Assessment of impression material accuracy in complete-arch restorations on four implants

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ABSTRACT

Statement of problem. New polyvinyl siloxane (PVS) materials with enhanced properties have been developed to improve and facilitate implant impression techniques. However, studies on their accuracy are lacking.

Purpose. The purpose of this in vitro study was to determine the accuracy and precision of implant impressions made with some recently introduced materials on a simulated patient requiring an all-on-4 implant-supported prosthesis. Well-established polyether materials were also evaluated as a comparison. The variables considered were material type, consistency, splinting or not splinting techniques, and implant angulation.

Material and methods. A reference master model was made by inserting 4 implants at angles of 0, 5, and 10 degrees. Eighty impressions were made at 37°C in wet conditions by using a standardized technique. Eight groups (n=10) were created using monophasic, single-viscosity materials (Hydrorise Implant Medium, HIM-ns; Hydrorise Implant Medium, HIM; Honigum Mono, HM; Impregum, IMP), and 2-viscosity materials (Hydrorise Implant Heavy+Light-ns, HIH+L-ns; Hydrorise Implant Heavy+Light, HIH+L; Honigum Heavy+Light, HH+L; and Permadyne and Garant [Heavy+Light, PeH+L]). Hydrorise materials were used with splinting and not splinting (ns) techniques. The reference points located on the connecting platforms of the transfer copings (TCP) were compared with the same points on the implant connecting platforms (ICP) located in the reference model. The accuracy and precision of the impressions were determined as linear 3D errors and standard deviation between each TCP-ICP couple by using an optical coordinate measuring machine (OCMM).

Results. PVS materials were generally better than polyether materials, with Hydrorise materials (HIM and HIH+L) showing significantly better accuracy and precision (30.9 ±14.4 µm and 28.7 ±15.5 µm, respectively) than IMP and PeH+L polyethers (44.2 ±16 µm and 43.8 ±17.6 µm, respectively; P<.001). Honigum materials were statistically similar to Hydrorise materials (P=.765). The values shown by Hydrorise nonsplinted groups (HIH+L-ns and HIM-ns) were not statistically different from those of the splinted polyether impressions (P=.386). The viscosities (monophasic or heavy+light) had no effect on accuracy, but monophasic material positively influenced precision (HIM and HIH+L, P=.001). No correlation was found between implant angulation and accuracy (multilevel analysis and Kendall rank correlation coefficient=-0.065; P=.133).

Conclusions. Recently introduced materials designed for implant impressions showed significantly higher accuracy and precision; even with the unfavorable nonsplinting technique, the new materials performed similarly to, or better than, polyether materials. Although the transfer coping splinting technique generally improved the accuracy and precision of Hydrorise materials, the effect was significant only within HIH+L groups. (J Prosthet Dent 2020; - - - - )

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The accuracy of impression materials and related techniques in implant prosthodontics has been widely studied, prompted by the increasing use of computer-aided design and computer-aided manufacturing (CAD-CAM) technologies and automated digital measurement systems.1-8 The passive fit of the prosthesis on the abutment teeth or implants depends firstly on an accurate impression and the impression technique.8 Complete-arch multi-implant prostheses with their machined connections to ankylosic, bone-integrated fixtures pose further restrictions to the fit tolerances of the superstructure, lacking a significant resilient connection to the bone. Thus, the implants should be passively connected to the framework to relieve permanent stresses on both biological tissues and prosthesis components.5,10 Although a certain degree of bone remodeling has been invoked as a mechanism that might reduce the built-in stresses from a poorly fitting framework,11 and several studies have failed to correlate bone loss with prosthesis incongruity,3,12-15 every effort should be made to optimize fit at the implant-prosthesis interface.13,16

