CONSENSUS REPORT

WILEY CLINICAL ORAL IMPLANTS RESEARCH

Group 5 ITI Consensus Report: Digital technologies

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*[Corrections added November 2018, after publication: author's forename changed from 'Aljeandro' to 'Alejandro' and affiliation changed from 'San Sebastian University' to 'Pontificia Universidad Católica de Chile']

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Abstract

Objectives: Working Group 5 was assigned the task to review the current knowledge in the area of digital technologies. Focused questions on accuracy of linear measurements when using CBCT, digital vs. conventional implant planning, using digital vs. conventional impressions and assessing the accuracy of static computer-aided implant surgery (s-CAIS) and patient-related outcome measurements when using s-CAIS were addressed.

Materials and methods: The literature was systematically searched, and in total, 232 articles were selected and critically reviewed following PRISMA guidelines. Four systematic reviews were produced in the four subject areas and amply discussed in the group. After emendation, they were presented to the plenary where after further modification, they were accepted.

Results: Static computer-aided surgery (s-CAIS), in terms of pain & discomfort, economics and intraoperative complications, is beneficial compared with conventional implant surgery. When using s-CAIS in partially edentulous cases, a higher level of accuracy can be achieved when compared to fully edentulous cases. When using an intraoral scanner in edentulous cases, the results are dependent on the protocol that has been followed. The accuracy of measurements on CBCT scans is software dependent.

Conclusions: Because the precision intraoral scans and of measurements on CBCT scans and is not high enough to allow for the required accuracy, s-CAIS should be considered as an additional tool for comprehensive diagnosis, treatment planning, and surgical procedures. Flapless s-CAIS can lead to implant placement outside of the zone of keratinized mucosa and thus must be executed with utmost care.

KEYWORDS

accuracy, computer-aided surgery, cone beam computed tomography, intraoral scans, oral implantology, patient-reported outcome measures

1 | INTRODUCTION

Digital technologies are gaining a predominant position in implant dentistry. Cone beam computed tomography (CBCT) scans provide clinicians with Digital Imaging and Communications In Medicine (DICOM) data which can be aligned with Standard Tessellation Language (STL) files obtained from intraoral scanners in computeraided design (CAD) software to plan implant treatment and design drill guides. However, the accuracy of these separate technologies, the drill guides as well as the patients' perception of the treatment when using these technologies are still subject of debate. Group 5 of the 6th ITI consensus conference was assigned the task to review the current knowledge in the area of digital technologies with a special focus on accuracy of linear measurements when using CBCT, using digital vs. conventional implant planning, using digital vs. conventional impressions and assessing the accuracy of static computer-aided implant surgery (s-CAIS).

They were asked to provide statements and recommendations based on their findings. Four systematic reviews which were prepared and reviewed prior to the consensus conference formed the basis for discussion within the working group. Minor modifications were made as required. Consensus statements and clinical 438

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recommendations were formed which were then presented and accepted following further discussion and modifications when required by the plenary. The working group also prepared recommendations for future research. The four systematic reviews are listed below.

2 | PAPER 1

Static computer-aided implant surgery (s-CAIS) analysing patientreported outcome measures (PROMs), economics, and complications: A systematic review.

Tim Joda, Wiebe Derksen, Julia Gabriela Wittneben, Sebastian Kuehl.

2.1 | Preamble

The objective of this study was to systematically evaluate the scientific literature for patient-reported outcome measures (PROMs) in static computer-aided implant surgery (s-CAIS). A PICO strategy was executed using an electronic (MEDLINE, EMBASE, CENTRAL) plus manual search up to 06-15-2017 focusing on clinical studies investigating s-CAIS with regard to patients' pain & discomfort, economics and/or intraoperative complications. Search strategy was assembled from multiple conjunctions of MeSH-Terms and unspecific free-text words. Assessment of risk of bias in selected studies was made at a trial level applying the Cochrane Collaboration Tool and the Newcastle-Ottawa Assessment Scale, respectively. The systematic search identified 112 titles. Seventy abstracts were screened, and 14 full texts were included for analysis. A total of 484 patients were treated with s-CAIS for placement of 2,510 implants. Due to the heterogeneity of the included studies, meta-analyses could not be performed.

2.2 | Consensus statement 1

It cannot be stated that s-CAIS, in terms of pain & discomfort, economics, and intraoperative complications, is beneficial compared with conventional implant surgery.

Consensus statement 1 is based on four RCTs, four prospective Cohort Studies, five retrospective Cohort Studies, and one Case Series.

