CLINICAL ORAL IMPLANTS RESEARCH

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Patient-centered outcomes comparing digital and conventional implant impression procedures: a randomized crossover trial

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Abstract

Objectives: The aim of this randomized controlled trial was to compare patient-centered outcomes during digital and conventional implant impressions.

Material and methods: In a crossover study design, intraoral scanning (IOS) [test] as well as classical polyether impressions [control] were both performed on 20 patients for single-tooth replacement with implant-supported crowns. The sequential distribution of either starting with the test or the control procedure was randomly selected. Patients' perception and satisfaction on the level of convenience-related factors were assessed with visual analogue scale (VAS) questionnaires. In addition, clinical work time was separately recorded for test and control procedures. Statistical analyses were performed with *Wilcoxon signed-rank tests* and corrected for multiple testing by the method of *Holm*.

Results: On VAS ranging from 0 to 100, patients scored a mean convenience level of 78.6 (SD ± 14.0) in favor of IOS compared to conventional impressions with 53.6 (SD ± 15.4) [$P = 0.0001$]. All included patients would prefer the digital workflow if in the future they could choose between the two techniques. Secondary, IOS was significantly faster with 14.8 min (SD ± 2.2) compared to the conventional approach with 17.9 min (SD ± 1.1) [$P = 0.0001$].

Conclusion: Based on the findings of this investigation, both impression protocols worked successfully for all study participants capturing the 3D implant positions. However, the digital technique emerges as the most preferred one according to patient-centered outcomes and was more time-effective compared to conventional impressions.

Healthcare-related validation should be associated with objective criteria to assess treatment efficiency. The various stakeholders representing patients, the healthcare providers, the industry or third-party players concentrate on different endpoints (Anderson 1998).

Treatment outcomes in implant therapy can be distinguished into four subgroups: (i) longevity and survival, (ii) physiological impact, (iii) psychological effect, (iv) economic factors (Guckes et al. 1996). This classification includes categories of primary relevance to patients but also outcomes of their indirect concern, though maybe of greater interest to the clinician. Therefore, the clinicians' as well as the patients' appraisals should be taken into account for efficiency assessment of implant treatment (Grogono et al. 1989).

However, studies are limited to dental implant survival and clinical/radiographically surrogate parameters (den Hartog et al. 2008). In contrast, patient-centered outcomes of implant treatment protocols have been unattended for years and are only gradually integrated into clinical trials (Pommer et al. 2011). Scientific information on patient satisfaction levels as well as the investigation of psychological and social effects following implant therapy is still rare in the current literature (Abduo & Lyons 2013). Most studies reported on edentulous patients with implant-supported removable prostheses

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only. In such cases, patient satisfaction was predominantly measured with regard to masticatory function and the ability to speak (Attard et al. 2005; Zitzmann et al. 2005).

Today, patients' demands have been expanded from functional implant rehabilitation concepts to less time-consuming and minimal-invasive therapy modalities, such as the avoidance of surgical bone augmentation procedures (Kaptein et al. 1998). In general, patients expect a successfully clinical outcome. Their interest is pointing to more convenience-oriented treatment protocols (Nkenke et al. 2007).

With the implementation of the digital workflow in dental medicine, patients' benefits have been presented such as reduced clinical treatment time and simplified protocols; preventing patients' harm during classical impression taking procedures due to suffocation hazard, gagging and taste irritation by means of intraoral scanning (IOS) (Fasbinder 2010; Patel 2010; van Noort 2012; Joda & Braegger 2014). *In vitro* investigations demonstrated a comparable level on accuracy and precision between classical impression taking procedures and different IOS systems for dentate full arches (Seelbach et al. 2013; Ender & Mehl 2015). Nevertheless, only limited clinical evidence is available focusing on patients' satisfaction ratings undergoing digital and conventional impressions in the field of implant prosthetic workflows. Therefore, the aims of this randomized-controlled trial were to investigate patient-centered outcomes and to analyze clinical work time comparing classical implant impression techniques to IOS in a randomized crossover design.

Materials and methods

The study was designed as a clinical crossover randomized-controlled trial. Inclusion criteria were prosthetic treatment with implant single crowns in premolar and molar sites with existing interproximal and antagonistic contacts. Study baseline started with the implant prosthetic therapy in a university setting. Twenty patients who had volunteered for implant-supported single-tooth replacement on transmucosal implant system (Straumann TL RN/WN, Institut Straumann AG, Basel, Switzerland) were recruited answering a questionnaire on their subjective perceptions of digital and conventional implant impressions.

