applied sciences

MDPI

Article

Clinical Comparative Study for Validation of Digital Impression Reliability with the Gypsum Check: A Simple and Fast Way to Evaluate the Trueness and Accuracy of Implant-Supported Rehabilitation

Giuseppe Barile [1,*], Giovanni de Rosa [1], Paride Papadia [2], Giovannino Muci [2], Saverio Capodiferro [1] and Massimo Corsalini [1]

[1] Department of Interdisciplinary Medicine, University of Bari "Aldo Moro", 70100 Bari, Italy; giovanni.derosa60@gmail.com (G.d.R.); saverio.capodiferro@uniba.it (S.C.); massimo.corsalini@uniba.it (M.C.)
[2] Dental School, University of Bari "Aldo Moro", 70124 Bari, Italy; papadia.paride@gmail.com (P.P.); giovanninomuci@studiomuci.it (G.M.)
* Correspondence: giuseppe.barile@uniba.it

Abstract: Despite many advantages, digital impressions, when compared to the conventional one, produce contrasting results and their complete substitution is still under debate. This comparative study aims to test a way to perform a clinical evaluation of digital impression Accuracy and Trueness with a gypsum check. After calculating the Trueness, Precision, and Accuracy of the digital impressions, a gypsum check was fabricated and screwed on implant abutments. The impression was not considered reliable if the gypsum check fractured during the insertion. The gypsum check test was correlated to a cut-off of 100 µm Trueness. Mean Trueness was 151.19 ± 37.23 µm of the first optical impression and 125.47 ± 41.90 µm of the second optical impression. The Precision mean was 39.76 ± 10.89 µm. The mean Accuracy percentage was 98.69 ± 0.29%. The gypsum checks fractured 10 times on 42 tests, and in any case, the Trueness value was above the 100 µm cut off, with a $p = 0.001$. A gypsum check screwed onto an implant abutment could be considered a way to perform clinical measurement of Trueness, allowing the clinician to understand if the Trueness value is higher or lower than 100 µm and reflecting the reliability of digital impressions.

Keywords: accuracy; intraoral scan; trueness; digital impression; gypsum check; passive fit

Citation: Barile, G.; de Rosa, G.; Papadia, P.; Muci, G.; Capodiferro, S.; Corsalini, M. Clinical Comparative Study for Validation of Digital Impression Reliability with the Gypsum Check: A Simple and Fast Way to Evaluate the Trueness and Accuracy of Implant-Supported Rehabilitation. *Appl. Sci.* **2023**, *13*, 7358. https://doi.org/10.3390/app13137358

Received: 27 May 2023
Revised: 17 June 2023
Accepted: 20 June 2023
Published: 21 June 2023

1. Introduction

Since the beginning of the contemporary era, dental impressions of oral hard and soft tissues have played a central role in dental practice because they represent the main communication medium between clinician and technician to fabricate a dental prosthesis. Historically, the first dental impression material used was beeswax, and a few years later the field benefited from the invention of the first dental tray [1]. The most crucial turning point was the discovery of alginate in 1947, an irreversible hydrocolloid derived from marine algae that is associated with good dimensional stability [2]. Alginate is still today the most used dental material in everyday practice. In order to improve accuracy and dimensional stability, dental industries developed another material that replaced alginate in precision impressions, especially in fixed prosthetic rehabilitations: elastomers. Elastomers could be divided into polyethers, polysulfides, and silicones, which provide better accuracy, elasticity, and dimensional stability than previous impression materials [3]. The materials mentioned above are used for conventional analogic impressions, but another impression technique is available nowadays: the optical impression. In 1983, dr. François Duret was the first clinician to fabricate a dental crown with an optical impression taken by an intraoral scanner (IOS) [4]. Digital impression provides many advantages: it is better tolerated by

patients, allows faster communication with the dental technician, provides a high accuracy level, and is highly powerful marketing tool because it is less invasive and has reduced chair time [5,6]. Optical impressions are still under debate because their accuracy could be affected by technical errors depending on clinical conditions (such as the presence of blood and saliva during scanning and clinician experience) and differs between each IOS [7]. This simple formula defines Accuracy as Accuracy = Trueness ± Precision, where Trueness indicates how far a measurement is from the reference value and Precision indicates how far measurements are far from each other [8]. Few comparative studies between conventional and digital impressions have been conducted with discrepant findings, considering that most were in vitro [9]. Impression accuracy remains the most critical factor in dental impressions, especially in multiple implant-prosthetic rehabilitation, because an accurate impression could guarantee a passive fit of a definitive prosthetic crown [10]. Passive fit, defined as the minimal gap at the framework–implant surface without tension, is the result of the best accuracy level that could have an impact on the final outcome of implant-based prosthesis, but misfit values are still under debate [11]. Many methods were proposed to evaluate the exact correspondence of implant positions between the definitive cast and the real clinical position, allowing the passive fit of future rehabilitations. These methods include polymeric, metal, and resin devices, but as suggested by Manzella et al. even Gypsum devices could be used to verify the implant position [12]. This comparative study aims to test a simple way to perform a clinical evaluation of digital impression reliability, through the outcomes of a gypsum check screwed on implant abutments. Moreover, it aims to propose a threshold value of clinical tolerance misfit, considering the hypothesis of the correlation between the fracture of gypsum check and a misfit above 100 µm, which does not allow the passive fit of prosthetic frameworks.

2. Materials and Methods

This prospective comparative study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethical Committee of University Hospital "Policlinico di Bari" (N. Prot. 0069684). All patients attend the Department of Dental Prosthetics of the Dental School of the University of Bari and have accepted and signed informed consent forms for treatment and documentation for scientific purposes.

2.1. Sample Description

The following inclusion criteria were adopted:

- A treatment plan which includes rehabilitation with at least two adjacent implants;
- The clinical indication of implant-supported FDP;
- Good periodontal conditions;
- Stable occlusion;
- No comorbidities that contraindicated implant surgery;
- Reduced gag reflex.

The exclusion criteria applied were:

- Clinical contraindications to implant treatment;
- Implants that exceeded the maximum mutual inclination allowed by manufacturers;
- Presence of parafunction or periodontal disease;
- Poor oral hygiene;
- Increased gag reflex;
- Presence of comorbidities that contraindicated implant surgery.

2.2. Workflow and Operating Protocol Description

The clinical protocol was structured on implants (Neoss-ProActive Straight, Neoss-ProActive Tapered, Milano, Italy) as follows:

- Initial evaluation: compilation of medical records with anamnesis, orthopantomography, and eventual intraoral radiograph, and, when necessary, CBCT; impression taking

using irreversible hydrocolloid impression material (Alginate—Kromopan LASCOD, Sesto Fiorentino, Italy); and analysis of the study models.