2.3 | Clinical recommendations

2.3.1 | However

- Based on PROMs, economics, and complications, there is no contraindication to use s-CAIS instead of conventional implant surgery.
- Flapless s-CAIS may be beneficial in fully edentulous cases in relation to postoperative pain intensity compared with open-flap procedures.

 Flapless s-CAIS may lead to implant placement outside the zone of keratinized mucosa; therefore, the quality and quantity of the keratinized mucosa must be assessed before planning s-CAIS.

2.4 | Recommendations for future research

Based on this systematic review and considering the different clinical indications, such as fully vs. partially edentulous, using flap vs. flapless techniques, the group recommended that there is a clear need for:

RCTs with appropriate power analysis investigating s-CAIS related to PROMs with standardized protocols, which allow reliable and reproducible assessments of:

- Oral health impact profile (OHIP);
- Standardized use of Visual Analog Scales (VAS) for pain & discomfort;
- Cost-benefit-analysis considering virtual planning, surgery, laboratory, and prosthetic work, including required equipment and materials;
- Time efficiency factor analyzing virtual planning, surgery, and the respective prosthetic phase;
- Complication rates.

3 | PAPER 2

The accuracy of different dental impression techniques for implant-supported dental prostheses: A systematic review and meta-analysis.

Tabea Flügge, Wicher Joerd van der Meer, Beatriz Gimenez Gonzalez, Kirstin Vach, Daniel Wismeijer, Ping Wang.

3.1 | Preamble

Digital impression technology is increasingly used in clinical practice as it is said to have many advantages above, and the potential to substitute for, conventional impression techniques.

Intraoral scanners use surface capturing technologies to acquire data. Scan bodies are captured by intraoral scanners and can be used to locate the implant positions in a virtual model.

The accurate transfer of implant positions in relation to neighboring implants or teeth is paramount for the design and the fit of implant-supported prosthesis.

Therefore, this systematic review has evaluated the scientific evidence for the accuracy of optical implant scans compared with scans of stone cast made from conventional implant impressions.

The term accuracy refers to trueness, describing the closeness of a measurement to the actual value, and to precision, describing the closeness of multiple measurement results (ISO 12836: 2015). The present systematic review includes 79 studies consisting of one RCT, one retrospective study, two clinical studies, and 75 bench studies. A meta-analysis of 63 studies was performed after dividing the data into subgroups; however, a high heterogeneity of reported data was detected.

One of the reasons for the lack of clinical studies is related to the difficulty of assessing the trueness of intraoral impressions, as the actual implant positions can only be approximated as there is no control.

Currently, there is limited clinical evidence on the accuracy of intraoral digital impressions of dental implants compared with conventional implant impressions. The data were based on bench studies and one clinical study.

3.2 | Consensus statement 1

The accuracy of digital impressions with intraoral scanners of single or adjacent implants in partially dentate jaws and multiple implants in edentulous jaws is comparable to the accuracy of conventional implant impressions under laboratory conditions.

Consensus statement 1 is based on six bench studies.

3.3 | Consensus statement 2

The accuracy of digital impressions is negatively influenced with an increase in the interimplant span between multiple implants in partially dentate and edentulous situations.

Consensus statement 2 is based on three bench studies

3.4 | Consensus statement 3

The scan protocol using intraoral scanners has a significant influence on digital implant impression accuracy in the edentulous jaw.

Consensus statement 3 is based on four bench studies using the same control

3.5 | Consensus statement 4

The accuracy of digital implant impressions of edentulous jaws varies when using different intraoral scanners.

Consensus statement 4 is based on four bench studies.

3.6 | Clinical recommendations

- **1.** The use of digital impressions for single implant restorations can be recommended.
- To optimize digital implant impressions for each clinical situation, device-specific intraoral scanning protocols must be followed.
- **3.** The use of scan bodies is recommended for accurate digital implant impressions.
- 4. Digital impressions of large interimplant spans are not yet recommended for routine clinical use.

 For routine clinical use, intraoral digital implant impressions of edentulous jaws cannot yet be recommended.

3.7 | Recommendations for future research

The evolution of software versions goes faster than the process of conducting a study. Major software upgrades may lead to changes in the scanning protocol and the resulting virtual model. The same hardware can produce different results when using the latest software release compared to the previous one.

Therefore, (a) there is a need for established study designs considering standardized conditions, and (b) it is crucial to address the software version and used scan protocol for further studies to create a reliable database for accurate statistical analyses.

Although in clinical practice, single unit restorations are being performed using a digital workflow, there is a need for further research to conclude if it is a predictable and reliable procedure when compared to the conventional workflow.

