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Accuracy of digital impressions for implant-supported complete-arch prosthesis,

using an auxiliary geometry part - an in vitro study

Running title: Digital impression for implant-supported complete-arch prosthesis

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ABSTRACT

Objectives: The aim of this study was to evaluate the accuracy of complete-arch digital impressions for fabrication of an implant-supported prosthesis in the edentulous maxilla using an auxiliary geometry part.

Material and Methods: A replica of the upper jaw of an edentulous patient with four scannable impression copings was fabricated in stainless steel. This model was scanned with an industrial non-contact 3D structured blue light 3D scanner and the measurements of three reference distances were established as reference values. Subsequently, the model was scanned in two different scenarios (with or without an auxiliary geometry part put in place and fixed to the model) using three intraoral scanners. Measurements were taken with 3D inspection software and a digital impression of the complete arch was built with mesh-processing software by combining 2 STL files obtained with an intraoral scanner.

Results: All measurements with the auxiliary geometry part gave significantly more accurate results (p<0.05). Trueness improved in the three reference distances, reaching values of $8 \pm 6\mu$ m at D12 reference distance, $20 \pm 11\mu$ m at D13 and $35 \pm 22\mu$ m at D14. Precision also improved significantly with the use of the auxiliary geometry part placed on the model (p<0.05). The best precision results at reference distances D13 and D14 were obtained with the True Definition scanner.

Conclusions: The proposed methodology significantly improves the accuracy of complete-arch digital impressions in edentulous patients obtained in vitro, regardless of which scanner is used.

Keywords:

Accuracy, digital impression, edentulous, implant-supported framework, intraoral scan, complete arch.

INTRODUCTION

Intraoral scanners were first introduced more than 30 years ago (Duret & Preston, 1991). Since then, continuous steps have been taken towards their development and nowadays, with the improvements implemented by new devices and software (Mangano, Gandolfi, Luongo, & Logozzo, 2017), together with social acceptance of these new technologies, conventional impressions are being replaced by digital ones(J.-F. Güth, Keul, Stimmelmayr, Beuer, & Edelhoff, 2013; J.-F. Güth et al., 2017).

Intraoral scanners offer many advantages: greater comfort, increased speed, reduced storage and transport requirements, and overall reduced cost (Ahrberg, Lauer, Ahrberg, & Weigl, 2016; Gjelvold, Chrcanovic, Korduner, Collin-Bagewitz, & Kisch, 2016; Lee & Gallucci, 2013; Patzelt, Lamprinos, Stampf, & Att, 2014; Yuzbasioglu, Kurt, Turunc, & Bilir, 2014). However, from a clinical point of view, more research is needed on the results achieved from digital impressions obtained directly in the mouth.

There is still a perceived lack of agreement regarding the accuracy and clinical acceptability of digital impressions (Giménez, Özcan, Martínez-Rus, & Pradíes, 2014; Papaspyridakos et al., 2016) and maximum acceptable deviations may vary depending on the patient's emotional level and the biological reactions of bones or soft tissues (Kan, Rungcharassaeng, Bohsali, Goodacre, & Lang, 1999). However, maximum deviations should not exceed values that would lead to osseointegration problems of the implants.

Recent studies had established varying values when considering the acceptable osseointegration of restorations and the passive fit should be within the range of these values (Carr & Toth, 1995; Christensen, 1966; Dodmon, 1982; Jemt, 1991). The passive fit of an implant-supported dental prosthesis depends on the accuracy of the framework and there are several factors that influence this accuracy (Jemt & Hjalmarsson, 2012; Papaspyridakos & Lal, 2013). In addition, the larger the prosthesis to be fitted, the greater the potential for mismatch, which forces the use of different techniques, thus making the process more complicated (Kan et al., 1999).

