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In vivo trueness and precision of full-arch implant scans using intraoral scanners with three different acquisition protocols

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ABSTRACT

Objectives: To evaluate an *in situ* reference acquisition method for implant positions in complete edentulous maxillae using an industrial scanner and allowing for *in vivo* trueness analysis of the restorative workflow. To assess *in vivo* trueness and precision of intraoral scanners (IOS) using different acquisition protocols. Furthermore, to compare IOS trueness with impression-based models and implant-supported fixed dentures (IFD) in a parallel study on the same cohort using the same *in situ* reference scan.

Methods: Six scan-bodies mounted to maxillary implants in five subjects were reference scanned (REF) using an industrial scanner. Subjects were scanned with IOS three times using three different protocols: control (CT), dental floss assisted (DF), and acrylic splint (SP). CAD-files of scan-bodies with inter-aligned analogues were geometry-aligned to REF, and SP. Scan-bodies were aligned to CT and DF in proprietary dental laboratory software and exported with analogue positions. Resulting six CAD-analogues per scan were Globally Aligned using a consistent geometry-based alignment. Deviations were computed after a Reference Point System Alignment at the implant/prosthetic platform for Cartesian axes with a linear Resultant.

Results: Resultant trueness was CT: 41±11 μm, DF: 49±22 μm, SP: 55±8 μm. Resultant precision was CT: 48±7 μm, DF: 50±7 μm, SP: 45±6 μm.

Conclusions: This method is applicable for assessing trueness of maxillary full-arch implant scans *in vivo*. The CT protocol was most accurate. CT trueness showed no difference to digitised impression-based models in parallel study. CT was more accurate than IFD in a parallel study. CT displayed similar numerical trueness as existing *in vitro* studies.

Clinical significance: Using IOS to acquire full-arch implant scans is controversial. The modified protocol in this pilot shows promising results in the maxilla where great care was taken to manage non-attached tissues when a modified scanning pattern was used. However, other IOS may show varying results *in vivo*. A completed scan does not necessarily equate to an accurate scan.

1. Introduction

To produce an implant fixed denture (IFD) by Computer-Aided Design/Computer-Aided Manufacturing (CAD/CAM), the inter-implant positions in the three-dimensional (3D) space requires a digitisation process. The conventional method for nearly two decades has been an indirect digitisation of models deriving from conventional impressions [1]. Methods for direct *in vivo* digitisation are available through stereo-photogrammetry (SPG) and intraoral scanners (IOS). Evaluation of SPG has shown promising results as a mode of acquisition primarily in complete edentulous cases [2–5]. However, the SPG method lacks the ability of acquiring data of soft tissues.

Scanning full arches with IOS to manufacture IFDs is a clinical controversy as there is conflicting *in vitro* evidence regarding the use of IOS for cross-arch fixed restorations [6–11]. Although manufacturers of implants and frameworks for IFDs do not recommend this type of acquisition based on limited clinical evidence, the dental industry is aware of the occurrence.

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This study uses the ISO-5725 terminology to describe trueness and precision [12], where trueness is defined as the closeness of agreement between the arithmetic mean of a large number of test results and the true or accepted reference value, and precision is defined as the closeness of agreement between test results. Although there are a multitude of IOS studies *in vitro,* there are few publications on *in vivo* trueness or precision [13–18]. Studies based on dentate subjects all show promising results for some systems, however, a lesser trueness in the posterior areas has been identified [15]. *In vitro* studies have investigated different factors which could affect the trueness of IOS with varying conclusions. The factors have ranged from previous operator experience, scanning strategy, material properties, as well as intrinsic parameters such as implant depth, angulation and the inter-implant distance [8,10,19–25].

Edentulous alveolar ridges can show varying degrees of general deficiencies and resorption, which leads to limited non-attached tissues [26]. This may further impact the acquisition of implants in the edentulous arch. *In vivo* studies evaluating precision of scan-bodies used in implant treatments have shown unfavourable results because of the lack of anatomical landmarks when using an older IOS technology [27]. Several methods have been proposed which could reduce distortions due to inter-scan-body distances [28,29]. Examples include adding artificial landmarks in the inter-scan-body gap, the use of removable splints or dental floss in inter-scan-body spaces and including a scan of the palate in maxillary full arch implant scans [30–33].

Other factors affecting the trueness of scanning scan-bodies with an IOS is manufacturing tolerances and scan-body identification. Tolerances in implant and prosthetic components are necessary both from a production and handling point, but ought to have only a small impact on the total misfit. Previous research has demonstrated that the misfit between an implant and an impression coping can vary depending on the implant connection type: 2.8 μm for an internal flat to flat connection, 4.3 μm for an external flat-to-flat connection and 21 μm for an internal conical connection [34]. The friction-fit interface of internal conical connections has also been found to increase the rotational displacement in scan-bodies [35].

There are major differences in how IOS software handles stitching due to the proprietary technology. Scanning patterns have been shown to influence the outcome [22,23]. Furthermore, varying resolutions and tessellations between manufacturers may introduce a greater level of error in the workflow when identifying scan-bodies [36].

3D Compare Analysis is a method analysing production and quality control through best-fit alignment where measured data is compared to a reference measurement or to an original CAD drawing [37–39]. A colour histogram based on 3D Compare Analysis is frequently used to present the magnitude of the deviations. This method has been applied extensively on free-form shapes of anatomical structures in dental research [16,36,40–43].

A frequent approach in industrial 3D inspection is the use of geometric structures, *Datums*, which do not carry the same limitations seen in 3D Compare Analysis of free-form shapes [38,39]. Scan-bodies commonly used in implant dentistry carry a combination of specific mathematically defined geometries such as planes, cylinders and hemispheres [44]. Dental related studies have to a certain extent used such geometries for alignment and deviation analysis [10,28,45–47].

In a previous study, CAD-files of scan-bodies and analogues are aligned to their counterpart in the scanned files through Datum Alignment [47]. The use of CAD files allows for a pair-wise comparison at the actual implant/prosthetic interface using a Reference Point System (RPS) Alignment. This method has an advantage over 3D Compare Analysis of free-form shape as it eliminates aliasing artefacts and phantom points found when scanning sharp edges of scan-bodies [48].

The aim of this pilot study was to investigate the possibility to acquire an *in situ* reference in full-arch implant treatments and to report both *in vivo* trueness and precision of IOS using different scanning protocols. Furthermore, the results in this study are compared to a parallel *in vivo* study on trueness of CAD/CAM restorations and impression-based models using the same reference measurement and subjects [47].

The primary null hypothesis was that there were no differences in trueness between three different IOS protocols and the reference-scan. Second, there were no differences in trueness from IFD or impression-based models evaluated in the parallel study.

