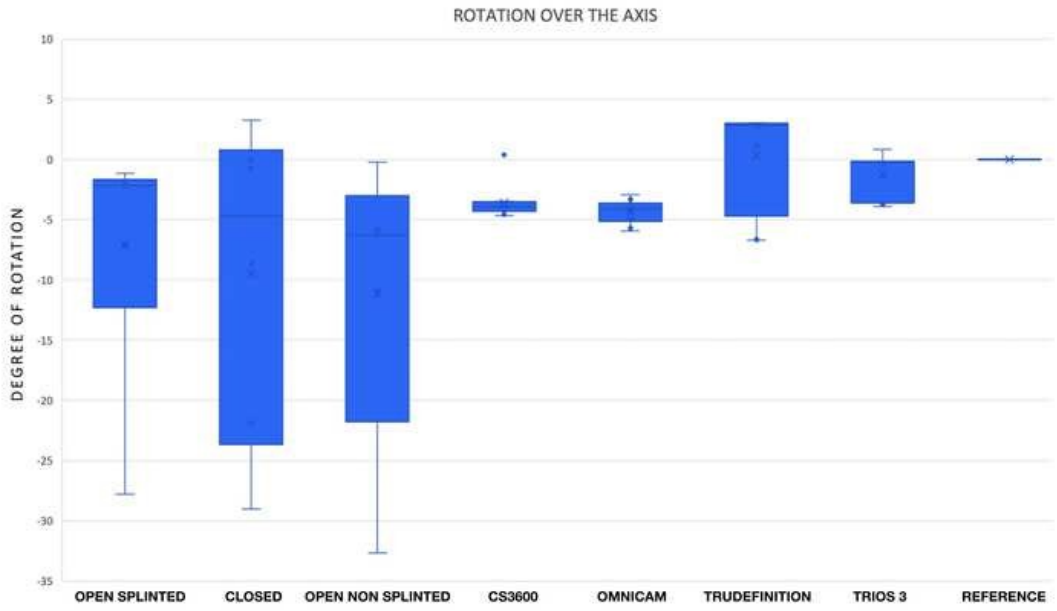
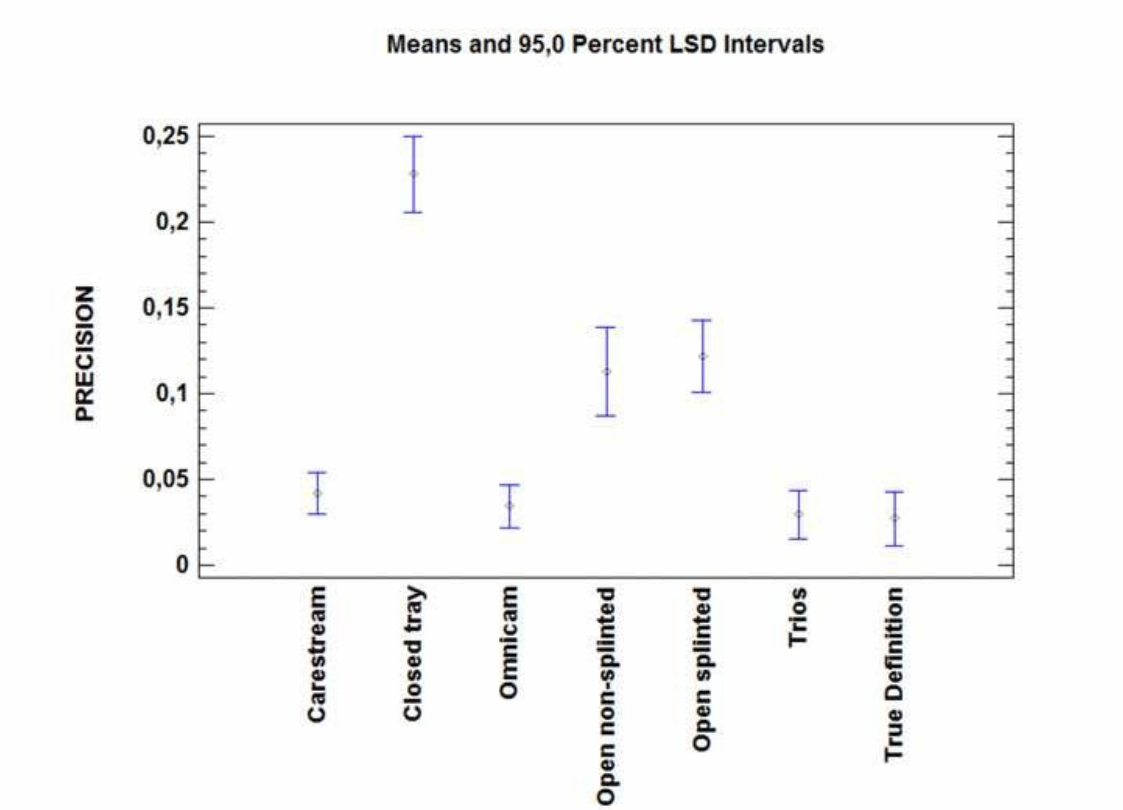


Figure 8. One-way ANOVA comparing the precision of the methods analyzed. The optical methods showed significantly more precision than the elastomeric methods did. The open tray impressions were significantly more precise than the closed tray impressions were ($p<0.05$).



ARTICLE 3. Fit of complete-arch implant-supported prostheses produced from an intraoral scan by using an auxiliary device and from an elastomeric impression: A pilot clinical trial.

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ARTÍCULO 3. Ajuste de una prótesis implanto-soportada de arcada completa fabricada a partir de un escáner intraoral y mediante el uso de un dispositivo auxiliar frente al de una idéntica fabricada a partir de un modelo obtenido de una impresión convencional: un ensayo clínico piloto.

Aceptado para publicación en The Journal of Prosthetic Dentistry

Fit of complete-arch implant-supported prostheses produced from an intraoral scan by using an auxiliary device and from an elastomeric impression: A pilot clinical trial

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RESUMEN

Planteamiento del problema. La exactitud de las prótesis impanto-soportadas es esencial para asegurar un ajuste pasivo de las prótesis definitivas. Los escáneres intraorales han sido desarrollados como una alternativa para las restauraciones

implanto-soportadas de arcada completa. Sin embargo, no está claro si son suficientemente exactas cuando están involucrados más de 3 implantes no alineados.

Objetivo. El objetivo de este estudio clínico piloto fue determinar si el ajuste de las estructuras de circona implanto-soportadas de arcada completa procesadas sobre un modelo obtenido mediante un escáner intraoral y ajustadas con un dispositivo auxiliar eran equivalentes a una prótesis obtenida de una impresión mediante elastómeros.

Material y métodos. Se incluyeron en el estudio doce participantes consecutivos que estaban preparados para una restauración de arcada completa sobre implantes ya osoeintegrados. Se tomaron dos registros, uno de cubeta abierta con poliéter y pilares de impresión ferulizados y otro con un escáner intraoral. Se utilizó una llave de verificación de escayola para las impresiones con elastómeros y un dispositivo auxiliar prefabricado para ajustar los escaneos intraorales. Se procesaron dos estructuras de circona con idéntico diseño que evaluaron intraoralmente por dos observadores independientes calibrados.

Resultados. En 11 de los 12 participantes, se prefirió la prótesis procesada digitalmente frente a la prótesis procesada de forma convencional. El ajuste clínico de las prótesis obtenidas por el flujo de trabajo totalmente digital fue mejor que el de las prótesis obtenidas con el flujo de trabajo convencional.

Conclusiones. El uso de un dispositivo auxiliar prefabricado tras el escaneo intraoral permitió la entrega de prótesis de circona monolítica implanto-soportadas de arcada completa con un ajuste mejor que aquellas fabricadas a partir de impresiones convencionales.

ABSTRACT

Statement of problem. The accuracy of impressions for implant-supported prostheses is essential to ensure a passive fit of the definitive prosthesis. Intraoral scanners (IOSs) have been developed as an alternative for complete-arch implant-supported restorations; however, it is unclear if they are sufficiently accurate when more than 3 nonaligned implants are involved.

Purpose. The purpose of this pilot clinical study was to determine whether the fit of complete-arch zirconia implant-supported frameworks processed on a cast obtained with an IOS and adjusted with an auxiliary device is equivalent to a prosthesis obtained from an elastomeric impression.

Material and methods. Twelve consecutive participants who were ready for complete arch restorations on already osseointegrated implants were enrolled. Two records were made, one open-tray with polyether and splinted impression copings and the second with an IOS. A verification gypsum device was used for the elastomeric impression and a prefabricated auxiliary device was used to adjust the intraoral scans. Two zirconia frameworks with the same design were processed and evaluated intraorally by 2 independent calibrated observers.

Results. In 11 of the 12 participants, the digitally processed prosthesis was preferred over the conventionally processed prosthesis. The clinical fit of prostheses obtained with the completely digital workflow was better than that of prostheses obtained with the conventional workflow.

Conclusions. The use of a prefabricated auxiliary device after intraoral scanning allowed delivery of complete-arch implant-supported monolithic zirconia prostheses with a fit better than those fabricated from conventional impressions.

CLINICAL IMPLICATIONS

Using an appropriate completely digital workflow, it is possible to produce complete-arch implant-supported prostheses with a superior fit to those produced from conventional impressions

INTRODUCTION

An accurate impression is essential to ensure an implant-supported prosthesis with a passive fit.[1] Without a passive fit, the components around the implant prosthetic framework are prone to biological and mechanical problems.[2-5] Even slight discrepancies can produce stress and strain on the framework and the implants,[4] with different effects depending on framework material.[6] The use of rigid frameworks such as those made from zirconia might magnify those effects.[7] Unlike tooth-supported restorations, where up to 100 μm of tooth movement can help absorb a certain amount of misfit, implant movements are limited to 10 μm.[8] Nevertheless, even in such situations, there remains a biologic tolerance to misfit.[9]

Since an absolute passive fit is not achievable,[10] some authors[4,11-15] have proposed an acceptable misfit range from 30 μm to 100 μm, although a quantifiable misfit without adverse effects is difficult to determine.[16,17] Although according to the recommended standard of practice, clinicians try to provide prostheses that exhibit

passive fit,[5,18] there is a lack of clear evidence of the impact of marginal misfit on the clinical outcome.[18] Only mechanical issues related to the screws have been associated with misfit.[18-20] Additional studies with improved designs are needed to determine the impact of misfit on the clinical outcome, the methods to assess misfit, or whether general or behavioral factors can make clinically acceptable misfit different.[18,20]

The most widely used impression systems are based on elastomeric materials, mainly polyvinyl siloxanes and polyether,[21,22] both of which are uncomfortable for the patient and inconvenient for the dental team to handle. Moreover, elastomeric materials are technique-sensitive, since they involve many steps.[23-28] The accuracy of elastomeric impressions is compromised by connection type,[28] impression technique,[28] and implant angulation.[29] Verification casts and splinting materials are required to achieve clinically acceptable accuracy.[29,30] To improve both patient and dental team experience, several optical scan systems have been developed to increase accuracy.[31] Intraoral optical scanners (IOSs) provide a standard tessellation language (STL) dataset, which allows digital reconstruction of a virtual cast. These systems appear to offer similar results to conventional systems when few and aligned implants are involved.[32] Although IOSs have been suggested as an alternative for complete-arch implant-supported restorations,[33] others have observed significant loss of accuracy with IOSs when more than 3 nonaligned implants were involved and when distances between implants were increased.[34-36]

Other systems can also be used for recording implant location, including stereophotogrammetry[37,38] and cone beam computerized tomography (CBCT),[39] both of which enhance accuracy; however, they require intraoral impressions (either optical or conventional) and involve expensive equipment[19] or radiation exposure. To ensure

optimal accuracy and to overcome these drawbacks, an auxiliary device has been proposed (medicalfit; DENTALesthetic) (Fig. 1). This device has been claimed to allow correction of the misfit caused by IOSs, thereby optimizing the fit.[40] The approach involves an additional scan of a reference-marked splint of known dimensions to correct deviations with intraoral optical scan.[40] Custom auxiliary devices have also been proposed to obtain reliable intraoral scans.[41]

The null hypothesis was that the fit of complete-arch implant-supported monolithic zirconia prostheses produced through a full digital workflow, with the final IOS output corrected with the medicafit device, is equivalent to the fit of those fabricated from conventional impressions.

MATERIAL AND METHODS

This clinical trial was approved by the Ethical Research Committee of Universitat Internacional de Catalunya (REST-ECT-2017-03) and registered at ClinicalTrials.gov (NCT03992300). Twelve consecutive participants who were ready for complete arch restorations on 5 to 7 already osseointegrated implants in the upper arch were enrolled. All implants had multiunit abutments (Nobel Biocare). Fifteen consecutive participants were selected during the recruitment period from April 2019 to March 2020. Three patients declined to take part in the study after reading the informed consent. The final sample size consisted of 12 patients: one who had 5 implants, two with 7 implants, and nine with 6 implants, for a total of 78 implants. Two records were made for each participant. Envelopes containing the name of one operator and the

record sequence were prepared, and one envelope was randomly selected for each participant.

One record was made using a conventional impression. Open-tray impression copings (Nobel Biocare) were placed using a torque wrench set at 10 N·cm on each implant, with the copings splinted using a Triad Gel light cure clear resin (Dentsply International), leaving at least a 3-mm diameter in the resin connectors. To avoid structural stress, a 0.3-mm bur was used to cut the resin down the center between the two connectors. The copings were then splinted again with a drop of the same resin. A polyether impression (Impregum; 3M ESPE) was made using a perforated plastic tray, and a master cast was fabricated in accordance with the manufacturer's instructions. A plaster verification cast (Snow White Plaster No. 2; Kerr) was fabricated on the master cast[42-43] (Fig. 2). One week later the vertical dimension of occlusion (VDO) was determined and the plaster cast placed on the implants was used to check passivity before proceeding to the definitive prosthesis. In the event of verification cast fracture, a new record would be made.

Additional record of the edentulous arch and the antagonist were made using an IOS (Trios3; 3Shape) (Fig. 3). A double scan of the edentulous arch was made, first with the healing abutments in place and then with the scan bodies (Core3D), in accordance with the manufacturer's recommendations. The scan bodies were then removed, and temporary copings (Nobel Biocare) were screwed onto the multiunit abutments. The medicalfit device was selected, and holes were drilled in the position of each implant to enable the device to fit over the temporary copings. The copings were then splinted to the device using Triad Gel clear resin. After splinting, the medicalfit device was removed and ScAnalog implant replicas (Dynamic Abutment

Solutions) were placed beneath the temporary copings on the medicalfit device, and intraoral scans were obtained (Fig. 4).

Additional extraoral images of the patient's face were made with the scan bodies in place, at rest, in forced smile, and in the frontal and 45-degree lateral views using cheek retractors. The images and STL datasets were sent to the laboratory to fabricate an interim prosthesis. The STL dataset from the medicalfit device scan was imported into Meshmixer (Autodesk Meshmixer, Autodesk Inc) and cut in as many pieces as the number of implants. The best fit feature was used to superimpose each piece onto the original STL output of the medicalfit device, allowing a more accurate positioning of the implants in the virtual cast (Fig. 5).

At the second appointment, a laboratory-made interim polymethyl methacrylate (PMMA) framework was tried in the patient's mouth. Adjustments were made to the occlusal and gingival contours and the esthetic parameters. Once these were corrected, a new IOS image was made with the interim framework in the patient's mouth.

At the follow-up visit, two independent, blinded, calibrated examiners tried two identical full-zirconia prostheses in the patient's mouth (Fig. 6). One framework was fabricated from the conventional cast (CF) and the second with a full digital flow (DF). The only noticeable difference between the two prostheses was a symbol ("∇" for conventional, "O" for digital) in the distal right molar, whose meaning was unknown to the observers.

Fit was assessed according to five criteria: perception of passivity during insertion of the prosthodontic screws, tactile perception, radiographic examination findings,[38] Sheffield test results,[20] and screwing torque.[44]

A visual analogue scale (VAS) was used to assess the perception of passivity during insertion of the prosthodontic screws. The operator marked the level of passivity on a 10-cm line with one end labelled “perfect passivity” and the other end labelled as “no passivity at all”. Thus, the distance between the mark and “perfect passivity” defined the framework passivity.

Marginal fit was examined using an exploratory probe (#23/3 explorer) under 3.8x magnification. Three scores were possible: 0 (no gap perceived), 1 (perception of gap without probing), and 2 (the tip of the probe clearly entered the gap).

After tightening all the screws at 15N·cm, periapical radiographs were made with a positioner (XCP-ORA; Dentsply Rinn) to detect gaps (Fig. 7). Gaps were assessed evaluated from 1 to 5, with 1 being no gap and increasing at 0.15-mm increments until reaching 0.60 mm (score 5).

For the Sheffield test, all the screws except the most distal right screw were loosened. A periapical radiograph was made with a positioning system (XCP-ORA; Dentsply Rinn) to evaluate the gap. Gaps were scored from 1 to 5 using the same approach as mentioned in the previous point.

An additional screwing torque measurement was made on each abutment using the iChiropro motor app (BienAir). All the screws were hand-screwed and then loosened three full turns. Subsequently, the torque was set at 15 N·cm and 5 rpm. The most distal right screw was tightened first, followed by the rest of the screws, going from the most mesial left to the most distal left, and then to the adjacent implant until all the screws were tightened. The torque-time diagram of each screw was analyzed to determine whether the level began to rise at the end of, or throughout, the tightening process. Three scores were possible: 1 for a linear value with a sharp rise at end of the

tightening, 2 for mild continuous growth with a steeper rise at the end, and 3 for a steep rise at the beginning of the tightening (Fig. 8).

The two operators compared the conventional framework with the digital framework (CF and DF) to select the one with the better overall fit. Where there was disagreement between the two operators, a consensus was reached regarding which framework to place. The selected framework was then tested for occlusion, phonetics, and esthetic parameters, and was then placed.

The sequence of the two tests was randomly assigned to each patient.

Since each patient was subject to both conventional and digital techniques, within-patient comparison was used for statistical analysis. The signed rank test was used to evaluate perception of passivity on a visual analogue scale, marginal fit, radiographic fit, Sheffield test, and screwing torque. When superiority was rejected, a noninferiority test for comparison of paired samples was used. A binomial test was used to evaluate the proportional preference for digital impression was significantly different from 0.5. Statistical power of the results was measured with Granmo calculator (IMIM).

RESULTS

The results show that no fractures occurred in the verification gypsum jig, and none of the frameworks processed on the intraoral scan and corrected with the auxiliary device had a fit inferior to those processed on the cast and obtained from the conventional impression. All the prostheses were considered clinically acceptable by the observers.

Table 1 shows the results obtained for perception of passivity on a VAS during insertion. The single rank test showed statistically significant differences between the two systems (Table 2). Figure 9 shows a graphic representation of the distribution of the differences between perception of passivity on a VAS in the analog and in the digital frameworks, with all the differences positive (worse perception of passivity in all frameworks processed from analog impressions). Statistical power of the results was over 80%.

Table 3 shows the results for the examination of the marginal fit with an exploratory probe. The signed rank test did not reject the hypothesis that the scores for the marginal fit with an exploratory probe were independent of the system used at the 95.0% confidence level. Better marginal adaptation with DF than with CF was rejected. Noninferiority of marginal adaptation with DF versus CF was demonstrated (Table 4).

Table 5 shows the results of the radiographic fit. The signed rank test rejected the hypothesis that the scores for radiographic fit were independent of the system used at the 95.0% confidence level (DF better than CF) (Table 6).

Table 7 shows the results for the Sheffield test. The signed rank test rejected the hypothesis that the scores were independent of the system used at the 95.0% confidence level (DF better than CF) (Table 8).

Table 9 shows the results for the screwing torque. The signed rank test did not reject the hypothesis that the scores for the screwing torque were independent of the system used at the 95.0% confidence level. Noninferiority for screwing torque with DF versus CF was demonstrated (Table 10).

Table 11 shows the results for overall performance. Since the P-value for the binomial test was less than 0.05 (0.0032), the hypothesis that the scores were independent of the system used was rejected at the 95.0% confidence level.

DISCUSSION

All the prostheses in this study were placed on multiunit abutments. The results might have been worse had the framework had been placed directly on the implants, since the use of abutments improves accuracy and reduces misfit.[28] The use of interfaces between the framework and multiunit abutments requires manual setting and luting of the interface, which can induce misfit; therefore, this was avoided. Hence, the zirconia framework was directly seated on the multiunit abutments. In order to increase framework resistance to screwing torque, the zirconia width in the screw setting was increased, and longer screws were used. Wear of the titanium abutments is one possible complication in this type of framework,[7] but in order to better determine the fit of the frameworks, it was decided to avoid the use of interfaces.

The medicalfit concept is somewhat similar to that proposed by Iturrate et al.,[41] which is based on a double IOS protocol, one with regular scan bodies and one with an auxiliary device that is designed after the first IOS output is obtained, three-dimensionally (3D) printed, and then luted to the scan bodies. The auxiliary device, thanks to its anatomical landmarks, allows better superimposition of the images obtained from the IOS, thereby improving the accuracy of the system.[41] The medicalfit device thus seems to offer several advantages as a prefabricated device, and it is luted to regular temporary copings. However, with the proposed assessment methods, it

was not possible to control vertical discrepancies. Although radiographic assessment can be very precise when the radiographic beam is perpendicular to the implant long axis, it is clinically impossible to ensure the presence of perfect perpendicularity.[39]

Since ScAnalog replicas are made from PEEK, proper care must be taken when screwing to avoid damage to the threads and incorrectly positioning the replica. This may explain the discrepancy in one of the implants in patient 7's DF prosthesis, and it also may have been responsible for the poorer results obtained with the digital system in that patient, which was the only treatment that showed worse results than the analog system. It might also explain how one implant in patient 7, with a score of 3 in the radiographic fit, had a corresponding score of 1 in the Sheffield test.

The use of complete-arch zirconia frameworks can be successful provided there is a good fit on the implant abutments.[7] Accuracy comparable to that of titanium frameworks can be achieved.[10] Zirconia frameworks flex less and are more likely to break due to stress. Discrepancies of up to 500 µm can disappear when the screws are tightened, even in stiff frameworks, implying stress within the framework.[19] In the case of misfit, the stiffer the material, the greater the stress experienced by the framework,[19] although the impact of stress on the framework and the implants has not been clearly demonstrated.[18-20]

The participants received different numbers of implants. In treatments with fewer implants, the distance between implants was greater, which might have caused problems in the intraoral impression.[36] Nevertheless, a clinically acceptable fit was found in all the digital treatments, probably due to the use of the auxiliary device to provide accuracy to the IOS output.

Angulation of multiunit abutments varied significantly across patients. Although increased angulation might represent a problem of accuracy, it has been demonstrated that even if the angulation is up to 20°, framework fit can be achieved, provided a verification cast is used.[29] In order to ensure maximum accuracy, a verification cast was used in the CF treatments.[29] No fractures were observed in the verification cast, implying that the splinting protocol of the open tray impressions was very accurate. Nevertheless, given the high cost of zirconia frameworks, the limited number of samples used meant it was difficult to determine whether it is reasonable to avoid a verification cast if good splinting has been performed. Triad Gel was used for splinting in this study. Although some studies consider that other materials might be more accurate,[30] from a clinical perspective, the ease of using Triad Gel makes it more suitable for all situations,[29] and it offers acceptable precision and trueness.[29] No fractures occurred in the verification gypsum cast, showing that Triad Gel is an adequate material for splinting.

Misfit should be ideally below 10 µm,[15] but clinical fit is difficult to assess using conventional or quantitative methods.[16-17,19] When using screwing torque to evaluate fit, it is advisable to measure the torque and angle of rotation of the screw.[44] In our study, time instead of the angle of rotation was used. Since the rotating speed was constant (iChiropro also registers rotational speed), time also represents the angle of rotation, and it can be used for torque-angle signature analysis.

In our study, screwing torque showed more passivity in 9 of the 14 digitally processed frameworks, and worse passivity in only 1, but larger samples would be necessary to confirm the superiority of one of the two systems in achieving passivity.

Further studies are also required to address chair-time, dental team experience, patient experience, and overall cost.

CONCLUSIONS

In this study, the use of a prefabricated auxiliary device after intraoral scanning allowed delivery of complete-arch implant-supported monolithic zirconia prostheses with a fit better than those fabricated from conventional impressions.

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TABLES

Table 1. Perception of passivity on a visual analogue scale. Results express the distance in millimeters on a line where 0 cm represents perfect passivity and 10 cm represents an unacceptable lack of passivity

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	0.25	1.80	0.96	0.48	1.34	1.02	1.11	0.96	0.75	0.86	1.3	0.42
DF	O2	0.72	0.24	0.72	0.52	0.74	1.38	1.92	1.32	1.10	1.14	0.88	0.74
CF	O1	2.40	2.77	5.42	5.36	2.45	1.44	1.33	2.77	2.16	2.4	3.45	2.81
CF	O2	0.24	0.24	7.10	1.36	1.95	1.29	2.32	1.98	3.17	2.93	2.92	1.87

Table 2. Signed rank test for the perception of passivity on a visual analogue scale. Perception of passivity during insertion of the prosthodontic screws was significantly better in digital than in analog frameworks.

Count	12
Average	2.40667
Standard deviation	2.10426
Coefficient of variation	87.4345%
Minimum	0.38
Maximum	7.65
Range	7.27
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	0
Average rank of values above hypothesized median	6.5
Large sample test statistic	3.02019 (continued correction applied)
P-Value	0.00252631

Table 3. Marginal fit on a scale from 0 to 2, where “0” represents no gap perceived with the probe, and “1” indicates a gap perceived without the probe entering the gap. FD represents the final decision taken by the two operators when different values had been determined

		Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	0	0	0	0	0	0	0	0	0	0	0	0
DF	O2	0	0	0	1	0	0	1	0	0	0	0	0
DF	FD	0	0	0	1	0	0	1	0	0	0	0	0
CF	O1	0	0	1	1	1	0	0	0	1	0	1	0
CF	O2	0	1	1	1	0	0	0	1	0	1	1	0
CF	FD	0	0	1	1	1	0	0	1	0	1	1	0

Table 4. Noninferiority of digital versus conventional frameworks in marginal fit assessment was demonstrated

Sample Statistics

Sample	n	Minimum	Maximum	Mean	Std. deviation
DIGITAL MF	12	0	1	0.166667	0.389249
ANALOG MF	12	0	1	0.5	0.522233

Equivalence analysis:

Comparison	n	Difference	Stnd. Error	Upper 95% CL
DIGITAL MF v ANALOG MF	12	-0.333333	0.19	0.004

Comparison	Upper t-value	Upper P-value
DIGITAL MF v ANALOG MF	-7.091	0

Comparison	Maximum P-value
DIGITAL MF v ANALOG MF	0

Comparison	Conclusion (alpha=5%)
DIGITAL MF v ANALOG MF	Noninferiority was demonstrated.