An inaccurate impression will fail to record the true position of the implants and the spatial relationships with the other oral structures (teeth, alveolar crests, soft tissues). Factors directly related to the materials (elastic recovery, stiffness or flexibility, dimensional stability, polymerization shrinkage, hydrophilicity, polymerization kinetics, rheology, or tear resistance) and their interactions within the impression technique might affect the accuracy of the impressions.8 Errors that are not immediately detected at the impression stage could be amplified in the subsequent manufacturing phases and then incorporated in the definitive prosthesis. Other sources of errors have been directly linked to the relative angulation of the implants and design of the connecting platforms. Yuzbasioglu et al17 reported that the angulation and the connecting geometry of implants may affect the degree of distortion of the impression material during impression tray removal. The laboratory manufacturing phases could also affect an implant impression as the connection of the analog to the impression transfer coping is a delicate procedure, and if special care is not taken, the transfer coping can rotate within the impression material.18 Thus, splinting of impression transfer copings (or their reciprocal connection with a rigid medium) is generally recommended to maintain their position.8,19-21 Various techniques such as the use of low-shrinkage acrylic resins, either alone or to connect rigid beams (metal or fiber composite) to the impression transfer copings, have been proposed to create passive stabilization.5,8

As the prosthesis design increases in extension and complexity, the impression accuracy becomes of paramount importance.5,8 Several methods have been adopted to evaluate impression accuracy in implant prosthodontics,4,22-25 including profile projectors,26,27 micrometers,28-29 and strain gauges.24-30

In the past decade, automated optical coordinate measuring machines (OCMMs) have been introduced, mainly for quality control during the industrial manufacturing process. These measuring instruments have also been used successfully for dental research31-35 because of their repeatability and high resolution (0.1 to 0.5 µm). Using an optical coordinate measuring machine (OCMM) and an appropriate software program, the distance between implants, transfer copings, and any other reference structures on a cast, framework, or impression can be compared in the 3D space with the actual position initially determined on a reference (calibrated) model that represent the patient’s dental arch.32-36,38

The aim of this study was to determine the accuracy and precision of complete-arch implant impressions made with different elastomeric materials on a reference model simulating an all-on-4 prosthesis. The direct technique (pick-up) with screw-attached transfer copings and standardized open resin trays was applied by using both PVS and polyether impression materials. The effect of rigid splinting of the transfer copings by means of carbon fiber beams (Fig. 1) was evaluated only in 2 types of PVS (Hydrorise Implant groups; Table 1) because they were designed to be possibly used without any splinting techniques. The null hypothesis was that the accuracy and the precision of the impressions would be similar regardless of the material types and their built-in properties, techniques used (splinted or nonsplinted transfer copings), and implant axis angulation.

**MATERIAL AND METHODS**

The experimental impression materials were assigned to 8 experimental groups distinguished by elastomer brand and type: medium-viscosity monophasic types (Hydrorise Implant Medium HIM-ns [Zhermack SpA]; Hydrorise Implant Medium, HIM [Zhermack SpA]; Honigum Mono, HM [DMG]; Impregum, IMP [3M ESPE]) and...
connecting platforms (ICPs), was defined through a calibration procedure performed with an OCMM system (SmartScope Flash CNC 300; Optical Gaging Products). The machine had a resolution of 0.5 μm, with a maximum permissible error of 3.5 μm within the implant layout area (46×36 mm) of the master model. The ICP position was defined as the point where the longitudinal axis of the implant crossed the center of the circular plane of the connecting platform, as calculated by the OCMM-integrated software program. The calibration of the model led to the construction of a 4-point reference frame (Fig. 2) used to calculate impression mismatch.

The same procedure was applied to establish the positions of the connecting platforms of the transfer copings (TCPs) obtained by using the elastomeric materials (Fig. 3). The automated measurement of the TCPs by means of the OCMM machine was the same as used for the ICPs, with the exception of the mounting brackets that were necessarily different between model and impressions.