2. Materials and methods

2.1. Ethical approval

The study was conducted in accordance with ethics approval (Dnr 2016/020; Regional Ethical Review Board, Uppsala) and conforming to the standard of the Declaration of Helsinki.

2.2. Inclusion and exclusion criteria

To avoid the increased misfit seen in components with conical connections, the inclusion criteria were six maxillary implants with butt-joint external hexagonal regular platform (RP) of either Brånemark System (Nobel Biocare AB, Gothenburg, Sweden) or Biohelix (Brånemark Integration, Gothenburg, Sweden) [34,35].

The requirements of the existing IFD were an abutment free CAD/CAM manufactured titanium framework based on milling or laser-sintering with straight or angulated screw channels.

Subjects who fulfilled the inclusion criteria and had received full-arch IFD in the edentulous maxillae at a private specialist centre of dental implantology between the years 2012 and 2017 were identified in the patient register.

2.3. Workflow and operators

The full workflow is depicted in Fig. 1. Abbreviations are listed in Table 1. Specific software commands and protocols are presented in the Appendix.

Inclusion and Exclusion criteria, as well as reference scan is shared between the present study and a parallel study [47]. Reference and IOS scans were performed by a specialist in oral prosthetics with training and several years' experience of handling both systems (RN). All scans were conducted without operator light and with dimmed indirect ambient lighting to avoid affecting the acquisition for both reference and IOS [49]. Impressions and IFD scans in the parallel study were conducted by the same clinician immediately after removal of scan-bodies in this study.

All instruments were calibrated according to manufacturer's recommendations.

2.4. Acquisition and virtual models

2.4.1. Reference scan

The only officially distributed scan-body by the implant manufacturer (Elos Accurate IO 6A-B; Elos Medtech) was connected and hand-tightened onto each implant with its 40-degree top angled plane orientated facially (Fig. 2A).

To limit movement during scanning with the reference-scanner, the head and neck of the subject was fixated with an orthopaedic vacuum pillow (223,940,000; Camp Scandinavia AB, Helsingborg, Sweden) with the chair raised at a 30-degree angle. Clear self-retractors were used to aid the visualisation of all scan-bodies (Adult Self Retracting; Photomed, USA).

An industrial-grade scanner (ATOS) was used to acquire the reference scans (ATOS Core 80 5MP; GOM, Braunschweig, Germany). The system was mounted on a proprietary tripod and used proprietary computer software (ATOS GOM Scan 2016 Hotfix 11, Rev. 104024; GOM). The system was calibrated according to VDI/VDIE 2634 (VDI e. V.; Düsseldorf, Germany), (Appendix 1.1).

To evaluate the precision of the scanner, three complete scans were

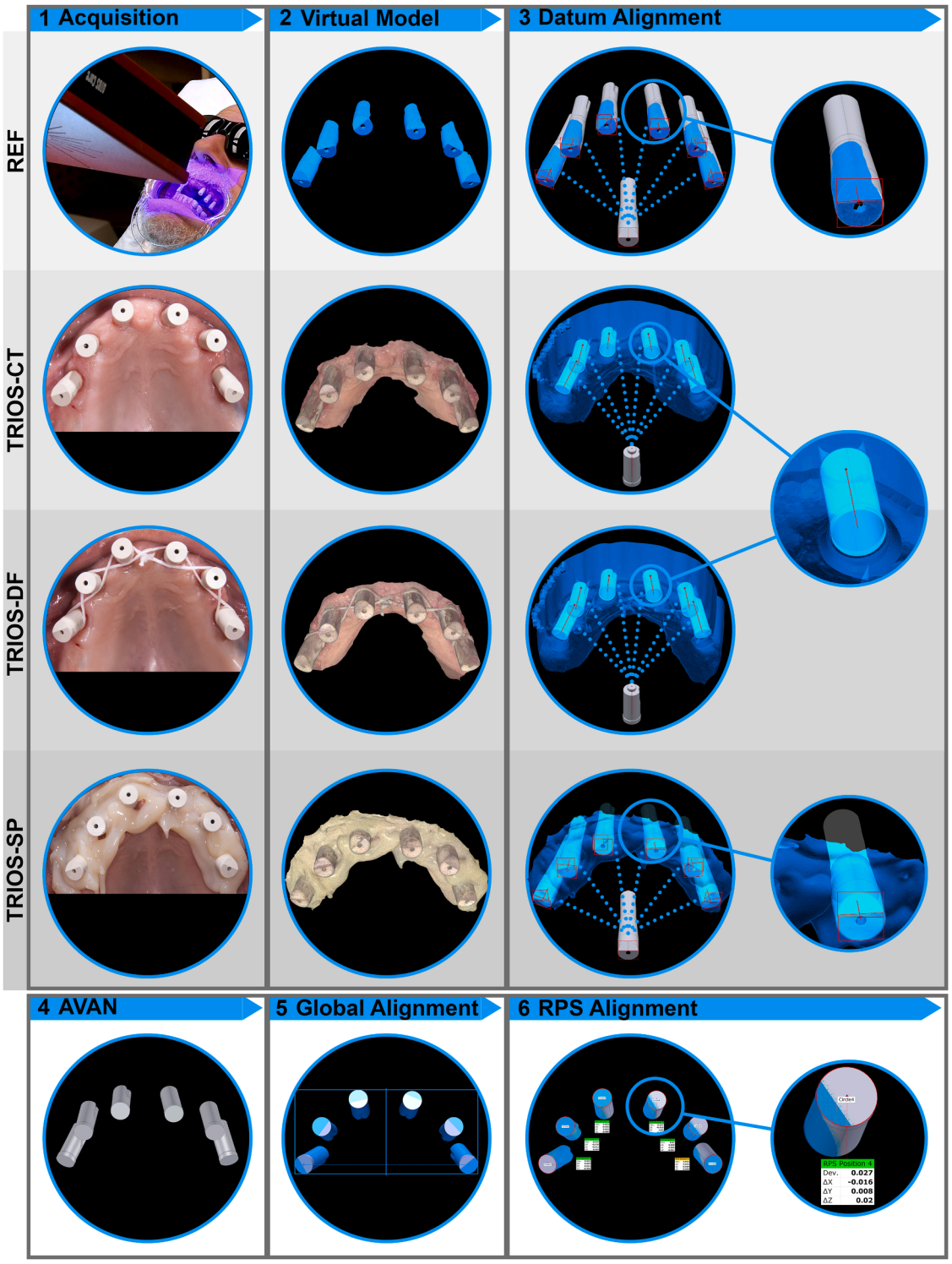

Fig. 1. Full workflow overview. **1**, acquisition of REF with ATOS scanner, TRIOS-CT, TRIOS-DF and TRIOS-SP with IOS. **2**, mesh of virtual models with subsequent proprietary scan-flag alignment of TRIOS-CT and TRIOS-DF, (not shown). **3**, Datum Alignment of VSB with indirect alignment of VAN for REF, TRIOS-CT and TRIOS-DF, and direct alignment of VAN for TRIOS-SP. **4**, ensuing alignment file AVAN from REF, TRIOS-CT, TRIOS-DF and TRIOS-SP. **5**, consistent Global Alignment using geometries. **6**, Example of RPS Alignment with deviations for each position, Resultant, DeltaX, DeltaY an DeltaZ.

conducted for each subject with each scan comprising 5–7 sequences depicting sufficient data for further scan-body alignment. The first sequence was initiated centrally with the scanner subsequently moved to an eccentric position at an angle to capture the scan-bodies' cylindrical part, faceted part, and the top partial circular surface, (Fig. 1).