- Surgical time: after local anesthesia, a full-thickness flap was elevated, two adjacent implants were inserted according to the actual guidelines of the operating protocol, and the implant site was immediately closed with a cover screw.
- Exposure of the cover screw and substitution with the healing abutment after four months from the surgical time;
- Definitive impression;
- Positioning of provisional PMMA composed of 3 elements (one single pontic);
- Definitive impression.

For the purpose of the study, each patient was subjected to one conventional impression with polyether and two digital impressions with an intraoral scanner to calculate Trueness and Precision.

Here, both impression protocols are described.

Conventional impression workflow

- Custom tray fabrication after alginate impression, perforated to allow the unscrewing of transfers;
- Removal of the healing screw;
- Positioning of impression transfer coping at 30–35 N;
- Radiological check of correct insertion;
- Splinting of impression transfer coping with Duralay (Reliance Dental, Worth, IL, USA), an autopolymerizing polymethylmethacrylate (PMMA) resin;
- Clinicians took the conventional impression with a polyether (Impregum, 3M ESPE, Dental Products, St. Paul, MN, USA);
- After 6 min, impression transfer copings were unscrewed, and the custom impression tray was removed from the patients;
- Assessment of definitive impression taken;
- Extra-hard plaster cast was made with 4th-type gypsum (Fujirock Ep Classic, GC Corporation, Tokyo, Japan);
- Plaster cast digitalization using 3Shape D500 (Copenhagen, Denmark) laboratory scanner.

Digital impression workflow

- Vivadent Optragate (Schaan, Liechtenstein) retractor was positioned;
- Healing screws were replaced by PEEK scanbodies;
- Optical impression was taken with Carestream 3600 (Rochester, New York, NY, USA);
- STL file was generated on CAD station and the digital cast was reconstructed.

2.3. Accuracy Analysis

In the beginning, after reconstructing the digital model on the CAD-CAM station of each three impressions, the authors manually measured the distance between each transfer axis in the conventional impression and between each center of the scanbody in the digital impression. The distance between the scanbodies' centers in the first optical impression was indicated as Digital Impression 1 (DI1), and the same distance for the second optical impression was indicated as Digital Impression 2 (DI2). The distance between transfers of conventional impression was indicated as RV (Reference Value) because it was considered as the reference value. First of all, to evaluate the reliability of the optical impression and its comparison with the analogic impression, Trueness, Precision, and Accuracy were calculated. Trueness is defined as the closeness of measurements to the reference data. In this study, it is the difference between the distance of the two transfers of the analogic impression and the distance of the two scanbodies of the optical impression. According to ISO rules [8], Trueness must be calculated on a minimum of 25 measurements, which is usually possible with superimposition software using the best-fit algorithm [13], but it is incompatible with a clinical investigation, as it could be very invasive to take 25 different impressions on the same patient. So, in this study, ISO Trueness was intended as the differ-

ence between the mean digital distance of 2 optical measurements and the conventional impression. Authors called the Trueness of two measurements "Specific Trueness", which is calculated as follows:

$$\text{Specific Trueness } (\mu\text{m}) = |\text{digital distance} - \text{real distance}|$$

Precision is defined as the closeness of repeated measurements, calculated as the distance between multiple measurements of the same object performed by the same instrument under the same conditions, calculated as follows:

$$\text{Precision } (\mu\text{m}) = \sqrt{\frac{(\text{distance}_1 - \text{mean distance})^2 + (\text{distance}_2 - \text{mean distance})^2}{\text{measurement number}}}$$

After Trueness and Precision calculation, the Accuracy value can be calculated for each patient. From the ISO definition, Accuracy could be defined as a linear distance: the range between the Trueness—Precision value and Trueness + Precision value. By definition, Accuracy is represented by the formula "Trueness ± Precision" and is expressed in µm.

In order to simplify the readability, allowing an immediate understanding of such value, the authors proposed to convert a distance value to a percentage value. To do so, Dimensional Error was considered, and can be calculated as follows:

$$\text{Dimensional Error } (\%) = \frac{|\text{mean digital distance} - \text{real distance}|}{\text{real distance}} \; x \; 100$$

Thus, the Accuracy percentage is calculated as = 100 − Dimensional Error. The last step of this research was to correlate the Accuracy of the digital models with the clinical situation. For each patient, three gypsum gigs were fabricated, respectively, for the two digital and the conventional impressions, assessing the impact of impression Accuracy on the passive fit of future rehabilitation. The gypsum check was inserted with a controlled torque of 10 N. If clinicians could insert it without complications, the impression was considered reliable. If partial or total fracture occurred, the impression would not allow the passive fit of future rehabilitation, so it was considered inadequate and had to be retaken. Patient information about single measurement, Trueness, Precision, Accuracy and percentage Accuracy, and the final clinical check of gypsum gigs were collected into a database.

2.4. Clinical Cases

Below are reported three clinical cases: the first one the optical impression leads to a good outcome, without the fracture of gypsum check, unlike the last two cases that showed a bad outcome, fracturing the gypsum check (Figure 1).

2.5. Statistical Analysis

The outcome of the gypsum check (fractured/not fractured) was correlated with the values of Specific Trueness of the first and second digital impressions, considered as dichotomic variables using a cut-off of 100 µm (<100 µm and >100 µm), and the Accuracy percentage values, using a cut-off of 98% (<98% and >98%). A Chi-Squared test between two paired groups was performed with STATA, version 13.0 (Stata Corp., College Station, TX, USA).

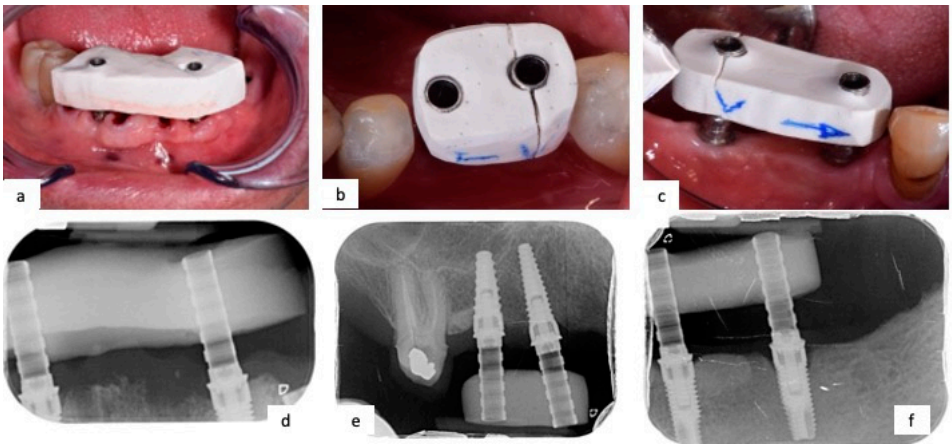

Figure 1. (**a**) Gypsum check screwed on abutments showed no fracture; (**b**,**c**) gypsum check fractured when screwed on abutments; (**d**–**f**) intraoral rx showed correct coupling between implant and abutments.