Table 5. Radiographic fit rated from 1 (no gap) to 5 (gap > 0.60 mm). The two observers had to agree on the results for each assessment (FD)

		Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	1	1	1	1	1	1	3	1	1	1	1	1
DF	O2	1	1	1	1	1	1	3	1	1	1	1	1
DF	FD	1	1	1	1	1	1	3	1	1	1	1	1
CF	O1	2	2	2	1	2	1	2	2	2	1	2	1
CF	O2	3	2	2	1	1	1	2	1	2	2	2	1
CF	FD	2	2	2	1	2	1	2	2	2	2	2	1

Table 6. Signed rank test for the results of radiographic examinations. Radiographic fit was significantly better in digital than in analog frameworks.

Count	12
Average	0.583333
Standard deviation	0.668558
Coeff. Of variation	114.61%
Minimum	-1.0
Maximum	1.0
Range	2.0
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	5.0
Average rank of values above hypothesized median	5.0
Large sample test statistic	2.26667(continued correction applied)
P-Value	0.0234105

Table 7. Sheffield test results. Scores ranged from 1 (no gap) to 5 (gap > 0.60 mm) with increments of 0.15 mm between each score. Where the two observers did not obtain the same result, they discussed it until a final score (FD) was agreed on for that sample.

		Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	1	3	1	1	2	2	1	1	1	1	2	1
DF	O2	2	1	1	1	1	1	1	1	1	2	1	1
DF	FD	2	2	1	1	1	2	1	1	1	1	2	1
CF	O1	2	3	5	1	3	3	2	3	2	2	3	2
CF	O2	3	2	3	3	2	3	2	3	2	2	3	1
CF	FD	2	3	3	2	3	3	2	3	2	2	3	2

Table 8. Signed rank test for the results of Sheffield test. Sheffield test was significantly better in digital than in analog frameworks.

Count	12
Average	1.16667
Standard deviation	0.57735
Coeff. Of variation	49.4872%
Minimum	0
Maximum	2.0
Range	2.0
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	0
Average rank of values above hypothesized median	6.0
Large sample test statistic	3.02407(continued correction applied)
P-Value	0.00249409

Table 9. Screwing torque results. Scores ranged from 1 (Excellent) to 3 (Regular). Where the two observers did not obtain the same result, they discussed it until a final score (FD) was agreed on for that sample

Screwing torque (1 to 3)

		Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
O1	DF	2	1	2	1	1	1	3	2	1	2	2	1
O2	DF	1	1	1	2	2	1	2	1	2	2	2	1
FD	DF	2	1	2	1	2	1	3	2	1	2	2	1
O1	CF	3	3	2	3	2	2	1	2	3	2	3	2
O2	CF	2	1	2	3	1	3	2	2	2	2	3	2
FD	CF	2	2	2	3	2	2	2	2	2	2	3	2

Table 10. Noninferiority of digital versus conventional frameworks in screwing torque assessment was demonstrated

Sample Statistics

Sample	n	Minimum	Maximum	Mean	Std. deviation
DIGITAL ST	12	1.0	3.0	1.66667	0.651339
ANALOG ST	12	2.0	3.0	2.16667	0.389249

Equivalence analysis:

Comparison	n	Difference	Stnd. Error	Upper 95% CL
DIGITAL ST v ANALOG ST	12	-0.5	0.230283	-0.0864372

Comparison	Upper t-value	Upper P-value
DIGITAL ST v ANALOG ST	12	-0.5

Comparison	Maximum P-value
DIGITAL ST v ANALOG ST	12

Comparison	Conclusion (alpha=5%)
DIGITAL ST v ANALOG ST	12

Table 11. Overall performance results. Scores ranged from DF (digital) and CF (analog). Where the two observers did not obtain the same result, they discussed it until a final score (FD) was agreed on for that sample. Binomial test rejected that the results were independent of the technique (P-value<0.05)

	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
O1	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF
O2	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF
FD	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF

Sample proportion=0.91666
Sample size=12
P-value=0.00317379
Null hypothesis: theta=0.05
Alternative hypothesis: theta>0.5
Values of theta supported by the data>0.66171

FIGURES

Figure 1. The medicalfit device has one flat surface (not shown) and another with anatomic forms. The device is attached to implant abutments by means of temporary abutments.

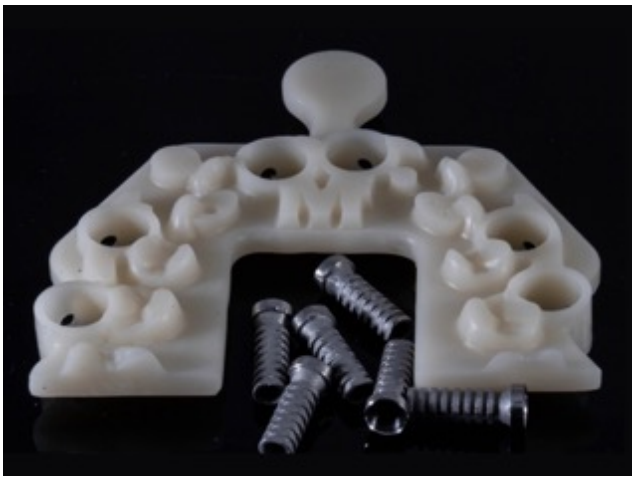


Figure 2. A plaster cast was used to verify the accuracy of the conventional impression.

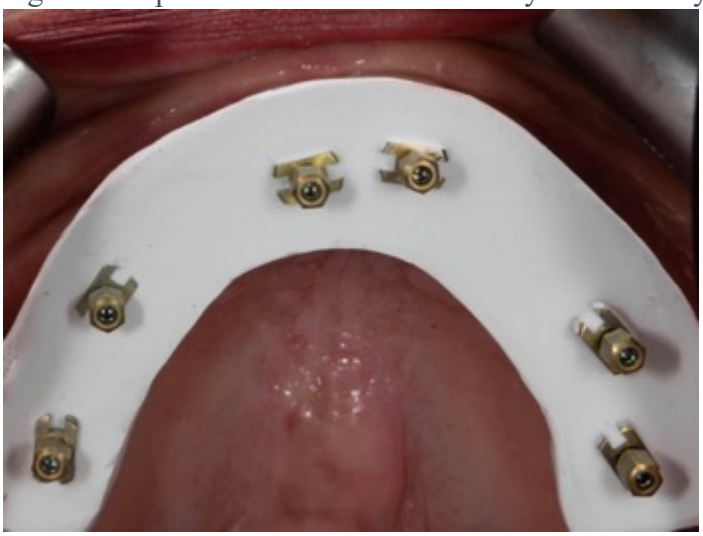


Figure 3. Intraoral impression with scan bodies in place was made with an IOS.

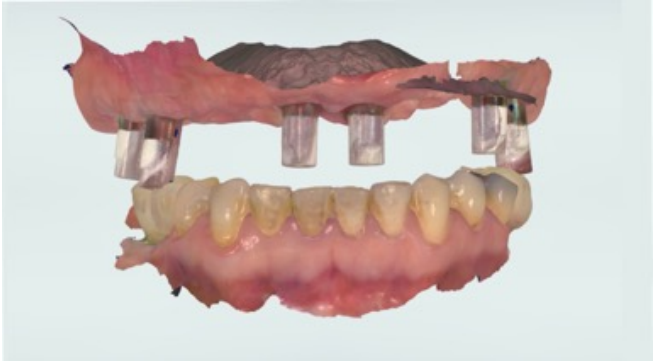


Figure 4. medicafit plate trimmed with the implant position is selected (A) and attached with Triad gel to temporary abutments in the patient's mouth (B). Once removed, ScAnalog scannable replicas are screwed to temporary abutments (C), and STL dataset is obtained with IOS (D).

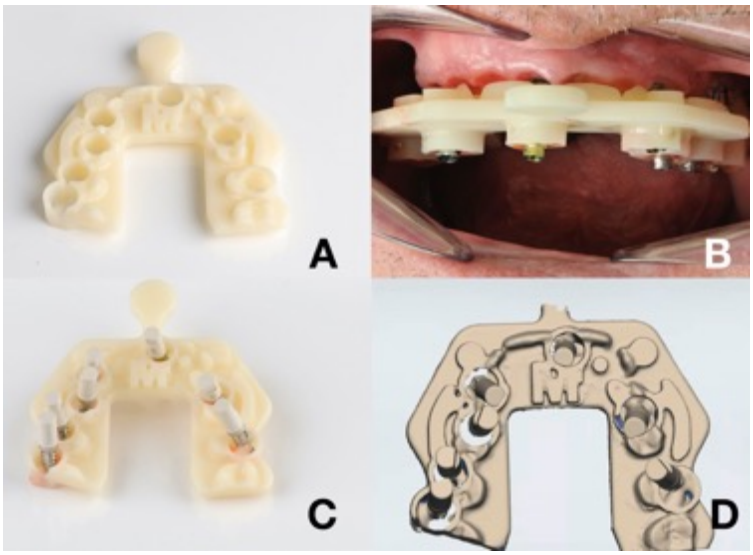


Figure 5. (A) STL dataset of the medicalfit device scanned with IOS is imported into Meshmixer. (B) Each section containing one implant is superimposed, using the best fit tool, on an STL file of the medicalfit device in library. (C) Each implant in the STL dataset obtained using intraoral scanning with scan bodies is sectioned. (D) Each implant is superimposed, using best fit tool, to its corresponding implant in the medicalfit device, yielding a final STL file with a more accurate position of the implants. As shown in the image, the farther the implant was from first implant to be scanned (*), the greater the fit required.

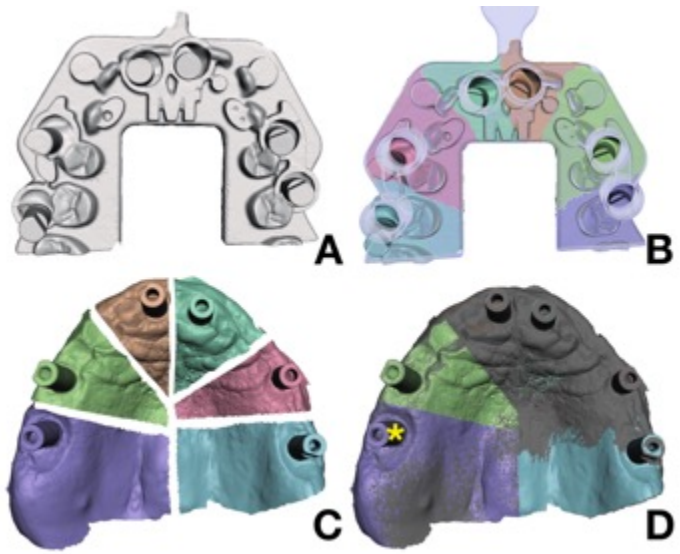


Figure 6. Two almost identical prostheses were delivered to the observers, one produced from digital flow (A) and the other from conventional flow (B).

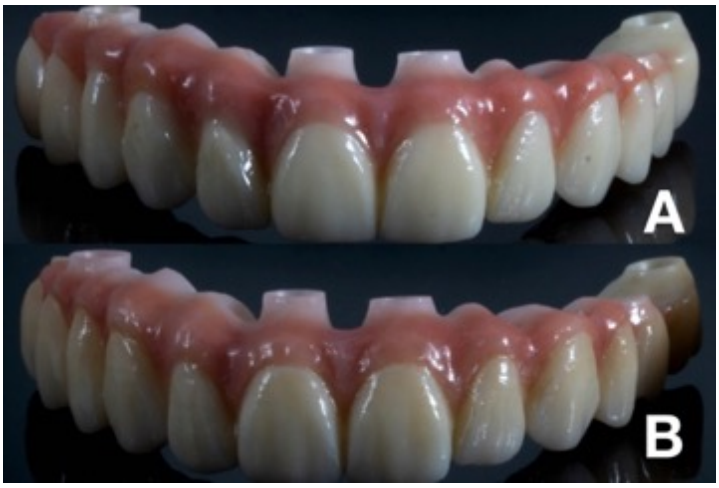


Figure 7. Radiographic assessment of misfit. Although a radiographic guide was used, perfect alignment of radiographic beam is not always possible. Even though a better fit is shown in the digital framework (A) than in the conventional framework (B) in the example, accurate measurement of misfit is difficult.

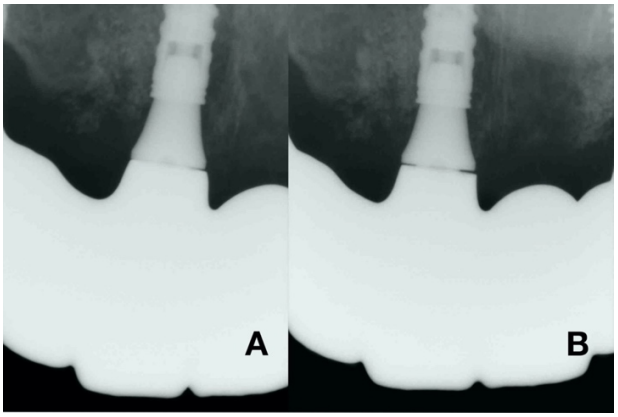


Figure 8. Screwing torque scores. The blue line represents torque and the black line indicates time. (A) Flat torque line with a steep final increase was scored 1. (B) Initial flat line followed by progressive increase was scored 2. (C). Early start of increase was scored 3.

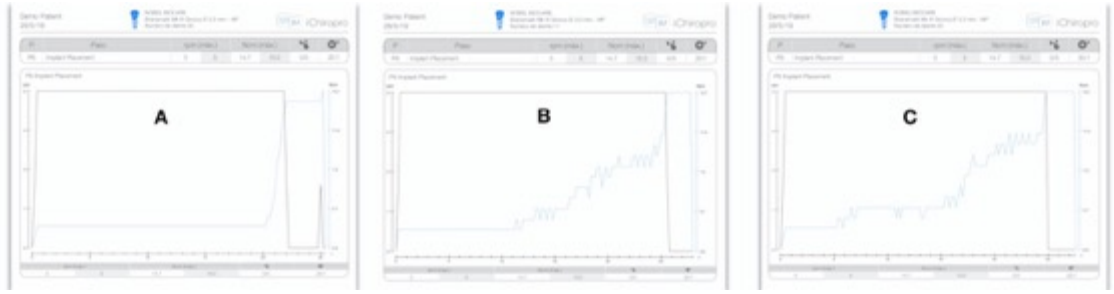
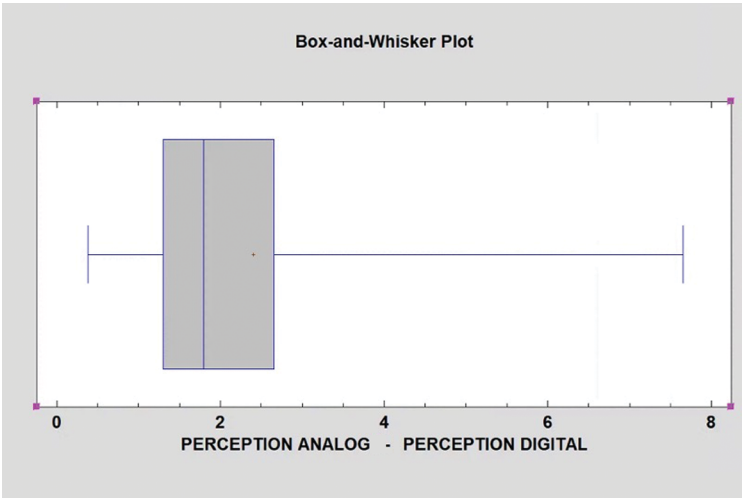


Figure 9. Box-and-Whisker Plot for the perception of passivity on a visual analogue scale and signed ranked test. All differences between perception in the analog and digital tests were positive (worse values in the analog group in all participants).



ARTICLE 4. Immediately loaded interim complete arch implant-supported fixed dental prosthesis fabricated with a completely digital workflow: A clinical technique.

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ARTÍCULO 4. Prótesis dental provisional implanto-soportada de arcada completa con carga inmediata fabricada con un flujo de trabajo totalmente digital: Una técnica clínica.

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Immediately loaded interim complete arch implant-supported fixed dental prosthesis fabricated with a completely digital workflow: A clinical technique

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RESUMEN

Se describe un método digital para entregar una estructura provisional implanto-soportada de arcada completa con carga inmediata. Se utilizan chinchetas de referencia para superponer con exactitud un escaneado postoperatorio con los pilares de escaneo colocados con un escaneado preoperatorio con el diseño de la estructura, incluyendo la relación intermaxilar y el esquema oclusal. Después de la cirugía se utiliza un dispositivo auxiliar prefabricado para capturar la posición de los implantes y,

una vez escaneado, corregir la posición de los implantes por medio de un programa informático libre, permitiendo un excelente ajuste. Esta técnica puede mejorar el ajuste de la estructura, ser más cómoda y necesitar menos tiempo clínico que tomar una impresión intraoral convencional preoperatoria o ajustar una prótesis prefabricada.

ABSTRACT

A digital method for delivering an immediate loading complete arch implant supported interim framework is described. Reference pins are used to accurately superimpose a postoperative scan with the scan bodies in place with a preoperative scan with the framework design, including interocclusal relation and occlusal scheme. A prefabricated auxiliary device is used after the surgery to capture the position of the implants, and once scanned, to correct the position of the implants by means of a free software program, allowing an excellent fit. This technique may improve framework fit and be more comfortable and less time-consuming than intraoperative impression or adjustment of a prosthesis previously fabricated.

INTRODUCTION

Immediate loading protocols for complete arch implant-supported frameworks is a predictable treatment if patient is properly selected and can be considered routine.[1-3] It provides patient-centered benefits as immediate fixed restoration in function,

postoperative discomfort reduction and overall treatment time reduction.[4] It is anyhow a complex procedure that requires adequate knowledge, skill and experience of the clinician.[4] Digital workflows are trying to be introduced in order to simplify the existing protocols, reducing the patients and dental team time.[5, 6] Surgical planning and prosthesis fabrication can be achieved completely digitally.[4] Nevertheless, standard workflow usually includes non-digital procedures such as impression making with elastomeric materials immediately after implant placement, to finish the interim prosthesis in the dental lab, and/or attaching the interim prosthesis to temporary copings by means of acrylic resin or flowable composite resin in the patient mouth.[7-9] Taking records immediately after the surgery or positioning the immediate interim prosthesis on the implants can be compromised by the type of surgery, bleeding or patient consciousness.[10] Transferring the desired vertical dimension of occlusion (VDO) to the prosthesis[11] and placing it in the proper interocclusal relation (ideally centric relation) needs very careful adjustment.[10]

Intraoral optical scan (IOS) might be a good alternative to elastomeric impression right after implant placement. One problem with IOS is the possible insufficient accuracy to allow passive fit of the frameworks in a complete arch implant scenario.[12, 13] Although the quantifiable misfit with mechanical or biological adverse effects has not been determined,[14] and consequences of misfit are uncertain,[15] the closest a prosthesis is to absolute passive fit, the better. The use of an auxiliary device can help to achieve enough accuracy.[16] To simplify the process a prefabricated device, MedicalFit device (MedicalFit) can be used instead of a customized device. MedicalFit is a plastic device with one surface flat and the other with anatomical teeth-forms on top (Figure 1). The device is attached to temporary copings screwed on the implants,

with the anatomic surface towards the implants. The device is then removed, and ScAnalog implant replicas (Dynamic Abutments Solutions) are screwed in the temporary copings attached to the auxiliary device. The device with the scan implant replicas is scanned and sent to the dental technician, who adapts the Standard Tessellation Language (STL) dataset of the scanned device to the STL dataset of the device in his library, to allow an accurate positioning of the implants on the intraoral STL. A second problem that arises with IOS immediately after the surgery is the difficulty to take interocclusal records due to the lack of anatomical references.[17] By placing several pins (Ti-System; Curasan) prior to the surgery, we can enhance accuracy in the overlapping of the presurgical and postsurgical intraoral scanning, allowing the dental technician to work with the interocclusal relation sent in the first set of STL files. Accuracy both in the impression and the intermaxillary relation allow the dental technician to deliver an interim prosthesis with optimal fit, the planned VDO and good occlusion and aesthetics. This implies the possibility of delivering an interim prosthesis in a monolithic material in only three visits, two of them in the same day or in two consecutive days.

TECHNIQUE

Step 1 (Clinical). Initial Clinical recordings. Make and intraoral optical scan (Trios3; 3Shape), including both dental arches and the occlusion (Figure 2). Make front and 45º pictures with mouth at rest, maximum smile, and smile with retractors. All picture must include the eyes. Make a cone beam computerized tomography (CBCT) (Carestream 8100; Carestream) to the patient, to obtain a Digital Imaging and Communications In Medicine (DICOM) file (Figure 3). Import and superimpose both

DICOM and STL datasets into an implant planning software (DTX; Nobelbiocare). Decide the initial treatment planning (Figure 4). Send all files and pictures to the dental technician.

Step 2 (Dental laboratory). Laboratory Import. Import the STL files and photographs into a computer assisted design-computer assisted machining (CAD-CAM) software (Dental System; 3Shape) and design a complete arch framework. Send the STL of the design to the clinician for approval prior to the surgery (Figure 5).

Step 3 (Dental laboratory/Clinician). Prepare surgical guide. Once the design has been approved, import the STL file with the final design into a surgical planning software (DTX) and superimpose it to the original STL file and to the DICOM file. Plan the implants and a surgical guide. Export the surgical guide STL file and 3D print or mill the guide.

Step 4a (Clinical). Reference pins. Place three to four Ti-system pins in the maxilla (or in the mandible depending on the arch to be restored) (Figure 6A). Take care to place them in areas that will not be touched during the surgery, not affecting implants insertion path, flap design or surgical guide sitting. Scan again the arch with the pins in place prior to the surgery (Figure 6B).

Step 4b (Clinical). Implants placement. Extract teeth to secure the surgical guide and place the implants. Leave some teeth if they do not interfere with the surgery to ease the superimposition of the before and after STL files. Select and screw multiunit abutments of the proper height, screw scan bodies (Core3D) to the abutments, and take a new intraoral optical scan, taking care to well capture all pins (Figure 6C).

Step 4c (Clinical). Auxiliary device adjustment. Remove the scan bodies, screw titanium temporary copings to the implant abutment. Adapt a MedicalFit auxiliary

device to the position of the temporary abutments, with the anatomical surface toward the implants, and attach it to the temporary copings by means of TriadGel Clear (Dentsply) or flowable composite resin(Figure 6D).

Step 4d (Clinical). Laboratory import. Once attached, removed the device, screw ScAnalog implant replicas to the temporary abutments, make an optical scan of the scan analogues and the auxiliary device and send it to the dental lab (Figure 7). Send all STL datasets obtained to the dental lab.

Step 5 (Dental Laboratory). Produce the framework. Superimpose the file with the scan bodies and the file with the Medicalfit device, and using a mesh managing software (Autodesk Meshmixer; Autodesk) reposition the scan bodies in the STL from the intraoral impression. Superimpose the corrected STL over the prosthodontic planning. If automatic superimposition does not work, or the result is not the desired one, use the pins as reference. Adapt the already designed framework to the implant analogues in the STL dataset, and then send it to mill. Once milled (in PMMA), send the framework to the clinician. As overall step takes three to four hours, schedule the patient for the next step the same day or if not the following day.

Step 6 (Clinical). Deliver the framework to the patient. Torque the interim framework to the multiunit abutments at 15 Ncm and close the access holes with Teflon tape and composite resin (Esthet-X; DentsplySirona) (Figure 8). Adjust occlusion, do aesthetic corrections (if needed), and give the patient your regular indications for this type of procedures (in our case mainly hygiene protocols and soft diet for three months), to be followed until the next treatment phase.

DISCUSSION

This digital workflow can help to optimize clinical efficiency and quality. It can help not only to achieve a guided surgery and guided prosthesis, but to deliver an interim prothesis with excellent fit, correct VDO and well-controlled occlusion as well, minimizing clinical time.

This technique requires less chair time and is more efficient and more comfortable for the patient than those that imply intraoperative register of implant positions and production of the prosthesis by the dental technician.

In respect to those techniques that imply clinical adaptation of a previously produced prosthesis, that are delivered immediately after implant placement, the proposed technique implies a delay of at least some hours or even one day. Nevertheless, the overall treatment time decreases, and patient comfort increases.

As the interocclusal records with the proposed technique are taken prior to the surgery, it allows an occlusal position almost identical to that designed for the patient, what is difficult to achieve with techniques that need to make those records intraoperative or need to clinically adapt a previously prepared prosthesis directly after the surgery.

The use of and auxiliary device allows a passive fit of the framework. The use of pins as a reference might not be necessary in certain situations where anatomical references as the palate could be use. Nevertheless, as changes in those anatomic references might happen and subsequently affect accuracy in the superimposition of the before and after STL, it seems advisable to use them in all treatments provided a full digital workflow is desired. Use of orthodontic micro-screws, with a larger exposed

head with geometrical forms would ease the superimposition of the models, but pins are enough in our experience and are less traumatic for the patient. Pins with a larger head would probably be a better option for this purpose.

In this protocol we used a non-trimmed MedicalFit device. Adapting the device to make it fit on the temporary abutments is not difficult, but needs some time. If a fully guided surgery is to be done, the dental technician can provide a pretrimmed device to reduce treatment time.

It is extremely important that the device used (in our case MedicalFit) is exactly as the STL in the dental technician library, in order to provide accuracy in the prosthesis. Trying to produce similar devices without being absolutely sure of the accuracy of the device might cause, independently of possible patent violations, important misfit in the delivered prosthesis.

The scan implant replicas (ScAnalog) proposed in this protocol are made out of polyether ether ketone (PEEK), and even a low torque applied can easily strip the threads of the replica, making it necessary to replace them by new ones. Metal threads (not found by us in the market) would make this procedure easier.

In certain last generation scanning software, as the metal of the temporary abutment can be not well captured by the scanner, some ScAnalog implant replicas can be deleted as if they were an artefact. In those situations, partially covering the exposed body of the temporary abutment with flowable composite resin, or just applying contrast powder (Titanium dioxide) on it can help to avoid that inconvenience.