Whenever the software would warn of excessive micro-movement, that particular sequence was manually discarded, and the scan sequence repeated. Each sequence was cropped to remove any measurement data beyond the surface of the scan-bodies. Post-processing was performed in the software through best-fit transformation of sequences and polygonization detail was set at highest detail for the three exported STL files (REF-S1, REF-S2 and REF-S3), the S1, S2 and S3 suffix

Table 1
List of abbreviations.

ATOS	Industrial-grade reference scanner (ATOS Core 80 5MP; GOM)
AVAN	Aligned Virtual Analogues, file containing six aligned VAN
BRIDGE	Scan of IFD with attached analogues. Results from parallel study.
CAD-AN	CAD file of analogue (modified platform diameter)
CAD-SB	CAD file of scan-body
IFD	Implant-supported fixed dentures
IGS	Initial Graphics Exchange Specification - file format
MOD1	Original model used to fabricate IFD based on polyether impression. Results from parallel study.
MOD2	New model based on polyether impression. Results from parallel study.
REF	Reference scan
RPS	Reference Point System Alignment
STL	Stereolithography - file format
STP	Standard for the Exchange of Product - file format
VAN	Virtual Analogue (defeatured CAD-AN)
VSB	Virtual Scan-Body (defeatured CAD-SB)

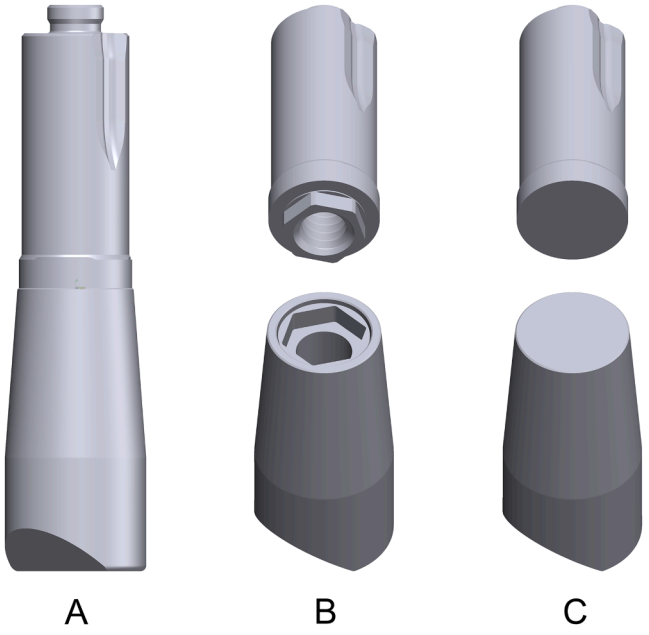

Fig. 2. A, Aligned CAD-SB (lower body) and CAD-AN (upper body). B, view of CAD-SB and CAD-AN connection. C, defeatured CAD-SB and CAD-AN connection.

denoting the scan iteration.

2.4.2. IOS scanning

IOS scans were performed immediately after the reference measurement and without removing scan-bodies. Soft retractors (Optragate; Ivoclar Vivadent) was used to facilitate tissue-management during scanning. After one initial test-scan, each subject was scanned with three different scanning protocols and with three repetitions each using TRIOS 3 (TRIOS), (3Shape, Copenhagen, Denmark) with proprietary software (Case Management: 1.5.1.3, TRIOS: 1.17.2.4).

The first protocol was a control scan (CT) of scan-bodies and inter-implant tissues. In the second protocol (DF) dental floss was used around scan-bodies, creating a cross-pattern in the inter-scan-body gap. The dental floss was removed and in the third protocol (SP), a bis-acrylic composite (Protemp 4 A3; 3 M ESPE, Seefeld, Germany) was applied around scan-bodies and above the alveolar ridge of the inter-scan-body gap comparable to a splint, (Fig. 1).

All scans were conducted with Scan Only mode and using a modified scanning pattern whilst attempting to limit the scanning of buccal non-attached tissues. The scan was started by a first swipe from subject's right to left. The scanner head was tilted occlusal to palatal to capture the scan-bodies' occlusal, palatal, mesial and distal surfaces as well as the inter-scan-body tissues for CT and DF, or the splint material for SP. After completion, the scanner was rolled to capture scan-bodies occlusally to buccally from subject's left to right and any remaining mesial and distal surfaces. The scans were conducted without exceeding the manufacturer's recommended 1500 captures.

2.4.3. Virtual 3D print models of IOS scans

To extract the position of scan-bodies using a routine dental laboratory workflow, IOS scans from protocol CT and DF were processed in proprietary software (3Shape Dental System Premium, version 18.2) by assigning implant restorations to each scan-body, (Appendix 2.1).

Open library scan-bodies (Elos Accurate – Single Abutment_7.0.0.dme, Elos Medtech) referred to as Scan-Flags in the software (3Shape Dental Designer, version 18.2), were aligned to the six scan-bodies in each scan's mesh using a semi-automatic three-point alignment.

To extract the analogue positions of the aligned Scan-Flags, a virtual 3D print model was created (3Shape Dental Designer, version 18.2 and 3Shape Model Builder, version 18.2). The transposition of Scan-Flags to 3D print analogue fittings of primitive mesh type was an exact geometrical fit (Fig. 1), (Appendix 2.2).

The virtual 3D print models were exported in 3Shape Dental System Premium as STL files (TRIOS-CT and TRIOS-DF) with suffix S1, S2 and S3 denoting the scan iteration.

3D print models could not be created for protocol SP as the proprietary scan-flag alignment failed in several positions because of splint-material interference in the cylindrical part of the scan-body. Scans of protocol SP were exported as STL with no further proprietary processing, (TRIOS-SP), with suffix S1, S2 and S3, respectively, (Fig. 1).

2.5. Datum alignment

2.5.1. Preparation of CAD files

CAD files of inter-aligned scan-body (CAD-SB) and modified analogue (CAD-AN) were provided as STP files (Standard for the Exchange of Product; ISO 10,303–21) by manufacturer (Elos Medtech), (Fig. 2A), (Appendix 3.1).