Using a crossover design, both IOS [test] as well as classical impressions [control] were performed subsequently on all included patients. For digital impression taking, an implant-specific 2-piece scanbody (Institut Straumann AG) was screwed in and a quadrant-like IOS including capturing of the antagonistic dentition as well as a bite registration was performed with the iTero system in accordance with the manufacturer's recommendation (Align Tech Inc., San Jose, USA). For conventional impression, an open-tray approach with polyether material (Impregum Penta, 3M Espe GmbH, Neuss, Germany) and an implant transfer post (Institut Straumann AG) were used. In addition, a high-viscosity alginate impression was taken from the opposite arch with Palgat Plus Quick (3M Espe GmbH) as well as occlusal registration with fast-setting vinyl polysiloxane Blu-Mousse (Parkell Inc., Edgewood, USA) (Fig. 1).

Evaluation criteria were independently created for both impression procedures. IOS was categorized as successful if the implant scanbody and the adjacent teeth could be clearly detected and a correct occlusal registration was confirmed by the computer system. The conventional impression had to capture the implant transfer post in an artifact-free setting without distortion of the impression material. Occlusal registration was clinically double-checked for interference-free reproducibility. One experienced team of the same dentist/dental assistance performed all treatments for both workflows. The responsible dentist measured the clinical success criteria of the impressions.

Primary outcome was defined as patients' perception and satisfaction comparing the two impression protocols; and as secondary outcome, work time needed for the conventional and digital workflows was assessed and analyzed.

All patients were asked about their perception and satisfaction concerning the convenience level as well as the clinical handling for both impression procedures. In detail, patients' opinions were assessed with visual analogue scale (VAS) questionnaires covering a total of 12 self-developed statements. VAS ranged from 0 to 100 as indicated in Table 1. For digital and conventional impressions, six question pairings each focused on treatment time, self-perception of the applied impression protocols with regard to overall convenience, anxiety, taste, nausea sensation, and possible pain sensation. In addition, patients were asked to express their personal favor using a linear scale with two endpoints, digital and conventional workflows, respectively. These supplementary questions focused on which workflow was subjectively more convenient, faster, and which process would be hypothetically preferred for future treatments. This measurement instrument allowed the direct visualization of the patients' preference.

Work time was recorded in minutes as well as treatment steps were accounted for both therapy strategies by a single dental assistance observing the clinical appointments and not involved in the treatment process. Detailed time assessment sequences were separately defined for digital and conventional procedures as shown in Table 2.

The sequential treatment distribution, weather starting with test or control protocols, was randomly chosen by the envelope technique. The principle investigator performed the random allocation sequence and the enrollment of all study participants. Due to the trial design, blinding was not applicable.

Statistical analysis was carried out to evaluate the differences between the test and the control groups in a randomized crossover design (Putt & Chinchilli 2004). *Wilcoxon signed-rank tests* were used for comparisons. It is crucial to except the confusion between treatment and period effects (confounding). Possible carry-over effects were excluded in a separate test. The data of both measurement rounds were used for analysis of test and control protocols, respectively. Tests on subsets of both protocols were considered as *post hoc tests* and corrected for multiple testing by the method of *Holm*. A P-value of < 0.05 was considered as statistically significant. Calculations were made with the computer program 'Software R' (version 3.0.2).

The Ethics Committee in Bern, Switzerland, officially approved this clinical trial under the registration number KEK 053/12

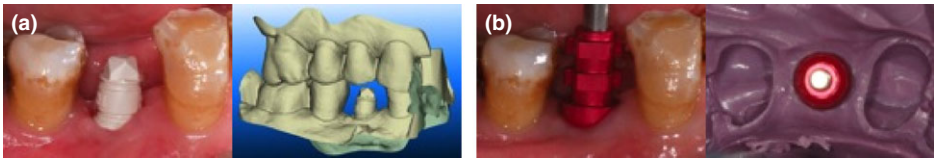

Fig. 1. (a–b) Patient #04 for implant prosthetic replacement of tooth 44: inserted scanbody and digital impression for test (a); and placed transfer post and conventional polyether impression with open-tray technique for control (b).

Table 1. **Questions on patient satisfaction with digital and conventional impression procedures and mean scores of the results [*Wilcoxon signed–rank test*]. (VAS = visual analogue scale)**