SUMMARY

The described technique may allow to produce interim complete arch implant-supported frameworks for immediate loading obtained from a fully digital work-flow. It avoids the need of intraoperative impressions or to adapt a previously produced prosthesis. The use of an auxiliary device provides excellent fit. The use of surgical pins as references allow accurately transfer the interocclusal position, minimizing the need of intraoral adjustment, reducing chair time and improving patients experience.

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FIGURES

Figure 1. Medicalfit device is a plastic plate which presents one flat surface and one surface with anatomical forms to ease scanning with an intraoral scanning

Figure 2. Initial optical intraoral scan is taken. Lower arch, upper arch and interocclusal relations are taken.

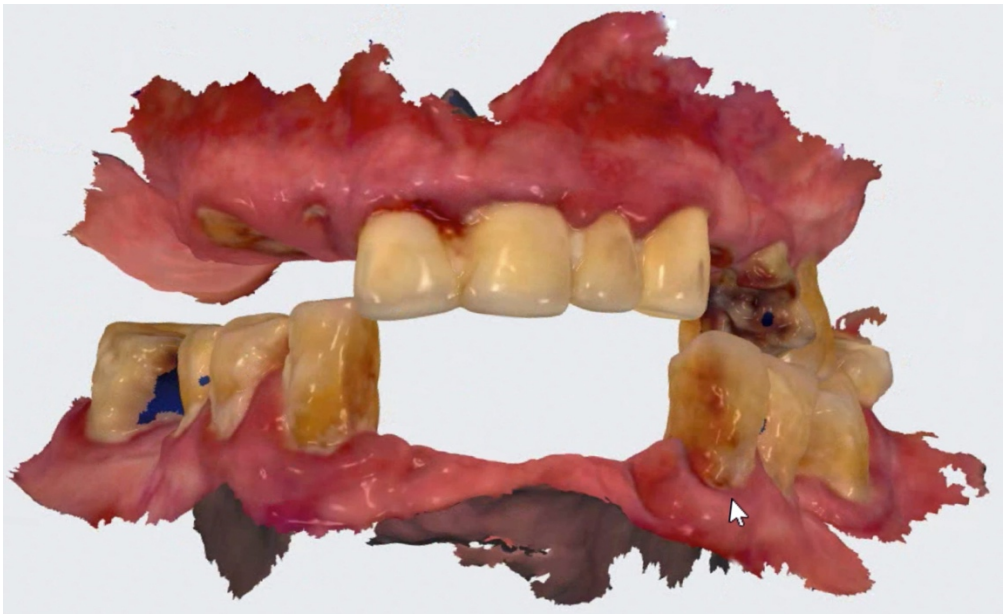


Figure 3. CBCT is taken in the first visit to better evaluate teeth and bone status

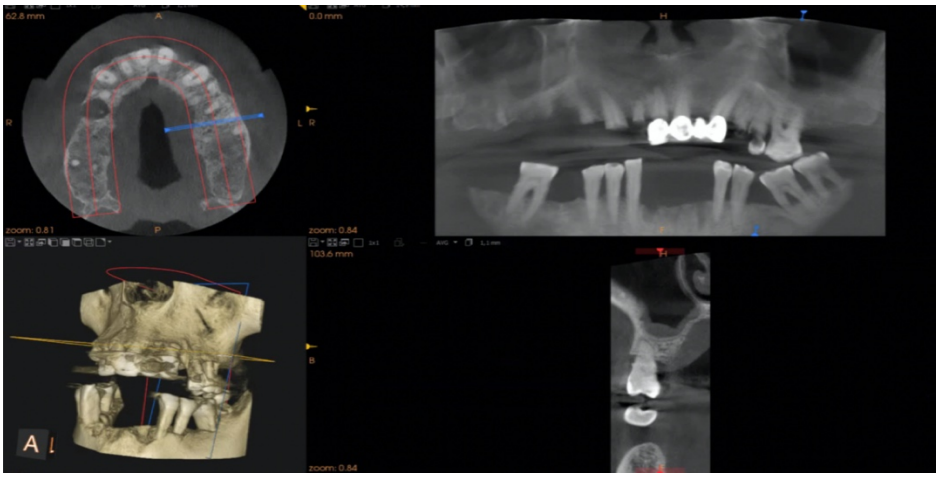


Figure 4. STL file obtained from the intraoral scanning and DICOM file obtained from the CBCT are imported to an implant planning program and an initial idea of the treatment planning is obtained.

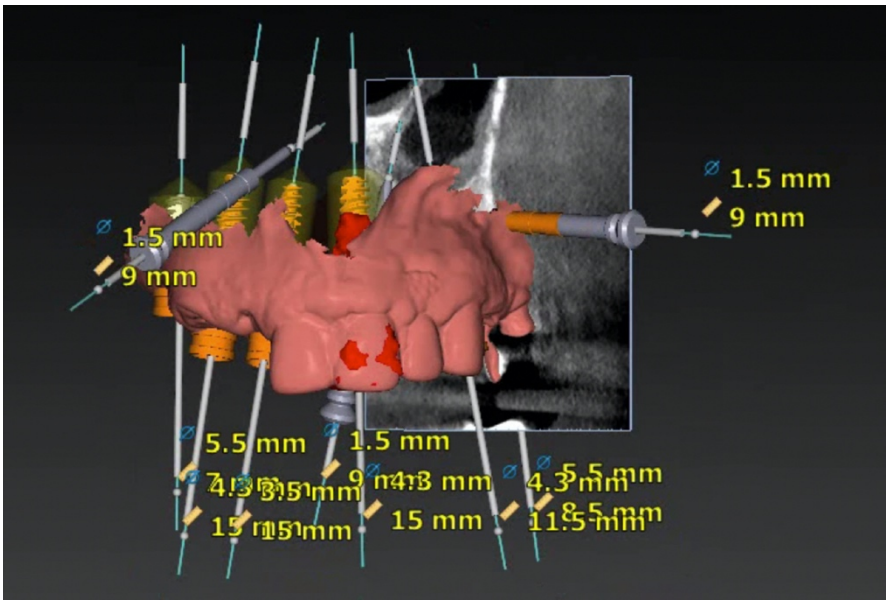


Figure 5. Dental laboratory sends a file with the digital set up, to be validated by the clinician

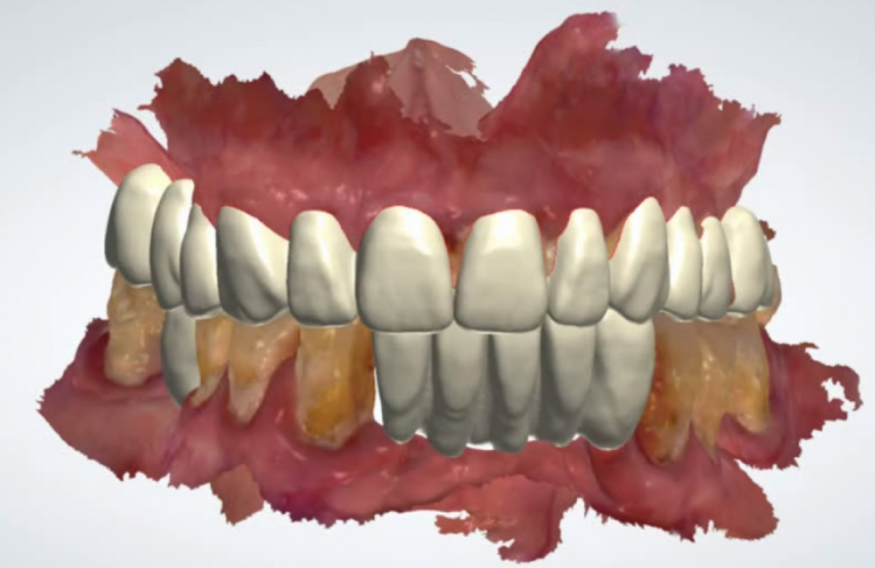


Figure 6. (a) Pins are placed prior to the surgery to be used as references for superimposition after the surgery, (b) and a new scan is taken making sure that the pins are completely captured. (c)After implants and multiunit abutments placement, scan bodies are screwed into the abutments and a new scan is taken, again making sure that pins are completely captured, allowing a perfect superimposition with the presurgical scan and enabling maintenance of the stablished vertical dimension of occlusion. Although pins are used, one tooth was left to ease the before and after STL files superimposition. (d) After removing the scan bodies, temporary copings are placed on the multiunit abutments and MedicalFit device is trimmed to fit on the temporary abutments and attached to them by means of Triad Gel.

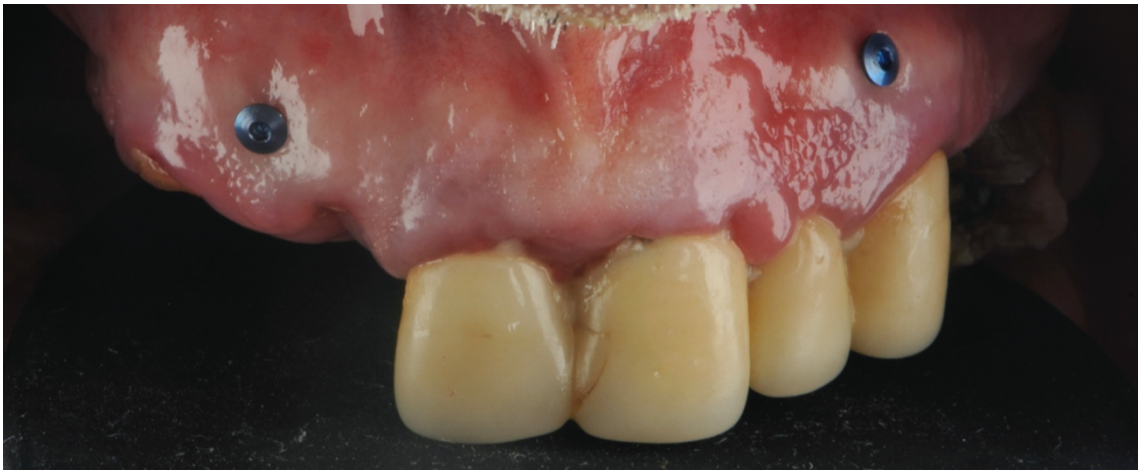


Figure 7. Once removed from the mouth, ScAnalog replicas are placed on the temporary copings. A scan of Medicalfit device is taken and the STL file obtained is sent to the dental laboratory

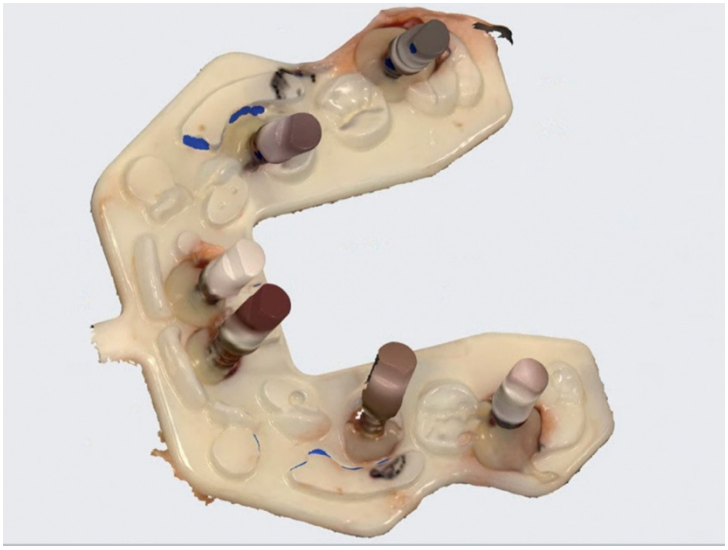
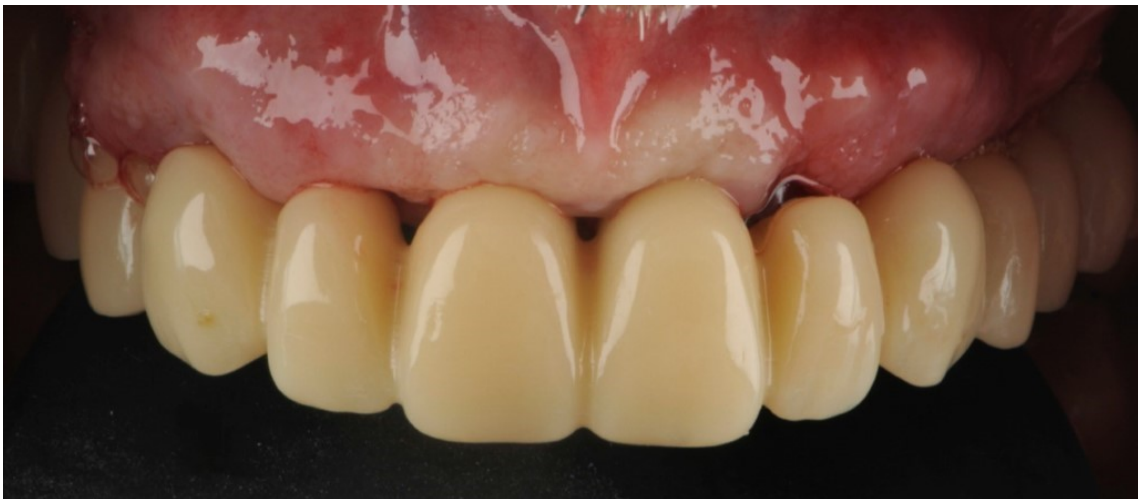


Figure 8. After less than four hours the dental laboratory delivers the final PMMA framework, which is easly screwed on the multiunit abutments. Minimal occlusal adjustment is needed. Small defects in the gingival adaptation are observed, that can be corrected immediately with some composite resin or left (this was our option in this treatment) to be corrected at the final phase of the treatment.



DISCUSIÓN

En los dos estudios realizados sobre modelo de yeso no solo se evaluó la precisión, sino que se trató de establecer si existían variaciones en el modelo maestro a lo largo del estudio. Al alargarse cada uno de los estudios por espacio de casi dos meses, podrían haberse producido cambios dimensionales en el modelo de referencia que determinasen a su vez errores en las mediciones. Por ello, se escaneó el modelo maestro cada 10 impresiones para evaluar posibles cambios en el mismo que influyesen en el resultado. Se observó estabilidad dimensional del modelo de trabajo a lo largo de todo el estudio. Como las variaciones dimensionales se mantuvieron por debajo de 6μm se consideraron los modelos estables y no hubo cambios en la posición de los implantes (32).

Para determinar la exactitud de los modelos se tiene que superponer una imagen STL del modelo obtenido con el STL del modelo maestro. Esa superposición se puede hacer de diferentes formas. Una sería alinear los dos primeros implantes de cada modelo con ajuste perfecto, lo cual centraría toda la deformación en el segundo implante(33). No obstante, eso no se corresponde bien con la realidad clínica, donde las posibles discrepancias de ajuste se distribuyen entre los distintos implantes que soporten la supraestructura. Recordemos que en clínica no se procede al atornillado a torque máximo del primer implante para seguir después con los demás, sino que poco a poco se van apretando los implantes, alternando donde se va dando torque para que de ese modo se distribuyan las tensiones entre los diferentes elementos de soporte. El método que mejor representa este modo de trabajo es realizar el alineamiento (o superposición) de los modelos por medio del método *"Best Fit"*, o mejor ajuste, eligiendo los dos implantes como elementos de referencia.

Nuestros resultados mostraron mínimas diferencias en la posición del centro de la cabeza teórica del implante. Los pilares con el diseño antiguo cortos fueron significativamente peores que los de los pilares con el nuevo diseño, tanto largos como cortos. No se encontró diferencia estadísticamente significativa entre los pilares con diseño antiguo cortos y los equivalentes largos. No se encontró diferencia estadística significativa entre los pilares de diseño antiguo largos y los de diseño nuevo largos y cortos. Así, parece que el diseño determina cambios en la exactitud conseguida, pero que una mayor longitud de los pilares puede ayudar a compensar los defectos.

Se eligió para el primer estudio un sistema de impresión de cubeta cerrada. Algunos autores afirman que la técnica de cubeta abierta es más exacta que la de cubeta cerrada (34). No obstante, muchos clínicos siguen utilizando la técnica de cubeta cerrada debido a su mayor facilidad de manejo, a la vez que algunos estudios muestran una exactitud semejante a la de la cubeta abierta (35-37) así como que el material y técnica de impresión parecen tener influencia cuando se trata de implantes muy angulados. Cuando las diferencias de angulación son pequeñas parece que no existe diferencia significativa (38). Por ese motivo fabricamos para el estudio un modelo con una divergencia entre los ejes de los implantes de 10^{o}. Nuestros resultados parecen indicar que la diferencia en general fue mínima, y que el nuevo diseño mejora significativamente los resultados respecto al viejo diseño.

Dos de las muestras de escaneo óptico del segundo estudio tuvieron que ser desechadas por presentar imperfecciones que impedían el alineamiento con los pilares de referencia con menos de 20μm de desajuste. Ello muestra la necesidad de

que el operador, en caso de impresiones digitales, preste atención a las impresiones antes de enviarlas al técnico, pues muchos de esos errores pueden ser detectados en el momento de la toma de impresiones.

En nuestro estudio las impresiones convencionales de implantes poco divergentes en un espacio edéntulo corto (dos implantes y tres dientes ausentes) fueron significativamente menos precisas que las ópticas, lo cual concuerda con lo mostrado por la literatura. En el caso de las convencionales, parece tener mucha influencia la experiencia del operador y el material, particularmente el tipo de yeso (39). La elección de poliéter como material para la toma de impresiones convencionales respondió a su mayor exactitud respecto al vinipolisiloxano(40). Fuimos muy ciudadosos en el respeto al tiempo de espera previo a vaciado de la impresión, el uso de vacío y las proporciones yeso/agua (18).

Pese a que algunos autores han informado de una mayor exactitud en las impresiones convencionales que en las ópticas para prótesis sobre dos implantes contiguos(35), nuestros resultados fueron los contrarios. Ello puede explicarse por los muchos pasos necesarios en la técnica convencional (toma de impresión, obtención del modelo de trabajo, llave de verificación de resina, encerado, revestimiento, colado, carga de cerámica y acabado), que pueden distorsionar la prótesis final (41). Los dispositivos de impresión óptica dieron un error en el rango de 50-60 µm, sugiriendo que pueden ser válidos para las impresiones intraorales. Otro factor condicionante puede haber sido la mejora constante de los equipamientos de escaneo, y sobre todo, las mejoras de los programas informáticos que los controlan.

Es necesario tener en cuenta la versión de *software* utilizada con cada equipo para poder hacer comparaciones a posteriori(42).

En este estudio no se hallaron diferencias estadísticamente significativas entre las impresiones de cubeta abierta ferulizada y no ferulizada. Ello está de acuerdo con los estudios que afirman que el uso de materiales rígidos como el poliéter hace innecesario ferulizar con resina acrílica los pilares de impresión (43).

No obstante, estos resultados, obtenidos en condiciones *in vitro*, no tienen por que coincidir con la realidad clínica. En caso de las impresiones ópticas las condiciones reales de humedad y movilidad de los tejidos blandos periimplantarios pueden afectar la exactitud. La humedad puede ser también un factor condicionante de la exactitud de las impresiones convencionales.

Un problema observado en el transcurso del estudio fue la rotación de los implantes al tomar las impresiones. En el estudio se tomó como referencia el "centroide", o centro de la cabeza del implante(44). La medición de la exactitud a partir de la posición del centroide dio resultados muy favorables en general. No obstante, al medir la posible rotación del implante sobre su eje longitudinal, se apreció que había errores considerables, que fueron significativamente menores en el caso de las impresiones convencionales. La presencia de esas rotaciones parece desaconsejar el uso de conexiones indexadas (anti rotatorias) en estructuras soportadas por dos implantes contiguos. La utilización de conexiones rotatorias evitaría la posible aparición de ese problema. El mayor error en la rotación en las impresiones convencionales puede provenir de un mal posicionamiento del pilar de

impresión en la impresión (en el caso de la impresión de cubeta cerrada) o a la rotación provocada por el atornillamiento del análogo de implante al pilar de impresión (en el caso de la impresión de cubeta abierta).

Este problema fue detectado en el transcurso del primer estudio, pero no fue medido. En el segundo estudio se incorporó esa medición, tomando además la precaución de posicionar siempre los análogos (en el caso de las impresiones convencionales) bajo buena iluminación y con magnificación, pese a lo cual persistieron los problemas.

En los dos primeros estudios los implantes se colocaron casi paralelos (menos de 10^0 de diferencia entre sus ejes longitudinales), y la distancia entre ambos fue la adecuada para poner un puente de tres unidades con un molar y un premolar sobre los implantes con un premolar como póntico. Haber colocado implantes más angulados probablemente habría empeorado los resultados de las impresiones convencionales (45), con poca afectación en el caso de las impresiones ópticas. Asimismo, la distancia entre implantes mayor no es tampoco el mejor escenario para las impresiones ópticas (46, 47). Sin embargo, pese a ello, las impresiones ópticas en todos los casos mostraron mejores resultados que las convencionales.

Desde el punto de visto clínico los escáneres intraorales tienen ventajas y desventajas. En general parece que la percepción general de los pacientes es mejor con estos equipos que con las impresiones convencionales (48). No obstante su utilización requiere formación, y presenta una curva de aprendizaje más larga que las impresiones convencionales (49).

Una de las áreas donde puede tener aplicación clínica directa con una mejora de la calidad de tratamiento es en el ámbito de la carga inmediata de implantes en arcadas completas. La carga inmediata de estructuras implanto-soportadas de arcada completa es un tratamiento predecible si se ejecuta adecuadamente y se selecciona bien el caso(50-52), si bien es un tratamiento complejo dependiente de la técnica y experiencia del operador(53). En esos casos proporciona beneficios claros al paciente, al reducir el tiempo de tratamiento y las molestias postoperatorias, a la vez que ofrece al paciente desde el primer momento una dentadura fija(53). La incorporación de flujos digitales en este ámbito puede simplificar los protocolos actuales, reduciendo el tiempo de trabajo del equipo dental y del paciente(54, 55).

En la actualidad tanto la planificación quirúrgica como la fabricación de las prótesis en el laboratorio pueden ya hacerse de forma totalmente digital(53). Sin embargo, el flujo de trabajo estándar suele incluir procedimientos no digitales como la toma de impresiones con elastómeros inmediatamente tras la cirugía, y acabado de la prótesis bien en el laboratorio, bien perforando la prótesis preparada al efecto y adaptándola a pilares temporales con resina acrílica o composite fluido directamente en la boca del paciente(56-58). Ese ajuste directo en boca inmediatamente tras la cirugía suele verse comprometido por el estado del paciente, el sangrado y el estado de los tejidos según el tipo de cirugía realizada(59). Un problema adicional viene dado por la dificultad de transferir la dimensión vertical correcta a la prótesis(60), y la posición oclusal adecuada(59).

A tenor de lo observado en nuestro estudio in vivo sobre procesos totalmente digitales para la confección de prótesis fijas de arcada completa implanto-

soportadas, los sistemas de impresión ópticos podrían ser una gran ayuda en ese sentido. Existe el problema (también en las convencionales) de la imposibilidad de conseguir una captura perfecta de la posición tridimensional de los implantes con una exactitud suficiente(61, 62). Ya hemos comentado que aun cuando el nivel de ajuste necesario para provocar efectos adversos mecánicos o biológicos no está determinado(4) y sus consecuencias no están claras(63), cuanto mejor sea el ajuste, mejor. El uso de dispositivos auxiliares puede ayudar a conseguir impresiones más exactas(64). Dispositivos auxiliares prefabricados como Medicalfit pueden ayudar a mejorar la exactitud de una forma mucho más simple(65). La combinación de impresiones digitales con escáneres ópticos complementado con un dispositivo auxiliar tipo Medicalfit permite conseguir en un tiempo de sillón muy reducido prótesis fijas implantosoportadas provisionales de gran calidad y ajuste.

CONCLUSIONES

Conclusión 1

El nuevo diseño de pilar de impresión mejora significativamente la exactitud de la impresión. Un diseño adecuado del pilar de impresión para técnica de cubeta cerrada puede ayudar a obtener impresiones clinicamente aceptables para puentes sobre dos implantes.

Conclusión 2

Nuestros resultados sugieren que las impresiones ópticas en las condiciones del estudio son superiores a las elastoméricas. La exactitud de las impresiones de cubeta cerrada fue a su vez inferior a las de cubeta abierta.

Conclusión 3

Las estructuras protésicas de circona obtenidas a partir de un escaneado intraoral y fabricadas por un proceso totalmente digital tienen una exactitud no inferior a la de las estructuras idénticas obtenidas de una impresión con elastómeros.

CONCLUSIONS

Conclusion 1

The new impression coping design significantly improves implant impressions accuracy. An proper design of impression copings for closed tray can help to obtained clinically acceptable impressions for a bridge on two implants.

Conclusion 2

Our results suggest that, in the conditions of the study, optical impressions are better than elastomeric impressions. Accuracy of closed tray implant impressions was significantly worse than that of open tray implant impressions.

Conclusion 3

Zirconia frameworks obtained from an intraoral scanner and manufactured through a full digital flow are not less accurate than those obtained form an elastomeric impression.

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ANEXOS

Anexo 1. Comunicado de admisión

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ESCUELA DE DOCTORADO

COMUNICADO RESOLUCIÓN SOLICITUD DE ADMISIÓN

Barcelona, 22 de septiembre de 2016

Apreciada Elena Roig

Por la presente le comunico que, en relación al Programa de Doctorado en Ciencias de la Salud, desde la dirección de la línea de investigación en el área de Odontología, de acuerdo a los criterios de valoración de las solicitudes de admisión (ámbito de línea de investigación, CV del candidato, trayectoria académica del solicitante y número de plazas disponibles), ha resuelto ADMITIR su solicitud a los estudios de doctorado para el curso 16-17.

