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Conformity, reliability and validity of digital dental models created by clinical intraoral scanning and extraoral plaster model digitization workflows

Christian Kirschneck[a,*], Benjamin Kamuf[b], Christine Putsch[b], Sachin Chhatwani[b], Mozhgan Bizhang[c], Gholamreza Danesh[b]

[a] Department of Orthodontics, University Medical Centre of Regensburg, Franz-Josef-Strauss-Allee 11, 93053, Regensburg, Germany
[b] Department of Orthodontics, School of Dentistry, Faculty of Health, Witten/Herdecke University, Alfred-Herrhausen Str. 50, 58448, Witten, Germany
[c] Department of Operative and Preventive Dentistry, School of Dentistry, Faculty of Health, Witten/Herdecke University, Alfred-Herrhausen Str. 50, 58448, Witten, Germany

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ABSTRACT

Background: In dentistry, digitization of dental arches with intraoral scanners could one day replace impressions and plaster model digitization processes, if accuracy is clinically sufficient. This study aimed to assess the reliability, validity and conformity of an intraoral scanning procedure (Lythos©, Ormco) and of two extraoral digitization workflows via alginate impression and plaster model scanning with the D810© (3shape) or the Atos II Triple Scan© (GOM) under clinical conditions.
Methods: In 20 subjects three consecutive intraoral scans, three alginate and one reference polyether impression were taken of both the upper and lower dental arch, respectively. The digital models created from the corresponding plaster models and the intraoral scans were superimposed with the polyether reference standard by both a global and a local best-fit algorithm. Reliability, validity and conformity of the three digital workflows were assessed via intraclass (ICC) and Lin's concordance correlation coefficients (CCC) as well as analyses according to Bland-Altman.
Results: The digital models created from the intraoral scanning procedure were less in agreement with the polyether reference (validity) than those from the extraoral procedures with reduced conformity and reliability. Local numerical deviations from the reference standard were approximately twice as high compared to the extraoral procedures, which showed high conformity and were equivalent and clinically acceptable in terms of reliability and validity.
Conclusions: Although the intraoral scanning method with Lythos© seems to have drawbacks in terms of reliability, validity and conformity to the indirect alginate methods, all procedures proved to be clinically equivalent for diagnostic purposes.

1. Introduction

Metric analysis of orthodontic study models of the upper and lower dental arches plays a pivotal role in the diagnostic and differential-therapeutic process in the dental specialty of orthodontics, which deals with the correction of malpositioned teeth and misaligned jaws. Traditionally used plaster models, however, have several disadvantages [1,2]. For their creation, a negative of the patient's upper and lower dental arch needs to be taken, which then allows the casting of the plaster model. To this aim, usually an initially plastic, then elastic impression material is used. Both the impression material and the plaster models are subject to physical and chemical influences and wear, particularly during repeated measurements [2]. In addition, changes in shape may occur over time due to changes in humidity and temperature [3,4]. The conventional workflow is also time-consuming and costly, both in terms of impression-taking and model-fabrication as well as model storage [2,5]. A possible solution for these problems are digital virtual models, which were introduced in orthodontics at the end of the 1990s [2].

Digital models have since then been gradually adopted in

* Corresponding author. Department of Orthodontics, University Medical Centre of Regensburg, Regensburg, D-93053, Germany.
E-mail addresses: christian.kirschneck@ukr.de (C. Kirschneck), b.kamuf@yahoo.de (B. Kamuf), cputsch@t-online.de (C. Putsch), Sachin.chhatwani@uni-wh.de (S. Chhatwani), Mozhgan.Bizhang@uni-wh.de (M. Bizhang), Gholamreza.Danesh@uni-wh.de (G. Danesh).

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orthodontics for diagnosis, treatment-planning and documentation of treatment results [5–8] and an increasing number of orthodontists have adopted this process for their daily clinical routine [7,9]. In the US, 55% of orthodontic practices in the Pacific region and 21% of practices in the Northeast region used digital models for diagnostic purposes in 2014 [10]. Digital models have several advantages, such as reduced requirements for model storage, faster access to three-dimensional diagnostic information and easy transmission of digital data for communication with professionals and patients [11–15]. In addition, virtual setups can be created for improved treatment planning and for manufacturing of individualized removable and fixed appliances [11,13–15], particularly in combination with 3D printing technologies.

Digital models can be created by direct or indirect digitization of structures and surfaces by means of intra- or extraoral scanning methods [2,16]. Currently, most digital models are created by laser or cone-beam computed tomography (CBCT) scanning of alginate impressions or plaster models [1,2,5] with various model scanners and clinical workflows available. Advances in intraoral scanning now also allow the direct chairside digitization of the clinical situation within the oral cavity, which can obviate the need for conventional impressions [7,17–19]. Until now, however, only a few studies are available on the accuracy, validity and reliability of digital models of complete dental arches created by direct and indirect digitization procedures, and none on the intraoral scanning procedure with Lythos© intraoral scanner (Ormco, Orange, CA, USA) [14].