To simplify the alignment procedure and handling, CAD files were defeatured, removing the complex internal threading of CAD-AN and the hexagonal connection not in use for multiple-unit restorations for CAD-SB and CAD-AN (Geomagic Design X, version 2019.0.0 64-bit; 3D Systems), (Fig. 2B-C), (Appendix 3.2).

All conducted modifications and defeaturing were based on exact geometries in the CAD files and did not affect the inter-alignment of the two objects or any following alignments.

The resulting files were exported separately in CAD STP file format as Virtual Scan-Body (VSB) and Virtual Analogue (VAN) whilst maintaining their global inter-alignment.

2.6. Datum alignment with modified CAD files

The purpose of the Datum Alignment was to transfer all scan-bodies or analogues in the scans to corresponding VAN using specific geometries, Datums. The Datums were created in 3D inspection software Geomagic Control X (Software version 2018.1.1 64-bit; 3D Systems) (Figs. 3 and 4), (Appendix 4.1–4.3).

In the following Datum Alignment protocol, VSB or VAN were paired to Datums for each scan-body or analogue in Measured Data, (Fig. 1).

For REF scans and TRIOS-SP, a VSB with an inter-aligned VAN was Datum Aligned to each scan-body as one entity, resulting in an indirectly aligned VAN.

For virtual 3D print files, TRIOS-CT and TRIOS-DF, the VAN was directly Datum Aligned to the scanned analogues, (Appendix 4.4).

Only directly or indirectly aligned six VAN in each scan were

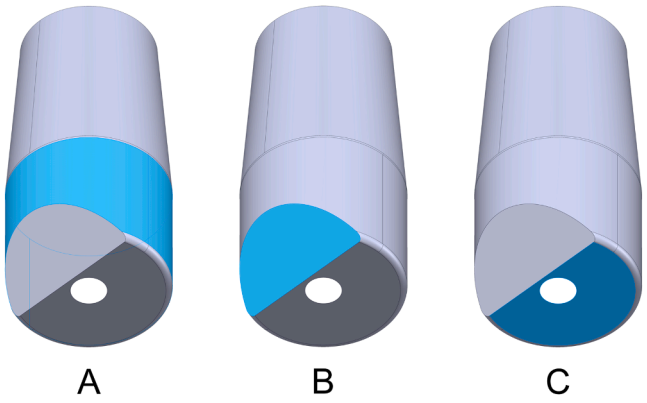

Fig. 3. Surfaces to construct VSB Datums, (blue colour), in Reference Data. A, VSB-Vector constructed from the axis of the highlighted cylinder. B, VSB-Plane1. C, VSB-Plane2. Equivalent geometry was constructed for each scan-body in Measured Data.

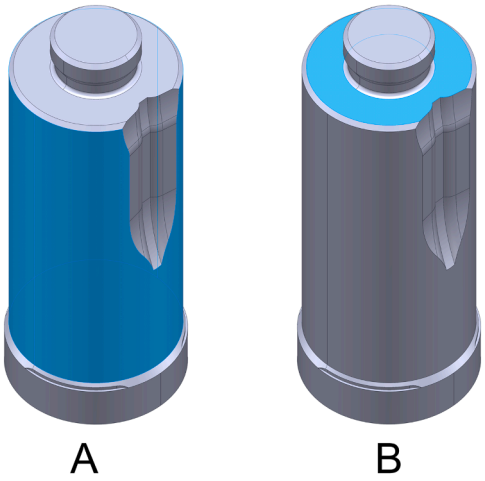

Fig. 4. Surfaces to construct VAN Datums, (blue colour), in Reference Data. A, VAN-Vector constructed from the axis of the highlighted cylinder. B, VAN-Plane 1. Point 1 was created at the intersection of VAN-Vector and VAN-Plane1 (not shown). Equivalent geometry was constructed for each analogue in Measured Data.

exported in the CAD file format Initial Graphics Exchange Specification (IGS), (National Institute of Standards and Technology, USA), creating files with suffix AVAN (Aligned Virtual Analogues): REF-AVAN, TRIOS-CT-AVAN, TRIOS-DF-AVAN and TRIOS-SP-AVAN, followed by scan iteration suffix S1, S2 and S3, (Appendix 4.5).

2.7. Global alignment

Because of different 3D orientation of models between scanners, a Global Alignment was performed using a consistent and repeatable protocol based on geometries in the AVAN files. (Fig. 1, 5). (Appendix 5.1).

2.8. RPS alignment

AVAN files assigned as Reference Data for cross-comparison analysis of trueness and precision at the implant/prosthetic interface were prepared by selecting automatically identifiable Datums based on circular geometry.

The order of the created geometry was from upper right posterior VAN (Position 1) ranging to the upper left posterior VAN (Position 6), (Fig. 5B).

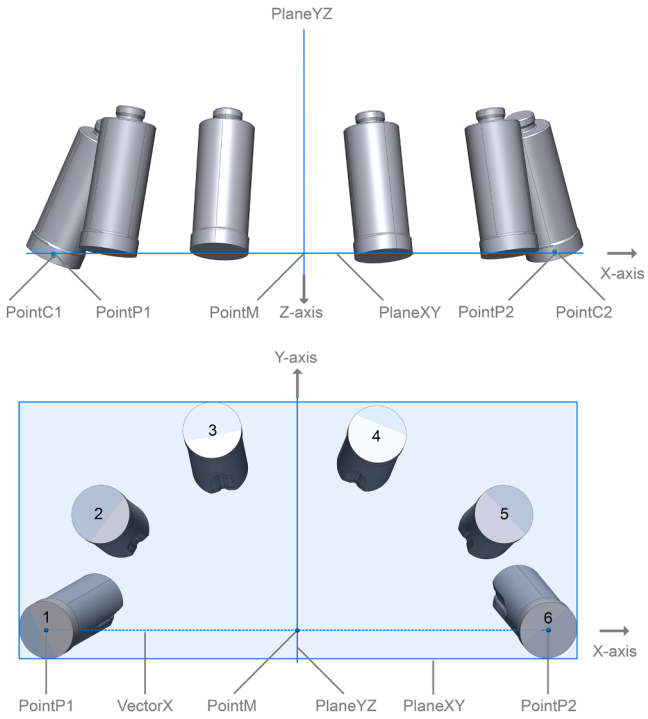

Fig. 5. AVAN after Global Alignment with Constructed Geometries. A, view of XZ plane (frontal view). B, view from XY plane (occlusal view). Created circle numerical order for Position 1 to Position 6.

An RPS Alignment protocol for the trueness and precision analysis was performed. The recorded deviations were Deviation Value (Resultant), DeltaX (DeltaX), DeltaY (DeltaY) and DeltaZ (DeltaZ), with the Deviation Value being a directional geometrical resultant of underlying DeltaX, DeltaY and DeltaZ, (Appendix 6.1–6.2), (Fig. 1).