Universitat Internacional de Catalunya Escola de Doctorat

Dra. Marta Gámiz
Secretaría Escuela de Doctorado

Anexo 2. Carta de aprobación del CER

CER Comitè d'Ètica de Recerca | Universitat Internacional de Catalunya

APROVACIÓ PROJECTE PEL CER/ APROBACIÓN PROYECTO POR EL CER

Codi de l'estudi / *Código del estudio*: REST-ELM-2017-11
Versió del protocol / *Versión del protocolo*: 1.0
Data de la versió / *Fecha de la versión*: 23/11/17
Títol / *Título*: Evaluación de la eficacia de sistemas digitales de toma de impresión de implantes dentales

Sant Cugat del Vallès, 14 de desembre de 2017

Investigador: Elena Roig Farga
Directores: Miguel Roig Cayón, Santiago Costa Palau
Tutor: Juan Ricardo Mayoral Molina

Títol de l'estudi / *Título del estudio*: Evaluación de la eficacia de sistemas digitales de toma de impresión de implantes dentales

Benvolgut/da,

Valorat el projecte presentat, el CER de la Universitat Internacional de Catalunya, considera que, el contingut de la investigació, no implica cap inconvenient relacionat amb la dignitat humana, tracte ètic per als animals ni atempta contra el medi ambient, ni té implicacions econòmiques ni conflicte d'interessos, **però no s'han valorat els aspectes metodològics del projecte de recerca degut a que tal anàlisis correspon a d'altres instàncies.**

Per aquests motius, el Comitè d'Ètica de Recerca, RESOLT FAVORABLEMENT, emetre aquest CERTIFICAT D'APROVACIÓ, per que pugui ser presentat a les instàncies que així ho requereixin.

Em permeto recordar-li que si en el procés d'execució es produís algun canvi significatiu en els seus plantejaments, hauria de ser sotmès novament a la revisió i aprovació del CER.

Atentament,

Apreciado/a,

*Valorado el proyecto presentado, el CER de la Universidad Internacional de Catalunya, considera que, el contenido de la investigación, no implica ningún inconveniente relacionado con la dignidad humana, trato ético para los animales, ni atenta contra el medio ambiente, ni tiene implicaciones económicas ni conflicto de intereses, **pero no se han valorado aspectos metodológicos del proyecto de investigación debido a que tal análisis corresponde a otras instancias.***

Por estos motivos, el Comitè d'Ètica de Recerca, RESUELVE FAVORABLEMENTE, emitir este CERTIFICADO DE APROBACIÓN, para que pueda ser presentado a las instancias que así lo requieran.

Me permito recordarle que si el proceso de ejecución se produjera algún cambio significativo en sus planteamientos, debería ser sometido nuevamente a la revisión y aprobación del CER.

Atentamente,

Dr. Josep Argemí
President CER-UIC

Anexo 3. Autorización de estancia de investigación

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ESCUELA DE DOCTORADO
PROGRAMA DE DOCTORADO EN CIENCIAS DE LA SALUD

AUTORIZACIÓN ESTANCIA DE INVESTIGACIÓN

Barcelona, 10 de diciembre de 2019

Apreciada Elena Roig,

Por la presente le comunico que la Comisión Académica del programa de Doctorado en Ciencias de la Salud (CAD) en relación a la documentación presentada ante la CAD, autoriza la siguiente estancia de investigación:

- Universidad: Egas Moniz Cooperativa de Ensino Superior (Portugal)
- Departamento: Cirugía
- Fechas: 08-01-2018 hasta 30-04-2018

Universitat Internacional
de Catalunya
Escola de Doctorat

uic barcelona

Sònia Soriano
Secretaría Escuela de Doctorado

Anexo 4. Aprobación de la defensa de la tesis

Universitat Internacional de Catalunya

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ESCUELA DE DOCTORADO

ADMISIÓN DE LA TESIS DOCTORAL A TRÁMITE DE DEFENSA Y DESIGNACIÓN DEL TRIBUNAL EVALUADOR

Título de la tesis: *Evaluación de la eficacia de sistemas digitales de toma de impresión de implantes dentales*
Doctorando: Elena Roig Farga
Dirección: Dr. Santiago Costa Palau y Dr. Paulo Rogério Figueiredo Maia

Por la presente les comunicamos que una vez examinada la documentación presentada, la Comisión Académica del Doctorado en Ciencias de la Salud autoriza la defensa pública de la tesis referenciada.

Al mismo tiempo, y a la vista de la propuesta formulada por los directores de la tesis, les comunicamos el tribunal designado para juzgar la tesis doctoral.

TRIBUNAL :

Presidente: Dr. Juan Jose Segura Egea
Universidad de Sevilla

Secretario: Dr. Luis Jane Noblom
Universitat Internacional de Catalunya

Vocal: Dr. Jose Joao Mendes
Instituto Universitario Egas Moniz

Suplentes: Dr. Oscar Figueras Álvarez (Universitat Internacional de Catalunya)
Dra. Beatriz Giménez González (Acta Dental Education)

Esta resolución se comunicará a todos los interesados en el procedimiento.

Atentamente,

Universitat Internacional de Catalunya
Escola de Doctorat

Dra. Marta Gámiz
Gestora de Centro
Escuela de Doctorado

Barcelona, 25 de marzo de 2021

Anexo 5. Artículos

Journal section: Prosthetic Dentistry
Publication Types: Research

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Impact of design and length on the accuracy of closed tray transfer copings

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Abstract

Background: The aim of this study was to evaluate the accuracy of two closed-tray transfer copings for implant impressions (a new design vs. an old design) in two different lengths (short and long).

Material and Methods: Four groups of transfer copings (NS - new short, NL - new long, OS - old short and OL - old long) were tested. An epoxy resin model was prepared of missing teeth 1.4, 1.5 and 1.6. Two Alpha-Bio analogues were placed in position of teeth 1.4 and 1.6, at a 10o angulation. Two calibrated operators took 10 closed-tray impressions for each group with polyether in a Rim-Lock impression tray.

Results: After measuring and comparing impressions, a significant difference was found between the two new transfer copings and the old short transfer coping.

Conclusions: The new transfer coping design significantly improved impression accuracy. An adequate transfer coping design for the closed-tray impression technique can help to achieve clinically acceptable impressions for two-unit implant supported bridges.

Key words: *Closed tray, impression coping, transfer coping, implant impression.*

Introduction

One of the key factors for a successful prosthetic treatment is the accuracy of the implant impressions (1). To do this, the clinician must choose the optimum impression technique, transfer coping and material for each case.

There are two techniques for taking implant level impressions: the open tray technique and the closed tray technique. Taking impressions with the closed tray technique entails a clinical and a laboratory step. The clinical step consists of screwing the transfer coping into the implant, after which an impression is taken. The laboratory step involves the repositioning of the transfer coping in the impression and then pouring it to obtain a cast model. However, many factors intervene in these two steps that may slightly alter the position of the implant in the cast (2-4). Some studies have reported the number of variables involved in this process implies that a true passive fit of multi-implant- supported prostheses is unattainable (5). These variables include tolerance among the components of the implant systems, changes in the materials, as well as the clinician´s skill at accurately repositioning the impression transfer copings and correctly connecting the components.

The imprecise fit of the prosthetic superstructure may subject these components to stress, consequently resul-

ting in mechanical complications, including screw loosening, screw fracture, occlusal inaccuracies, implant fracture, as well as biologic consequences, such as increased plaque accumulation and tissue retraction, which often lead to peri-implant bone loss (6-8). In order to prevent possible complications, every effort must be taken to ensure an accurate impression and master model. Both open tray and closed tray impression techniques are widely used in clinical practice for transferring the position of the implant to the working cast, for which the choice of the transfer coping plays a decisive role.

Depending on the implant system, impression transfer copings come in different shapes, lengths, widths, retention systems and depths of indentations, all of which can affect the accuracy of final impression (5,9). The shape and retention system are two factors that must be considered in the design of closed tray transfer copings. Shape refers to the conicity and to the presence of a flat surface, which provides not only the insertion path for the transfer coping in the impression but also prevents rotation. The retention system maintains the transfer coping in place in the vertical axis.

The present *in vitro* study compares the accuracy of closed tray impression transfer copings in two different geometries, the old and the new designs. The old design has a conical-trunk shape with two wide flat surfaces and two narrow ones. The new design is cylindrical shaped with a flat surface. The differences between them according to the retention system are the oval-shaped tip in the old design, whereas the new design has two horizontal grooved notches. In addition, two different lengths (short and long) of transfer copings were compared (Fig. 1).

Fig. 1: Main view of the two different implant transfers (green is the "old", silver is the "new") in short and long lengths.

The aim of the present study was to compare the accuracy of four different implant transfer copings for the closed-tray technique in a standardised *in vitro* setting.

Material and Methods

1.1 Master model making

Epoxy resin was used to fabricate a master model of missing teeth 1.4, 1.5 and 1.6 with two internal conical standard connection Alpha-Bio analogues (Alpha-Bio, Petah Tikva, Israel) in position 1.4 and 1.6 with a 10o angulation. A scan body was then screwed into each analogue, after which the model was scanned thrice with an industrial scanner (Steinbichler COMET L3D, Zeiss, Germany). Each scan was exported as a Stereolithographic (STL) file and imported into Geomagic Control X software (3D systems, Rock Hill, South Carolina, USA), with which a cylinder was drawn in accordance with the shape of each scan body. A plane was sketched on top of the cylinder and was then moved 10 mm apically along the length of the scan body (Fig. 2). The intersection between the plane and the axis of the cylinder was identified as the centre of the analogue head, or centroid. The Best Fit method was used to compare the three STLs by aligning them in pairs. The mean difference between the centroids measured was acceptably precise (no more than 20 μm); therefore, the shortest file was selected as the STL reference file.

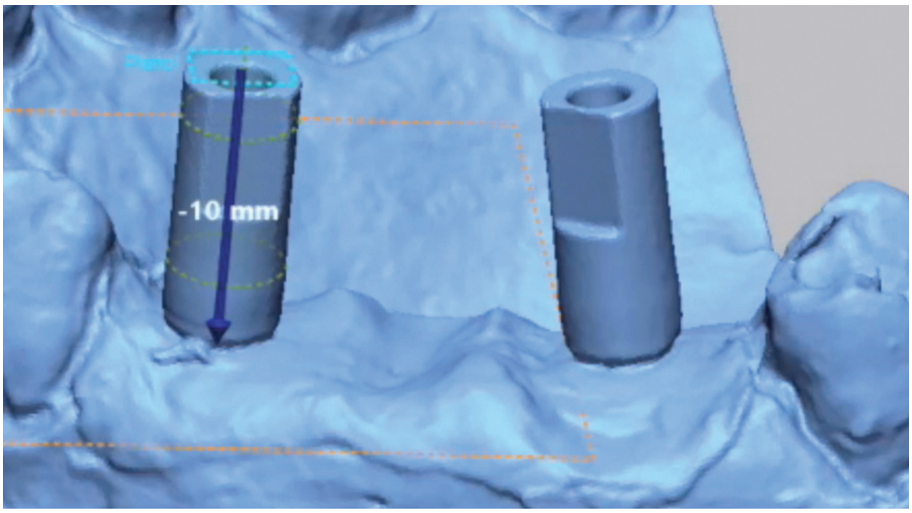

Fig. 2: A plane was sketched on top of the cylinder and was then moved 10 mm apically along the length of the scan body. The centroid was determined by intersection of the apically moved plane and the axis of the scan body.

1.2 Closed tray impressions

Closed tray impressions of the master model were taken by two calibrated experienced operators (10) using four different types of transfer copings (new short - NS, new long - NL, old short - OS and old long - OL). Four cycles of ten impressions were taken following the same protocol, in which the type of the transfer coping was randomly selected. After every 10 impressions, the master model was re-scanned and compared to assess possible alterations during the process.

For each impression, two closed-tray transfer copings were screwed into the analogues using a 10 Ncm torque, and the impressions were taken with polyether (Impregum Penta 3M ESPE, St. Paul, MN, EEUU), in accordance with the manufacturer's instructions. A syringe was used to place the material around the transfer copings, and then a Rim-Lock tray was filled with the same material and placed on the master model. Once the material had set, the impression was removed from the master model. Subsequently, the transfer copings were unscrewed from the master model and the implant analogues were inserted into them. The transfer copings were repositioned in the impression at magnification 3.8x under good lighting. At 30 minutes, CAD/CAM stone plaster (Ventura scan stone, Madespa, Toledo, Spain) was mixed in a vacuum, according to the water/powder proportions recommended by the manufacturer and poured into the impression. Once the plaster had set, the impression tray was removed and the transfer copings were replaced by the scan bodies. As each scan body has six possible positions in the implant analogue, care was taken to place them in the same position as in the reference model. The model was then scanned using a dental desktop scanner (D200 3Shape, Copenhagen, Denmark) and exported as an STL file.

1.3 Data Comparison

Geomagic Control X software was used to superimpose

the STL reference file over the STL test files, then the STL scan bodies were aligned, using Best fit alignment, and exported as a single file.
Each centroid was established using the same procedure used for the reference model (Fig. 3). The 3D distance between the two centroids was measured and the mean between the groups was compared using one-way analysis of variance (ANOVA).

Discussion

No differences were found between the STL files of the master model taken after every ten impressions, indicating there were no changes in the model after the impressions.
The Best Fit method was used to superimpose the impression over the working model, locating a position between the two scan bodies simultaneously, thus distributing the discrepancy between points 1 and 2. This method is more clinically relevant, since this is the accepted method for testing the accuracy of a superstructure over implants. The first scan body could also provide a reference in order to match point 1 in the STL reference file with point 1 in the STL test file, allowing all the differences to be measured in point 2.
Our results showed minimal changes in the position of the centroid in both implants 1 and 2. Group OS yielded a significantly poorer result than that of the NL and the NS did. No significant difference was observed between OL and OS. No significant difference was found among the OL and the NS and NL. The new design of the transfer coping appears to perform better than the old one, and the long transfer coping of the old design performs better that short one.
Some authors have claimed that the open tray impression technique is more accurate than the closed tray impression technique (11). Nevertheless, there is a preference

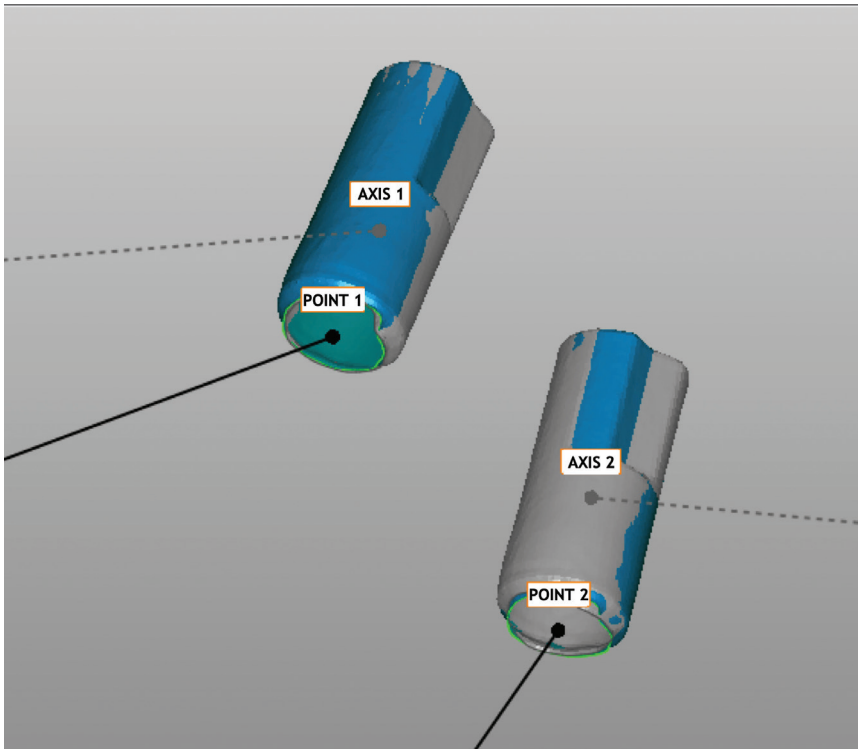

Fig. 3: The center of the implant head and the axis of the scan body (which is the same as the implant axis) is determined.

Results

Comparison of distance between points: The distance between the centroids, the centre of the implant heads, (point 1 and 2) in the STL reference file and STL test files were compared. No significant difference was found among Groups NS, NL and OL or
between OS and OL. However, a significant difference was observed among Groups NS and OS as well as between NL and OS ($p > 0.05$) (Fig. 4). The Box-and-Whiskers plot shows the results obtained with the different transfer copings (Fig. 5).
Angular displacement: The two reference vectors (vector 1 and 2) compared using Best Fit showed no significant difference among any of the groups ($p > 0.05$). The comparison of all the transfer copings revealed a significant difference among the groups, the new transfer coping coming closer to the reference measurement of the model (Fig. 6).

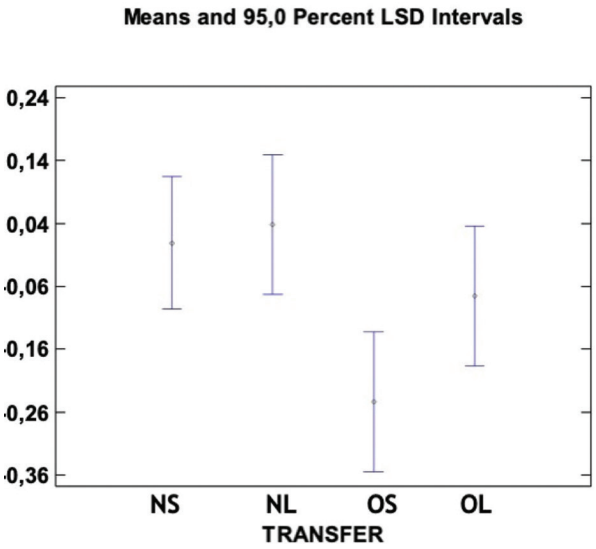

Fig. 4: Means and 95% LSD intervals for the difference between the center of the two implants in the test model and the difference between the center of the two implants in the reference model in the four transfer coping types. Value "0" corresponds to the reference value. There is significant difference between groups NS and OS and between groups NL and OL. There is not significant difference between the other groups.

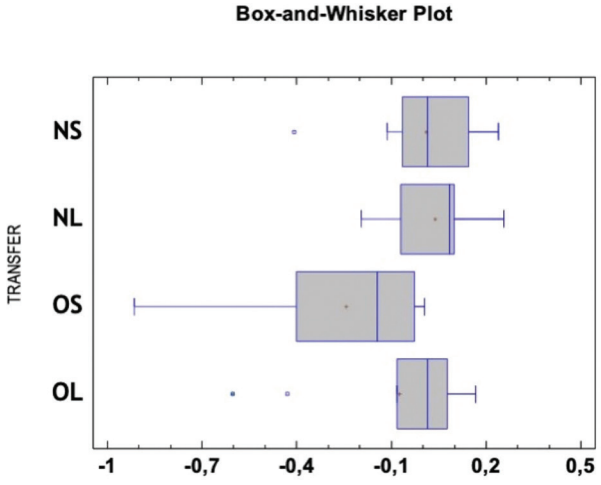

Fig. 5: Box-and-Whisker Plot showing the distance between the two implants centre in all groups. Each value is the difference between the measurement in the test model and in the reference model. Value "0" corresponds to the reference value.

for the closed tray technique for its easy handling, yet some studies argue that the open-tray technique is similarly accurate (12-14) and that the influence of the impression material and technique appears to be significant for highly non-axial implant angulations. Moreover, those differences are non-significant if the axial angulation remains small (15). Hence, we prepared a model with a 10o axial angulation between two implants. Our results suggest that the overall difference was minor, and that

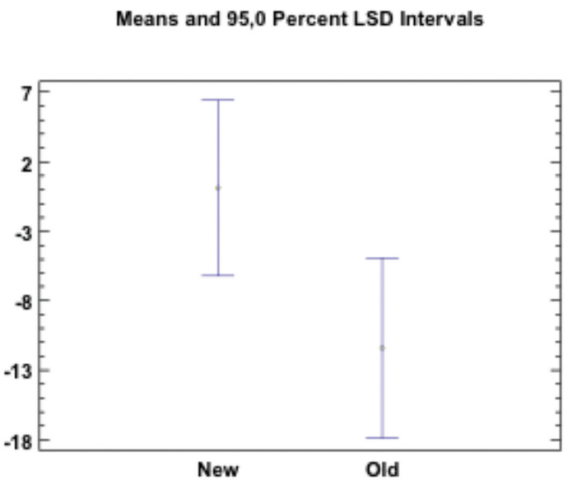

Fig. 6: Angle between the two implants axis in the reference model and in the test model. There is significant difference according to means and 95% LSD intervals. New and old transfer copings are grouped. Value "0" corresponds to the reference angle.

the new design offered significantly improved results over the old one.

Conclusions

The new transfer coping design significantly improved impression accuracy. An adequate transfer coping design for the closed-tray impression technique can help to achieve clinically acceptable impressions for two-unit implant supported bridges.

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Conflict of interest
The authors have declared that no conflict of interest exist.

PLOS ONE

RESEARCH ARTICLE

In vitro comparison of the accuracy of four intraoral scanners and three conventional impression methods for two neighboring implants

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Competing interests: The authors have declared that no competing interests exist.

Abstract

Purpose

To determine whether the accuracy of two-implant model impressions taken with optical scanners was inferior to that of those taken with elastomeric materials.

Materials and Methods

Impressions of a resin reference model with two almost parallel implants were taken using three elastomeric impressions (closed tray technique, open tray nonsplinted technique and open tray splinted technique) and scanned with four optical scanners (CEREC Omnicam, 3M True Definition Scanner, 3Shape TRIOS3 and Carestream CS 3600). STL files of the different methods were superimposed and analyzed with control software (Geomagic Control X, 3D systems) to determine the mean deviation between scans.

Results

Compared to elastomeric impressions, optical impressions showed a significantly improved mean precision. TRIOS3 and CS3600 showed a significantly improved mean trueness compared to that of closed tray, CEREC Omnicam and TrueDefinition. All methods showed a certain degree of implant rotation over their axes, which was significantly higher in the closed tray and the open tray nonsplinted techniques.

Conclusions

Optical impressions, taken under these in vitro conditions, showed improved accuracy compared with that of elastomeric impressions.

Introduction

Accuracy is crucial to the true passive fit of implant prostheses[1], which the existing clinical procedures and laboratory fabrication methods are unable to achieve. Without a true passive fit, also called misfit, the stresses in the implanted prostheses are directly transferred to the mechanical components and surrounding bone[2]. Misfit may lead to bacterial microleakage, screw loosening or component stress and fracture[3–5].

Taking impressions using elastomeric materials to capture the position of the dental implant has become the most widely used technique and remains the gold standard. However, the elastomeric method has procedural shortcomings, and this technique is uncomfortable for the patient and inconvenient for the clinician[6–8].

To address these downsides and to maintain or improve the accuracy of elastomeric methods, several new optical impression systems have been introduced to the market[9]. These systems appear to improve patient experience[10–12] and reduce material costs and time[11, 13]. Some authors believe these optical impression systems have minimal distortion, which confers adequate clinical longevity to the prosthesis due to acceptably associated stress[14]; but these systems are, at present, unable to achieve a true "passive" fit. However, when used for short bridges or crowns, these systems fulfil the minimum requirements of accuracy[15]. A number of studies have reported that the inaccuracies associated with the systems used for implant impressions are too significant to be acceptable[16]. Although some studies claim that these systems provide sufficient accuracy in complete-arch impressions, scientific evidence on the intraoral scanning of complete-arches with teeth is lacking and outdated[17]. Elastomeric impressions of complete arches are significantly more accurate than those of optical arches[18] and the precision of intraoral scanners decreases as the distance between each scan body increases[19–21]. However, when only two implants are scanned, the accuracy of IOS improves[22]. In the case of IOS, in contrast to conventional impressions, the angulation of the implants does not affect the accuracy [23]. Digital systems have gained wider acceptance in dentistry due to the emergence of more user-friendly and more accurate systems.

The verdict on digital impression accuracy remains inconclusive, and direct comparisons between implant impressions and digital alternatives are needed[24]. The present study aims to compare the accuracy of optical impressions recorded by several intraoral scanners with the accuracy of conventional impressions using elastomeric materials over implants in a partially edentulous model. To this end, we selected four optical systems: TrueDefinition (3M, USA), TRIOS3 (3Shape, Copenhagen, Denmark), CEREC Omnicam (Dentsply-Sirona, Bensheim, Germany), and CS3600 (Carestream, Atlanta, USA). The null hypothesis of the present study was that optical intraoral impressions were less accurate than conventional implant impressions were.

According to ISO 5725[24], the term "accuracy" refers to both trueness and precision. "Trueness" denotes the closeness of agreement between the arithmetic mean of a large number of test results and the "true" or accepted reference value. "Precision", referring to the closeness of agreement between test results, is normally expressed in terms of standard deviations. To evaluate accuracy, both trueness and precision must be assessed.

The clinically acceptable degree of inaccuracy is difficult to determine because even minimal discrepancies seem to cause significant stress in the framework[4]. Some authors consider 30 μm to be acceptable[25], while other studies have proposed a limit of 150 μm to avoid long-term prosthetic problems[26].

However, the purpose of this study was not to determine the acceptable degree of inaccuracy but to establish whether optical impression systems were inferior to conventional impression systems in a two-implant model.

Materials and methods

Epoxy resin was used to fabricate a master model missing teeth 1.4 to 1.6 restored with two internal connection implants at an almost parallel configuration (C1 MIS Implants, MIS-Implants Inc., Shlomi, Israel) in positions 1.4 and 1.6. A scan body (Scan Post CS-SP102, MIS implants) was screwed onto each implant, and the model was scanned three times with a desk-top scanner (3Shape D810; 3Shape, Copenhagen, Denmark) (Fig 1). Three stereolithographic (STL) files obtained from the scanner were imported into Geomagic Control X (3D Systems Inc., Rock Hill, SC, USA) and aligned by pairs using the best fit method. The axis of the scan body was established, after which a plane was constructed on its coronal flat surface (plane 1) and then moved 10 mm apically (offset 1). The intersection between the offset and the scan body axis was identified as the center of the implant analog head, or centroid (point 1) (Fig 2). The differences between the centroids in each STL file were measured. The STL file with the least differences was selected as the STL reference file.

Impressions of the model were taken using 4 intraoral optical scanners and 3 conventional impression techniques, and ten impressions were fabricated for each group.