3. Results

This comparative study included 14 patients who were subjected to two adjacent implant prosthetic rehabilitation: 9 were males (64.3%) and 5 were females (35.7%). Prosthetic rehabilitations were located in different sextants: one in the first sextant (7.1%), one in the second sextant (7.1%), six in the third sextant (42.9%), two in the fourth sextant (14.4%), one in the fifth sextant (7.1%) and three in the sixth sextant (21.4%). These data are reported in the following table (Table 1)

Table 1. Sex, age, and rehabilitation distribution of sample.

Patient N.	Sex	Age	Localization (Sextant)
1	M	72	V
2	M	69	VI
3	M	74	IV
4	M	69	III
5	M	62	III
6	F	81	III
7	M	71	VI
8	M	72	IV
9	M	69	VI
10	F	75	I
11	F	73	III
12	F	80	III
13	M	58	III
14	F	73	II

Considering that the original Trueness ISO definition is "on more than 30 measurements" and does not apply to a clinical study, Specific Trueness considered only two measurements, consisting of two different digital impressions. The distances between scanbodies of the first and second optical impression were indicated, respectively, as Digital Impression 1 (DI1) and Digital Impression 2 (DI2). The distance between transfers of a conventional impression was indicated as Reference Value (RV). The Specific Trueness of the first and second optical impressions was indicated as Specific Trueness 1 (ST1) and Specific Trueness 2 (ST2). The last column is represented by Precision, which evaluates the repeatability of measurements under the same clinical conditions performed by the same instrument. The results of these measurements and calculations are reported in the following table (Table 2).

Table 2. Measurements for all patients are listed here. DI1 represents the distance between the interaxes of the scanbodies measured in the first digital impression; DI2 represents the same distance in mm calculated by the second scan. RV (Reference Value) indicates the real value obtained from the pick-up impression scanned in the laboratory in mm. ST1 expresses the difference in absolute value between S1 and RV in µm. ST2 describes the difference in absolute value between S2 and RV in µm. Precision represents the difference between two digital impressions performed for the same clinical case with the same intraoral scanner.

Patient	DI1 (mm)	DI2 (mm)	RV (mm)	ST1 (µm)	ST 2 (µm)	Precision (µm)
1	19.517	19.560	19.520	3.33	40.00	21.67
2	5.770	5.747	5.730	40.00	16.67	11.67
3	6.840	6.793	6.890	50.00	96.67	23.33
4	13.950	13.900	13.990	40.00	90.00	25.00
5	13.300	13.020	13.017	283.33	3.33	140.00
6	18.323	18.323	18.770	446.67	446.67	0.00
7	6.607	6.660	6.847	240.00	186.67	26.67
8	14.127	13.970	13.837	290.00	133.33	78.33
9	7.567	7.630	7.767	200.00	136.67	31.67
10	9.673	9.683	9.607	66.67	76.67	5.00
11	20.927	21.130	20.637	290.00	493.33	101.67
12	9.313	9.427	9.437	123.33	10.00	56.67
13	13.110	13.120	13.117	6.67	3.33	5.00
14	11.510	11.570	11.547	36.67	23.33	30.00
Mean				151.19 ± 37.23 µm	125.47 ± 41.90 µm	39.76 ± 10.89 µm

Regardless of the absolute distance between the two scanbodies/transfers, which differs for each patient, it is interesting to evaluate the values of Specific Trueness and Precision. The ST of the first impression is in a range from 3.33 µm of the digital impression, most similar to the analogic one, to reach 446.67 µm in a patient, and the digital impression is very different from the conventional one with a mean calculated Trueness of 151.19 ± 37.23 µm. Regarding the second impression, ST2 was from a minimum of 3.33 µm to a maximum of 493.33 µm, with a mean ST of 125.47 ± 41.90 µm, similar to the first digital impression. Precision values ranged between 0 and 140.0 µm of a discrepancy, with a mean of 39.76 ± 10.89 µm. As reported in the literature [14], a cut-off of 100 µm was considered: the impression with an ST of less than 100 µm was considered reliable, and the impression with an ST of more than 100 µm was considered unreliable. The distribution of the different STs of both impressions is in Figure 2.

After measuring the Specific Trueness and Precision, the authors calculated the Accuracy values with the formula proposed by ISO rules (as Trueness ± Precision), expressed as a range in µm units. The closer it is to 0, the more accurate the impression is. As the authors have two different values of Specific Trueness (one for each Digital impression), two different values of Accuracy were reported. To make it easier and faster to understand, the authors proposed the calculation of Accuracy in percentages through the Dimensional Error, as shown previously. Accuracy is reported as follows (Table 3).

The accuracy value of the first and second optical impressions have, respectively, a mean of 151.19 ± 39.76 µm and 125.48 ± 39.76 µm. Dimensional Error was within a range between 0.02 and 3.50, with a mean of 1.3, leading to an Accuracy percentage between 96.50% and 99.98%, with a mean of 98.70%. The overall Accuracy mean value was 138.34 ± 39.76 µm (Figure 3).

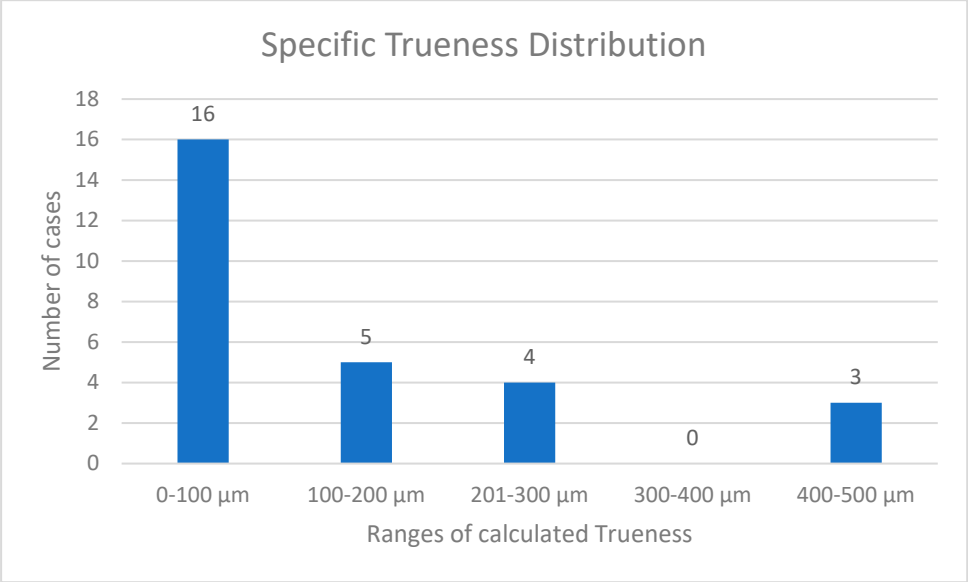

Figure 2. Specific Trueness values distribution: the 57% of digital impressions were within 100 µm.