12 Questions (2 × 6)	Digital impression	Conventional impression
What is your opinion on the treatment time required for the impression procedure? VAS: unsatisfactory 0–100 excellent [$P = 0.0007$]	Mean 79.2; SD ± 12.1 median 83.0; range 50–95	Mean 57.6; SD ± 15.6 median 59.5; range 17–95
How convenient was the impression procedure for you? VAS: unsatisfactory 0 – 100 excellent [$P = 0.0001$]	Mean 78.6; SD ± 14.0 median 84.0; range 35–90	Mean 53.6; SD ± 15.4 median 53.5; range 15–85
How high was your anxiety level before the impression procedure? VAS: low 0 – 100 high [$P = 0.0003$]	Mean 24.2; SD ± 19.4 median 19.0; range 0–50	Mean 45.9; SD ± 23.6 median 50.0; range 0–90
Was there a bad oral taste present and/or after the impression procedure? VAS: no sensation 0 – 100 a lot of sensation [$P < 0.0001$]	Mean 10.9; SD ± 9.5 median 6.5; range 0–36	Mean 71.3; SD ± 15.7 median 77.5; range 25–87
Did you experience a nausea sensation during impression procedure? VAS: no sensation 0 – 100 a lot of sensation [$P < 0.0001$]	Mean 12.2; SD ± 11.4 median 7.0; range 0–51	Mean 68.7; SD ± 18.0 median 74.0; range 10–93
Did you experience pain during impression procedure? VAS: no pain 0 – 100 a lot of pain [$P < 0.0001$]	Mean 13.9; SD ± 10.3 median 13.0; range 0–36	Mean 44.6; SD ± 20.7 median 45.0; range 5–77

Table 2. **Baseline demographic characteristics for included study participants**

Demographic data	
Study participants	$n = 20$
Mean age	Ø 55.4 years
Gender ratio	47% females 52% males
Implant sites	$n = 13$ molar sites $n = 7$ premolar sites

(www.kek-bern.ch). The research protocol was in accordance with the Helsinki Declaration of 1975, as revised in 2000 and again in 2008, and patients provided an informed consent to participate in the study.

Results

A total of 20 participants were included, randomly assigned, received intended treatment, and were analyzed for primary and secondary outcomes. Baseline demographic characteristics for included study participants are presented in Table 2. There were no losses and exclusions after randomization. Therefore, the analysis was by original assigned groups. Both impression protocols worked successfully for all study participants capturing the 3D implant positions; no complications and failures were recorded. Treatment of test and control workflows was performed for all study participants within two clinical appointments.

For VAS analysis, the overall 12 questions were independently evaluated for the digital and the conventional impression taking procedures (2 × 6). In Table 1, the calculated mean results are presented related to treatment time, patients' subjective convenience-level, anxiety, bad oral taste, nausea sensation, and possible pain sensation during impression taking. In general, significant differences [$P < 0.05$] were evident for all six questions' pairings, always favoring the digital technique over the conventional approach (Table 1).

Three additional questions directly compared subjective patients' satisfaction concerning convenience, speed, and generally methodological preference for both workflows. Again, analysis demonstrated mean satisfaction scores with a trend favoring the digital protocol for the defined categories: mean convenience 78.8 % (SD 13.5%; Median 83.0) [$P < 0.0001$], mean speed 72.5 % (SD 17.8%; Median 76.0) [$P < 0.0001$], and mean overall preference 77.3 % (SD 15.2%; Median 79.0) ($P < 0.0001$; Fig. 2). All patients would have selected the digital workflow in case of choice if they needed future implant prosthetic treatments.

Work time analysis for the digital and the conventional implant impression procedures revealed a significantly reduced mean chair time for the digital workflow of 14.8 min (SD ± 2.2) compared with the conventional approach with 17.9 min (SD ± 1.1) [$P = 0.0001$] (Table 3).

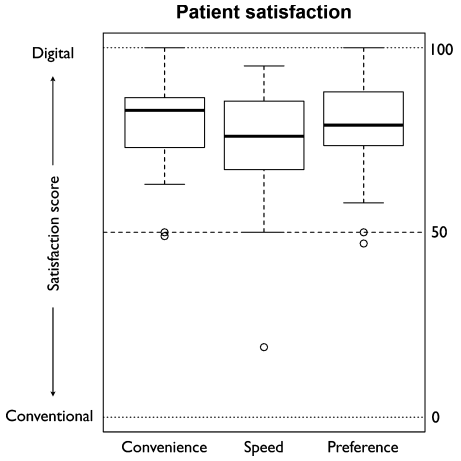

Fig. 2. Box-plot diagram for patient satisfaction depicting mean scores of questionnaire analysis comparing digital and conventional workflows with regard to convenience, speed and methodological preference [*Wilcoxon signed–rank test*].

Discussion

Digital media have become a central part of social life today (Schoenbaum 2012; van der Zande et al. 2013). Similarly, the technical development in the field of digital dental medicine has also opened new opportunities for the entire treatment sequence (Fasbinder 2010). The implant prosthetic fabrication process starting with IOS, followed by virtual designing and constructing even without any physical models, can be technically simplified within the complete digital workflow (Patel 2010).

New technologies may not only provide advanced possibilities of prosthetic rehabilitation, but also change the patients' attitude due to this digitization trend (Schoenbaum 2012). Patients are accustomed to digital tools from their everyday life, such as smartphones and tablet computers, and they are well informed about the various technical opportunities using healthcare-related online platforms. Therefore, the patients' mindset on dental implant therapy has continuously changed over the last years (Pommer et al. 2011; van der Zande et al. 2013).