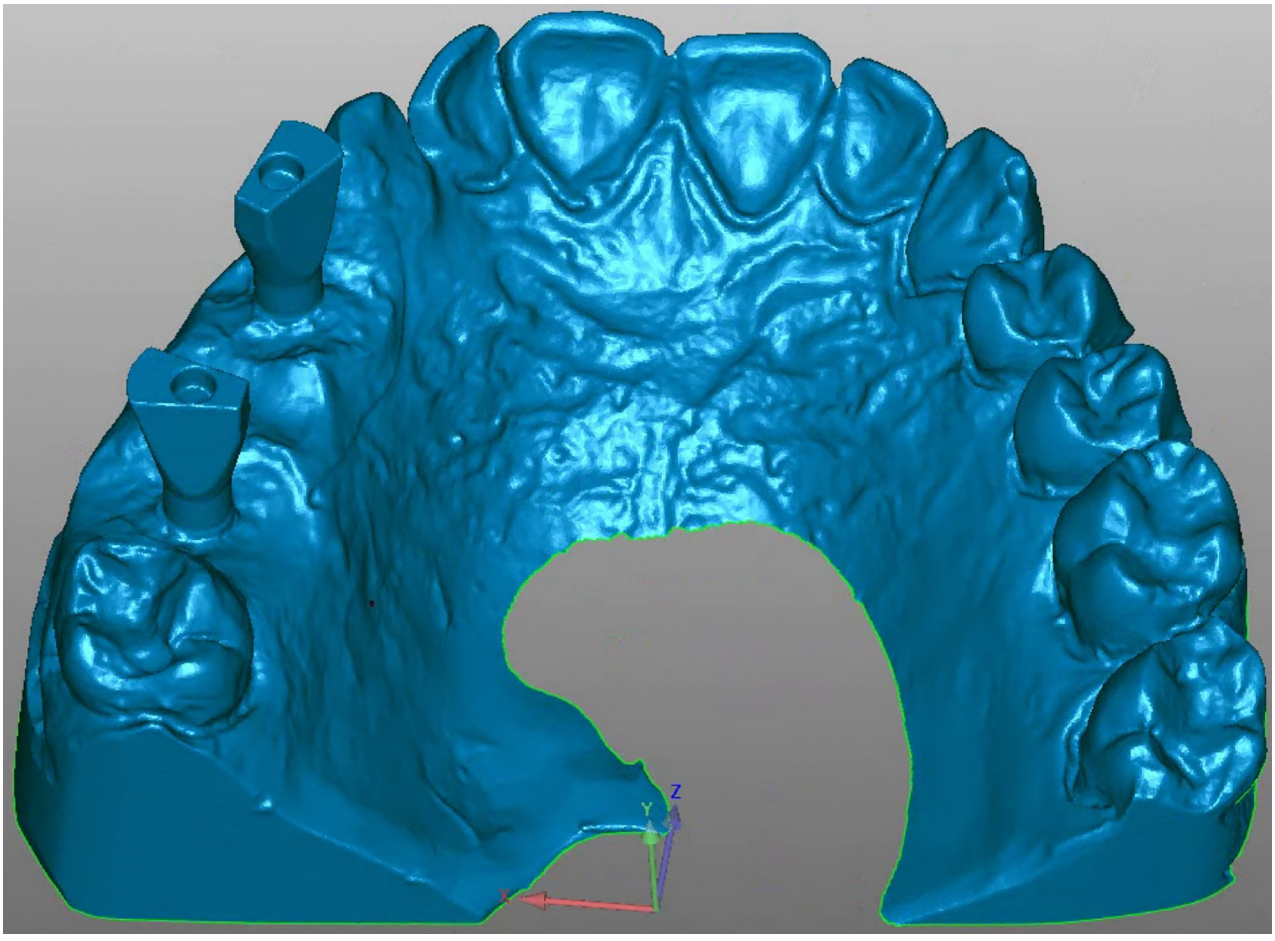

Fig 1. STL model obtained by scanning the model with the scan bodies screwed onto the implant analogs.

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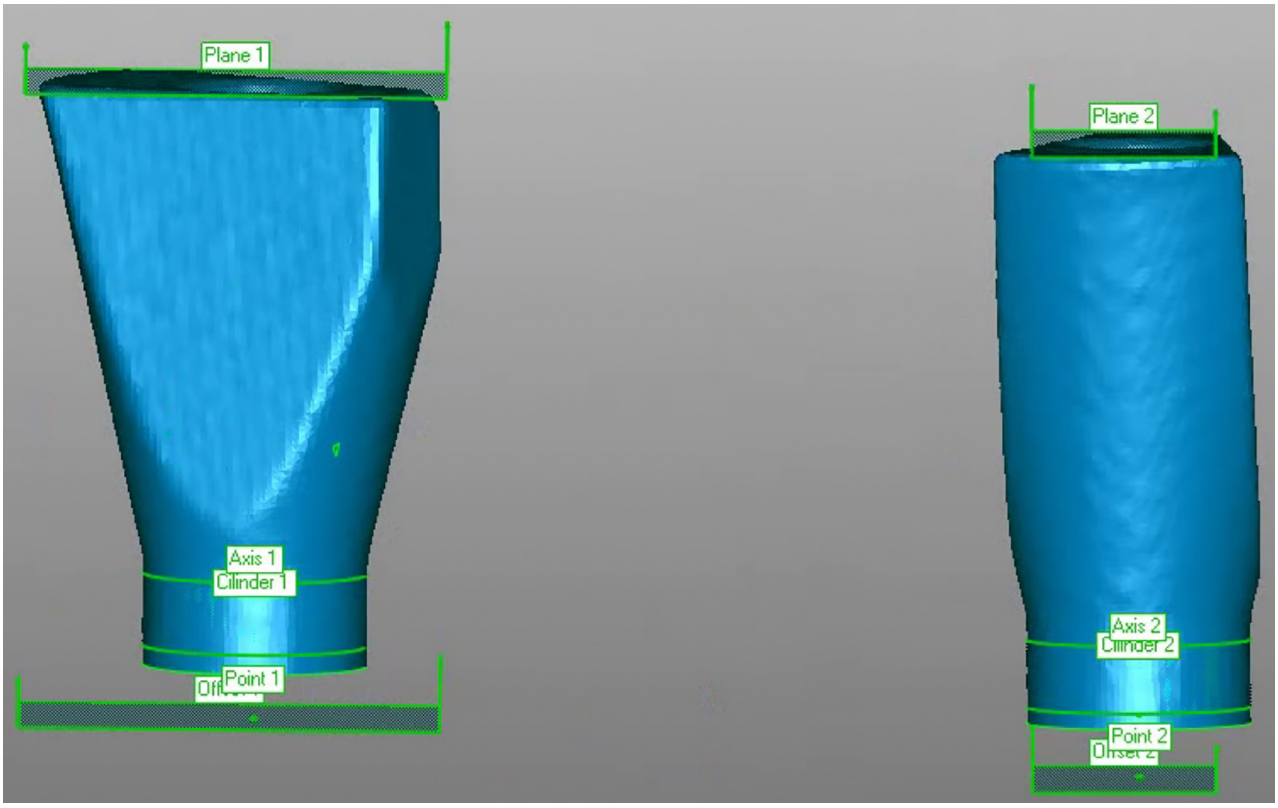

Fig 2. A plane was constructed on top of the scan body (plane 1). An offset plane was obtained by a -10 mm reduction apically (offset 1). A cylinder was constructed based on the shape and the axis (axis 1) of the scan body (cylinder 1). The intersection of offset 1 and axis 1 was considered the center of the implant head, or centroid (Point 1).

https://doi.org/10.1371/journal.pone.0228266.g002

Optical intraoral scanners

The scan bodies were screwed into the implants position closest to that in the reference model, with a 10 Ncm screwing torque. Two calibrated operators used each scanner to take five optical impressions of the model, and these scans were exported as STL files. The scanning protocol was started at the second right molar, the tooth distal to the distal implant, and subsequently the scanner was swept over the occlusal surface up to the first left molar. Returning to the second right molar, the operator rolled and wiggled the scanner to capture the buccal-palatal surfaces up to the second left molar. The following groups were studied:

1. **Group CS**. CS3600 3.1 (Carestream, USA)
2. **Group TR**. TRIOS3 1.18.2.10 (3Shape TRIOS, Denmark)
3. **Group OC**. CEREC Omnicam SW4.6.1 (Dentsply Sirona, Germany)
4. **Group TD**. TrueDefinition L51 V01.33 (3M True Definition, Germany). To facilitate scanning with this scanner, powder (3M High resolution scanning spray, 3M, Germany) was first sprayed onto the model surface.

Conventional impressions

1. **Group CT**—closed tray impression. After placing two closed tray impression copings (CS IC485, MIS implants) onto the dental implants of the master model, a polyether halfway (Impregum Penta; 3M ESPE, Germany) complete arch impression was taken following the manufacturer's instructions. Rim-Lock metal trays (Dentsply Sirona, Orange, USA) without polyether adhesive were used. Once the material had set, the impression was removed from the model. Subsequently, the transfer copings were unscrewed from the master model, and the implant analogs were repositioned under 3.8x magnification and good lighting into the transfer copings. One hour later, CAD/CAM type IV stone plaster (Ventura scan stone, Madespa, Spain) was vacuum-mixed, in accordance with the water/powder proportions (20 ml, 100 g) recommended by the manufacturer, and poured into the impression. According to the manufacturer, expansion at 2 h is 0.08%. After 2 h, the impression tray was removed, and the transfer copings were replaced with the scan bodies. Given that each scan body has six possible positions in the implant analog, utmost care was taken to place the two scan bodies in the same position as that in the reference model. Subsequently, the model was scanned using a desktop scanner (D810; 3Shape, Copenhagen, Denmark), and an STL file was obtained.

2. **Group OS**—open tray splinted impression. Two open tray implant impression copings (CS IO485, MIS implants) were placed on the dental implant, where they were splinted and unified with a clear colorless Triad gel light cure material (Dentsply International, York, PA), which was polymerized for at least 60 seconds in each section. After polymerization, the resin structure was cut using a 0.8 diamond disk approximately halfway between the implants. Twenty-four hours later, the structure was resplinted with tiny amounts of the same gel to reduce the shrinkage of the resin. A plastic tray (Impression Tray, 3M ESPE) was perforated with two holes corresponding to the positions of the transfer copings to allow the placement and removal of the screws. An impression was taken with polyether, in accordance with the manufacturer's instructions. Once the impression material had set, the impression was removed by unscrewing the transfer copings. Implant analogs were then screwed into the transfer copings fixed to the impression. The impression was then poured, as in group CT.

3. **Group ON**—open tray nonsplinted impression. Two open tray transfer impression copings (CS IO485, MIS implants) were screwed into the dental implants. Two perforations were made in a plastic tray (Impression Tray, 3M ESPE) according to the positions of the transfer copings to allow the placement and removal of the screws. The impressions were then taken and poured, as in the OS group.

Two calibrated operators took the impressions using the scanners that they had been trained to use following the same scanning protocol. As differences between operators have been shown, operators completed a one-hour session on how to take elastomeric impressions[27].

Different measurements were taken to assess accuracy:

3D displacement of the centroids

Geomagic Control X was used to superimpose the STL test files over the STL reference files. The STL scan bodies were then aligned using the reference alignment and the best fit alignment and exported as a single file.

After determining a point at the center of each implant head, also called the centroid[28], each scan body axis was established. This procedure provided data on the three-dimensional axes (x, y and z-axes) as the coordinate values that are transformed into linear and angular data. Then, the distances between the reference files and the test centroids were analyzed (Fig 3). The reference and best fit superimposition methods were used. In the reference method, the test STL and the reference STL were aligned with the first implant using a scan body, while for the best fit method, all the scan bodies were aligned with the implants at the same time. The best fit method distributes the differences among all implants, while the reference method shows the maximum possible differences.

Distance between the two implant centers

The distance between the centers of each implant head was measured and subtracted from the distance in the reference (Fig 4).

Rotation of the implants over their axes

After constructing a plane on a wall parallel to the axis of each scan body, the angle between the two planes was determined (Fig 5). The deviation was then calculated by subtracting the angle of the reference model.

Precision

Precision was analyzed by comparing each set of STL files with all STL files taken with the same scanning system. The root mean square (RMS) error obtained was used to assess precision[29].

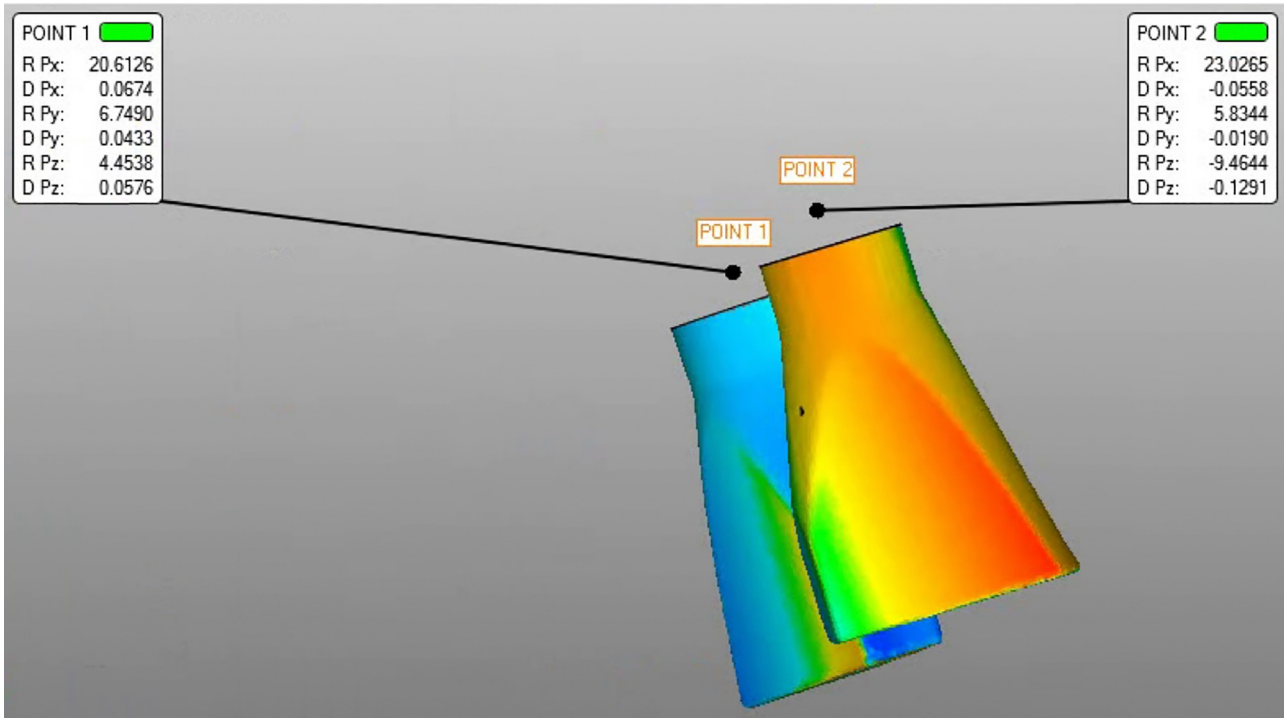

Fig 3. The best fit alignment was used to measure the distance between the two points.

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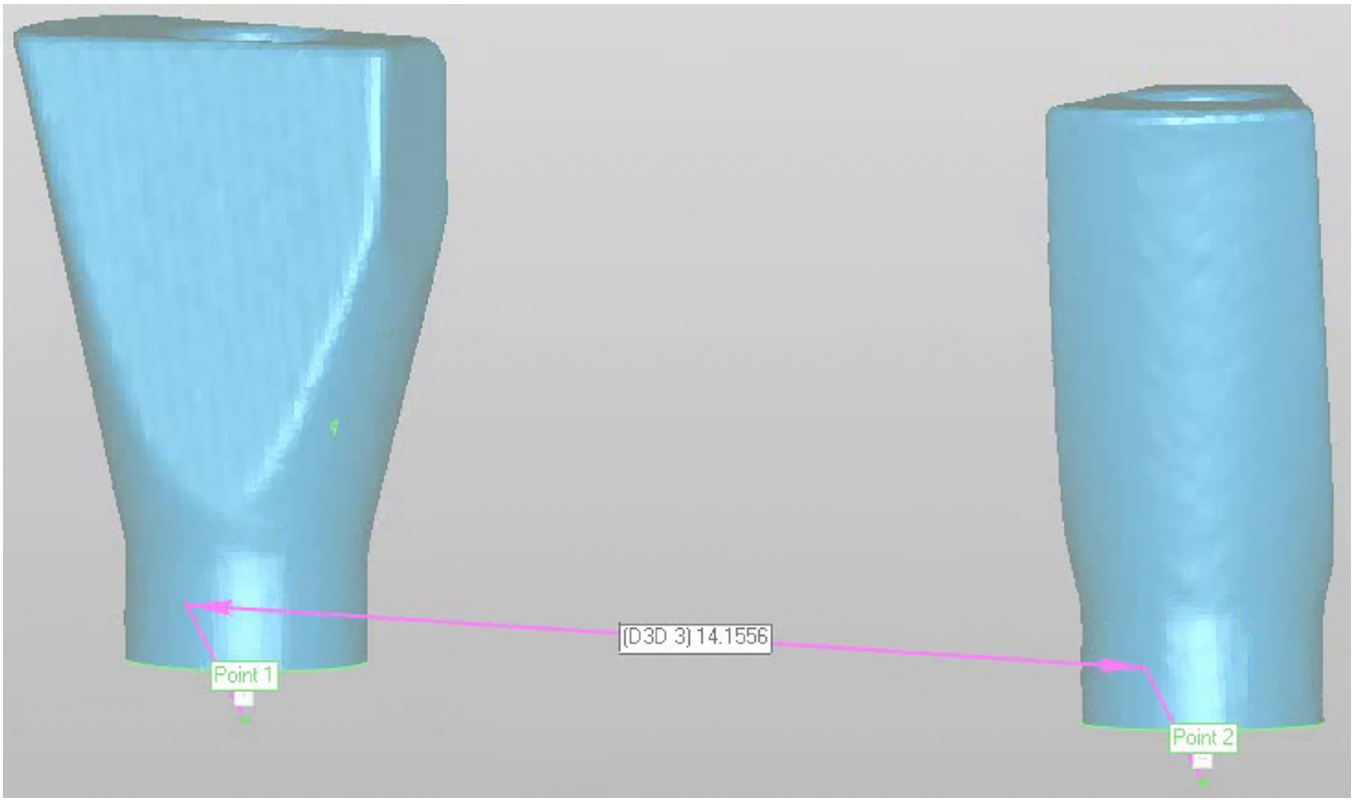

Fig 4. Measuring the distance between the centroids of the two implant heads.

https://doi.org/10.1371/journal.pone.0228266.g004

Levene's test and the Shapiro-Wilk test ($p<0.05$) were used to determine normality of variance and distribution. One-way analysis of variance (ANOVA) with Fisher's least significant difference (LSD) post hoc test was used to compare means between groups ($p<0.05$). Statgraphics centurion XVII software (Statgraphics Technologies, Virginia, USA) was used to analyze the results.

Results

3D displacement of the centroids

Significant differences ($p<0.05$) were observed with one-way analysis of variance (ANOVA). As significant differences were found ($p<0.05$), the LSD post hoc test was used to identify homogeneous groups. Group means were compared in pairs to ensure homogeneity (Table 1). The results of Carestream 3600 and TRIOS3 were significantly inferior to those of the closed tray technique, open tray technique, CEREC Omnicam and True Definition scanning systems.

Distance between the two implant centers

Fig 6 shows the distances between the two centroids of the test model and the reference model. The distances of the optical impression groups did not appear to be inferior to those of the conventional groups.

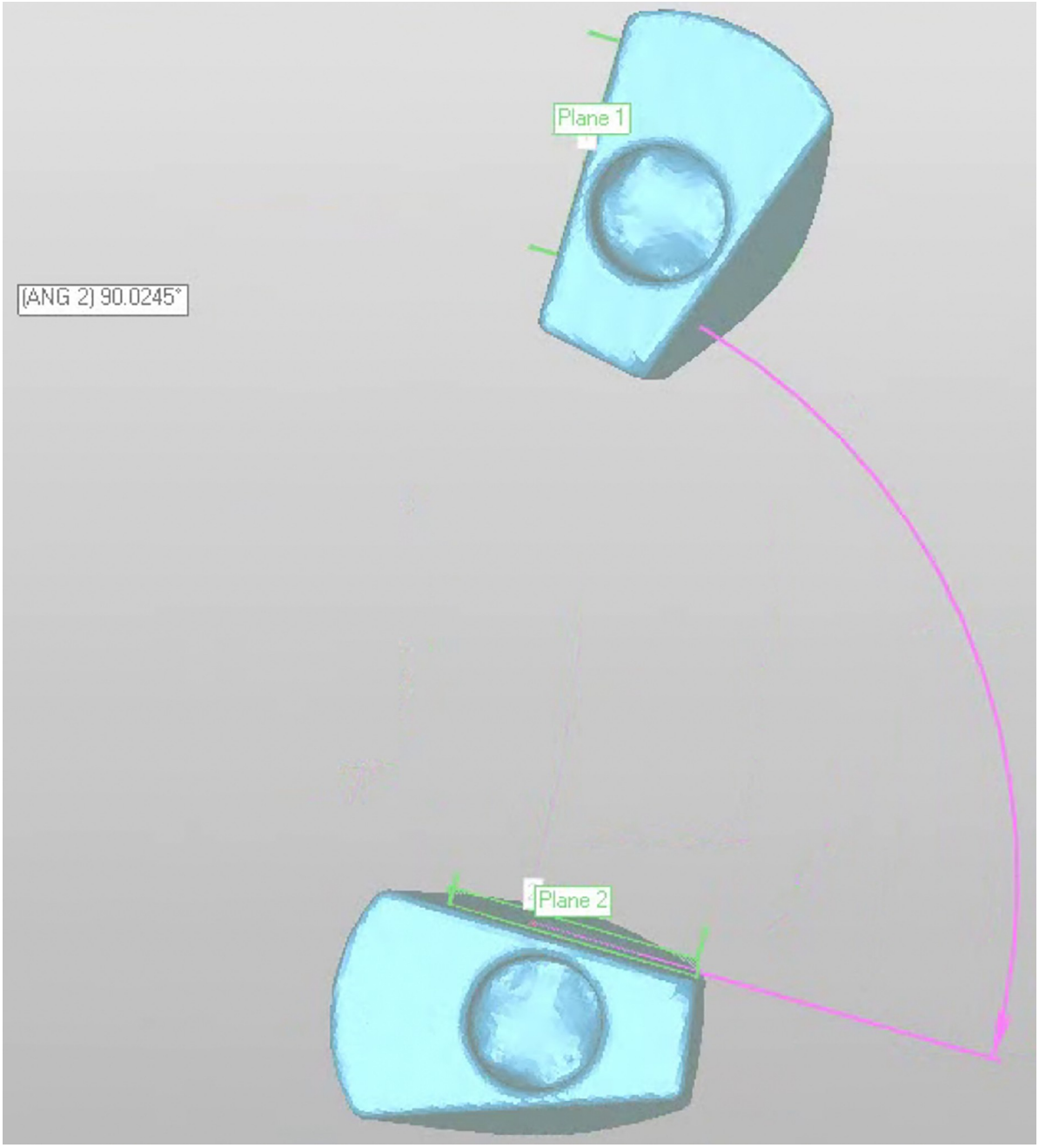

Fig 5. Two planes were constructed on a wall parallel to the implant axis of each scan body, and the angle between them was determined.

https://doi.org/10.1371/journal.pone.0228266.g005

Rotation of the implants over their axes

All systems used showed a certain degree of rotation. The differences in the angle between the two flat horizontal surfaces of the two implants in the test and the reference models are shown in Fig 7. The nonsplinted elastomeric impressions revealed significantly inferior results than those of the optical impressions. No significant differences were found between the open

Table 1. Comparison of the mean distance between each implant head center in the STL test file and the STL reference file. As significant differences were found ($p<0.05$), the LSD post hoc test was used to identify homogeneous groups.

	POINT 1		POINT 2	
SYSTEM	Mean (mm)	Homogeneous groups	Mean (mm)	Homogeneous groups
CS3600	0.012	X	0.018	X
Master model	0.018	X X	0.020	X
TRIOS3	0.019	X	0.024	X X
Closed tray	0.034	X	0.047	X
Open tray non-splinted	0.047	X	0.056	X
Open tray splinted	0.059	X	0.060	X X
CEREC Omnicam	0.225	X	0.063	X X
TrueDefinition	0.235	X	0.078	X

Method: 95.0 percent LSD. Within each column, the levels containing X's for a group of means within there are not statistically significant differences.

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splinted elastomeric impressions and any of the other 6 impression systems analyzed or between the closed impression and any of the other six impression systems (Table 2).

Precision

No significant differences were observed between the optical impressions. In addition, these impressions were significantly more precise than the elastomeric impressions ($p<0.05$)

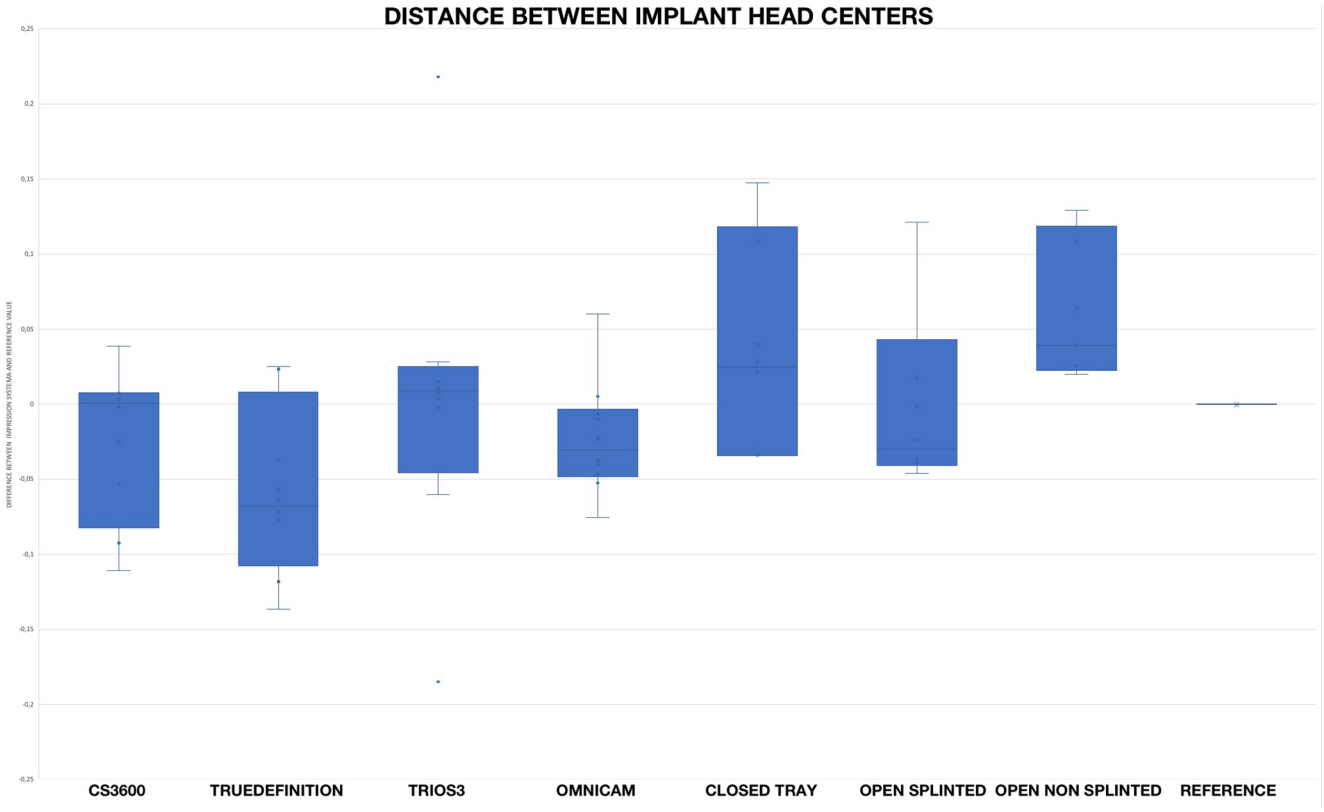

Fig 6. Differences between the distance of the two centroids of the test model and the reference model.