Table 3. Accuracy: Accuracy 1 refers to the first optical impression, and Accuracy 2 to the second optical impression. Dimensional Error and Accuracy % were calculated and are reported in this table.

Patient	Accuracy 1 (µm)	Accuracy 2 (µm)	Dimensional Error	Accuracy %
1	3.33 ± 21.67	40.00 ± 21.67	0.02	99.98
2	40.00 ± 11.67	16.67 ± 11.67	0.70	99.30
3	50.00 ± 23.33	96.67 ± 23.33	0.73	99.27
4	40.00 ± 25.00	90.00 ± 25.00	0.29	99.71
5	283.33 ± 140.00	3.33 ± 140.00	2.18	97.82
6	446.67 ± 0	446.67 ± 0	2.38	97.62
7	240.00 ± 26.67	186.67 ± 26.67	3.50	96.50
8	290.00 ± 78.33	133.33 ± 78.33	2.10	97.90
9	200.00 ± 31.67	136.67	2.58	97.42
10	66.67 ± 5.00	76.67 ± 5.00	0.70	99.30
11	290.00 ± 101.67	493.33 ± 101.67	1.41	98.59
12	123.33 ± 56.67	10.00 ± 56.67	1.31	98.69
13	6.67 ± 5.00	3.33 ± 5.00	0.05	99.95
14	36.67 ± 30.00	23.33 ± 30.00	0.32	99.68
Mean	151.19 ± 39.76	125.48 ± 39.76	1.3	98.70

Finally, the last section of this study is the comparison between the numeric data calculated above and an in vivo clinical correlation. A gypsum check of 3 mm thickness and 8 mm height was fabricated with type IV plaster (FujiRock, GC, Tokyo, Japan) for each impression and screwed onto implant abutments at 10 N. If a gypsum check was inserted and screwed without complication, the impression was considered reliable, but if it presented some cracks or fracture, the impression was not considered reliable because it would not have allowed the passive fit of future prosthetic rehabilitation. The outcomes of the gypsum check (intact or fractured) are reported in Table 4.

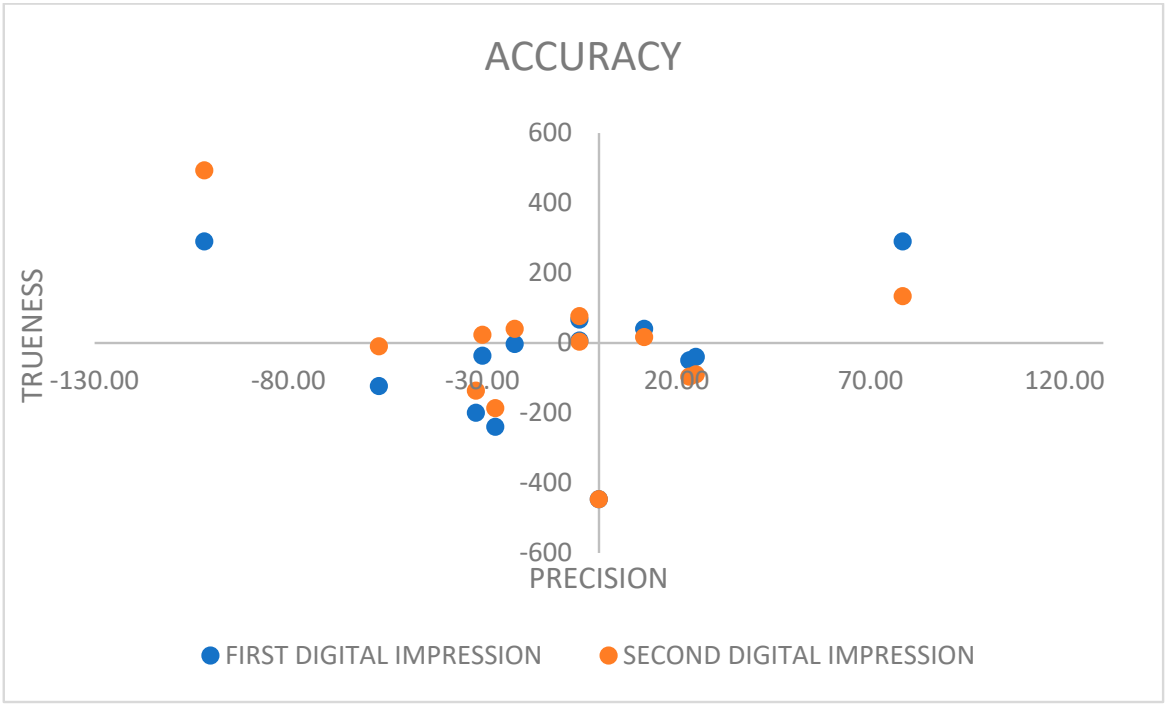

Figure 3. Scatter plot of Accuracy comparison between the first and the second digital impression.

Table 4. Gypsum check outcomes.

Patient N.	First Digital Impression	Second Digital Impression	Conventional Impression
1	Intact	Intact	Intact
2	Intact	Intact	Intact
3	Intact	Intact	Intact
4	Intact	Intact	Intact
5	Fractured	Intact	Intact
6	Fractured	Fractured	Intact
7	Fractured	Fractured	Intact
8	Fractured	Intact	Intact
9	Fractured	Fractured	Intact
10	Intact	Intact	Intact
11	Fractured	Fractured	Intact
12	Intact	Intact	Intact
13	Intact	Intact	Intact
14	Intact	Intact	Intact

So, out of 42 gypsum checks that were fabricated, 32 were able to be screwed without complications, and 10 failed to be screwed onto the prosthetic abutment, resulting in a partial or total fracture. The conventional impression, considered as the reference value, showed no fracture of gypsum check. These results were matched with the Specific Trueness of the digital impression and the Accuracy percentage, allowing us to understand better the clinical implication of the calculated data (Table 5).

Table 5. Outcomes of gypsum check matched with Specific Trueness values.