2.9. Precision

For each subject, the Globally Aligned S1 assigned as Reference Data: REF-AVAN, TRIOS-CT-AVAN, TRIOS-DF-AVAN and TRIOS-SP-AVAN was RPS Aligned to its respective S2 and S3 file imported as tessellated CAD in Measured Data. Similarly, each Globally Aligned S2, set as Reference Data, was cross compared to its respective S3, set as Measured Data.

2.10. Trueness REF

To establish *in vivo* trueness, the Globally Aligned REF-AVAN S1, was assigned Reference Data, and RPS-aligned to file S1 through S3 of TRIOS-CT-AVAN, TRIOS-DF-AVAN and TRIOS-SP-AVAN imported as tessellated CAD in Measured Data. The comparison process was repeated for Globally Aligned REF-AVAN S2 and S3 set as Reference Data.

2.11. Statistical methods

Trueness and precision were evaluated using a mixed linear model with patient ID as a random factor, using the R package nlme [50]. Residuals were assessed graphically, and the model fit was deemed to be adequate. Confidence intervals for the effect estimates were computed using t-statistics. To test whether accuracies were greater than 10 μm, a t-statistic was used. A Wald test was used to test for differences in trueness. Level of significance was set at $p < 0.05$.

Since there is no prior *in vivo* precision reported for the industrial scanner acting as a reference or trueness of IOS in full-arch implants scans, a priori power analysis could not be performed as it would have to

be based on assumption of deviations in three dimensions. A post hoc power analysis using a Monte Carlo simulation was conducted on the Resultant deviation.

3. Results

3.1. Subjects

Of nineteen potential subjects, nine declined participation, one was deceased, one was excluded because of Parkinson's disease, and one was excluded for pronounced implant angulation in the molar region and thus deemed outside the limit of the reference system as established in previous studies [15,51]. Seven subjects participated after prior informed consent. Six of the participants had been treated with Brånemark Implants and one subject had received Biohelix implants.

After unmounting existing IFD, two subjects were further excluded. In one subject, scan-bodies could not be attached because of two converging implants. In the subject with Biohelix implants, two implants lacked osseointegration.

The prior prosthetic treatments of the remaining five subjects with Nobel Biocare implants had been provided by three different specialists in prosthodontics and finalised by certified dental technicians at the same dental laboratory. Frameworks were laser-sintered (Dentware Scandinavia AB, Kristianstad, Sweden) and designed for angulated screws (Dynamic Abutment Solutions, Lleida, Spain). The restorations had been in function between 33 and 73 months, with a mean of 56 months.

Fig. 6 shows a superimposition of all subjects' REF-AVAN, displaying the implant distributions and relative angulations after Global Alignment.

3.2. Precision

All IOS, indifferent of scanning protocol or directional deviation, showed statistically significantly larger differences than REF ($p<0.001$).

Table 2 shows the precision for reference scanner REF and IOS scans based on three investigated protocols. Precision for *in vivo* Resultant REF were within 9.3 ± 1 μm. TRIOS Resultant varied between 48 ± 7 μm for TRIOS-CT, 50 ± 7 for TRIOS-DF and 45 ± 6 μm for TRIOS-SP.

Visualisation of deviations per position indicates a generally higher posterior deviation and variation in position 1 and position 6 for TRIOS-CT and TRIOS-DF, (Fig. 7).

3.3. Trueness

All three IOS protocols, TRIOS-CT, TRIOS-DF and TRIOS-SP showed statistically significantly larger differences from REF regarding Resultant, DeltaX and DeltaY, (Table 3).

Trueness for Resultant varied between 41 ± 11 μm for TRIOS-CT, 49 ± 22 μm for TRIOS-DF and 55 ± 9 μm for TRIOS-SP, (Table 3).

The results of the IOS protocols in the present study are visualised in relation to the results from a parallel study sharing the same REF [47]. MOD1 and MOD2 represents the *in vivo* trueness of polyether impression-based models digitised by a dental laboratory scanner. BRIDGE shows the results of *in vivo* trueness of the IFD manufactured through a CAD/CAM processes based on MOD1. Both MOD1 and BRIDGE were conducted as part of routine treatment and outside the scope of a study. Impression and digitisation of MOD2 was conducted as part of the study using a strict study protocol, (Fig. 8, Table 4).

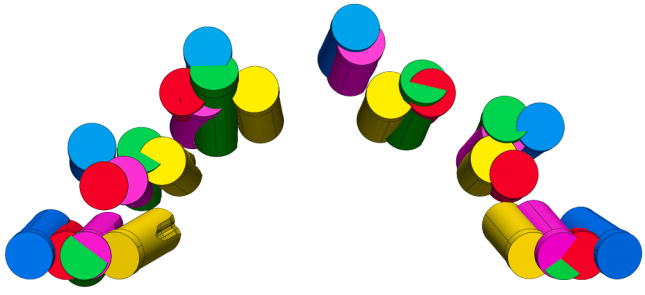

Fig. 6. Implant distribution seen in Global Aligned AVAN for all subjects. Each colour represents one subject with six implants.

Table 2
Precision, (prec), with 95% confidence interval in micrometres, (μm), for REF and IOS protocols TRIOS-CT, TRIOS-DF and TRIOS-SP.

Scanner	Resultant prec	DeltaX prec	DeltaY prec	DeltaZ prec
REF	9.3 ± 1.0	7.2 ± 1.1	4.3 ± 0.7	1.6 ± 0.3
TRIOS-CT	48 ± 7	32 ± 7	24 ± 4	11 ± 2
TRIOS-DF	50 ± 7	37 ± 8	21 ± 4	11 ± 2
TRIOS-SP	45 ± 6	32 ± 5	24 ± 5	8 ± 1

Only TRIOS-SP showed statistically significantly higher deviations from MOD1 or MOD2 regarding Resultant and DeltaX.

3.4. Post HOC power analysis

A post hoc power analysis using a Monte Carlo simulation showed that REF *versus* all three scanning protocols had a power of at least 94% (TRIOS-CT: 95%, TRIOS-DF: 94%, TRIOS-SP: 98%). The analysis further showed that TRIOS-CT *versus* measurements of BRIDGE acquired from the parallel study had a power of 84%.

4. Discussion

The results in this study reject all null hypotheses. First, there were differences in trueness and precision of IOS relative to REF, and there were differences between IOS protocols. Second, there were statistically significant differences for IOS *versus* an IFD based on impressions in a parallel study.