In this context, patients assume functional and esthetic treatment results with implant-supported reconstructions. In fact, their expectations are even higher compared to conventional prosthetic rehabilitation concepts (Buch et al. 2002; Tepper et al. 2003). In addition, the patients' demands are also addressed to more comfortable treatment protocols. These include streamlined treatment sessions combined with a shortened overall therapy as well as convenience-oriented

Table 3. **List of the protocol-dependent impression work steps for time analysis of digital and conventional implant impressions [*Wilcoxon signed-rank test*]**

Implant impression procedure	
Test – Intraoral optical scan	Control – Conventional polyether impression
Removal healing cap + insertion scanbody	Removal healing cap + insertion transfer post
Intraoral scan process	Impression taking
Implant site + adjacent teeth	Implant site + adjacent teeth
Opposite arch	Opposite arch
Occlusal registration	Occlusal registration
Removal scanbody + insertion healing cap	Removal transfer post + insertion healing cap
Color determination	Color determination
Mean 14.8 min (SD ± 2.2)	Mean 17.9 min (SD ± 1.1)

appointments without affecting their personal schedules (Nkenke et al. 2007).

With this background, it is not surprising that the results of this patient-related satisfaction analysis confirm a generally observed trend of socialized digitization acceptance. This could be a possible explanation, why all included patients clearly favored the digital impression procedure with IOS in case of future implant prosthetic treatments. Another important factor is the human curiosity about new methods – especially technically animated 3D media. Therefore, the interpretation of the results of patients' preference might not be tangled with patients' satisfaction in general.

The digital impression protocol offers the chance to streamline the workflow by means of quadrant-like IOS of the implant site as well as the opposite arch including occlusal registration within one operational approach (Joda & Braegger 2014; Joda & Brägger 2014). This capability reduces the preparation time and the workflow itself compared to the conventionally full-arch impression taking procedure with adapting of the open impression tray, providing different materials for implant transfer, capturing of the opposite arch and occlusal registration within the sequential treatment steps. This fact might have influenced the patients' subjective perceptions in this study design.

New treatment protocols have to be trained in advance. And, learning curves also have to be considered while implementing digital dental workflows in daily routine (Gimenez et al. 2014). The correct application is a prerequisite and crucial for the success of the overall therapy, and finally, for a satisfied patient. This includes equally the dentist, the dental assistance, and the technician as well (van der Zande et al. 2013). The performance of digital and conventional impressions heavily depends on operators' experience. This also affects patient's perception and preference. It has to be considered that all included patients in this study were treated by one experienced team of the same dentist/dental assistance in the field of IOS.

Two recently published clinical studies could be identified comparing patient-related outcomes for digital versus conventional implant impressions in the dental literature (Wismeijer et al. 2014; Yuzbasioglu et al. 2014). Both studies revealed mostly consistent findings analogous to the results of this presented crossover trial: the overall preference of the patients' preference was significantly in favor of the digital workflow rather than the conventional approach. Moreover, one pilot study evaluated the operators' perceptions comparing digital and conventional impression techniques in a standardized setting for single implant crowns (Lee & Gallucci 2012). Study participants were inexperienced undergraduate dental students performing both techniques on a phantom model. In this study, the digital protocol also resulted in higher operators' acceptance than the conventional procedure.

Several *in vitro* investigations reported on accuracy and precision of different intraoral scanning devices with heterogeneous results for full-arch dentate digital impressions, indicating a strong dependency on the used system (Mehl et al. 2009; Persson et al. 2009). However, the results also demonstrated a level of precision that was within the range of analogue impressions (van der Meer et al. 2012; Andriessen et al. 2014).

It has to be stated in particular that the performed comparative study analyzed one specific digital implant impression protocol. Other digital systems and their corresponding workflows may lead to different results. Therefore, it is not possible to generalize the trial findings. In addition, the findings are yet preliminary in nature analyzing a small sample. Further scientific validation on digital implant treatment is necessary to understand the impact of this technology for modifying well-established conventional protocols to improve patients' satisfaction and their perceptions. Supplementary large-scale clinical studies including different digital systems are necessary to confirm the results of this clinical investigation.

Conclusion

Within the limitations of this clinical crossover study, the following conclusions can be summarized:

- The digital workflow was significantly accepted as the most preferred and time-effective implant impression procedure compared to the conventional technique with regard to the patients' perception and satisfaction.
- With regard to treatment comfort, the digital impression protocol with IOS was more patient-friendly than the conventional approach when it was performed by an experienced team of dentist/dental assistance.
- Both workflows worked clinically successful restoring single-tooth gaps with implant-supported crowns.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial*.