In accordance with the method used in a previous study,39 all TCP positions, expressed in X, Y, and Z coordinates, were exported into a 3D graphics and CAD application software program (Rhinoseros 5.0; Robert McNeel & Associates) and analyzed with an ad hoc plug-in module programmed in Python, an interpreted high-level, general-purpose programming language. Analysis with Rhinoseros allowed calculation of 3D positioning errors between 1 (out of 4) ICPs belonging to the reference model frame (Fig. 3) and the corresponding TCP position as recorded on that particular impression (Fig. 4); for all the experimental groups, the errors were expressed as linear distances using the following Euclidean formula:

\[ \varepsilon_{pi} = \sqrt{(x_i - x_{refi})^2 + (y_i - y_{refi})^2 + (z_i - z_{refi})^2}, \]

where \((x_i, y_i, z_i)\) pertain to the center point \((i)\) coordinates of the TCP in the Euclidean space and \((x_{refi}, y_{refi}, z_{refi})\) pertain to the corresponding center point \((\text{refi})\) of the ICP reference frame coordinates. \(\varepsilon_{pi}\) is the linear distance between the 2 points, defined as the Euclidean length of the line segment connecting them.

In accordance with the International Organization for Standardization (ISO) 5725-1 standard,22-26,39-40 to describe the 3D error between each TCP and corresponding ICP, this study used the term accuracy rather than trueness. Trueness is related to repeated measures of the same object, whereas in the present study, a single measurement was made on each TCP.1,22 Similarity, the term precision was used to describe the agreement among a set of results, which for a group of measurement data is represented by the standard deviation (SD).
Ten impressions for each material group were made (N=80). Four standard impression transfer copings (Premium Transfer, 3.80 mm; Sweden & Martina) were used for each impression. They were screwed to the implants with a torque of 10 Ncm to make a pick-up type direct impression. Except for groups HIH+L-ns and HIM-ns, the transfer copings were splinted with carbon fiber and epoxy resin beams as previously described. To facilitate image acquisition of the TCP during the measuring procedures, a 3-mm-long silicone tube section was applied around the transmucosal portion of the transfer copings to repel the impression material from the implant-to-transfer coping connecting interface. Standard resin trays (Hi-tray Light Clear; Zhermack SpA) were used to make all impressions (Fig. 4). Each tray was modified by drilling 4 holes to allow direct transfer of coping heads and screw access. The tray positioning was standardized creating a matching line between the reference model and the buccal edge of the impression tray (Fig. 4).

The monophasic materials (groups HIM-ns, HIM, HM, and IMP) were extruded with an automatic mixing machine (Modulmix; Zhermack SpA) in both the impression tray and in a manual syringe for the selective injection around the transfer copings; similarly, heavy+light materials (groups HIH+L-ns, HIH+L, HH+L, and PeH+L) were extruded directly in the tray (heavy paste), whereas the light paste was injected around the transfer copings by using the standard 50-mL double cartridge syringe with the proper mixing tip. All the impressions were made at a temperature of 23 ±1 °C. At the end of the working time (90 seconds), the impression model assembly was placed in a thermostatic water bath at 37 °C.
±0.5 °C. After 5 minutes and 30 seconds, the impression tray was removed from the reference model. Any fins and excess material were removed to avoid interference with the OCMM mounting brackets. Each impression was gently dried with compressed air and stored in plastic bags at 23 ±1 °C. After 48 hours, the short silicone tubes were removed from the impression transfer copings to make them ready for the TCP measurement procedures (Fig. 5).

The analyzed variables that could affect accuracy and precision were material types (PVS and polyether), material consistency (monophasic and heavy+light materials), splinting or no-splinting techniques (limited to Hydrorise groups), and implant angulation.

As a preliminary test of reliability of the measurement methodology, 15 impressions were selected and measured 3 times, consecutively, with the OCMM. To experimentally determine the precision of the OCMM, the 3 TCP data sets from each impression were compared by intraclass correlation (ICC). High reliability was present among OCMM measurements (intraclass correlation=0.999, P=.001, 95% confidence interval: 0.998 to 1).