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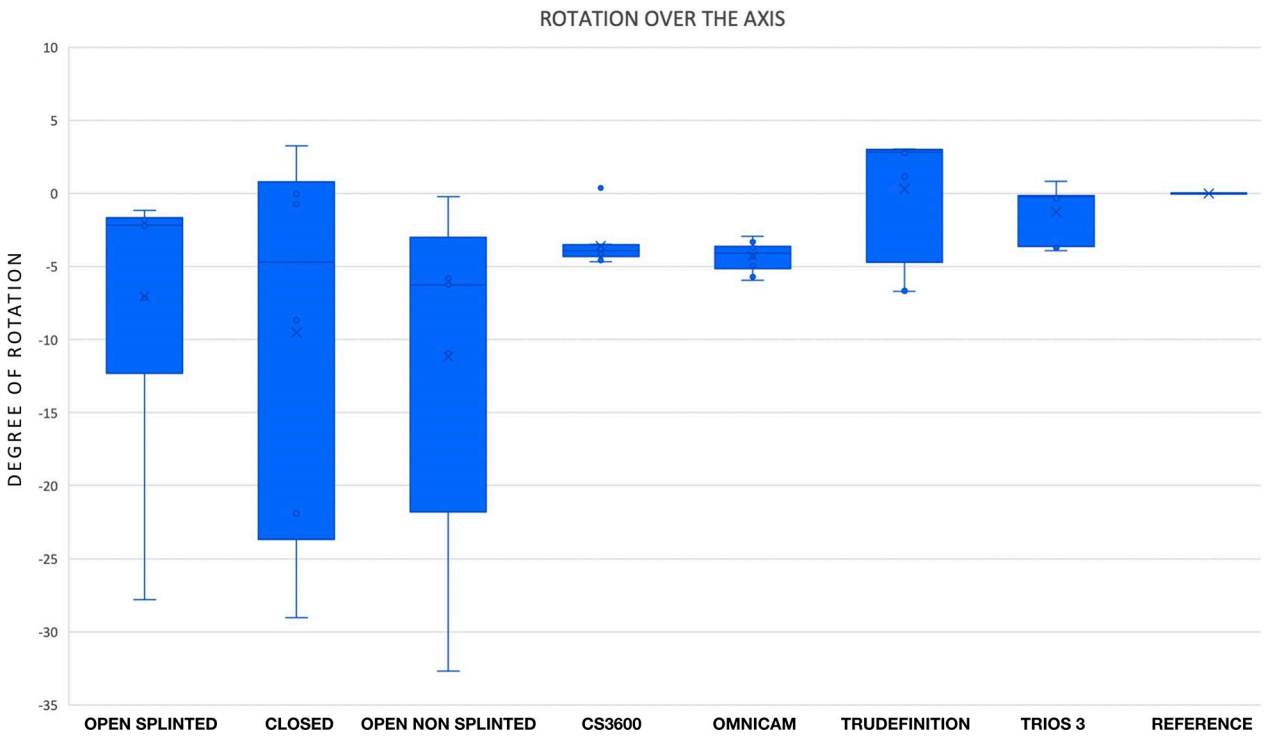

Fig 7. The differences in the angle between the two flat horizontal surfaces of the two implants in the test and the reference models.

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(Table 3). No significant difference was found between the two open tray methods, although both methods were significantly more precise than the closed tray method ($p<0.05$) (Fig 8).

Discussion

Two samples (CEREC Omnicam and CS3600) were discarded because they could not be aligned with less than 20 μm of misfit, despite the calibration of the operators. Both discarded files revealed evident defects in the impressions. Following the same protocol as that for conventional impressions, the clinician must carefully check optical impressions for defects before

Table 2. Comparison of the implant rotation over their axes for each group.

Multiple Range Test for Angle by System		
System	**Mean (degree of rotation)**	**Homogeneous groups**
Open tray non-splinted	86.040	X
CEREC Omnicam	87.568	X X
CS3600	88.259	X X X
Open tray splinted	88.939	X X X X
Closed tray	90.296	X X X
TRIOS3	90.579	X X
TrueDefinition	92.153	X

Method: 95.0 percent LSD. Within each column, the levels containing X's for a group of means within there are not statistically significant differences.

https://doi.org/10.1371/journal.pone.0228266.t002

Table 3. Comparison of the precision among systems.

Multiple Range Test for Precision by System		
System	**Mean**	**Homogeneous group**
TrueDefinition	0.027	X
TRIOS3	0.029	X
CEREC Omnicam	0.034	X
CS3600	0.042	X
Open tray non-splinted	0.113	X
Open tray splinted	0.121	X
Closed tray	0.227	X

Method: 95.0 percent LSD. Within each column, the levels containing X's for a group of means within there are not statistically significant differences.

https://doi.org/10.1371/journal.pone.0228266.t003

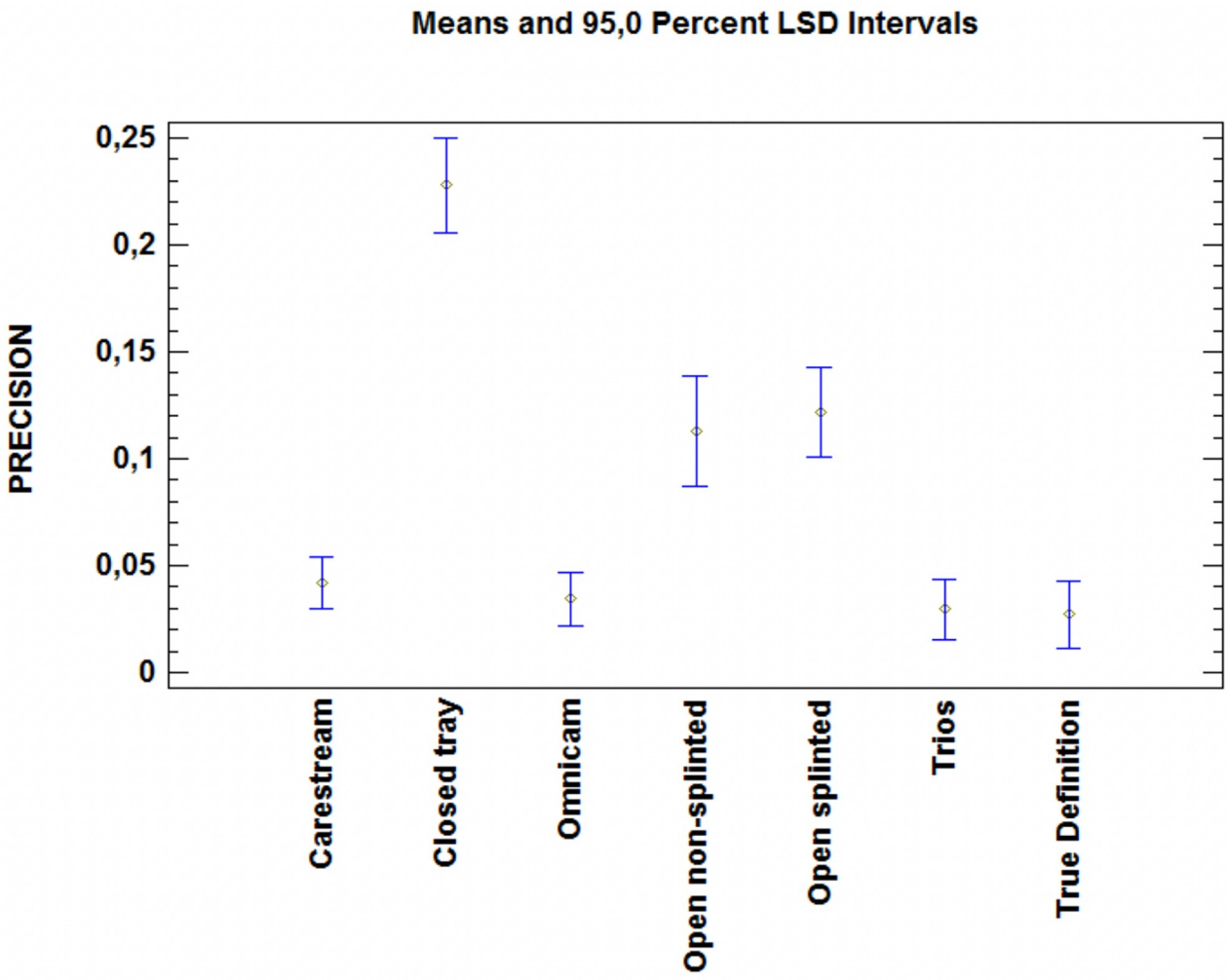

Fig 8. One-way ANOVA comparing the precision of the methods analyzed. The optical methods showed significantly more precision than the elastomeric methods did. The open tray impressions were significantly more precise than the closed tray impressions were ($p<0.05$).

https://doi.org/10.1371/journal.pone.0228266.g008

delivering them to the technician. If a defect is identified, then a new optical impression must be taken.

Regarding the precision of conventional impressions, in the conditions of our in vitro study, conventional impressions are significantly less precise than optical impressions are. It is important to highlight the high variability in different studies on linear and 3D distortion values, which range between 2 μm and 180 μm [30–33]. According to Baig [34], there is currently no evidence to support the splinting of impression copings to improve implant impression accuracy. Nevertheless, our results with respect to conventional impressions are similar to those of Izadi et al., who also found that open tray impressions were better than closed tray impressions [35]. The type of implant used might also contribute to differences in accuracy. Osman et al. also concluded that open tray impressions were more accurate than closed tray impressions, although in some implants, there was no difference [23]. Osman et al showed that the accuracy values were low, but these authors only measured the horizontal discrepancy in micrometers, whereas in the case of vertical discrepancy, a qualitative assessment of the presence or absence of discrepancy was performed. In our case, overall 3D discrepancy was measured[23]. Additionally, the type of gypsum might explain the differences between the studies, although some authors consider that the type of gypsum used is not important[36], while other authors claim better accuracy for certain types of gypsum [37]. The morphology and length of the impression copying can also determine differences between different studies [38].

Both the test and the reference STL files were aligned using Geomagic reference fit and best fit options. The reference fit option superimposes the first scan body and then calculates the difference between the centroid of the first and the second scan body[39]. Nevertheless, as superimposition is never perfect[39], the error is magnified in the subsequent scan body. Therefore, we discarded the models based on the first implant references and used the best fit option, which aligns the two scan bodies simultaneously.

When screwing the bridge on several implants, the clinician never screws on each implant individually but alternates between the implants. Once all screw joints have been tightened, the final torque is applied. This procedure compensates for any inaccuracies. The final result we obtained was the maximum difference in every implant, instead of the increasing difference in every next implant.

As the impression-taking process in all the groups took almost two months, we had to scan the master model every week to ensure its stability and to check whether any possible variations in the position and rotation of the implants occurred in the master model. A mean deviation below 6 μm indicated that the model was stable and that there were no changes in the implant position over time[40].

According to our results, under in vitro conditions, optical scanners are not inferior to conventional techniques for taking impressions of two almost parallel implants between teeth. Nevertheless, the results of the present study do not necessarily correspond to the clinical results. In the case of optical impressions, the presence of humidity and the mobility of the soft tissues surrounding the scan bodies can significantly affect the scanning process and the impression accuracy. In the case of elastomeric impressions, humidity can also alter the accuracy of the results. Closed tray impressions were significantly less accurate in terms of 3D displacement than were splinted open tray impressions. No significant difference was found between closed tray and nonsplinted open tray impressions or between splinted and nonsplinted open tray impressions.

Given that some studies have claimed polyether to be more accurate than polyvinyl siloxane impression material, we chose polyether for conventional impressions[41]. Knowing that time can affect impression accuracy, we waited one hour before pouring the impression[7]. Water

to powder proportions were followed according to the manufacturer's instructions. Although some authors have claimed that conventional impressions are more accurate than optical impressions for two consecutive implants[16], our results did not show an inferior performance of the optical impression techniques when compared to conventional impressions. These findings could be because the many steps involved (impression making stages, master cast, resin verification jig, waxing, investing, casting, veneer addition and finishing) can distort the final outcome[1]. The optical devices yielded a result in the range of 50–60 μm, suggesting these devices could be used for clinical impressions.

No significant difference was found between splinted and nonsplinted open tray impressions in the present study. This finding is in accordance with studies claiming that when highly rigid impression material (such as polyether) is used, the splinting of pick-up impression copings with acrylic resin is not useful to improve precision[42].

One possible issue regarding precision is the rotation of the implant analog, which might clinically affect the model. Implant analog rotation over the axis was determined by the angle between the two vertical flat surfaces of the scan body. Unlike elastomeric impressions, optical impressions appeared to reduce the risk of implant analog rotation. However, elastomeric impressions with splinted abutments rotated less than the nonsplinted abutments. When splinted frameworks with nonengaging connections are required, no rotation occurs, but the use of engaging connections might compromise the clinical result. In open tray impressions, extreme care was taken when placing the implant analogs in the impression transfer copings. All procedures were performed under magnification and good lighting.

The implants used in the model were placed almost parallel to each other, and the distance between them was the ideal for placing a molar and a premolar on top with a premolar pontic between them. According to Chia et al.[43], placing the implants angulated would probably lead to worse results for conventional impressions, while optical results would have probably been less affected. The distance between the implants was relatively wide (one pontic in between), which is not the best scenario for implant impressions[22, 44], but this scenario does not seem to affect conventional impressions[21]. Nevertheless, the results for the optical impressions did not seem to be affected.

A possible limitation of this study is the use of a desktop scanner to evaluate conventional models because it is not as accurate as a probe[22]. Nevertheless, we preferred the use of a desktop scanner because it is still highly accurate[38] and, moreover, a desktop scanner is commonly used by lab technicians to capture conventional models to proceed with their prosthodontic designs.

Another possible limitation is the continuous changes in the device software. Although accuracy should be improved, it could also become worse [22], so continuous assessment of the new software versions is needed.

From a clinical perspective, intraoral scanners have advantages and drawbacks. Patients generally have an overall better perception of IO scanning than of conventional impressions [45]. Optical scanning seems to be a more didactic and preclinical instruction; however, this method requires a rapid increase with multiple practice attempts [46].

Conclusions

Our findings suggest that optical impressions are superior to elastomeric impressions for placing two implants in one quadrant. Closed tray impression accuracy was significantly lower than that of open tray impressions for placing two implants in one quadrant.

Supporting information

S1 File. Results of the study. All results obtained in the study are listed in this file.
(DOCX)

Author Contributions

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Data curation: José Espona.

Formal analysis: José Espona.

Investigation: Elena Roig, Luis Carlos Garza, Natalia Álvarez-Maldonado, José Espona.

Methodology: Elena Roig, Paulo Maia, Miguel Roig, José Espona.

Project administration: Elena Roig, Paulo Maia, José Espona.

Software: Luis Carlos Garza, Natalia Álvarez-Maldonado, Miguel Roig, José Espona.

Supervision: Santiago Costa, Miguel Roig, José Espona.

Validation: Paulo Maia.

Writing – original draft: Elena Roig, Luis Carlos Garza, Miguel Roig.

Writing – review & editing: Luis Carlos Garza, Natalia Álvarez-Maldonado, Miguel Roig, José Espona.

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THE JOURNAL OF PROSTHETIC DENTISTRY

CLINICAL RESEARCH

Fit of complete-arch implant-supported prostheses produced from an intraoral scan by using an auxiliary device and from an elastomeric impression: A pilot clinical trial

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ABSTRACT

Statement of problem. The accuracy of impressions for implant-supported prostheses is essential to ensure a passive fit of the definitive prosthesis. Intraoral scanners (IOSs) have been developed as an alternative to complete-arch implant-supported restorations; however, whether they are sufficiently accurate when more than 3 nonaligned implants are involved is unclear.

Purpose. The purpose of this pilot clinical study was to determine whether the fit of complete-arch zirconia implant-supported frameworks processed on a cast obtained with an IOS and adjusted with an auxiliary device is equivalent to a prosthesis obtained from an elastomeric impression.

Material and methods. Twelve consecutive participants who were ready for complete-arch restorations on already osseointegrated implants were enrolled. Two records were made, one open-tray with polyether and splinted impression copings and the second with an IOS. A verification gypsum device was used for the elastomeric impression, and a prefabricated auxiliary device was used to adjust the intraoral scans. Two zirconia frameworks with the same design were processed and evaluated intraorally by 2 independent calibrated observers.

Results. In 11 of the 12 participants, the digitally processed prosthesis was preferred over the conventionally processed prosthesis. The clinical fit of the prostheses obtained with the completely digital workflow was better than that of those obtained with the conventional workflow.

Conclusions. The use of a prefabricated auxiliary device after intraoral scanning allowed delivery of complete-arch implant-supported monolithic zirconia prostheses with a fit better than those fabricated from conventional impressions. (J Prosthet Dent 2021;■:■-■)

An accurate impression is essential to ensure an implant-supported prosthesis with a passive fit.[1] Without a passive fit, the components around the implant prosthetic framework are prone to biological and mechanical problems.[2-5] Even slight discrepancies can produce stress and strain on the framework and the implants,[4] with different effects depending on framework material.[6] The use of rigid frameworks such as those made from zirconia might magnify those effects.[7] Unlike tooth-supported restorations, where up to 100 μm of tooth movement can help absorb a certain amount of misfit, implant movements are limited to 10 μm.[8] Nevertheless, even in such situations, there remains a biologic tolerance to misfit.[9]

Since an absolute passive fit is not achievable,[10] some authors[4,11-15] have proposed an acceptable misfit range from 30 μm to 100 μm, although a quantifiable misfit without adverse effects is difficult to determine.[16,17] Although according to the recommended standard of practice, clinicians try to provide prostheses that exhibit passive fit,[5,18] evidence of the impact of marginal misfit on the clinical outcome is clearly lacking.[18] Only

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Clinical Implications

Using an appropriate completely digital workflow, complete-arch implant-supported prostheses with a better fit than those from conventional impressions can be produced.

mechanical issues related to the screws have been associated with misfit.[18-20] Additional studies with improved designs are needed to determine the impact of misfit on the clinical outcome, the methods of assessing misfit, or whether general or behavioral factors can affect the clinical acceptability of a misfit.[18,20]

The most widely used impression systems are based on elastomeric materials, mainly polyvinyl siloxanes and polyether,[21,22] both of which are uncomfortable for the patient and inconvenient for the dental team to handle. Moreover, elastomeric materials are technique-sensitive, since they involve many steps.[23-28] The accuracy of elastomeric impressions is compromised by connection type,[28] impression technique,[28] and implant angulation.[29] Verification casts and splinting materials are required to achieve clinically acceptable accuracy.[29,30] To improve both patient and dental team experience, several optical scan systems have been developed to increase accuracy.[31] Intraoral scanners (IOSs) provide a standard tessellation language (STL) data set, which allows digital reconstruction of a virtual cast. These systems appear to offer similar results to conventional systems when few and aligned implants are involved.[32] Although IOSs have been suggested as an alternative for complete-arch implant-supported restorations,[33] others have observed significant loss of accuracy with IOSs when more than 3 nonaligned implants were involved and when distances between implants were increased.[34-36]

Other systems can also be used for recording implant location, including stereophotogrammetry[37,38] and cone beam computerized tomography (CBCT),[39] both of which enhance accuracy; however, they require intraoral optical scans or conventional impressions and involve expensive equipment[19] or radiation exposure. To ensure optimal accuracy and to overcome these drawbacks, an auxiliary device has been proposed (medicalfit; DENTALesthetic) (Fig. 1). This device has been claimed to allow correction of the misfit caused by IOSs, thereby optimizing the fit.[40] The approach involves an additional scan of a reference-marked splint of known dimensions to correct deviations with the intraoral optical scan.[40] Custom auxiliary devices have also been proposed to obtain reliable intraoral scans.[41]

The null hypothesis of this pilot clinical study was that the fit of complete-arch implant-supported monolithic zirconia prostheses produced through a completely digital workflow, with the final IOS output corrected with the medicafit device, would be equivalent to the fit of those fabricated from conventional impressions.

Figure 1. medicalfit device has one flat surface (not shown) and another with anatomic forms. Device attached to implant abutments by means of interim abutments.

MATERIAL AND METHODS

This clinical trial was approved by the Ethical Research Committee of Universitat Internacional de Catalunya (REST-ECT-2017-03) and registered at ClinicalTrials.gov (NCT03992300). Twelve consecutive individuals who were ready for complete-arch restorations on 5 to 7 already osseointegrated implants in the maxillary arch were enrolled. All implants had multiunit abutments (Nobel Biocare). Fifteen consecutive patients were selected during the recruitment period from April 2019 to March 2020. Three patients declined to take part in the study after reading the informed consent. The final sample size consisted of 12 participants: one who had 5 implants, 2 with 7 implants, and 9 with 6 implants, for a total of 78 implants. Two records were made for each participant. Record sequence was randomly assigned. Envelopes containing the name of 1 operator and the record sequence were prepared and shuffled, and 1 envelope was selected for each participant.

One record was made by using a conventional impression. Open-tray impression copings (Nobel Biocare) were placed with a torque wrench (Nobel Biocare) set at 10 Ncm on each implant, with the copings splinted by using a light polymerizing clear resin (Triad Gel; Dentsply Sirona), leaving at least a 3-mm diameter around the resin connectors. To avoid structural stress, a 0.3-mm-thick diamond disk (365D fine; Meisinger) was used to section the resin between the 2 connectors. The copings were then reattached with a drop of the same resin. A polyether impression (Impregum; 3M ESPE) was made in a perforated plastic impression tray, and a definitive cast was fabricated in accordance with the

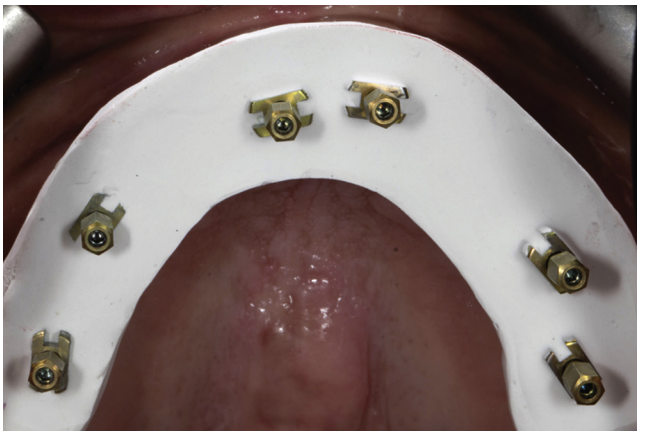

Figure 2. Plaster cast used to verify accuracy of conventional impression.

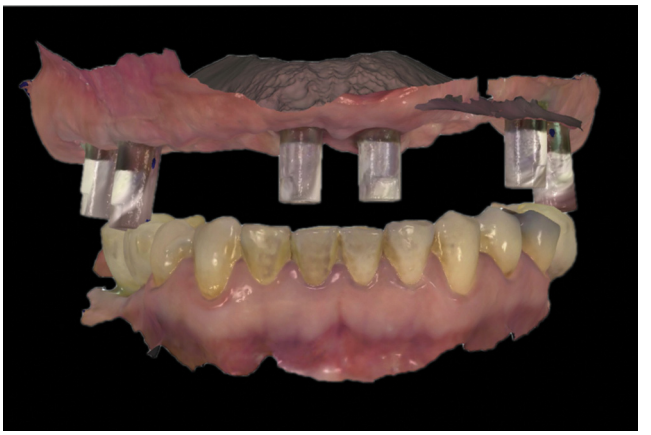

Figure 3. Intraoral scan with scan bodies in place.