- There is a lack of literature about the accuracy of different intraoral scan bodies in terms of geometry, dimension, material, and surface characteristics. More studies regarding these aspects should be conducted.
- In studies using scan bodies, design, and characteristics should be defined to make studies comparable.
- Regarding multiple implant-supported restorations for partially dentate or edentulous cases, different scanning protocols should be developed and compared.

The influence of distance between scan bodies, length and geometry of the edentulous span, mucosal morphology, and on the accuracy of digital impressions should be studied.

4 | PAPER 3

Accuracy of linear measurements on CBCT images related to presurgical implant treatment planning: A systematic review.

George Fokas, Vida M. Vaughn, William C. Scarfe, Michael M. Bornstein.

4.1 | Preamble

The aim of this systematic review was to identify studies that assessed the accuracy of linear measurements of bone dimensions related to implant dentistry using CBCT. For inclusion, the studies could be designed as ex vivo or in vivo investigations, but were only included when the linear values from CBCTs were also compared to a control, which could be considered as the gold standard. The review was performed using the PICOs framework, where intervention was described as the use of CBCT for the purpose of determining outcomes associated with \mathbf{Y} — Clinical oral implants research

the accuracy and reliability (repeatability/reproducibility) of linear measurements.

There was great variability in the methodology of the included studies as well as the extracted data; thus, a direct comparison of the available evidence was not possible. The data were therefore compared using descriptive modalities, and no meta-analysis was performed.

The present systematic review identifies, reviews, analyses, and summarizes available evidence on the accuracy of linear measurements when using CBCT imaging specifically in the field of implant dentistry.

The primary outcome of this systematic review was demonstration of the accuracy of linear CBCT measurements of alveolar bone at edentulous sites or anatomical structures related to implant dentistry.

The secondary outcomes of this review were as follows:

- Demonstration of reliability (repeatability within one observer / reproducibility between different observers) of linear measurements from CBCTs.
- Assessing the potential impact of imaging factors such as voxel size, FOV, rotational arc, and software package used on the accuracy of linear measurements in CBCTs.

From 2516 titles retrieved initially, a total of 22 studies were included for the final analysis. Of those, two were clinical and 20 were ex vivo investigations.

4.2 | Consensus statement 1

With regard to implant treatment planning, CBCT provides crosssectional images that demonstrate high accuracy and reliability for linear bone measurements with a relatively low radiation dose according to As Low As Diagnostically Acceptable (ALADA) guidelines.

This statement is based on a total of 19 studies: one clinical, five cadavers, and 13 dry jaws/skulls studies.

4.3 | Consensus statement 2

The actual linear dimensions taken from CBCT scans can be over- or underestimated, and the range of error can exceed 1 mm in selected cases.

This statement is based on a total of six studies: two clinical, two cadavers, and two dry skull studies.

4.4 | Consensus statement 3

A smaller voxel size resulting in a higher resolution does not lead to a higher accuracy of linear measurements on CBCTs for bone dimensions at edentulous sites.

This statement is based on a total of four studies: one cadaver, and three dry skull/jaws studies.

4.5 | Consensus statement 4

The size of the field of view and partial rotations (180° vs. 360°) do not adversely affect linear measurements.

This statement is based on one cadaver study (addressing the FOV) and one dry mandibles' study (addressing the impact of rotation).

4.6 | Consensus statement 5

Reported accuracy is independent of the software package used. This statement is based on one study (dry mandibles).

4.7 | Clinical recommendations

- CBCTs should be considered the imaging tool of choice for three-dimensional (3D) dental implant site assessment.
- Based on consensus statement 2, a minimal safety margin of 2 mm to relevant adjacent anatomic structures should be considered.
- 3. Smaller voxel sizes do not result in increased accuracy of linear measurements on CBCT scans. A voxel size of 0.3–0.4 mm³, the smallest FOV, and if possible partial rotations should be used for preoperative implant treatment planning in order to reduce radiation dose exposure: this should result in similar image quality as scans comprised of smaller voxel size or larger FOV.

4.8 | Recommendations for future research

- Due to the inhomogeneity of the extracted data from the included studies, it was not possible to conduct a multivariate analysis. Further studies should focus on identifying specific exposure and acquisition parameters that influence the accuracy of linear measurements. Moreover, it is of interest to know the mechanics of how these parameters influence linear accuracy, how they may interact, and develop dose reduction imaging protocol strategies.
- Additional In vivo studies to assess the linear accuracy of CBCT for implant site assessment are suggested comparing radiographic data with true clinical values and to determine the validity of currently used in vitro models.
- Additional investigations should focus on determining the influence of the choice of software and specific display protocols (e.g. volumetric orientation and image enhancements) on the accuracy of linear measurements at implant sites.