There are several limitations in this pilot. The study investigates a new methodology using an industrial grade scanner as a reference in implantology where there are no prior comparable *in vivo* studies. To avoid confounding factors from varying implant platforms and different connections, the inclusion criteria were strict and greatly limited the number of participants. Because of the time-consuming investigation, scan-bodies were not reseated, hence horizontal deviations were not investigated. Furthermore, the only officially recommended scan-body was used in combination with one single commercially available IOS based on a modified scan protocol. Finally, no randomization was possible as detaching scan-bodies to remove the splint used in TRIOS-SP would effectively void all reference measurements.

Studies on trueness requires a measurement device providing ground truth measurement with considerably higher trueness than the investigated instrument. The method to acquire an *in vivo* reference measurement using ATOS or a similar industrial scanner has been described in prior studies on dentate subjects [15,51]. ATOS is not intended for this specific use and factors such as micro-movement in the subject, limited accessibility, relying on best-fit transformation without assisted transformation and only capturing part of the scan-body will have an impact on the trueness as described in the parallel study [47]. It was presumed that the trueness of the ATOS scanner may change accordingly, which was considered in the applied statistical method. To the authors' knowledge an *in vivo* precision below 10 μm is within a range of what is possible to acquire with existing technology due to challenging anatomical and physiological reasons.

The cohort in this study is relatively small due to the strict inclusion criteria and the willingness to participate in a four-hour long investigation. In effect, each subject is their own reference, resulting in a total of fifteen scans per protocol ($n = 15$). The supporting post-hoc analysis

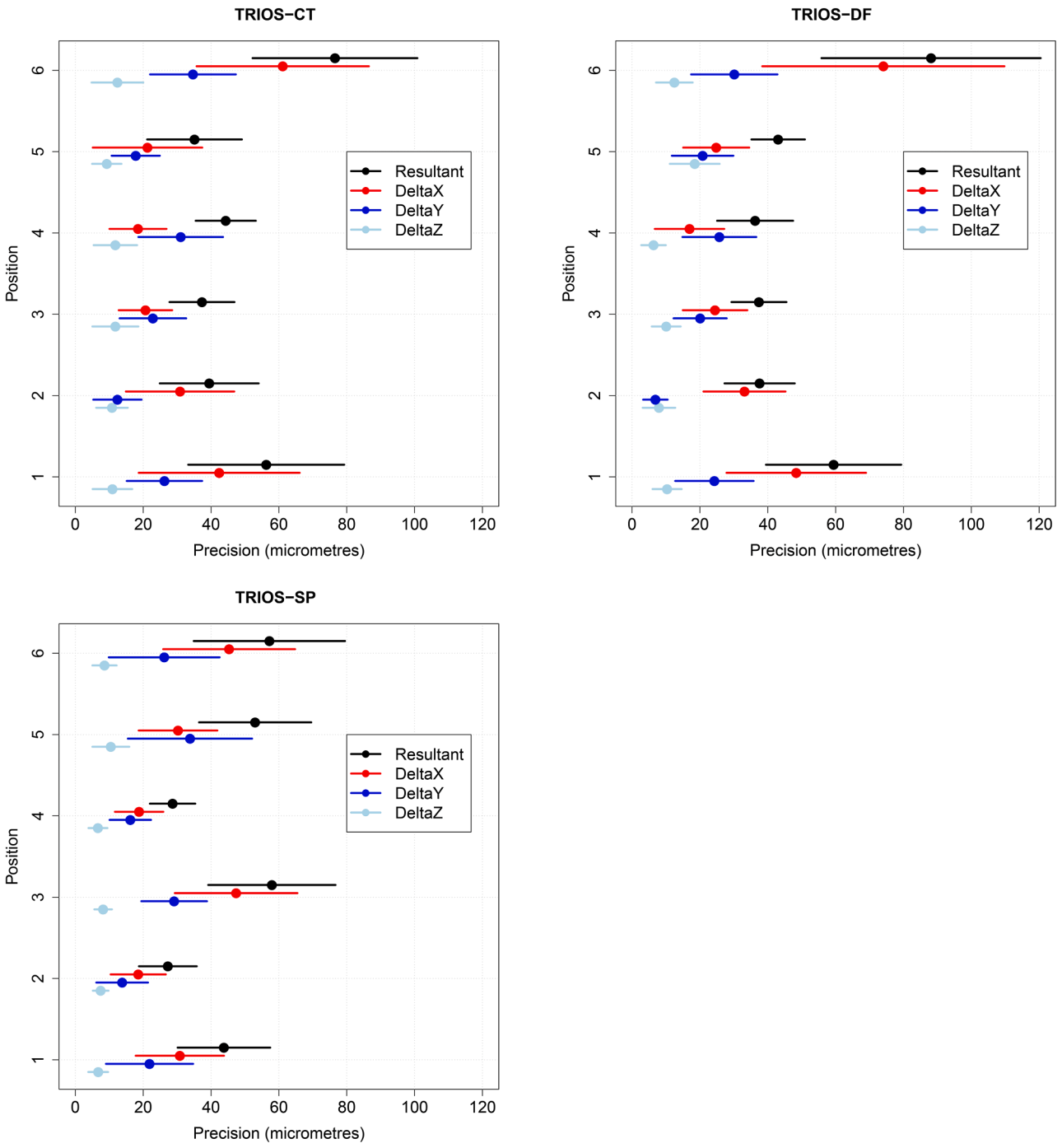

Fig. 7. Precision with 95% confidence interval of IOS protocols per position: TRIOS-CT, TRIOS-DF and TRIOS-SP.

presents a high power of 94–98% for REF *versus* IOS protocols.

In vitro studies do not suffer the same logistical problems, yet trueness of IOS or SPG in acquisition of full-arch implant scans are frequently investigated on cohorts with sample size: $n = 5$ [3,52,53], $n = 7$ [33] and $n = 10$ [10,29,32,46]. Nevertheless, *in vivo* studies will include similar bias as *in vitro* studies based on inter-operator differences and clinical experience. It can be argued that *in vivo* studies cannot be controlled to the same extent. On the other hand, inter-subject variability combined with clinical challenges attributed to anatomical and physiological parameters such as non-attached tissues, a non-compliant tongue and presence of saliva will reflect clinical reality which *in vitro* studies cannot replicate.

Lastly, the trueness of IFDs (BRIDGE) and models based on conventional impressions (MOD1, MOD2) in the parallel study may not be representative in all settings as the measurements for the cohort was based on work conducted by experienced prosthodontists and dental technicians.

The rationale of only including abutment-free flat-to-flat connections with identical platforms greatly reduced the number of potential subjects. However, the flat-to-flat connection limited the axial displacement seen in conical connections, allowing for hand-tightening of scan-bodies with maintained axial fit [34,35].

This study did not investigate horizontal displacements occurring due to reseating of scan-bodies. Furthermore, rotational displacement was not investigated or reported in this study as multi-unit IFDs do not include an anti-rotational feature.