Several studies have addressed these variables by examining the accuracy of intraoral scanners: in narrow spaces such as those for crowns or bridges (Ahrberg et al., 2016; Hack & Patzelt, 2015; Omar Ali, 2015; Pradíes, Zarauz, Valverde, Ferreiroa, & Martínez-Rus, 2014; Syrek et al., 2010); covering larger parts of the dental arch such as a quadrant (Ender, Zimmermann, Attin, & Mehl, 2016); and covering the complete arch (Andriessen, Rijkens, Van Der Meer, & Wismeijer, 2014; Ender, Attin, & Mehl, 2016; Ender & Mehl, 2013, 2014; Flügge, Att, Metzger, & Nelson, 2016; Güth, Edelhoff, Schweiger, & Keul, 2016; Patzelt, Bishti, Stampf, & Att, 2014; Patzelt, Emmanouilidi, et al., 2014; van der Meer et al., 2012; Zhang, Suh & Lee, 2016). Although the accuracy values in these studies differ from one case to another, it has been demonstrated that digital impressions are sufficiently accurate in small spaces (Ahrberg et al., 2016; Amin et al., 2017; Ender, Attin, et al., 2016; Ender & Mehl, 2013; Ender, Zimmermann, et al., 2016; Joda & Brägger, 2015; Joda et al., 2017; Pradíes, Zarauz, et al., 2014; Sakornwimon & Leevailoj, 2017; Schepke, Meijer, Kerdijk, & Cune, 2015; Syrek et al., 2010; Zhang et al., 2016) and the improvements implemented in the new versions of the scanners are resulting in improved accuracy (Imburgia et al., 2017; Mangano et al., 2017). However, in large spaces with uniform features (with no geometric differentiation in the radius of curvature), such as those typically associated with edentulous patients, the results are less impressive. The complete-arch impression of an edentulous patient can be one of the most challenging tasks for an intraoral scanner.

The aim of this study is to investigate the effects of the use of an auxiliary geometry part (AGP) and different intraoral scanners on the accuracy (trueness and precision) of the intraoral scans of edentulous patients. The lack of geometric variation can be overcome by simulation, thus providing a solution for the challenging task of obtaining a complete-arch digital impression for an edentulous patient. The null hypothesis states that there are no differences in the accuracy of digital impressions using the auxiliary geometry part regardless of which intraoral scanner was used.

MATERIAL AND METHODS

A stainless steel model was manufactured taking as reference a completely edentulous patient who had a restoration with four implants in the positions of maxilla right third molar, maxilla right canine, maxilla left canine and maxilla left third molar (Fig. 1A). This model was machined with four protrusions simulating four scannable impression copings placed in the aforementioned implant positions. The stainless steel model was scanned 10 times (n=10) with an industrial reference scanner (ATOS Compact Scan 5M/300, GOM) in order to replicate the presumed repeatability. Afterwards, strict measurement protocols were followed to measure three reference distances (D12, D13 and D14) in each of the 3D images obtained with the reference scanner. Based on these measurements, reference values were set (mean \pm SD) which were later used to determine the accuracy values of the intraoral scanners used.

Then, the reference model was scanned with three intraoral scanners: Trios 3 (3Shape A/S) with 2015-1 software version (TRI group); 3MTM True Definition (3M ESPE) with 5.1.1 software version (TRU group); and Itero Element 1 (Align Technology Inc.) with 1.5.0.361 software version (ITE group), in two different scenarios (10 scans in each scenario and with each scanner, resulting in a total of 60 scans). The first scenario simulated a normal scanning process in which a specialist digitized the complete arch of a patient who had four scannable impression copings placed in the implants (agpN group). In the second scenario, the same complete arch was digitized, but in this case the AGP simulating a jaw with teeth was placed, thus filling in the gaps between the scannable impression copings (agpY group) (Fig 1B). The AGP was positioned by matching its circular holes with the corresponding scannable impression copings (Fig 1B). Then, to prevent movement during scanning it was fixed with

light-polymerizing resin (CONLIGHT, Kuss Dental). The upper side of the scannable impression copings were left visible (Fig 1B) because they were used to perform best-fit alignments while generating the digital impression. This AGP was made in a 3D printing machine (Dimension Elite, Stratasys) using Acrylonitrile Butadiene Styrene (ABS Plus) material.

The 60 scans were performed at the Complutense University of Madrid by a single specialist and under the same humidity and temperature conditions. The scanning protocols defined by the manufacturers of each intraoral scanner were strictly adhered to. In addition, when using the True Definition scanner, the model – and when necessary, the AGP – were powdered (Lava COS Powder, 3M ESPE), as recommended by the manufacturer. This action was not recommended for scanning with Itero and Trios 3. In all cases, both with the reference scanner and the intraoral scanners, 3D images of the model in standard tessellation language file format (STL) were obtained.