The aim of this study was therefore to assess and compare the diagnostic accuracy, that is the reliability, validity and conformity of three different digital workflows for the creation of virtual orthodontic study models, based on either intraoral scanning of the dental arches with the Lythos© intraoral scanner or extraoral scanning of plaster models derived from alginate impressions with the two different laser scanners D810© (3Shape, Copenhagen, Denmark) and Atos II Triple Scan© (GOM, Braunschweig, Germany).

2. Materials and methods

2.1. Study design, setting and participants

In this cross-sectional study of diagnostic accuracy 20 young adults were enrolled at Witten-Herdecke University (students and staff). The study was conducted according to the principles of the Declaration of Helsinki (1964) and its later amendments as well as approved by the Institutional Ethics Review Board Witten-Herdecke (No. 57/2014). All participants provided their written informed consent prior to the start of the study. The selection of subjects was based on the following inclusion criteria: age between 18 and 30 years as well as at least 28 natural teeth (complete permanent dentition up to the second molars) with no current caries activity, gingivitis, periodontal disease or other oral pathology, as assessed by clinical examination and anamnesis. Exclusion criteria comprised the presence of systemic diseases, congenital anomalies and syndromes affecting the dentition and the craniofacial system including cleft lip and palate as well as current orthodontic treatment and allergies to any component of the applied impression materials.

Three consecutive intraoral scans (A/B/C) and thus digital virtual models of both the maxillary and mandibular dental arch each were taken per subject with the Lythos© intraoral scanner (Ormco, Orange, CA, USA) by the same, trained orthodontic clinician according to the manufacturer's instructions (Fig. 1). Furthermore, three consecutive alginate impressions (A/B/C) of both the upper and lower dental arch each (Tetrachrome©, Kaniedenta, Herford, Germany) and one polyether impression per dental arch (Impregum Penta©, 3 M ESPE, Seefeld, Germany) were subsequently performed according to the manufacturers' instructions with the aid of automatic mixing devices (alginate: Migma 200©, Mikrona, Spreitenbach, Switzerland; polyether: MixStar©, DMG, Hamburg, Germany). Plaster model positives of the dental arches were then created from the three alginate and one polyether impression per dental arch per subject by a dental technician using Class III dental stone (Orthodur©, Protechno, Direct Dental Services, Kelheim, Germany) and each model digitized once with both the D810© dental model scanner (3Shape, Copenhagen, Denmark) and the Atos II Triple Scan© industrial high-precision 3D scanner (GOM, Braunschweig, Germany) (Fig. 1) to assess reliability, validity and conformity of commonly used extraoral workflows for clinical use.

The plaster models created from the polyether impressions were exclusively digitized with Atos II Triple Scan©. The derived digital models, assumed to accurately reproduce the actual intraoral situation due to the high precision of polyether impressions, were used as reference standard for determining reliability, validity and conformity of the three to-be-investigated clinical digitization workflows I (intraoral scan – Lythos©), II (plaster model scan – D810©) and III (plaster model scan – Atos II Triple Scan©), which were each repeated three times A/B/C for reliability assessment. All digital data were saved and stored in the STL file format.

2.2. Assessment of reliability

Reliability is the overall consistency of a workflow for the creation of a digital model, that is whether mostly identical digital models are achieved, when repeating a workflow under consistent conditions. To assess reliability (repeatability), each of the three digital models (A/B/C) per dental arch and workflow (I/II/III, Fig. 1) was superimposed with the digital reference model of the same subject from the polyether (PVE) reference procedure (Fig. 2).

Matching was performed with GOM Inspect Professional V8© data processing and 3D inspection software. The digital models were imported into the software in STL data format and all structures beyond the tooth surfaces removed. The superimpositions of the virtual models were performed with two different best-fit alignments, a global best-fit algorithm and a local best-fit algorithm. The global best-fit algorithm was based on the entire surface of the digital dental arches, achieving a superimposition with minimum discrepancies across the entire dental arch (Fig. 3A). The local best-fit algorithm on the other hand focused exclusively on matching the respective first molars of one side (tooth 16 or 46) at minimum discrepancy (Fig. 3C). For each of the three clinical workflows tested, the local numerical best-fit deviations of the respective digital models A, B and C to the digital model of the polyether reference standard were determined at 14 buccal measuring sites at the centre of the buccal surface of each tooth in both best-fit alignments as an absolute value (Fig. 3B/D). The global and local best-fit deviations of models A, B and C to the reference standard were then tested for concordance and thus reliability with the interclass correlation coefficient (ICC, random two-way model, absolute agreement, 95% ICC confidence intervals). In addition, concordance was tested separately for certain selections of measuring sites (tooth groups). Analogous to Landis and Koch [20] an ICC $> 0.8/0.6/0.4/0.2$ was considered to represent an almost perfect, substantial, moderate or mediocre concordance and thus reliability/repeatability, respectively.

2.3. Assessment of validity

Validity is defined as how well a digital model accurately corresponds to the actual clinical situation represented in this study by the digital models created from the polyether reference workflow. Before assessing the validity of the three clinical workflows evaluated, we calculated the arithmetic means of the corresponding best-fit deviations of the three reliability superimpositions (models A, B and C to reference standard) per subject and measurement site, which were then used for further analyses.

Validity was determined via the median best-fit difference (global and local) of the three clinical workflows tested to the polyether reference workflow as well as via 95% limits of agreement (LOA, Bland-