Ten impressions were evaluated for each group, and the medium 3D error relative to the 4 TCP positions of each impression was calculated; this yielded 40 accuracy values for each impression material. All 40 raw data were used to calculate the standard deviation (SD) and then assumed as the precision value. Multilevel analysis (mixed-effects model) was used preliminarily to evidence the influence of group and inclination (fixed effects) on accuracy.

For the assessment of the accuracy, the Shapiro-Wilk test was used to determine whether the accuracies of the 8 groups exhibited a Gaussian distribution; as a normal distribution was seen only for group HIM-ns, the nonparametric Kruskal-Wallis test was performed for the group comparison. The Kolmogorov-Smirnov test was used to compare the shapes of distributions, denoting that only 8 out of 28 comparisons were significant and presenting different shapes. To determine significant differences in accuracy between pairs of groups, the Mann-Whitney U test was used with the reduced α=.05 in accordance with the Holm-Bonferroni correction method.

For the comparison of precision among groups, the F-test was used to determine whether there was a significant difference in variance among the groups (n=8) (Table 2). The Kendall Tau-b and partial correlation coefficient (first grade) for the 4 implants were calculated in the analysis of the correlation between the angulation of each implant and the 3D error. To confirm the absence of relationship between accuracy and angle, a 1-way ANOVA model of the distance at a given implant angle was performed.

### Results

A multilevel mixed-effect model was used considering “implant-to-transfer copings” as first level unit and “group” and “implant angulation” as fixed effects; only “group” significantly affects accuracy as reported in Table 3 (P=.001), and significant differences were found for groups HIM (P=.002), HIH+L (P=.001), HM (P=.047), and HH+L (P=.018) that presented the highest accuracies. Significant differences were found in the accuracy values among the 8 groups (Kruskal-Wallis test: H=33.51; P=.001, Table 3). The type of impression material had statistically significant effects on the impression accuracies, with Hydrorise PVS groups HIM and HIH+L showing significantly higher values than those of the polyether groups IMP and PeH+L (P=.001), as well as Honigum PVS group HH+L in comparison with the same polyether materials (IMP (P=.002) and PeH+L (P=.005)). The consistency (monophasic or heavy+light materials) considered within each material brand had no significant effects on accuracy.

| Table 2. Statistical tests used |
|--------------------------------|
| Statistical Test | Tested Variable | Test Properties |
|------------------|-----------------|-----------------|
| ICC              | Accuracy        | Reliability     |
| Shapiro-Wilk     | Accuracy        | Gaussian distribution |
| Kruskal-Wallis (nonparametric) | Accuracy, Precision | Group comparison |
| Kolmogorov-Smirnov | –              | Shapes of distribution |
| Mann-Whitney U test | Accuracy | Differences between pairs of groups |
| Holm-Bonferroni  | Correction      | Reduction of a threshold |
| F-test           | Precision       | Variance difference among groups |
| Mixed effect model | Accuracy, group, inclination | Influence on accuracy of group and inclination |
| Kendall Tau-b    | Inclination, Accuracy | Correlation between 2 variables |
| ANOVA            | Inclination, Accuracy | Accuracy by inclination |

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**Figure 5.** Impression positioned on OCMM table ready for measurement procedure. Gap between TCP (green colored) and elastomer (Hydrorise Implant H+L group), created by a silicone tube spacer, facilitated the scanning of the TCP margins. OCMM, optical coordinate measuring machine; TCP, transfer coping platform.
Generally, the splinting technique improved the accuracy of the impressions in both Hydorise material types (HIH+L and HIM), but the difference was not statistically significant between HIH+L-ns and HIH+L (P=.015) or HIM-ns and HIM (P=.013). The angulation of the implants was not significantly correlated either to the accuracy or to precision of the impressions (multilevel analysis and Kendall’s Tau-b = -0.065; P=.133).