Patient N.	Specific Trueness 1	First Digital Impression	Specific Trueness 2	Second Digital Impression	Accuracy %
1	3.33	Intact	40.00	Intact	99.98
2	40.00	Intact	16.67	Intact	99.30
3	50.00	Intact	96.67	Intact	99.27
4	40.00	Intact	90.00	Intact	99.71
5	283.33	Fractured	3.33	Intact	97.82
6	446.67	Fractured	446.67	Fractured	97.62
7	240.00	Fractured	186.67	Fractured	96.50
8	290.00	Fractured	133.33	Intact	97.90
9	200.00	Fractured	136.67	Fractured	97.42
10	66.67	Intact	76.67	Intact	99.30
11	290.00	Fractured	493.33	Fractured	98.59
12	123.33	Intact	10.00	Intact	98.69
13	6.67	Intact	3.33	Intact	99.95
14	36.67	Intact	23.33	Intact	99.68

To find a possible correlation with the Chi-Squared test, a cut-off of 100 µm for Specific Trueness and a cut-off of 2% for Dimensional Error, resulting in a threshold value of 98% Accuracy, were considered to find a correlation between the gypsum check clinical outcomes and the Trueness and Accuracy values (Table 6).

Table 6. Statistical analysis of correlation between gypsum check outcomes and Specific Trueness and Accuracy.

Independent Variable	Gypsum Intact	Gypsum Fractured	$p < 0.05$
Specific Trueness of first Digital Impression			***p = 0.001***
<100 µm	7	0	
>100 µm	1	6	
Specific Trueness of second Digital Impression			***p = 0.001***
<100 µm	9	0	
>100 µm	1	4	
Accuracy			***p = 0.001***
<98%	0	5	
>98%	8	1	

Out of 28 digital measurements, 16 were within the established acceptability threshold of 100 µm (57%), and 12 were over the threshold (43%). The Chi-Squared test demonstrate a strong association between the fracture of gypsum check and values of Specific Trueness of more than 100 µm for the first and the second digital impression. Moreover, the same test demonstrates the correlation between the fracture of the gypsum check and an Accuracy below the threshold value of 98%.

4. Discussion

This study aims to validate the gypsum check to perform a clinical evaluation of the Trueness and the Accuracy of digital impressions in everyday practice, suggesting a threshold value for an acceptable misfit. Despite the latest technological progress of dental companies, which permit clinical procedures to be simpler, faster, and more reliable, the comparison between digital and conventional impressions is still under debate.

4.1. Accuracy Evaluation of Digital Impression

Many studies have reported better results for conventional impression [10,15,16], although different authors consider digital impression to be superior to the conventional one [17,18]. In addition, many authors report the similarity of both techniques considering

the accuracy [18,19]. Accuracy is expressed as Trueness ± Precision, so these two values should be calculated. Specifically, Trueness represents the difference between a measured distance on digital impressions and the same measurement made on the reference model scanned by a laboratory scanner. So, the Trueness will then express how far our measurement of digital impression deviates from the value most like true clinical situations. Precision will express the "scattering", counted as the dispersion of measurements taken with the intraoral scanner; it will show how much several scans of the same patient differ from each other. Accuracy will thus be affected by Precision and Trueness, being an indicator of the quality of the procedure and the instrument. To perform these calculations, following the ISO rules, the measurements should be conducted on at least 30 samples [8]. This indication is incompatible with clinical study, considering the difficulty of taking at least 60 impressions for each patient. In fact, most studies are conducted in vitro with superimposition software [20,21]. So, in this study, the authors have proposed "Specific Trueness" because they considered the linear distance within a specific sector evaluated with three impressions.

4.2. Comparison between Digital and Conventional Impressions

After these technical considerations, the clinical implications of the discrepancy between digital and reference impressions should be considered. These differences are primarily due to procedural, methodological, and instrumental factors. The scanner used, the methodology used to compare impressions, and the scanning technique are variables that could influence the outcome [22]. Son et al., in their in vitro study, evaluated the accuracy of different scanners, and the results varied depending on the scanner used and the scanning strategy applied. According to Mennito et al., who suggest the best scanning pathway that provides better Accuracy values, we used a sequential approach: starting from the occlusal side, going from the distal to mesial to the contralateral tooth, we then recorded the buccal side and completed the lingual/palatal side [23]. Additionally, the distance between the intraoral scanner tip and the tooth could severely affect the Accuracy value. In their in vitro study, Rotar et al. demonstrated that the best distance between tip and tooth is 10 mm and Accuracy values worsen in direct proportion to moving away from this distance [24]. In the present study, the authors maintained a distance of about 10 mm, which, however, is very difficult to keep throughout the duration of the scan, due to the patient's movements.

4.3. Comparison between Different Intraoral Scanners (IOS)

Another technical variable is represented by the intraoral scanner, as diffusely reported. In this study, the authors used the Carestream 3600 intraoral scanner (Carestream, Rochester, NY, USA), previously tested by different authors. When this device was tested in vitro on a prototype, the partially (PEM) or totally (FEM) edentulous mandible showed excellent results for Trueness and Precision values: for PEM 45.8 ± 1.6 µm and 24.8 ± 4.6 µm, respectively, and for FEM 60.6 ± 11.7 µm and 65.5 ± 16.7 µm, respectively [25]. Another study conducted on nine intraoral scanners concluded that the same machine performed excellently, reporting an overall Accuracy value of 26.9 ± 15.9 µm [26]. Similar results were obtained by Di Fiore et al., using a model with scanbodies with an accuracy of 61 ±14 µm [27]. Mangano et al. concluded that the sectoral scan of scanbodies has better performances compared to the full arch scan, with Accuracy values of 23 ± 1.1 µm and 44.9 ± 8.9 µm, respectively [5]. In this study, the authors found a lower Accuracy than previously cited authors: an average Accuracy value of 138.34 ± 39.76 µm was reported in the results. This may be explained by this being a clinical study, which differs from in vitro studies for many reasons.

4.4. Limitations of Previous Studies

Many authors have concluded that several factors could adversely affect the quality of intraoral scans in vivo: saliva, blood, limited buccal opening, and possible movements

of the patient [28]. For such reasons, very few in vivo studies have been able to report some discrepant results. In addition to clinical variables, technical features must also be considered: scanned area, number of elements, scanning pattern technique, and the type of scanbodies and their mutual inclination could affect the Accuracy value, as reported by Lee et al. [29]. However, the limitations of these studies are many: Most of all, the methods to calculate Trueness, Precision, and Accuracy are not standardized. This issue was also highlighted by Miyoshi [30], who proposed a solution which provides "Reference Points" for measurements; this was the reason why in our study only the center of scanbodies was considered to produce a reliable Trueness and Precision evaluation. A similar system was used by Roig et al. [31] in vitro: two scanbodies were analyzed and Accuracy was measured in the two center points. After these considerations, the final aim of both digital and conventional impressions is to faithfully reproduce the clinical situation as best as possible in order to transfer correct data to the dental laboratory, leading to reliable rehabilitation.