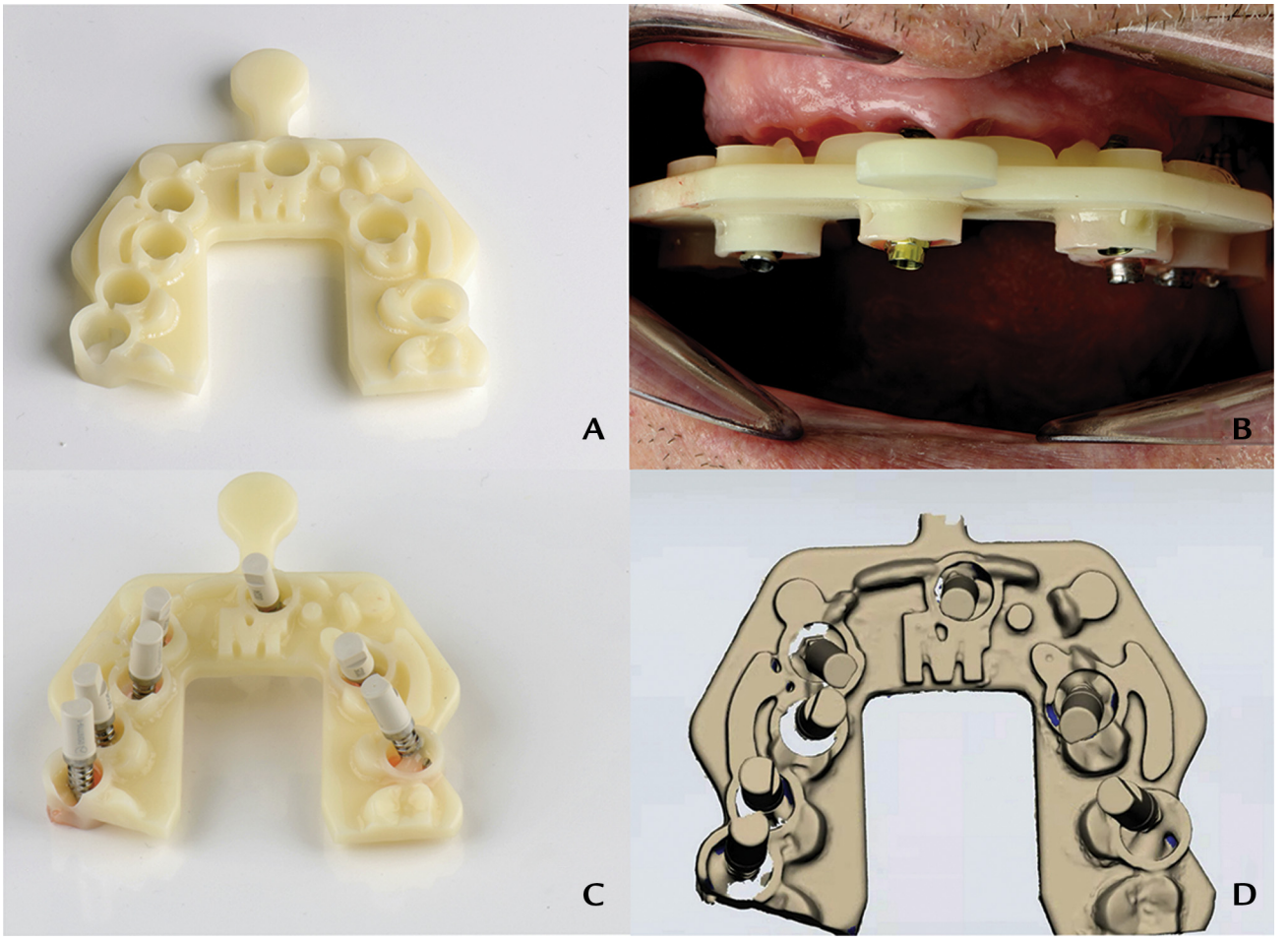

Figure 4. A, medicafit plate trimmed with implant position selected. B, Attached with Triad Gel to interim abutments in mouth. C, Once removed, ScAnalog scannable replicas screwed to interim abutments. D, STL data set obtained with intraoral scanner. STL, standard tessellation language.

manufacturer's instructions. A plaster verification cast (Snow White Plaster No. 2; Kerr Corp) was fabricated on the definitive cast[42,43] (Fig. 2). One week later the vertical dimension of occlusion (VDO) was determined, and the verification cast placed on the implants was used to assess passivity before proceeding to the definitive prosthesis. In the event of verification cast fracture, a new record would have been made.

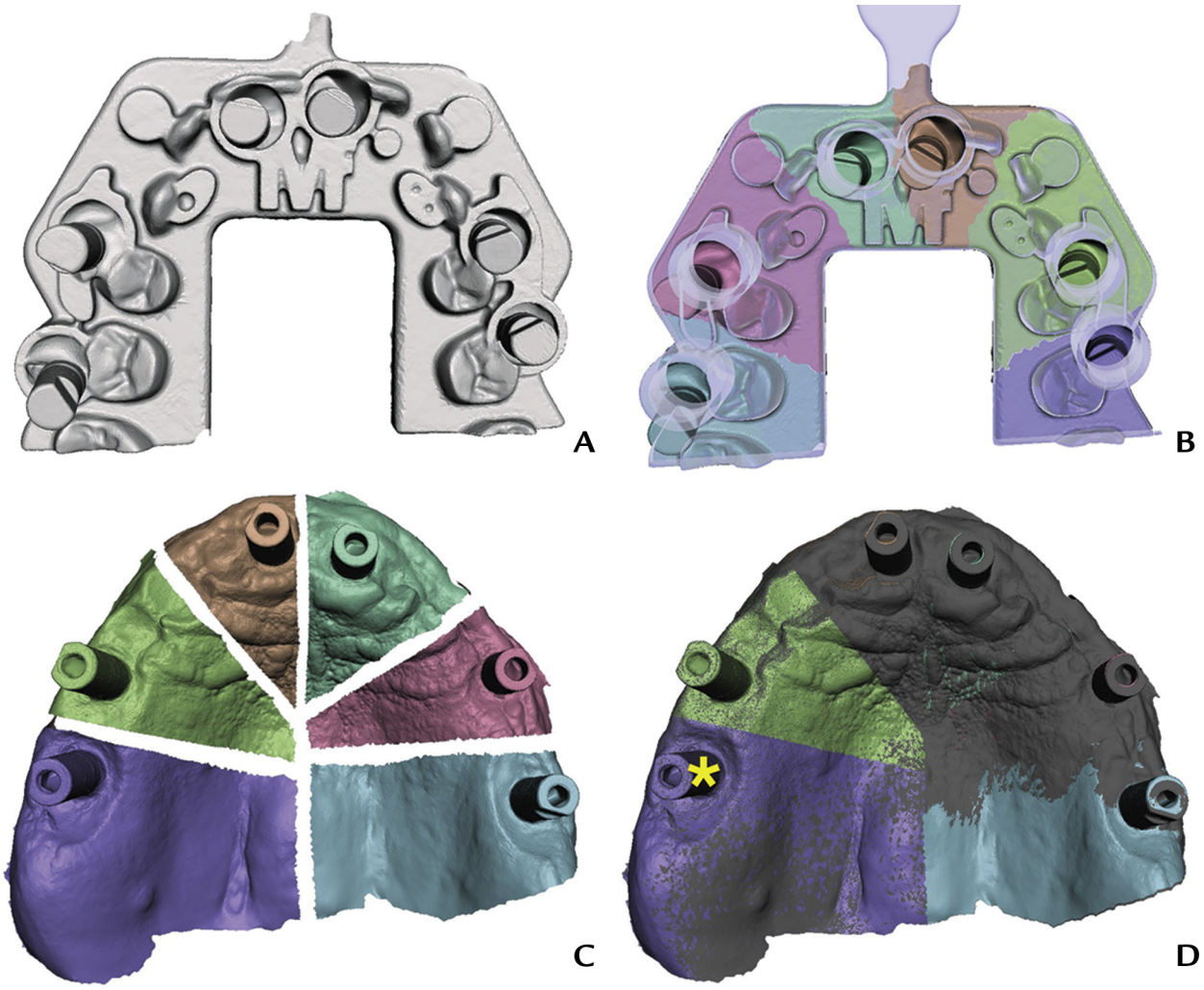

Figure 5. A, STL data set of medicalfit device scanned with intraoral scanner imported into Meshmixer. B, Each section containing one implant superimposed using best fit tool on STL file of medicalfit device in library. C, Each implant in STL data set obtained using intraoral scanning with scan bodies sectioned. D, Each implant superimposed using best fit tool to its corresponding implant in medicalfit device, yielding final STL file with more accurate position of implants. As shown in image, farther implant from first implant scanned (*), greater required fit. STL, standard tessellation language.

Additional records of the edentulous arch and the antagonist were made by using an IOS (TRIOS3; 3Shape A/S) (Fig. 3). A double scan of the edentulous arch was made, first with the healing abutments in place and then with the scan bodies (Core3D), in accordance with the manufacturer's recommendations. The scan bodies were then removed, and interim copings (Temporary Coping Multi-unit; Nobel Biocare) were screwed onto the multiunit abutments. The medicalfit device was selected, and holes were drilled in the position of each implant to enable the device to fit over the interim copings. The copings were then splinted to the device by using the clear resin (Triad Gel; Dentsply Sirona). After splinting, the medicalfit device was removed and implant replicas (ScAnalog; Dynamic Abutment Solutions) were placed beneath the interim copings on the

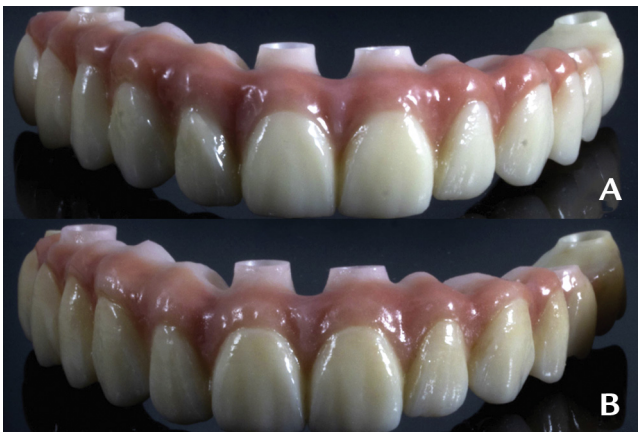

Figure 6. Two almost identical prostheses delivered to observers. A, Produced from digital flow. B, Produced from conventional flow.

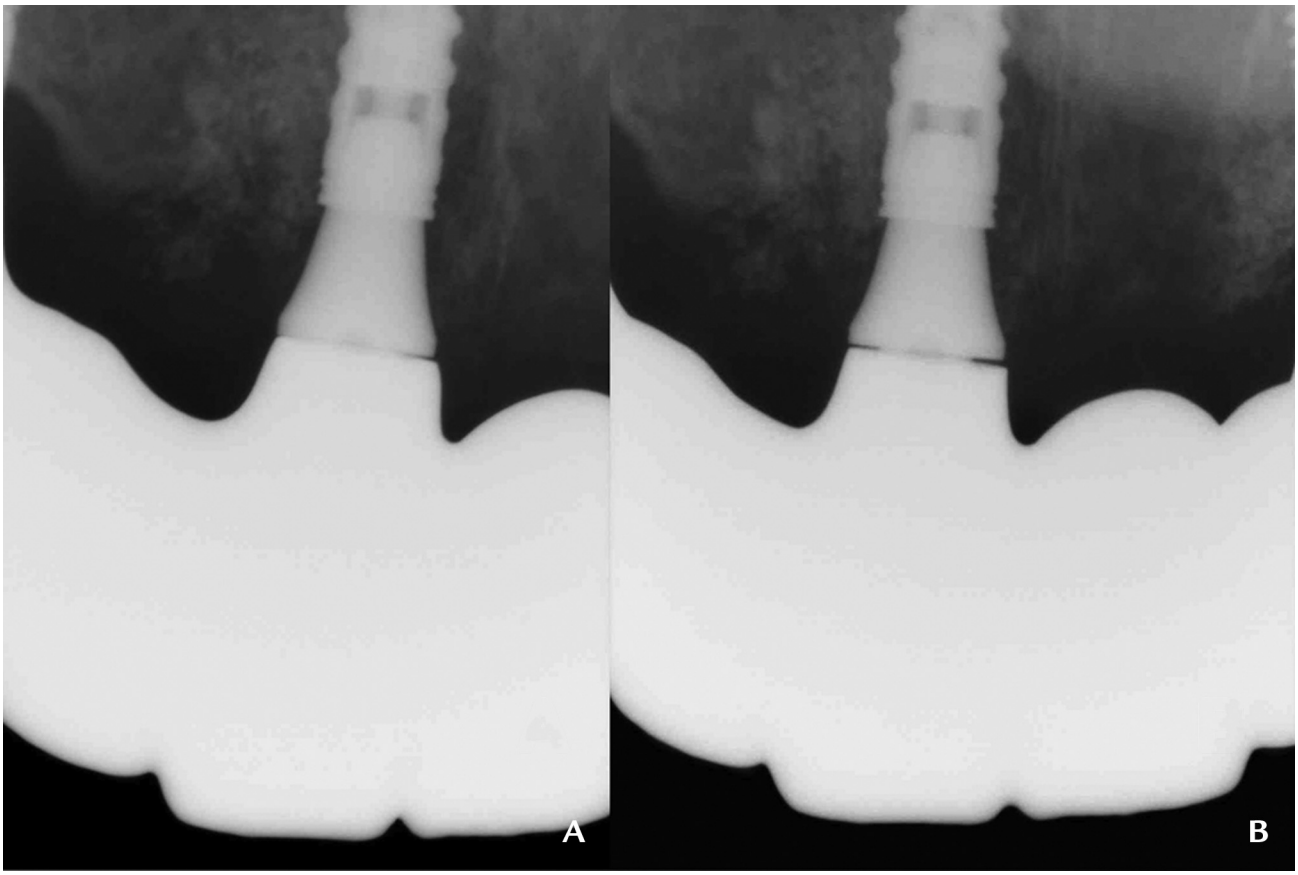

Figure 7. Radiographic assessment of misfit. Although radiographic guide used, perfect alignment of radiographic beam not always possible. A, Digital framework with better fit. B, Conventional framework.

Figure 8. Tightening torque scores. Blue line represents torque and black line indicates time. A, Flat torque line with steep final increase scored 1. B, Initial flat line followed by progressive increase scored 2. C, Early start of increase scored 3.

Table 1. Perception of passivity on visual analog scale (0 cm perfect passivity, 10 cm unacceptable lack of passivity)

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	0.25	1.80	0.96	0.48	1.34	1.02	1.11	0.96	0.75	0.86	1.3	0.42
DF	O2	0.72	0.24	0.72	0.52	0.74	1.38	1.92	1.32	1.10	1.14	0.88	0.74
CF	O1	2.40	2.77	5.42	5.36	2.45	1.44	1.33	2.77	2.16	2.4	3.45	2.81
CF	O2	0.24	0.24	7.10	1.36	1.95	1.29	2.32	1.98	3.17	2.93	2.92	1.87

CF, conventional fabrication; DF, digital fabrication; Pt, participant.

Table 2. Signed-rank test for perception of passivity on visual analog scale

Count	12
Mean	2.41
Standard deviation	2.10
Coefficient of variation	87.4%
Minimum	0.38
Maximum	7.65
Range	7.27
Null hypothesis	Median=0
Alternative	Not equal
Average rank of values below hypothesized median	0
Average rank of values above hypothesized median	6.5
Large sample test statistic	3.02 (continued correction applied)
P	.003

Perception of passivity during insertion of prosthodontic screws significantly better in digital than in analog frameworks.

medicalfit device, and intraoral scans were obtained (Fig. 4).

Additional extraoral images of the patient's face were made with the scan bodies in place, at rest, in forced smile, and in the frontal and 45-degree lateral views by using cheek retractors. The images and STL data sets were sent to the dental laboratory technician to fabricate an interim prosthesis. The STL data set from the medicalfit device scan was imported into a 3D image manipulation software program (Meshmixer; Autodesk Inc) and sectioned into as many pieces as the number of implants. The best fit feature was used to superimpose each piece onto the original STL output of the medicalfit device, allowing a more accurate positioning of the implants in the virtual cast (Fig. 5).

At the second appointment, a laboratory-made interim polymethyl methacrylate (PMMA) framework was evaluated intraorally. Adjustments were made to the occlusal and gingival contours and the esthetics. Once these were corrected, a new IOS image was made with the interim framework in the participant's mouth.

At the follow-up visit, 2 independent, blinded, calibrated examiners evaluated 2 similar zirconia prostheses in the patient's mouth (Fig. 6). One framework was fabricated from the conventional cast (CF) and the second with a completely digital workflow (DF). The prostheses were identified only by symbols ("∇" for conventional, "O" for digital) in the distal right molar, whose meaning was unknown to the evaluators.

Fit was assessed according to 5 criteria: perception of passivity during insertion of the prosthodontic screws, tactile perception, radiographic examination findings,[38] Sheffield test results,[20] and tightening torque.[44]

A visual analog scale (VAS) was used to assess the perception of passivity during insertion of the prosthodontic screws. The operator marked the level of passivity on a 10-cm line with one end labeled "perfect passivity" and the other end labeled as "no passivity at all." Thus, the distance between the mark and "perfect passivity" defined the framework passivity.

Marginal fit was examined by using an explorer (Explorer 17-23; LM) under ×3.8 magnification. Three scores were possible: 0 (no gap perceived), 1 (perception of gap without probing), and 2 (the tip of the explorer clearly entered the gap).

After tightening all the screws to 15 Ncm, periapical radiographs were made with a positioner (XCP-ORA; Dentsply Sirona) to detect gaps (Fig. 7). Gaps were assessed from 1 to 5, with 1 being no gap and increasing at 0.15-mm increments until reaching 0.60 mm (score 5).

For the Sheffield test, all the screws except the most distal right screw were loosened. A periapical radiograph was made with a positioning system (XCP-ORA; Dentsply Sirona) to evaluate the gap. Gaps were scored from 1 to 5 as previously.

An additional tightening torque measurement was made on each abutment by using a motor controlled by an iPhone application (iChiropro; Bien-Air Dental USA, Inc). All the screws were hand screwed and then loosened 3 full turns. Subsequently, the torque was set at 15 Ncm and 5 rpm. The most distal right screw was tightened first, followed by the other screws, going from the most mesial left to the most distal left, and then to the adjacent implant until all the screws were tightened. The torque-time diagram of each screw was analyzed to determine whether the level began to rise at the end of, or throughout, the tightening process. Three scores were possible: 1 for a linear value with a sharp rise at the end of the tightening, 2 for mild continuous growth with a steeper rise at the end, and 3 for a steep rise at the beginning of the tightening (Fig. 8).

The 2 operators compared the conventional framework with the digital framework (CF, DF) to select the one with the better overall fit. Where there was disagreement, a consensus was reached regarding which framework to place. The selected framework was then tested for occlusion, phonetics, and esthetic parameters and then delivered. Twelve cards, 6 with letters CF written on top and 6 with letters DF on top, were shuffled. The sequence of the 2 tests was randomly assigned to each patient using the shuffled deck of cards. After each participant, the selected card was discarded.

Since each patient was subject to both conventional and digital techniques, within-patient comparison was used for statistical analysis. The signed rank test was used to evaluate perception of passivity on the visual analog scale, marginal fit, radiographic fit, Sheffield test, and tightening torque. When superiority was rejected, a noninferiority test for comparison of paired samples was used. A binomial test was used to evaluate

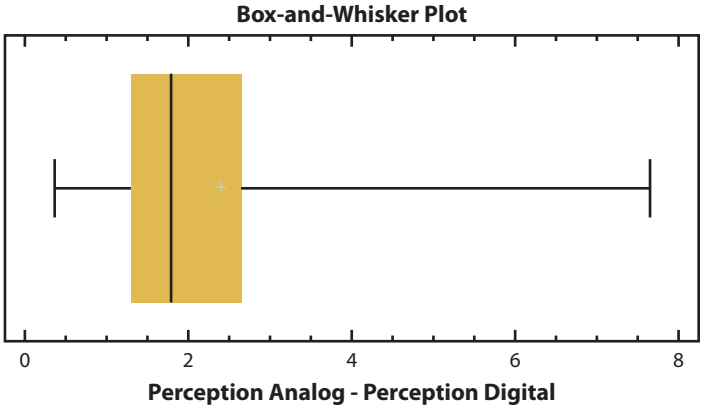

Figure 9. Box-and-whisker plot for perception of passivity on visual analog scale and signed-ranked test. All differences between perception in analog and digital tests positive (worse values in analog group in all participants).

Table 3. Marginal fit on scale from 0 to 2, where "0" represents no gap perceived with explorer, and "1" indicates gap perceived without explorer entering the gap

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	0	0	0	0	0	0	0	0	0	0	0	0
DF	O2	0	0	0	1	0	0	1	0	0	0	0	0
DF	FD	0	0	0	1	0	0	1	0	0	0	0	0
CF	O1	0	0	1	1	1	0	0	0	1	0	1	0
CF	O2	0	1	1	1	0	0	0	1	0	1	1	0
CF	FD	0	0	1	1	1	0	0	1	0	1	1	0

CF, conventional fabrication; DF, digital fabrication; FD, final decision by 2 operators when different values determined; Pt, participant.

whether the proportional preference for digital scanning was significantly different from 0.5. Statistical power of the results was measured with a sample size and power calculator (GRANMO; Institut Municipal d'Investigació Mèdica).

RESULTS

None of the gypsum verification devices fractured, and none of the frameworks processed on the intraoral scan and corrected with the auxiliary device had a fit inferior to those processed on the cast and obtained from the conventional impression. All the prostheses were considered clinically acceptable by the observers.

Table 1 shows the results obtained for perception of passivity on a VAS during insertion. The signed-rank test showed statistically significant differences between the 2 systems (Table 2). Figure 9 shows a graphic representation of the distribution of the differences between perception of passivity on a VAS in the analog and in the digital frameworks, with all the differences positive (worse perception of passivity in all frameworks processed from analog impressions). Statistical power of the results was over 80%.

Table 3 shows the results for the examination of the marginal fit with an explorer. The signed-rank test did not reject the hypothesis that the scores for the marginal fit with an explorer were independent of the system used at the 95% confidence level. Better marginal adaptation with DF than with CF was rejected. Noninferiority of marginal adaptation with DF versus CF was demonstrated (Table 4).

Table 5 shows the results of the radiographic fit. The signed-rank test rejected the hypothesis that the scores

Table 4. Noninferiority of digital versus conventional frameworks in marginal fit assessment demonstrated

Sample Statistics					
Sample	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Digital MF	12	0	1	0.17	0.39
Analog MF	12	0	1	0.5	0.52

Equivalence Analysis				
Comparison	**n**	**Difference**	**Standard Error**	**Upper 95% CL**
Digital MF vs Analog MF	12	-0.33	0.19	0.004

Comparison	Upper *t*-Value	Upper *P* Value
Digital MF vs Analog MF	-7.09	0

Comparison	Maximum *P* Value
Digital MF vs Analog MF	0

Comparison	Conclusion (alpha=5%)
Digital MF vs Analog MF	Noninferiority demonstrated

MF, manufacturer.

Table 5. Radiographic fit rated from 1 (no gap) to 5 (gap>.60 mm)

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	1	1	1	1	1	1	3	1	1	1	1	1
DF	O2	1	1	1	1	1	1	3	1	1	1	1	1
DF	FD	1	1	1	1	1	1	3	1	1	1	1	1
CF	O1	2	2	2	1	2	1	2	2	2	1	2	1
CF	O2	3	2	2	1	1	1	2	1	2	2	2	1
CF	FD	2	2	2	1	2	1	2	2	2	2	2	1

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Two observers had to agree on results for each assessment (FD).

for radiographic fit were independent of the system used at the 95.0% confidence level (DF better than CF) (Table 6).

Table 7 shows the results for the Sheffield test. The signed-rank test rejected the hypothesis that the scores were independent of the system used at the 95.0% confidence level (DF better than CF) (Table 8).

Table 9 shows the results for the tightening torque. The signed-rank test did not reject the hypothesis that the scores for the tightening torque were independent of the system used at the 95.0% confidence level. Non-inferiority for tightening torque with DF versus CF was demonstrated (Table 10).

Table 11 shows the results for overall performance. Since the *P* value for the binomial test was less than .05 (.003), the hypothesis that the scores were independent of the system used was rejected at the 95.0% confidence level.

Table 6. Signed-rank test for results of radiographic examinations

Count	12
Average	0.58
Standard deviation	0.67
Coeff. of variation	114.61%
Minimum	-1.0
Maximum	1.0
Range	2.0
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	5.0
Average rank of values above hypothesized median	5.0
Large sample test statistic	2.27 (continued correction applied)
P	.023

Radiographic fit significantly better in digital than in analog frameworks.

DISCUSSION

All the prostheses in this study were placed on multiunit abutments. The results might have been adversely affected had the framework had been placed directly on the implants, since the use of abutments improves accuracy and reduces misfit.[28] The use of titanium bases (ti-bases) between the framework and multiunit abutments requires manual setting and luting of the ti-base, which can induce misfit; therefore, this was avoided. Hence, the zirconia framework was directly seated on the multiunit abutments. To increase framework resistance to tightening torque, the zirconia width in the screw setting was increased, and longer screws were used. Wear of the titanium abutments is one possible complication in this type of framework,[7] but to better determine the fit of the frameworks, it was decided to avoid the use of ti-bases.

The medicalfit concept is somewhat similar to that described by Iturrate et al,[41] which is based on a double IOS protocol, one with regular scan bodies and one with an auxiliary device that is designed after the first IOS output is obtained, 3D-printed, and then luted to the scan bodies. The auxiliary device, on account of its anatomic landmarks, allows better superimposition of the images obtained from the IOS, thereby improving the accuracy of the system.[41] The medicalfit device thus seems to offer several advantages as a prefabricated device, and it is luted to conventional interim copings. However, with the proposed assessment methods, it was not possible to control vertical discrepancies. Although radiographic assessment can be precise when the radiographic beam is perpendicular to the implant long axis, it is clinically impossible to ensure perfect perpendicularity.[39]

Since ScAnalog replicas are made from polyetheretherketone (PEEK), proper care must be taken when tightening to avoid damage to the threads and incorrectly positioning the replica. This may explain the discrepancy in 1 of the implants in participant 7's DF prosthesis, and it also may have been responsible for the poorer results obtained with the digital system for that participant, which was the only treatment that showed worse results than the analog system. It might also explain how 1 implant in participant 7, with a score of 3 in the radiographic fit, had a corresponding score of 1 in the Sheffield test.

The use of complete-arch zirconia frameworks can be successful, provided the fit on the implant abutments is good[7] and accuracy comparable with that of titanium frameworks can then be achieved.[10] Zirconia frameworks flex less and are more likely to fracture because of stress.

Table 7. Sheffield test results

Digital/Analog	Examiner	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5	Pt 6	Pt 7	Pt 8	Pt 9	Pt 10	Pt 11	Pt 12
DF	O1	1	3	1	1	2	2	1	1	1	1	2	1
DF	O2	2	1	1	1	1	1	1	1	1	2	1	1
DF	FD	2	2	1	1	1	2	1	1	1	1	2	1
CF	O1	2	3	5	1	3	3	2	3	2	2	3	2
CF	O2	3	2	3	3	2	3	2	3	2	2	3	1
CF	FD	2	3	3	2	3	3	2	3	2	2	3	2

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Scores ranged from 1 (no gap) to 5 (gap>.60 mm) with increments of 0.15 mm between each score. Where 2 observers did not obtain same result, discussed until final score (FD) agreed.

Table 8. Signed-rank test for results of Sheffield test

Count	12
Average	1.17
Standard deviation	0.58
Coeff. of variation	49.5%
Minimum	0
Maximum	2.0
Range	2.0
Null hypothesis	Median=0
Alternative	No equal
Average rank of values below hypothesized median	0
Average rank of values above hypothesized median	6.0
Large sample test statistic	3.02(continued correction applied)
P	.002

Sheffield test significantly better in digital than in analog frameworks.