For measurement, 3D mesh inspection and processing software were used (GOM Inspect, GOM) for all the digital impressions obtained. The first step was to determine the procedure for taking reference measurements. According to this protocol, it was necessary to create four points in each mesh, one in each model protrusion (parts resembling scan bodies). Each point was created at the intersection of a cylinder axis and a plane, which also had to be created in each mesh. By measuring three distances between these four points (as shown in Fig. 2), three reference distances, D12, D13 and D14, were defined. The procedure to determine the four points was based on the Gaussian best-fit method to create both the cylinders and the planes. For the creation of the geometry using this method approximately 99.7% of the polygons of the mesh resembling the scan body were selected. The intersection between the created planes and cylinders resulted in four points that were used to take distance measurements.

All measurements were taken, and data were exported for analysis as Microsoft Excel worksheet files (XLS). This analysis was performed using a program for statistical inquiry (IBM SPSS Statistics 24, IBM Corp). Accuracy of measurements was analyzed in terms of trueness and precision. Trueness assessment was achieved by measuring the deviation of each measurement from the reference measurement, whereas for precision assessment the dispersion of measurements in each reference distance was analyzed. This assessment was repeated for each reference distance (D12, D13 and D14) in each of the previously mentioned two scenarios (agpN group and agpY group) and with each of the intraoral scanners (TRI group, TRU group and ITE group). Mean values of accuracy and precision were obtained with their corresponding standard deviations and the differences were evaluated to determine whether or not they were statistically significant depending on the use of the AGP or the intraoral scanner (IBM SPSS Statistics 24, IBM Corp) employed.

Finally, using mesh-processing software (Geomagic Studio, 3D Systems, Inc), digital impressions of the edentulous arch were built by combining two STL files. One of these STLs was achieved in the first scenario (agpN group), that is without the AGP placed in the model, and the other was obtained in the second scenario (agpY group), with the AGP in place. The first showed the complete digital impression with the scannable impression copings and soft tissues surrounding them. The second gave a digital impression with spaces between the scannable impression copings hidden by the AGP but, predictably, in a more accurate position. The digital impression of the dental arch without the AGP was split into as many parts as scannable impression copings (Fig 3). At the same time, the AGP was virtually erased from the digital impression, leaving only the scannable impression copings accurately positioned (Fig. 4A and B). By aligning each partition of the first STL with the corresponding scannable impression coping of the second, a final model of the edentulous arch was built (Fig. 5).

RESULTS

Distances obtained with the reference scanner and used as reference values for evaluating the data obtained with intraoral scanners were established at 22.401 mm for D12 with a precision value of $2\pm 2 \mu m$; 42.290 mm for D13 with a precision value of $2\pm 1 \mu m$; and 44.528 mm for D14, with a precision value of $2\pm 2 \mu m$.

Regarding the effect of the AGP on each reference distance and taking into account the three intraoral scanners used, the significance of the effects of both the AGP and the type of scanner varied from one case to another. The 2-way ANOVA showed that at D12 and D13 reference distances, the intraoral scanner had no statistically significant effect (p>0.05) on trueness values, while the use of the AGP had statistically significant effects (p<0.05). The interaction between the intraoral scanner used and the AGP did not have any significant effect (p>0.05) (Table 1). However, in D14, the 2-way ANOVA showed that both the intraoral scanner used and the use of the AGP had a statistically significant effect (p<0.05) on the deviation measurement and consequently on trueness (Table 1). The interaction between the intraoral scanner and the use of the AGP had no significant effect (p>0.05).

Regarding trueness values for the three reference distances (D12, D13 and D14), the Levene test showed statistically significant differences (p<0.05) in the TRU group with or without the AGP, but not in the TRI group and ITE group (p>0.05).