The PVS and polyether material impressions had similar precision (SD); thus, the material type did not influence this parameter (Table 3). As regards consistencies, monophasic materials showed better results than biphasic materials, especially within the nonsplinted groups HIM-ns and HIH+L-ns, where the influence of the material consistency was statistically significant (P=.001) Biphasic, heavy+light materials of groups HIH+L-ns and HH+L demonstrated the worst precision (30.3 μm and 20.2 μm, respectively). The impression transfer coping splinting technique improved the precision of the impressions, showing significant effects between groups HIH+L-ns and HIH+L (P=.001) but not between groups HIM-ns and HIM (P>.05).

### DISCUSSION

The null hypothesis that the accuracy and the precision of the impression transfer copings would be similar regardless the variables considered was partially rejected depending on the variables considered.

Accuracy is an indicator of how close a measurement is to the true value and can be calculated based on the average 3D position error of the TCP in comparison with the matching ICP. Impressions procedures with low accuracy cannot reproduce the true implant position, generating the mismatch between framework and ICP that can trigger the pathological sequela widely described in the literature.41-43

Precision is an indicator of the distribution of the data obtained from a series of measurements on the same object (The reference model was the “measuring device” of the TCPs contained in the impressions.) around an average value and can be represented by the extent of statistical dispersion, such as standard deviation. The clinical significance of the precision of an impression procedure is related to its repeatability or capacity to provide consistent results. Accuracy and precision are equally important in clinical practice and were therefore given equal weight in this study that compared different materials. The comparison of the global quality, possibly defined as a balance of accuracy and precision, is shown for each material in Figure 6, where the groups showing the highest global quality were the closest to zero. Although a consensus for a safe clinical threshold for misfit is lacking,43 the error should be reduced as much as possible. In the present study, impressions made with different materials, consistencies, and techniques exhibited errors within the range of tolerance described previously (30 to 150 μm),44-46 and it is unlikely that the differences found among the impression groups, even when statistically significant, could affect the clinical outcome in the absence of other sources of error in the manufacturing process.

Being the first highly accurate and stable elastomer introduced into clinical practice, polyether materials have been considered the material of choice for implant impressions because of their favorable hydrophilic and elastic behavior. However, PVS materials have improved in the last decades, and no significant superiority in performance of polyether materials has been clearly demonstrated.48 Rather, some studies report that accuracy tended to be higher for PVS impression materials,49,50 and these findings are consistent with the present data.

To satisfy both the polyether requirement for individual trays and research standardization constraints, the same small plastic tray (Size small, Hi-Tray; Zhermack SpA) was used for all impressions to limit the impression manufacturing process.

Table 3. Summary of accuracy and precision mean ±standard deviation values (μm) in groups tested. Groups with different uppercase or lowercase letters are significantly different. Mann-Whitney test; α=.007 with Holm-Bonferroni correction and F-Test α=.05.

| Group       | HIM-ns | HIH+L-ns | HIM     | HIH+L   | HM     | HH+L   | IMP          | PeHL    |
|-------------|--------|----------|---------|---------|--------|--------|--------------|---------|
| Product     | Hydorise Implant | Hydorise Implant | Hydorise Implant | Hydorise Implant | Hydorise Implant | Hydorise Implant | Hydorise Implant | Hydorise Implant |
|             | Medium | Heavy+Light | Medium | Heavy+Light | Medium | Mono   | Heavy+Light  | Medium |
| Accuracy    | 38.0 A | 44.3      | 30.9 B  | 28.6 a,C | 35.6   | 34.01 D| 44.2 b,c,d   | 43.7 b,c,d   |
| Precision   | 13.7 A | 30.3 a,B  | 14.4 b,C| 15.5 b   | 13.5 bd| 20.2 a,b,c,d| 16 b         | 17.6 b         |

NS, Not splinted. Accuracy (first row): Mann-Whitney test; α=.007 with Holm-Bonferroni correction. Precision (second row): F-Test α=.05.
However, viscous elastomers have a limited ability to better stabilize the transfer copings. The use of high viscosity phases is to achieve a stiffer and heavy+light viscosity materials; the rationale for the Closer group to axis origins (zero point), higher quality of impressions. (A, HIM-NS: B, HIH+L-NS: C, D: HIH+L; G: IMP; H: PeH+L).