4.5. Clinical Considerations of Misfit

Besides natural tooth rehabilitations, a key role in long-term implant survival in implant fixed dental prostheses (FDPs) consists of the passive fit of future prosthetics frameworks, which can only be achieved by the excellent reproduction of the clinical situation in the laboratory stages [32]. Clinical passive fit depends on the Trueness of impression: the lower the discrepancy values expressed by Trueness, the higher the ability of the digital impression to reproduce the real clinical situation. Many authors have proposed different threshold values of Trueness to consider faithful or unfaithful impression. Like most of them, we considered a threshold value of 100 µm of the average Trueness [14, 33], in contrast with some researchers who have proposed a more stringent limit, set at 75 µm [34]. In Oreja's study, several repeated scans with different scanners performed on a single patient lead to a 78% discrepancy of less than 75 µm in the maxillary, while in the mandible discrepancy occurred 68% of the time below the set threshold [34]. Presently, there is no universally accepted maximum misfit threshold in the literature; this is because the passive fit could have some degrees of variability due to the different amounts of friction to which the FDP is subjected during insertion [35]. This study reflects the need of dental clinicians to evaluate quickly the passive fit of future prosthetic rehabilitation, as well as collect information of Trueness of digital impression without carrying out difficult virtual measurements and calculations. The method considered is the gypsum jig, or "Check", which is present in the literature and has been used with excellent results for many years [12,36]. An alternative to gypsum is the Duralay check; however, the Young modulus of gypsum is usually between 1 and 2 GPa [37], while the Young modulus of Duralay (PMMA) is between 3 and 5 GPa [38]. These features of the two different materials reflect undoubtedly their elasticity and their ability to forfeit energy during their deformation. Gypsum, which is less elastic than Duralay, allows less deformation, so it fractures much quicker than Duralay when subjected to deformation. In particular, these studies revealed the excellent sensitivity of this system in detecting "misfits" as dimensional and angular inaccuracies. As in previous studies, the gypsum check was performed with type IV plaster (FujiRock, GC, Tokyo, Japan) milled by CAD-CAM on a digital model developed after optical impression and built on an analogic model developed after conventional impression. When screwed to implant abutments of the patient, every gypsum check performed after the traditional impression retained its integrity, but the gypsum checks fractured 10 times out of 28 when they were CAD-CAM-milled by digital models after optical impression. This outcome was correlated with the Specific Trueness and Accuracy values, and the authors found a strong correlation between the fracture of the gypsum check and Specific Trueness values over 100 µm and Accuracy percentage values below 98% ($p = 0.001$).

4.6. Clinical Comparative Studies Evaluation

The lack of clinical study makes it difficult to compare our results to similar studies. Most clinical studies have aimed to compare the Accuracy of digital impressions to con-

ventional ones: Liczmanski et al. compared the Accuracy between digital and alginate impressions in mixed dentition, showing no clinically relevant differences [39]; Gan et al. found similar values of Trueness and Accuracy to this study [40], concluding that differences were clinically acceptable. Rhee et al. found some differences between the 3D model's superimposition, but did not suggest any conclusions about their clinical acceptability [41]. Considering that the first clinical study to evaluate the difference between digital and conventional impressions in implant rehabilitations was conducted in 2018 by Alsharbaty et al., who found significant differences between conventional and digital impressions regarding implant positions [10], this is a very novel topic that should be investigated further. A 2020 review of clinical studies considered only six studies, concluding that conventional impression is more accurate than digital but underlining the lack of consensus on the clinically tolerable values of Accuracy for dental impressions [42]. Another clinical study that compared both suggests that the digital impression displayed better the interdental areas in periodontally compromised dentitions; nevertheless, their results were "clinically not satisfactory" [43]. Only a similar single pilot study evaluated the measurement of Trueness and Precision in five volunteers, using a Co-Cr alloy appliance fitted on a mandibular dentate arch, showing more precise values of Trueness and Precision than this study and concluding, however, that conventional impression showed significantly better values, in agreement with this study's results [44]. To the best of our knowledge, this is the first study to correlate the digital Trueness and Accuracy values with the outcomes of screwed gypsum checks on implant abutments. Our results suggest a clinical tolerance threshold value of over 100 µm for Trueness and over 98% for Accuracy.

4.7. Limitations and Recommendations for Future Research

Many limitations must be considered in this study: Firstly, the small sample size, which was a convenience sample, and the measurements were conducted by a not-blinded expert clinician directly on a virtual cast. There were too few images to permit the software superimposition measurement, which reduces the power of this study's conclusions. It is also necessary to take into account that the authors assumed that the elastic properties of abutments, implants, plaster, and Duralay are included in the range of tolerance which allows the passive fit, established by the outcomes of gypsum checks. Understanding the elastic behavior of these materials better could lead to a better interpretation of the results. Moreover, the lack of clinical studies and of a real consensus regarding the clinically acceptable misfit means that there is no significant reference to compare these results, so it could be considered as a pilot study, which may pave the way for further studies with larger samples and more images to superimpose with 3D software analysis for more powerful results.

5. Conclusions

- Despite the limitations of this pilot study, the authors suggest that the gypsum check screwed onto implant abutments is an effective method to quickly detect the Trueness and Accuracy values of digital impressions, considering, respectively, cut-off threshold values of 100 µm for Trueness and 98% for Accuracy percentage.
- Considering that the passive fit of the framework plays a central role in prosthetic rehabilitations which involve multiple implants, the authors propose 100 µm as a maximum clinical tolerance misfit value: at values over 100 µm of misfit, the impression could not be considered reliable because it does not allow the passive fit of future prosthetic frameworks.
- Further clinical studies on larger samples with many years of follow-up may confirm these considerations or propose a more accurate method.