The lowest measured mean deviation value was $8\pm6\mu$ m. It was achieved from digital impressions achieved with the True Definition scanner, using the AGP and at D12 reference distance. The highest mean deviation value of $189 \pm 70\mu$ m was achieved with Itero without using the AGP and at D14 reference distance. All deviation values influenced by the AGP are summarized for each reference distance in Table 2, which also takes into consideration which intraoral scanners was used.

Precision was also assessed at each reference distance, always differentiating which of the three intraoral scanners was used in each case. The 2-way ANOVA test showed that at both the reference distances D12 and D13, neither the scanner nor the interaction between it and the AGP had statistically significant effects on the results (p>0.05). In contrast, the use or not of the AGP did have a statistically significant effect on precision results (p<0.05). However, at reference distance D14 the intraoral scanner used did have statistically significant effects on the results (p<0.05) while the use or not of the AGP and the interaction with the scanner used did not have statistically significant effects (p>0.05) (Table 3).

Taking into consideration only the effect on the precision of AGP placement in the model, Levene's equal variance test showed different results of significance. At reference distance D12, with or without the AGP, the values differed significantly in the TRI group whereas no statistically significant differences were found in the TRU group and the ITE group values. In contrast, for reference distances D13 and D14, the precision values statistically did not differ significantly in the TRI group, whereas they were significantly different in the TRU group and ITE group.

As shown in the summary table (Table 4), with the analysis of descriptive statistics, all mean precision values and corresponding standard deviations were obtained. The highest mean precision values were 8 $\pm 6\mu$ m and 7 $\pm 7\mu$ m. They were measured in digital impressions achieved with the True Definition and Trios3, respectively, using the AGP and at D12 reference distance. The lowest mean precision values, 118 $\pm 97\mu$ m, were achieved with Itero without using the AGP and at D14 reference distance.

DISCUSSION

The aim of this study was to analyse the effects of the use of the AGP on the accuracy of intraoral scans. It was pretended to demonstrate that large edentulous areas hinder the process of taking digital dental impressions and to offer a simple but effective solution. This solution basically consisted of concealing the large homogeneous surfaces that arise in edentulous patients by simulating the scanning process of a patient with teeth. The results support rejection of the null hypothesis. There are differences in the accuracy of digital impressions when they are obtained using the AGP. Both accuracy and precision are significantly improved.

Intraoral scanners build digital impressions by performing best-fit alignments of multiple captured images and in each best-fit alignment an error is generated. Therefore, the more alignments the scanner has to make, the greater the error. Geometry with differentiating radius of curvature facilitates the best-fit alignment; that is, dentition in the scanned areas facilitates the process, whereas the absence of teeth makes this process so difficult as to be impossible (Andriessen et al., 2014; Vandeweghe, Vervack, Dierens, & De Bruyn, 2016). Splinting the scannable impression copings (Papaspyridakos et al., 2016) or placing artificial markers on these edentulous spaces to help achieve more accurate dental impressions (Kim, Amelya, Shin, & Shim, 2017) are two proposed solutions.

Stereophotogrammetry technology also offers an accurate solution to these problems. Using an extraoral camera (PIC Camera, PIC DENTAL) together with external markers (PIC Abutments, PIC DENTAL), this technology combines two digital files to build a highly accurate digital impression. The external markers are positioned in each abutment and using the extraoral camera is determined their spatial position without making physical contact. The position of the implants and the distances and angles between them are stored as an STL file, however, this STL file does not contain information about the soft tissues or possible teeth (Peñarrocha-Oltra, Agustín-Panadero, Bagán, Giménez, & Peñarrocha, 2014; Pradíes, Ferreiroa, Özcan, Giménez, & Martínez-Rus, 2014). Meanwhile, the same arch is captured using an intraoral scanner to also produce an STL file of the surface to be restored, but in this case both the soft tissues and possible teeth in the mouth are digitized. Accurate completearch digital impressions are obtained from the combination of both STL files. However, this technology requires the use of two devices, the extraoral camera and an intraoral scanner, whereas the solution proposed in this study is to use a single device, which is more common in clinical practice.