Closer group to axis origins (zero point), higher quality of impressions. (A, HIM-NS: B, HIH+L-NS: C, D: HIH+L; G: IMP; H: PeH+L).

Figure 6. Accuracy and precision (μm) integration for all groups. (A, HIM-NS: B, HIH+L-NS: C, D: HIH+L; E: HM; F: HH+L; G: IMP; H: PeH+L).

Closer group to axis origins (zero point), higher quality of impressions. (A, HIM-NS: B, HIH+L-NS: C, D: HIH+L; G: IMP; H: PeH+L).

This study used both medium viscosity (monophase) and heavy+light viscosity materials; the rationale for the use of high viscosity phases is to achieve a stiffer impression to better stabilize the transfer copings. However, viscous elastomers have a limited ability to replicate fine details. The difficulty of the heavy materials to completely penetrate the retentive grooves of the impression transfer copings, failing to completely embrace and stabilize them in spite of the injected light phase, could be an issue if a technique without splinting is used, possibly explaining the relatively low accuracy and precision recorded in HIH+L-ns in comparison with medium body HIM-ns group.

Splinting of impression transfer copings using acrylic resin may influence the accuracy of the impression material, although the data are somewhat conflicting. The effect of the splinting technique was tested only in the Hydrorise Implant material groups, since these PVS have been designed to be possibly used without splinting techniques, there are some limitations. Only wet conditions and mouth temperatures have been simulated in this study, even with internal connection implants.

Although the results obtained in this study contribute to updating the accuracy data of the impression techniques, there are some limitations. Only wet conditions and mouth temperatures have been simulated in this study, even with internal connection implants. Furthermore, its higher flexibility could better recover the displacement of the transfer copings during the impression removal in comparison with the stiffer heavy viscosity material. The high accuracy and precision showed by HIM-ns group suggest that HIM could be used without the time-consuming splinting technique for all-on-4 implant impressions, simplifying the clinical process.

The implant angulation variable and its effect on the accuracy of the impression have been evaluated in previous studies, demonstrating that accuracy is inversely proportional to angulation. Elshenawy et al. assessed Osseolink implants placed in 3 reference models at different angles (0, 15, and 30 degrees) by using 3 different impression techniques (indirect, unsplinted-direct, and acrylic resin splinted-direct) and reported that nonparallel implants placed at 30 degrees did not show significant reductions in accuracy and precision. The present study confirmed these findings. No significant differences were detected for accuracy and precision in all groups, except for accuracy in the group HIM-ns when evaluated with ANOVA (Table 4): it is likely that, when the axis inclination of an implant is moderate (5 or 10 degrees), the displacement of the transfer coping during impression removal is well within the elastic recovery of both the splints and impression materials used in this study, even with internal connection implants. Furthermore, its higher flexibility could better recover the displacement of the transfer copings during the impression removal in comparison with the stiffer heavy viscosity material. The high accuracy and precision showed by HIM-ns group suggest that HIM could be used without the time-consuming splinting technique for all-on-4 implant impressions, simplifying the clinical process.

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CONCLUSIONS

Based on the findings of this in vitro study, the following conclusions were drawn:

1. Some recently introduced PVS have shown significantly better accuracy than well-established polyether impression materials; however, the precision did not significantly differ among the groups.

2. Splinting significantly improved the accuracy in the Hydorise Implant PVS groups.

3. Hydorise Implant Medium without splinted transfer copings showed better accuracy than splinted polyether materials, although the differences were not statistically significant.

4. The accuracy and precision of the impressions were not significantly affected by implant angulation.

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