Table 3
Trueness with 95% confidence interval in micrometres, (μm), and respective p value between REF and the protocols TRIOS-CT, TRIOS-DF and TRIOS-SP.

Reference	Measurement	Resultant	DeltaX	DeltaY	DeltaZ
REF	TRIOS-CT	$p < 0.001$ Trueness: 41 ± 11	$p < 0.001$ Trueness: 27 ± 10	$p = 0.001$ Trueness: 22 ± 8	$p = 0.923$ Trueness: 8 ± 3
REF	TRIOS-DF	$p < 0.001$ Trueness: 49 ± 22	$p = 0.002$ Trueness: 37 ± 18	$p = 0.016$ Trueness: 22 ± 11	$p = 0.999$ Trueness: 9 ± 1
REF	TRIOS-SP	$p < 0.001$ Trueness: 55 ± 9	$p < 0.001$ Trueness: 45 ± 8	$p < 0.001$ Trueness: 21 ± 3	$p = 0.87$ Trueness: 9 ± 2

Although there are numerous scan-bodies from third-party manufacturers for different implant systems with varying design and material properties [24,54], the scan-body from a third-party used in this study is the only officially available scan-body distributed from the implant manufacturer. The implant connection is based on technical drawings of the actual implant in combination with physical measurements. However, this is not always the case as implant manufacturers are not willing to share original technical drawings, resulting in third party manufacturers having to reverse-engineer the implant connections, relying on physical measurements of implants. This can introduce higher tolerances and potential misfit in third-party products.

This pilot used a Scan Only approach and not the dedicated two-step scanning protocol available within the evaluated IOS system. Although both protocols offer similar mesh resolution, the workflow and rationale vary greatly. The two-step protocol offers a method to acquire a full-arch primary scan, and after cropping the surface around the implant site, a second local scan of the scan-body and adjacent hard and soft tissues is matched to the primary scan in the proprietary software.

This two-step approach offered by the software may be better suited for single or short-spanning partially edentulous cases where the implants are surrounded by teeth, especially when scan-bodies are blocking approximal surfaces or where there may be an interest in acquiring the emergence profile of the tissues.

It is the authors' opinion that it ought to be beneficial to directly capture all mounted and rigidly fixed scan-bodies and acquire the inter-implant positions in the edentulous arch in a single definitive scan minimising the reliance on inter-implant tissues.

This is opposed to the indirect two-step protocol where scan-body, would have to be matched from the secondary scan to the cropped primary tissue scan with large holes in the mesh and matched using a greatly limited surface. This is further to the clinical reality that the edentulous maxillae frequently displays resorptions and atrophy, resulting in limited keratinized attached tissues buccally of the implants [26]. Introducing a greater element of non-attached tissues can potentially lead to stitching errors and warping of the model [15]. Even though studies have investigated the effects of scan-body materials, little is known regarding the light dynamics in soft tissues and the effect of *in vivo* scans with IOS in edentulous full-arches [54].

Previous studies have shown that scan-pattern can influence the outcome *in vitro* when using the same IOS system [22]. The scan pattern used in this study was further modified compared to official recommendation in dentate maxillae for the same reason. The priority was to capture the scan-bodies, the inter-implant space and the palatal aspect of the maxilla whilst reducing the amount of non-attached tissues buccal of the scan-bodies.

Although angulation and inter-implant distance have been discussed *in vitro* studies, it is the authors' opinion that the subjects' inter-implant distance and angulation in the cohort were within clinical reality and expectation as seen in Fig. 6 [8]. The superimposition shows implants being relatively well clustered and there are no extreme angulations

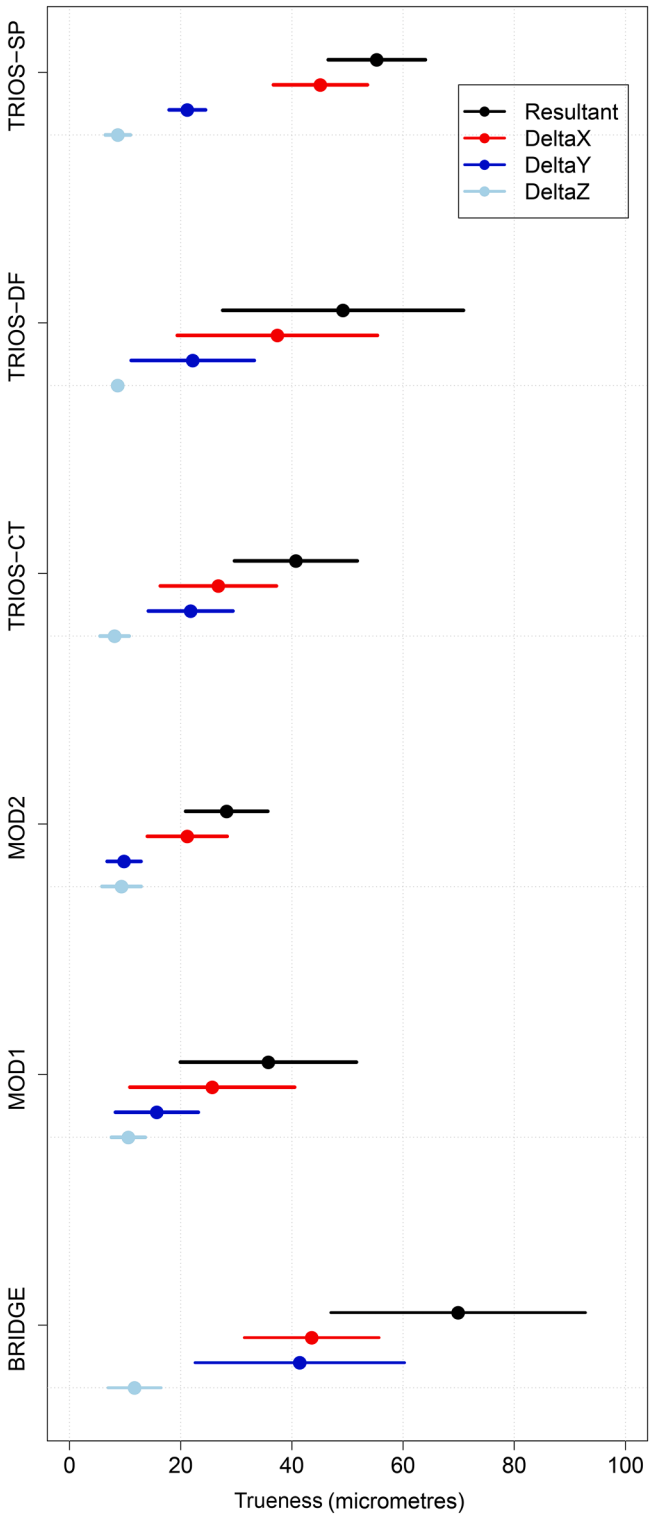

Fig. 8. Trueness with 95% confidence interval of IOS protocols, TRIOS-CT, TRIOS-DF and TRIOS-SP compared to MOD1, MOD2 and BRIDGE from parallel study.

present. However, the superimposition displays a greater variation in maxillary width of implant positions and *in vitro* research has shown this to potentially affect the result. The results for TRIOS-CT and TRIOS-DF shows higher deviations in the posterior section of the scan similar to a prior *in vivo* study on dentate subjects (Fig. 7A, B andC) [15,54].