The use of the proposed AGP requires additional processes, such as the customized design of the part and its manufacture, its placement in the mouth and the difficulty to secure it in the soft tissues of the upper or lower jaws, double scanning and the process of creating digital impressions from two scans. However, it could be a solution to overcome the difficulties involved in obtaining digital impressions of edentulous patients with implants. Furthermore, in the present study only digital impressions have been measured, i.e. virtual models, and it is yet to be verified whether a structure fabricated from this type of digital impression would in fact fit better on implants.

The study was carried out by digitalizing a replica of the complete upper jaw of an edentulous patient and even though the study was performed in vitro, there is no reason to believe that the results obtained are not transferable to in vivo work. The same technique can also be applied to the lower jaw even though it is known that digitization of the mandible is more challenging: the reduced space, the absence of firm palatal tissue and the interference of the tongue make scanning difficult. However, the use of the AGP is also possible since its purpose is to simulate a non-edentulous scenario. Indeed, accuracy values may vary, but it is a fact that the use of an AGP improves the accuracy of full-arch dental digital impressions of edentulous patients. Several authors have discussed the difficulties of obtaining dental impressions from edentulous patients (Andriessen et al., 2014; Kim et al., 2017; Vandeweghe et al., 2016), some even state the impossibility of obtaining them. During the present study, these difficulties were confirmed even before the results were obtained. With the Itero intraoral scanner it was even necessary to mark with a pen some spaces between the scannable

impression copings in order to scan the complete arch. Regardless of the scanner used, in several cases the scanner confused the different scannable impression copings and took them to be one, thus generating faulty 3D images, just as Andriessen described (Andriessen et al., 2014).

After an analysis of these difficulties, it was decided to simulate a non-edentulous scenario by placing the AGP over the edentulous areas. As Kim recently proved, an artificial landmark placed in an edentulous space facilitates scanning (Kim et al., 2017), which is similar to the method used in this study. However in this case, the study was performed for a complete arch. A piece was specifically designed and manufactured to fit in the edentulous model and this model was scanned in two different scenarios: with the AGP in place and without the AGP.

Accuracy results improved both in precision and trueness. The improvement was repeated with the all three intraoral scanners and almost at all reference distances analyzed. The only exception was the precision in TRI Group and reference distance D14 (Table 4). It must be noted that when using the True Definition scanner, the model – and when necessary, the AGP – were powdered (Lava COS Powder, 3M ESPE), and this could have introduced a bias in comparing the outcomes of the 3 scanners The best mean values of trueness at each reference distance were obtained with the AGP in place and in all cases using the True Definition intraoral scanner. It is also remarkable that at each reference distance, the highest mean deviation achieved with the AGP was lower than the lowest mean deviation achieved without the AGP. In addition, this study also confirmed that the larger the area to be scanned, the greater the accumulated error. With the defined reference distances, the influence of the length to be restored was observed together with the corresponding error increase, and it was presumed that the larger the size of the dental arch to be digitized, the greater the error. Results confirmed this presumption.

In recent years, some authors have validated the usefulness of intraoral scanners to make digital impressions of crowns or even three-unit fixed dental prostheses (Ahrberg et al., 2016; Amin et al., 2017; Ender, Attin, et al., 2016; Ender & Mehl, 2013; Ender, Zimmermann, et al., 2016; Joda & Brägger, 2015; Joda et al., 2017; Pradíes, Zarauz, et al., 2014; Sakornwimon & Leevailoj, 2017; Schepke et al., 2015; Syrek et al., 2010; Zhang et al., 2016). However, when the area to be restored, and consequently the scanning area, grows, the results clearly worsened (Ender, Attin et al., 2016; Ender, Zimmermann, et al., 2016; Flügge et al., 2016; van der Meer et al., 2012). This fact was confirmed in the present study. However, during the study, there was evidence that the influence of the AGP was more significant than that of the intraoral scanner used. At reference distances D12 and D13, the differences between the use or non-use of the AGP were statistically significant (p<0.05) while the scanner used was not. In contrast, at reference distance D14, besides the use of the AGP, the scanner used also provided significantly different results.