Author Contributions: Conceptualization, G.M. and P.P.; methodology, G.M.; software, P.P.; validation, G.M.; formal analysis, M.C.; investigation, P.P.; resources, G.M.; data curation, G.d.R.; writing—original draft preparation, G.B.; writing—review and editing, G.B.; visualization, S.C.; supervision, M.C.; project administration, M.C.; funding acquisition, M.C. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Ethics Committee of University Hospital "Policlinico di Bari" (N. Prot. 0069684/2022).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to the privacy regulations of Local Ethical Committee.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Papadiochos, I.; Papadiochou, S.; Emmanouil, I. The Historical Evolution of Dental Impression Materials. *J. Hist. Dent.* **2017**, *65*, 79–89. [PubMed]
2. Cervino, G.; Fiorillo, L.; Herford, A.S.; Laino, L.; Troiano, G.; Amoroso, G.; Crimi, S.; Matarese, M.; D'Amico, C.; Nastro Siniscalchi, E.; et al. Alginate Materials and Dental Impression Technique: A Current State of the Art and Application to Dental Practice. *Mar. Drugs* **2018**, *17*, 18. [CrossRef] [PubMed]
3. Jayaraman, S.; Singh, B.P.; Ramanathan, B.; Pazhaniappan Pillai, M.; MacDonald, L.; Kirubakaran, R. Final-Impression Techniques and Materials for Making Complete and Removable Partial Dentures. *Cochrane Database Syst. Rev.* **2018**, *4*, CD012256. [CrossRef] [PubMed]
4. Duret, F.; Preston, J.D. CAD/CAM Imaging in Dentistry. *Curr. Opin. Dent.* **1991**, *1*, 150–154. [PubMed]
5. Mangano, F.G.; Hauschild, U.; Veronesi, G.; Imburgia, M.; Mangano, C.; Admakin, O. Trueness and Precision of 5 Intraoral Scanners in the Impressions of Single and Multiple Implants: A Comparative in Vitro Study. *BMC Oral Health* **2019**, *19*, 101. [CrossRef]
6. Schepke, U.; Meijer, H.J.A.; Kerdijk, W.; Cune, M.S. Digital versus Analog Complete-Arch Impressions for Single-Unit Premolar Implant Crowns: Operating Time and Patient Preference. *J. Prosthet. Dent.* **2015**, *114*, 403–406.e1. [CrossRef]
7. Rapone, B.; Palmisano, C.; Ferrara, E.; Di Venere, D.; Albanese, G.; Corsalini, M. The Accuracy of Three Intraoral Scanners in the Oral Environment with and without Saliva: A Comparative Study. *Appl. Sci.* **2020**, *10*, 7762. [CrossRef]
8. *ISO 5725-1:1994*; Accuracy (Trueness and Precision) of Measurement Methods and Results—Part 1: General Principles and Definitions. ISO: Geneva, Switzerland, 1994. Available online: https://www.iso.org/standard/11833.html (accessed on 12 January 2023).
9. Amin, S.; Weber, H.P.; Finkelman, M.; El Rafie, K.; Kudara, Y.; Papaspyridakos, P. Digital vs. Conventional Full-Arch Implant Impressions: A Comparative Study. *Clin. Oral Impl. Res.* **2017**, *28*, 1360–1367. [CrossRef]
10. Alsharbaty, M.H.M.; Alikhasi, M.; Zarrati, S.; Shamshiri, A.R. A Clinical Comparative Study of 3-Dimensional Accuracy between Digital and Conventional Implant Impression Techniques. *J. Prosthodont.* **2019**, *28*, e902–e908. [CrossRef]
11. Katsoulis, J.; Takeichi, T.; Sol Gaviria, A.; Peter, L.; Katsoulis, K. Misfit of Implant Prostheses and Its Impact on Clinical Outcomes. Definition, Assessment and a Systematic Review of the Literature. *Eur. J. Oral Implantol.* **2017**, *10* (Suppl. S1), 121–138.
12. Manzella, C.; Bignardi, C.; Burello, V.; Carossa, S.; Schierano, G. Method to Improve Passive Fit of Frameworks on Implant-Supported Prostheses: An in Vitro Study. *J. Prosthet. Dent.* **2016**, *116*, 52–58. [CrossRef]
13. Wulfman, C.; Naveau, A.; Rignon-Bret, C. Digital Scanning for Complete-Arch Implant-Supported Restorations: A Systematic Review. *J. Prosthet. Dent.* **2020**, *124*, 161–167. [CrossRef]
14. Gedrimiene, A.; Adaskevicius, R.; Rutkunas, V. Accuracy of Digital and Conventional Dental Implant Impressions for Fixed Partial Dentures: A Comparative Clinical Study. *J. Adv. Prosthodont.* **2019**, *11*, 271. [CrossRef]
15. Ender, A.; Mehl, A. Accuracy of Complete-Arch Dental Impressions: A New Method of Measuring Trueness and Precision. *J. Prosthet. Dent.* **2013**, *109*, 121–128. [CrossRef]
16. Ender, A.; Mehl, A. In-Vitro Evaluation of the Accuracy of Conventional and Digital Methods of Obtaining Full-Arch Dental Impressions. *Quintessence Int.* **2015**, *46*, 9–17. [CrossRef]
17. Menini, M.; Setti, P.; Pera, F.; Pera, P.; Pesce, P. Accuracy of Multi-Unit Implant Impression: Traditional Techniques versus a Digital Procedure. *Clin. Oral Investig.* **2018**, *22*, 1253–1262. [CrossRef]
18. Hayama, H.; Fueki, K.; Wadachi, J.; Wakabayashi, N. Trueness and Precision of Digital Impressions Obtained Using an Intraoral Scanner with Different Head Size in the Partially Edentulous Mandible. *J. Prosthodont. Res.* **2018**, *62*, 347–352. [CrossRef]