Table 10. Noninferiority of digital versus conventional frameworks in tightening torque assessment demonstrated

Sample Statistics					
Sample	**N**	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Digital ST	12	1.0	3.0	1.67	0.65
Analog ST	12	2.0	3.0	2.17	0.39

Equivalence Analysis				
Comparison	**n**	**Difference**	**Standard Error**	**Upper 95% CL**
Digital ST versus Analog ST	12	-0.5	0.23	-0.086

Comparison	**Upper *t* Value**	**Upper *P* Value**
Digital ST versus Analog ST	12	-0.5

Comparison	**Maximum *P* Value**
Digital ST versus Analog ST	12

Comparison	**Conclusion (α=.05)**
Digital ST versus Analog ST	12

Discrepancies of up to 500 μm can disappear when the screws are tightened, even in stiff frameworks, generating stress within the framework.[19] In the case of misfit, the stiffer the material, the greater the stress experienced by the framework,[19] although the impact of stress on the framework and the implants has not been clearly demonstrated.[18-20]

Table 9. Tightening torque results

		Tightening Torque (1-3)											
Examiner	**Digital/ Conventional Fabrication**	**Pt 1**	**Pt 2**	**Pt 3**	**Pt 4**	**Pt 5**	**Pt 6**	**Pt 7**	**Pt 8**	**Pt 9**	**Pt 10**	**Pt 11**	**Pt 12**
O1	DF	2	1	2	1	1	1	3	2	1	2	2	1
O2	DF	1	1	1	2	2	1	2	1	2	2	2	1
FD	DF	2	1	2	1	2	1	3	2	1	2	2	1
O1	DF	3	3	2	3	2	2	1	2	3	2	3	2
O2	DF	2	1	2	3	1	3	2	2	2	2	3	2
FD	DF	2	2	2	3	2	2	2	2	2	2	3	2

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Scores ranged from 1 (excellent) to 3 (regular). Where 2 observers did not obtain same result, discussed until final score (FD) agreed.

Table 11. Overall performance results

Examiner	**Pt 1**	**Pt 2**	**Pt 3**	**Pt 4**	**Pt 5**	**Pt 6**	**Pt 7**	**Pt 8**	**Pt 9**	**Pt 10**	**Pt 11**	**Pt 12**
O1	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF
O2	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF
FD	DF	DF	DF	DF	DF	DF	CF	DF	DF	DF	DF	DF

CF, conventional fabrication; DF, digital fabrication; Pt, participant. Sample proportion=0.92; sample size=12; *P*=.003; null hypothesis: theta=0.05; alternative hypothesis: theta >0.5. Values of theta supported by data >0.66. Scores ranged between DF (digital) and CF (analog). Where 2 observers did not obtain same result, discussed until final score (FD) agreed. Binomial test rejected that results independent of technique (*P*<.05).

The participants received different numbers of implants. In treatments with fewer implants, the distance between implants was greater, which might have caused problems for intraoral impression making.[36] Nevertheless, a clinically acceptable fit was found in all the digital treatments, probably because the use of the auxiliary device improved the accuracy of the IOS output.

Angulation of multiunit abutments varied significantly across patients. Although increased angulation might represent a problem of accuracy, it has been demonstrated that even if the angulation is as high as 20 degrees, framework fit can be achieved, provided a verification cast is used.[29] In order to ensure maximum accuracy, a verification cast was used in the CF treatments.[29] No fractures were observed in the verification cast, implying that the splinting protocol of the open-tray impressions was accurate. Nevertheless, given the high cost of zirconia frameworks, the limited number of participants evaluated meant it was difficult to determine

whether it is reasonable to avoid a verification cast if good splinting has been performed. Triad Gel was used for splinting in this study. Although other materials have been reported to be more accurate,[30] from a clinical perspective, the ease of using Triad Gel makes it more suitable for all situations,[29] and it offers acceptable precision and trueness.[29] No fractures occurred in the gypsum verification cast, showing that Triad Gel is an acceptable material for splinting.

Misfit should be ideally below 10 μm,[15] but clinical fit is difficult to assess from conventional or quantitative methods.[16,17,19] When using tightening torque to evaluate fit, it is advisable to measure the torque and angle of rotation of the screw.[44] In the present study, time instead of the angle of rotation was used. Since the rotating speed was constant (iChiropro also registers rotational speed), time also represents the angle of rotation and can be used for torque-angle signature analysis.

In the present study, tightening torque showed more passivity in 9 of the 14 digitally processed frameworks, and less passivity in only 1, but a larger sample size would be necessary to confirm the superiority of 1 of the 2 systems in achieving passivity. Further studies are also required to address chair time, dental team experience, patient experience, and overall cost.

CONCLUSIONS

Based on the findings of this pilot clinical study, the following conclusion was drawn:

1. The use of a prefabricated auxiliary device after intraoral scanning allowed delivery of complete-arch implant-supported monolithic zirconia prostheses with a fit better than those fabricated from conventional impressions.

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DENTAL TECHNIQUE

Immediately loaded interim complete-arch implant-supported fixed dental prostheses fabricated with a completely digital workflow: A clinical technique

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ABSTRACT

A digital method for delivering an immediately loaded interim complete-arch implant-supported prosthesis is described. Reference pins were used to accurately superimpose a postoperative scan with the scan bodies in place on a preoperative scan with the framework design, including the interocclusal relationship and the occlusal scheme. A prefabricated auxiliary device was used after surgery to record the position of the implants and after scanning to obtain an accurate transfer of the implant positions by means of a free software program, allowing an excellent fit of the fabricated prosthesis. This technique can help in the fabrication of an interim prosthesis with better fit and comfort and reduced chair time than conventional techniques. (J Prosthet Dent 2020;124:423-7)

Immediate loading of a complete-arch implant-supported prosthesis is predictable and is a standard treatment option for selected patients.[1-3] The procedure is complex and requires adequate knowledge, skill, and clinical expertise.[4] Digital workflows have been introduced to simplify the protocol, reducing treatment time.[5,6] Nevertheless, standard workflows are usually required, which include impression making immediately after implant placement, finishing of the interim prosthesis in the dental laboratory, and/or cementing the interim prosthesis to interim copings in the patient's mouth.[7-9] Accurately transferring the vertical dimension of occlusion (VDO) to the prosthesis[10] and recording the optimal interocclusal relationship may require time-consuming adjustments.[11]

An intraoral scanner (IOS) can be a good alternative to elastomeric impressions for accurately recording the location of the implants immediately after placement. However, the accuracy of the scan may be insufficient to allow passive fit of the framework in a complete-arch implant-supported prosthesis.[12,13] The use of an auxiliary device can help achieve adequate accuracy.[14] A prefabricated device such as the MedicalFit device (Dentalesthetic) can be used to simplify the process and eliminate the time required for the fabrication of a custom device. This plastic device has one flat surface and the other surface with anatomic teeth shapes (Fig. 1).

Another problem in using IOS immediately after surgery is the difficulty in making interocclusal records because of the lack of anatomic references.[15] By placing several pins (Ti-System; curasan) before the surgery, the accuracy in overlapping the presurgical and postsurgical intraoral scans can be improved, allowing the dental technician to work with the interocclusal records sent with the first set of standard tessellation language (STL) files. Recording an accurate scan and the intermaxillary relationship allows the dental technician to deliver an interim prosthesis with an optimal fit, the planned VDO, and well-controlled occlusion and esthetics. The protocol allows the delivery of the interim prosthesis in a monolithic material in 3 visits. The second and third visits can be in 1 day or on 2 consecutive days.

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Figure 1. MedicalFit device used. Plastic plate with one flat surface and other with anatomic forms to facilitate intraoral scanning.

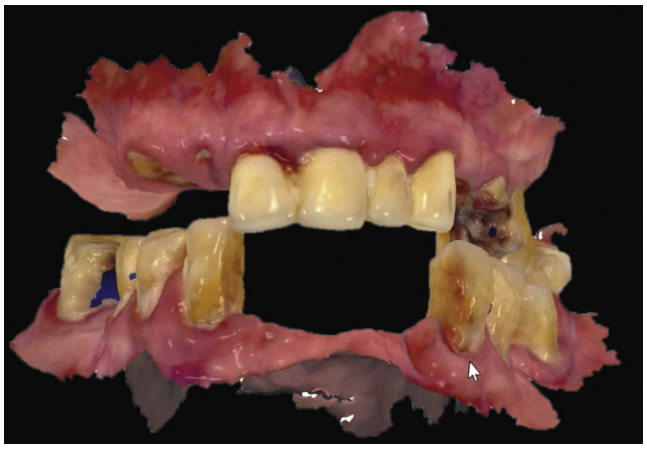

Figure 2. Initial optical intraoral scan. Mandibular and maxillary arches and interocclusal relationships recorded.

TECHNIQUE

1. Obtain intraoral optical scans (TRIOS 3; 3Shape A/S) of both the arches and the occlusion (Fig. 2). Obtain frontal photographs from a 45-degree angle with the lips at rest, with a maximum smile, and by using lip retractors. All photographs must include the eyes. Make a cone beam computed tomography (CBCT) (CS 8100; Carestream Dental LLC) scan of the patient to obtain a Digital Imaging and Communications in Medicine (DICOM) file (Fig. 3). Import and superimpose both DICOM and STL data sets into an implant planning software program (DTX Studio; Nobel Biocare Services AG). Determine the initial steps of the treatment (Fig. 4). Send all files and pictures to the dental laboratory technician.
2. Import the STL files and photographs into a computer-aided design and computer-aided manufacturing (CAD-CAM) software program (Dental System; 3Shape A/S) and design a complete-arch implant-supported fixed dental prosthesis. Approve the STL data sets of the design before the surgery (Fig. 5).
3. Import the STL file with the definitive design into the surgical implant planning software program (DTX Studio) and superimpose it on the original STL file and the original DICOM file. Plan the implants and design a surgical guide. Export the STL file of the surgical guide and 3D print or mill the guide.
4. Place 3 to 4 Ti-System pins in the maxilla (Fig. 6A). Ensure the pins are placed in locations that will not be contacted during surgery. Scan the arch again with the pins in place before surgery (Fig. 6B).
5. Extract the teeth that might interfere with the complete seating of the surgical guide and place the implants. Select and screw multiunit abutments (Nobel Biocare Services AG), screw scan bodies (AVINENT) into the abutments, and make a new intraoral optical scan, ensuring that all the pins are included in the scan (Fig. 6C).
6. Remove the scan bodies and screw the interim copings (Temporary Snap Coping Multi-unit Plus; Nobel Biocare Services AG) to the multiunit abutments. Adapt a MedicalFit device to the interim copings, with the anatomic surface toward the implants, and attach the device to the interim copings with flowable composite resin (Tetric EvoFlow; Ivoclar Vivadent AG) (Fig. 6D).
7. Once attached, unscrew the interim copings to remove the device, screw ScAnalog implant replicas (Dynamic Abutment Solutions) to the interim copings, make an optical scan of the ScAnalog replicas and the auxiliary device, and send all obtained STL data sets to the dental laboratory (Fig. 7).
8. Superimpose the file with the scan bodies on the file with the MedicalFit device. By using a mesh managing software program (Autodesk Meshmixer; Autodesk Inc), reposition the scan bodies in the STL file of the intraoral scan. Superimpose the corrected STL file over the prosthodontic planning file by using the pins as reference. Adapt the designed framework to the ScAnalog implant replicas in the STL data set and mill the prosthesis in polymethylmethacrylate (PMMA) resin (PMMA BLOK; Huge Dental Material Co). As the overall procedure requires 3 to 4 hours, schedule the patient for the next step, the same, or the following day. Screw the interim prosthesis to the multiunit abutments at a torque of 15 Ncm.
9. Close the access holes with Teflon tape and composite resin (Esthet-X; Dentsply Sirona) (Fig. 8).

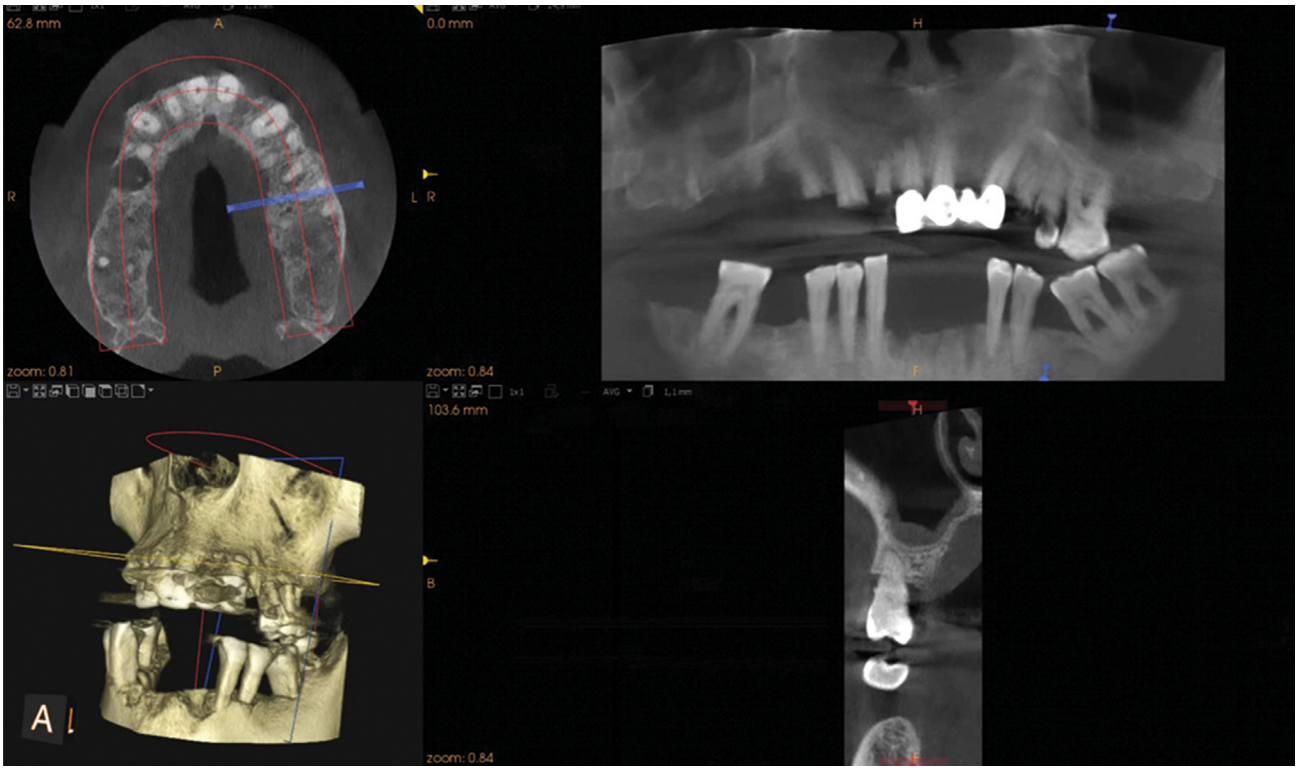

Figure 3. Cone beam computed tomography (CBCT) scan.

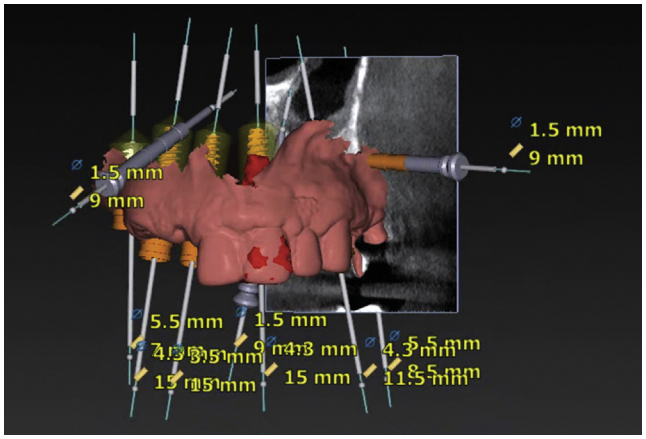

Figure 4. STL file obtained from intraoral scanner and DICOM file obtained from CBCT scan imported to implant planning program for initial phase of treatment planning. CBCT, cone beam computed tomography; DICOM, Digital Imaging and Communications in Medicine; STL, standard tessellation language.

Adjust the occlusion, perform the required esthetic corrections, and explain the usual postoperative instructions.

DISCUSSION

The current digital workflow can help optimize clinical efficiency and quality. It can deliver an interim prosthesis with excellent fit, correct VDO, and well-controlled occlusion, minimizing the required clinical time.

As the interocclusal records with the proposed technique are made before surgery, an occlusal position is produced that is almost identical to the preoperative occlusion. Such precision is difficult to achieve with techniques that record these details intraoperatively or that clinically adapt a previously fabricated prosthesis directly after surgery. Compared with the techniques that use a previously fabricated prosthesis and are delivered immediately after implant placement, the proposed technique requires a delay of at least some hours or even a day. Nevertheless, the overall treatment time decreases, and patient comfort increases.

The use of pins for reference might not be essential in situations where anatomic references, such as the palate, can be used. Nevertheless, as changes in these anatomic references might affect the accurate superimposition of the STL files, it seems prudent to use the pins in all the patients where a completely digital workflow is used.

For an accurate prosthesis, the device used (in this case, MedicalFit) should be exactly the same as the STL file in the dental laboratory technician's library. Attempts to use or design similar devices without being sure of the accuracy of the device will lead to inaccuracies in the fit of the prosthesis.

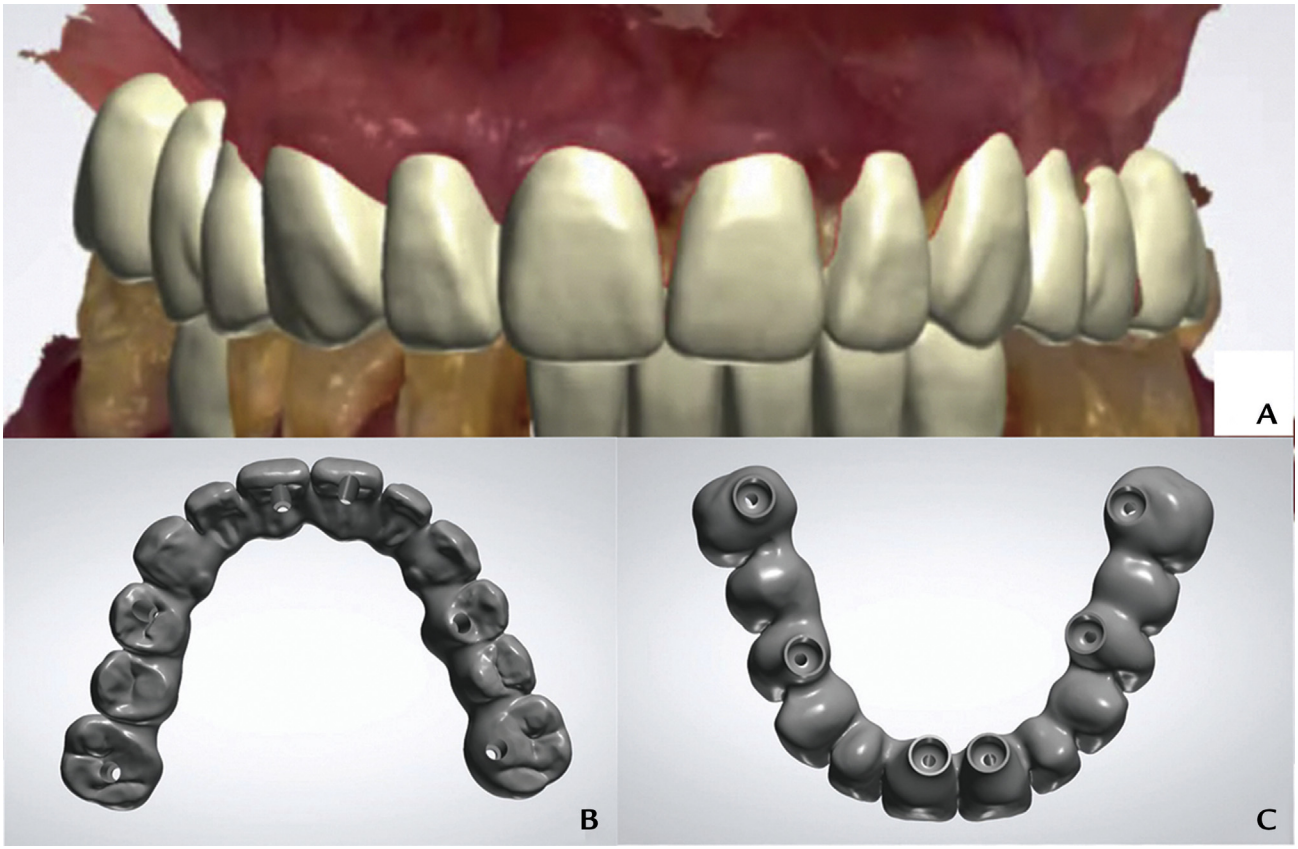

Figure 5. Files evaluated by clinician before surgery. A, Digital design. B, C, Interim prosthesis design.

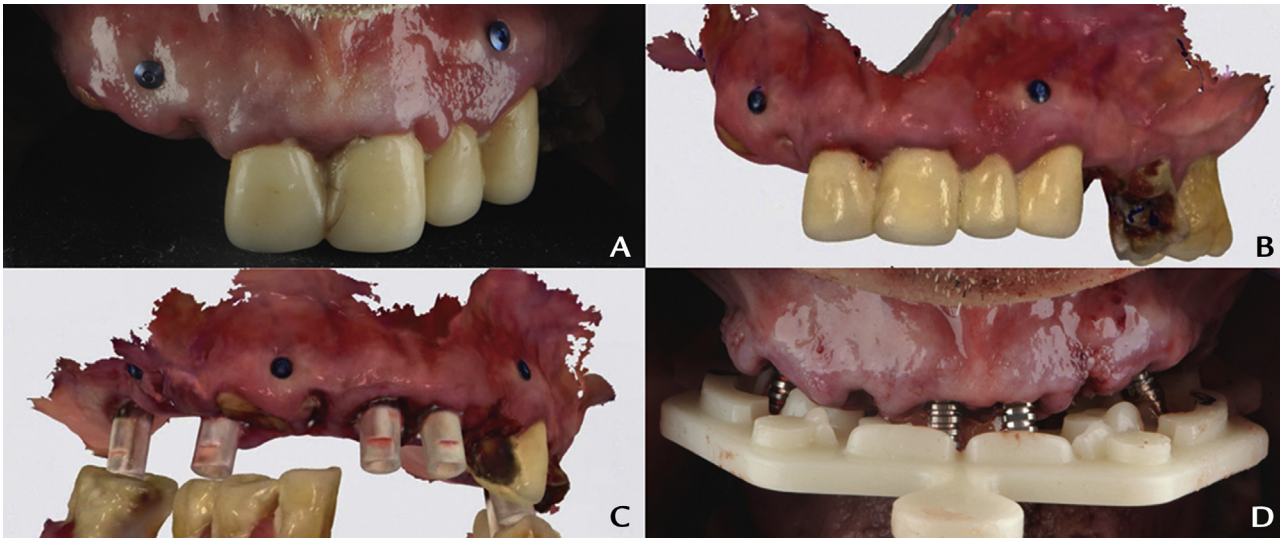

Figure 6. A, Pins placed before surgery to be used as references for superimposition after surgery. B, New scan made ensuring that all pins included. C, Scan bodies screwed to abutments after placement of implants and multiunit abutments, and new scan made, ensuring that pins included, allowing superimposition with presurgical scan and maintenance of established vertical dimension of occlusion. Although pins used, one tooth retained for STL file superimposition. D, After removing scan bodies, interim copings screwed on multiunit abutments and MedicalFit device trimmed to fit on interim abutments and attached by using Triad Gel. STL, standard tessellation language.

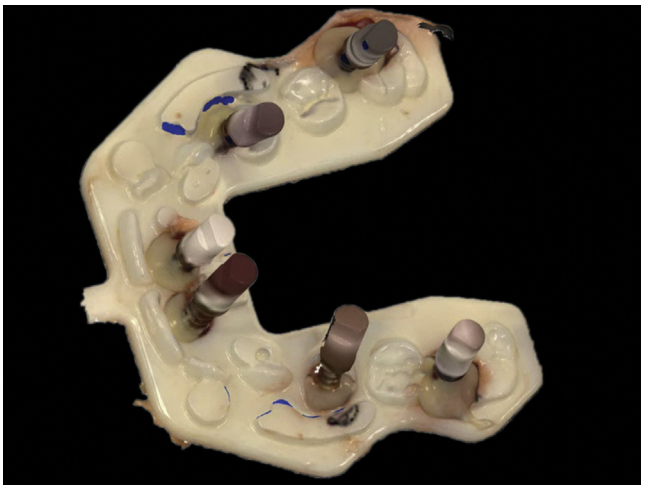

Figure 7. After removal from mouth, ScAnalog replicas screwed on interim copings. MedicalFit device scanned, and obtained STL file sent to dental laboratory. STL, standard tessellation language.

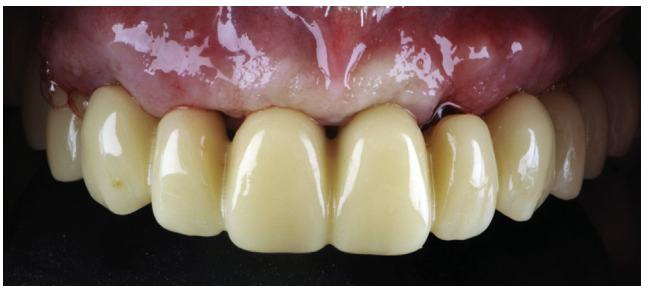

Figure 8. Interim polymethylmethacrylate (PMMA) fixed prosthesis delivered in less than 4 hours. Easily screwed on multiunit abutments with minimal occlusal adjustments required. Small discrepancies in gingival adaptation can be corrected immediately with composite resin or corrected in definitive restoration.

SUMMARY

The current technique uses a completely digital workflow to fabricate interim complete-arch implant-supported prostheses for immediate loading. It avoids the need for intraoperative impressions or adaptation of a previously fabricated prosthesis. The use of an auxiliary device helps achieve an excellent passive fit. The use of surgical pins as references allows the accurate transfer of the interocclusal records, minimizing the need for intraoral adjustments, reducing chair time, and improving patient experience.

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