As expected, there are differences between intraoral scanners in terms of measurement accuracy. Nevertheless, taking into consideration the studies on osseointegration of implants (Carr & Toth, 1995; Christensen, 1966; Dodmon, 1982; T Jemt, 1991), it can be confirmed that all three are valid for working on a dental quadrant, having maximum deviation values of 101 μ m (CI95%) but mean deviations of less than 70 μ m. This is not the case in complete arch, at the equivalent to distance D14, where the results were influenced by the scanner used, and the non-utilization of the AGP gives somewhat high deviation values. The maximum deviation was 239 μ m (CI95%) and highest mean deviation 189 ±70 μ m, both with the Itero and without using the AGP.

CONCLUSIONS

Despite the limitations of this in vitro study, we conclude that the use of an auxiliary geometry piece improved the accuracy of complete-arch digital impressions of the edentulous

maxilla, as well as facilitating the scanning process itself. Both trueness and precision measurements obtained by covering wide edentulous spaces with the auxiliary geometry piece showed remarkable improvement in digital impressions.

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TABLES

Inter-subject effects tests					
Dependent variable: deviation	D12	D13	D14		
Source	\mathbf{P}^*	\mathbf{P}^*	\mathbf{P}^*		
SCANNER	0.369	0.171	0.001		
AGP	0.004	0.001	0		
SCANNER * AGP	0.486	0.816	0.111		
*Significance at B<0.05					

Table 1. 2-way ANOVA results for trueness analysis at each reference distance

*Significance at P<0.05

Table 2. Deviation values (μm) for each reference distance obtained with each of the intraoral scanners

			CI 95%	CI 95%	Mean
			Min.	Max.	(SD)
D12	TRI	agp_N	6	27	17±15
	Group	agp_Y	7	17	12±7
	TRU	agp_N	8	32	20±16
	Group	agp_Y	4	12	8±6
	ITE	agp_N	14	38	26±17
	Group	agp_Y	4	20	12±11
D13	TRI	agp_N	38	101	70±44
	Group	agp_Y	12	56	34±31
	TRU	agp_N	27	84	55±40
	Group	agp_Y	12	28	20±11
	ITE	agp_N	41	97	69±39
	Group	agp_Y	26	66	46±28
D14	TRI	agp_N	48	155	101±75
	Group	agp_Y	30	116	73±61
	TRU	agp_N	43	126	85 ± 58
	Group	agp_Y	19	51	35±22
	ITE	agp_N	139	239	189±70
	Group	agp_Y	46	121	83±52

CI=Confidence Interval

Inter-subject effects tests					
Dependent variable: Precision	P12	P13	P14		
Source	\mathbf{P}^*	\mathbf{P}^*	\mathbf{P}^*		
SCANNER	0.478	0.118	0.048		
AGP	0	0.049	0.174		
SCANNER * AGP	0.509	0.387	0.263		
*Significant at P<0.05					

Table 3. 2-way ANOVA results for precision analysis for each reference distance

Table 4. Precision values (μm) for each reference distance obtained with each of the intraoral

scanners

			CI 95% Mín.	CI 95% Max.	Mean (SD)
D12	TRI Group	agp_N	3	25	14±15
		agp_Y	2	12	7±7
	TRU Group	agp_N	6	30	18±17
		agp_Y	3	12	8±6
	ITE Group	agp_N	15	30	23±11
		agp_Y	3	12	8±6
	TRI Group	agp_N	15	58	37±30
D13		agp_Y	12	56	34±30
	TRU Group	agp_N	16	79	47±44
		agp_Y	11	26	19±11
	ITE Group	agp_N	38	79	58±29
		agp_Y	27	60	44±23
D14	TRI Group	agp_N	22	89	55±47
		agp_Y	26	113	70±61
	TRU Group	agp_N	34	122	78±62
		agp_Y	20	50	35±22
	ITE Group	agp_N	48	187	118±97
		agp_Y	56	110	83±38

CI=Confidence Interval

FIGURES

Fig. 1A. Stainless steel model.



Fig. 1B. Stainless steel model with the AGP placed on it.



Fig. 2. D12, D13 and D14 reference distances.



Fig. 3. Virtual partition of the full-arch digital impression.



Fig. 4. AGP erasing process. A: In red, the area to be deleted. B: Highly accurately positioned scannable impression copings.



Fig. 5. Alignment of split parts. A: Aligning first split part. B: Aligning second split part. C: Aligning third split part. D: Aligning fourth split part.