The results from using alternative scanning protocols TRIOS-DF and TRIOS-SP showed no improvement over TRIOS-CT and follows the

Table 4
P-value for trueness cross-comparison for IOS protocols and trueness cross-comparison for MOD1, MOD2 and final restoration (BRIDGE) from parallel study.

Method 1	Method 2	Resultant	DeltaX	DeltaY	DeltaZ
TRIOS-CT	TRIOS-DF	$p = 0.491$	$p = 0.312$	$p = 0.956$	$p = 0.690$
TRIOS-CT	TRIOS-SP	$p = 0.042$	$p = 0.007$	$p = 0.888$	$p = 0.734$
TRIOS-DF	TRIOS-SP	$p = 0.609$	$p = 0.443$	$p = 0.868$	$p = 0.973$
TRIOS-CT	MOD1	$p = 0.614$	$p = 0.906$	$p = 0.261$	$p = 0.223$
TRIOS-CT	MOD2	$p = 0.065$	$p = 0.384$	$p = 0.004$	$p = 0.572$
TRIOS-CT	BRIDGE	$p = 0.024$	$p = 0.039$	$p = 0.057$	$p = 0.194$
TRIOS-DF	MOD1	$p = 0.324$	$p = 0.323$	$p = 0.341$	$p = 0.228$
TRIOS-DF	MOD2	$p = 0.072$	$p = 0.099$	$p = 0.034$	$p = 0.702$
TRIOS-DF	BRIDGE	$p = 0.196$	$p = 0.575$	$p = 0.083$	$p = 0.217$
TRIOS-SP	MOD1	$p = 0.034$	$p = 0.025$	$p = 0.184$	$p = 0.326$
TRIOS-SP	MOD2	$p<0.001$	$p<0.001$	$p<0.001$	$p = 0.755$
TRIOS-SP	BRIDGE	$p = 0.240$	$p = 0.835$	$p = 0.037$	$p = 0.263$
MOD1	MOD2	$p = 0.40$	$p = 0.59$	$p = 0.15$	$p = 0.60$
MOD1	BRIDGE	$p = 0.016$	$p = 0.066$	$p = 0.012$	$p = 0.70$
MOD2	BRIDGE	$p<0.001$	$p = 0.002$	$p = 0.001$	$p = 0.44$

results of *in vitro* studies [31]. The TRIOS-SP protocol was included to evaluate if elimination of the inter-scan-body tissues, together with the shorter range from the top of the scan-body to the splint-material, could eliminate tissue movement and reduce the adaptive focal depth of the specific IOS in this study. However, a shortcoming was the limited space for adding the splint material which in several instances interfered with the cylindrical section of the scan-body. Because of this infringement, the scan-flags could not be aligned in the dental laboratory software similar to TRIOS-CT and TRIOS-DF. The alignment in Geomagic Control X for protocol TRIOS-SP required manual removal of several areas in multiple scan-bodies where material interference occurred, thus decimating the cylinder height and incorporating a higher level of axial misfit. It is the authors' opinion that if a splint technique could be adopted, it may assist in scanning advanced cases with larger edentulous spans and atrophied alveolar ridges frequently seen in the mandible. An analysis with a taller scan-body or a modified splint technique may be of future interest.

The statistical analysis failed to show a difference for TRIOS-CT *versus* models based on analogue impressions, MOD1 and MOD2, from a parallel study [47]. However, similarly to MOD1 and MOD2, TRIOS-CT was statistically significantly different from the manufactured IFD in the same study. Hence, within the limitations of this study, no difference could be shown between analogue and digital impressions in the maxilla.

Studies on IOS are based on varying methodology, making a direct comparison difficult. An almost identical *in vitro* study on six implants with the same IOS, although based on best-fit-alignment between CAD files without RPS Alignment, reports the trueness at 28 μm and precision at 33 μm [46]. A study comparing twelve different IOS using multiple analysis methods have found trueness to vary between 16.1 μm to 69.9 μm [10]. The Trios IOS in that study showed a trueness of 20.2 μm *in vitro* which is comparable to the results in the present *in vivo* study for the Resultant of TRIOS-CT of 41 μm and precision of 39 μm.

These numerical values can be compared further with an *in vitro* study of SPG on five implants *versus* a reference Coordinate Measuring Machine (CMM), showing mean trueness of a similar linear measurement to Resultant of 27 μm [3].

It is essential to note that this and the parallel study have investigated only one specific IOS for the use in the maxilla due the extensive time-requirements needed to conduct repetitive reference-scans, repetitive IOS scans using three different protocols, impression, and scans of the subjects' bridges during one visit. These results can neither be immediately transferred to other IOS, nor can clinicians expect similar results when scanning an edentulous mandible. Even though there was a limited amount of attached tissue buccally of scan-bodies due to varying degrees of alveolar resorption, the scans relied on the closeness of scan-bodies, attached inter-implant tissues and palatal tissues, the latter to which there is no equivalent in the mandible.

With recent advancements in Artificial Intelligence (AI) which has been introduced in some IOS to a certain extent, machine learning may allow for future real-time analysis of underlying anatomy and compensate both focal depth and the stitching process in challenging cases.

In vivo research on IOS is challenging and time-consuming. Further studies are required to validate the results in this study, the feasibility of *in vivo* trueness studies and to assess if results from *in vitro* studies are comparable and clinically relevant.

5. Conclusions

The described method can be applied *in vivo* for trueness studies in maxillary full-arch implant treatments.

The control group (TRIOS-CT) showed overall better trueness and precision than the dental floss group (TRIOS-DF) and splinted group (TRIOS-SP).

The control group failed to show any difference from conventional impressions in a parallel study.

The Control group was more accurate than the final restoration (BRIDGE) in a parallel study.

CRediT authorship contribution statement

Robert Nedelcu: Conceptualization, Investigation, Methodology, Formal analysis, Writing – original draft, Writing – review & editing, Visualization. **Pontus Olsson:** Methodology, Formal analysis, Visualization, Writing – original draft, Writing – review & editing. **Måns Thulin:** Formal analysis, Visualization. **Ingela Nyström:** Methodology, Formal analysis, Visualization, Writing – original draft, Writing – review & editing. **Andreas Thor:** Methodology, Formal analysis, Visualization, Writing – original draft, Writing – review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Supplementary materials

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