5 | PAPER 4

The accuracy of static computer-aided implant surgery: A systematic review and meta-analysis.

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Ali Tahmaseb, Vivian Wu, Daniel Wismeijer, Wim Coucke, Christopher Evans.

5.1 | Preamble

Prosthetically driven implant placement is considered the optimal approach when treating patients with dental implants. Detailed pretreatment planning is necessary to ensure a correct three-dimensional (3D) implant position within the alveolar bone relative to surrounding anatomical structures and the future prosthetic restorations.

The virtual model of the area of interest in static computer-aided implant surgery (s-CAIS) can be created by aligning the 3D volumetric data scan (DICOM file) with the surface scans (STL file) of the patient in the appropriate planning software. In addition, design and production software (CAD/CAM) and associated hardware are necessary to design and produce the surgical guide to perform static computer-guided implant surgery.

The findings of previous systematic reviews have highlighted a clinically unacceptable range of deviations in accuracy between the planned and final implant position. Due to developments in the technology used in computer-aided implant surgery, the authors of the current systematic review decided to search the literature staring form 2008 to find out if these developments do lead to improved accuracy of treatment.

The primary aim of this study was to assess the literature on the accuracy of static computer-aided implant surgery. In addition, factors such as guide support, implanted jaw, and degree of edentulism were assessed for their effect on accuracy.

Electronic and manual literature searches were applied to collect information about the accuracy of static computer-assisted implant systems. Meta-regression analysis was performed to summarize the accuracy studies. From a total of 372 articles, 19 studies were selected for inclusion for qualitative synthesis. A total of 2,238 implants in 471 patients that had been placed using static guides which were available for review.

There was a wide variation in levels of evidence in the studies included on static computer-assisted implant placement.

Sufficient data were available to perform meta-analysis on the primary outcome of 3-D implant position. The only factor found to influence the accuracy was the state of edentulism.

5.2 | Consensus statement 1

The number of included clinical studies was limited to 20 with a heterogeneous mix of study designs.

5.3 | Consensus statement 2

The mean 3-D deviation for static computer-aided implant surgery (s-CAIS) at the entry point was 1.2 mm [1.04, 1.44, 95% CL], at the apical position was 1.5 mm [1.29, 1.62 mm, 95% CL], and for angular deviation was 3.5 [3.00, 3.96, 95% CL].

Consensus Statement 1 is based on 20 clinical trials (one RCT, 11 UPCS's, and eight URCS 's).

5.4 | Consensus statement 3

With s-CAIS, there is a vertical discrepancy in the apical point of the implant between the planned and actual positions of -0.25 and -0.57 mm, 95% CL.

Consensus statement 2 is based on eight publications (one RCT, five UPCS's, and two URCS 's).

5.5 | Consensus statement 4

With s-CAIS, there is a vertical discrepancy in the apical point of the implant between the planned and actual positions of -0.08 and 1.13 mm, 95% CL.

Consensus statement 3 is based on four publications (three UPCS's and one URCS's).

5.6 | Consensus statement 5

Partially edentulous cases show better accuracy using s-CAIS compared to fully edentulous cases.

Consensus statement 4 is based on eight publications (one RCT, five UPCS's, and two URCS 's).

5.7 | Clinical recommendations

- Static computer-aided implant surgery (s-CAIS) should be considered as an additional tool for comprehensive diagnosis, treatment planning and surgical procedures.
- 2. s-CAIS should be prosthetically driven.
- **3.** Surgical experience and general comprehensive training are desirable to achieve an accurate and favorable outcome for implants placed using s-CAIS.
- 4. While recent studies indicate improved accuracy when using s-CAIS in partially edentulous cases, a safety margin of 2mm from critical anatomical structures should be maintained.
- 5. The alignment of surface scans, including the prosthetic planning, with 3D volumetric imaging data is recommended to improve the accuracy of the anatomical position of the implant.
- **6.** Surgical guides should be digitally designed on surface scan files which have been aligned with DICOM data, which is more accurate than using DICOM data alone.
- 7. Manufacturer's guidelines should be followed with respect to calibration protocols, for all hardware to maintain optimal accuracy.

5.8 | Recommendations for future research

- Future research should not use CBCT/CT for pre- and postimplant position evaluation.
- Future research should focus on evaluating implant position accuracy using surface scans of the final implant positions. This will reduce patient radiation exposure and improve evaluation accuracy data.

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- Future research should more precisely define the degree of edentulism and the treatment protocols that are followed.
- Future research should quantify the effect of every step in the digital workflow.
- A number of factors within the digital workflow contribute to deviations in the actual implant position from the initially planned positions, and these should be investigated separately.

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