19. Nedelcu, R.; Olsson, P.; Nyström, I.; Rydén, J.; Thor, A. Accuracy and Precision of 3 Intraoral Scanners and Accuracy of Conventional Impressions: A Novel in Vivo Analysis Method. *J. Dent.* **2018**, *69*, 110–118. [CrossRef]
20. Schmidt, A.; Billig, J.-W.; Schlenz, M.A.; Wöstmann, B. Do Different Methods of Digital Data Analysis Lead to Different Results? *Int. J. Comput. Dent.* **2021**, *24*, 157–164.
21. Revilla-León, M.; Jiang, P.; Sadeghpour, M.; Piedra-Cascón, W.; Zandinejad, A.; Özcan, M.; Krishnamurthy, V.R. Intraoral Digital Scans—Part 1: Influence of Ambient Scanning Light Conditions on the Accuracy (Trueness and Precision) of Different Intraoral Scanners. *J. Prosthet. Dent.* **2020**, *124*, 372–378. [CrossRef]
22. Son, K.; Jin, M.-U.; Lee, K.-B. Feasibility of Using an Intraoral Scanner for a Complete-Arch Digital Scan, Part 2: A Comparison of Scan Strategies. *J. Prosthet. Dent.* **2021**, *129*, 341–349. [CrossRef] [PubMed]
23. Mennito, A.S.; Evans, Z.P.; Lauer, A.W.; Patel, R.B.; Ludlow, M.E.; Renne, W.G. Evaluation of the Effect Scan Pattern Has on the Trueness and Precision of Six Intraoral Digital Impression Systems. *J. Esthet. Restor. Dent.* **2018**, *30*, 113–118. [CrossRef] [PubMed]
24. Rotar, R.N.; Faur, A.B.; Pop, D.; Jivanescu, A. Scanning Distance Influence on the Intraoral Scanning Accuracy—An In Vitro Study. *Materials* **2022**, *15*, 3061. [CrossRef] [PubMed]
25. Imburgia, M.; Logozzo, S.; Hauschild, U.; Veronesi, G.; Mangano, C.; Mangano, F.G. Accuracy of Four Intraoral Scanners in Oral Implantology: A Comparative in Vitro Study. *BMC Oral Health* **2017**, *17*, 92. [CrossRef] [PubMed]
26. Nulty, A.B. A Comparison of Full Arch Trueness and Precision of Nine Intra-Oral Digital Scanners and Four Lab Digital Scanners. *Dent. J.* **2021**, *9*, 75. [CrossRef]
27. Di Fiore, A.; Meneghello, R.; Graiff, L.; Savio, G.; Vigolo, P.; Monaco, C.; Stellini, E. Full Arch Digital Scanning Systems Performances for Implant-Supported Fixed Dental Prostheses: A Comparative Study of 8 Intraoral Scanners. *J. Prosthodont. Res.* **2019**, *63*, 396–403. [CrossRef]
28. Chochlidakis, K.M.; Papaspyridakos, P.; Geminiani, A.; Chen, C.-J.; Feng, I.J.; Ercoli, C. Digital versus Conventional Impressions for Fixed Prosthodontics: A Systematic Review and Meta-Analysis. *J. Prosthet. Dent.* **2016**, *116*, 184–190.e12. [CrossRef]
29. Lee, J.-H.; Bae, J.-H.; Lee, S.Y. Trueness of Digital Implant Impressions Based on Implant Angulation and Scan Body Materials. *Sci. Rep.* **2021**, *11*, 21892. [CrossRef]
30. Miyoshi, K.; Tanaka, S.; Yokoyama, S.; Sanda, M.; Baba, K. Effects of Different Types of Intraoral Scanners and Scanning Ranges on the Precision of Digital Implant Impressions in Edentulous Maxilla: An in Vitro Study. *Clin. Oral Implants Res.* **2020**, *31*, 74–83. [CrossRef]
31. Roig, E.; Garza, L.C.; Álvarez-Maldonado, N.; Maia, P.; Costa, S.; Roig, M.; Espona, J. In Vitro Comparison of the Accuracy of Four Intraoral Scanners and Three Conventional Impression Methods for Two Neighboring Implants. *PLoS ONE* **2020**, *15*, e0228266. [CrossRef]
32. Huang, R.; Liu, Y.; Huang, B.; Zhang, C.; Chen, Z.; Li, Z. Improved Scanning Accuracy with Newly Designed Scan Bodies: An in Vitro Study Comparing Digital versus Conventional Impression Techniques for Complete-arch Implant Rehabilitation. *Clin. Oral Implants Res.* **2020**, *31*, 625–633. [CrossRef]
33. Andriessen, F.S.; Rijkens, D.R.; van der Meer, W.J.; Wismeijer, D.W. Applicability and Accuracy of an Intraoral Scanner for Scanning Multiple Implants in Edentulous Mandibles: A Pilot Study. *J. Prosthet. Dent.* **2014**, *111*, 186–194. [CrossRef]
34. Orejas-Perez, J.; Gimenez-Gonzalez, B.; Ortiz-Collado, I.; Thuissard, I.J.; Santamaria-Laorden, A. In Vivo Complete-Arch Implant Digital Impressions: Comparison of the Precision of Three Optical Impression Systems. *Int. J. Environ. Res. Public Health* **2022**, *19*, 4300. [CrossRef]
35. De Sousa, S.A.; De Arruda Nobilo, M.A.; Henriques, G.E.P.; Mesquita, M.F. Passive Fit of Frameworks in Titanium and Palladium-Silver Alloy Submitted the Laser Welding: PASSIVE FIT OF IMPLANT FRAMEWORKS. *J. Oral Rehabil.* **2008**, *35*, 123–127. [CrossRef]
36. Alhashim, A.; Flinton, R.J. Dental Gypsum Verification Jig to Verify Implant Positions: A Clinical Report. *J. Oral Implantol.* **2014**, *40*, 495–499. [CrossRef]
37. Plachý, T.; Tesárek, P.; Padevět, P.; Polak, M. Determination of Young' s Modulus of Gypsum Blocks Using Two Different Experimental Methods. In *Recent Advances in Applied and Theoretical Mechanics, Proceedings of 5th WSEAS International Conference on Applied and Theoretical Mechanics, Puerto De La Cruz, Spain, 14–16 December 2009*; Bulucea, C., Ed.; WSEAS Press: Athens, Greece, 2009.
38. Najeeb, S.; Zafar, M.S.; Khurshid, Z.; Siddiqui, F. Applications of Polyetheretherketone (PEEK) in Oral Implantology and Prosthodontics. *J. Prosthodont. Res.* **2016**, *60*, 12–19. [CrossRef]
39. Liczmanski, K.; Stamm, T.; Sauerland, C.; Blanck-Lubarsch, M. Accuracy of Intraoral Scans in the Mixed Dentition: A Prospective Non-Randomized Comparative Clinical Trial. *Head Face Med.* **2020**, *16*, 11. [CrossRef]
40. Gan, N.; Xiong, Y.; Jiao, T. Accuracy of Intraoral Digital Impressions for Whole Upper Jaws, Including Full Dentitions and Palatal Soft Tissues. *PLoS ONE* **2016**, *11*, e0158800. [CrossRef]
41. Rhee, Y.-K.; Huh, Y.-H.; Cho, L.-R.; Park, C.-J. Comparison of Intraoral Scanning and Conventional Impression Techniques Using 3-Dimensional Superimposition. *J. Adv. Prosthodont.* **2015**, *7*, 460–467. [CrossRef]
42. Giachetti, L.; Sarti, C.; Cinelli, F.; Russo, D.S. Accuracy of Digital Impressions in Fixed Prosthodontics: A Systematic Review of Clinical Studies. *Int. J. Prosthodont.* **2020**, *33*, 192–201. [CrossRef]

43. Schlenz, M.A.; Schubert, V.; Schmidt, A.; Wöstmann, B.; Ruf, S.; Klaus, K. Digital versus Conventional Impression Taking Focusing on Interdental Areas: A Clinical Trial. *Int. J. Environ. Res. Public Health* **2020**, *17*, 4725. [CrossRef] [PubMed]
44. Atieh, M.A.; Ritter, A.V.; Ko, C.-C.; Duqum, I. Accuracy Evaluation of Intraoral Optical Impressions: A Clinical Study Using a Reference Appliance. *J. Prosthet. Dent.* **2017**, *118*, 400–405. [CrossRef] [PubMed]