A Randomized Controlled Clinical Trial Comparing Conventional And Computer-Assisted Implant Planning and Placement in Partially Edentulous Patients. Part 2: Patient Related Outcome Measures

The objective of this study was to compare patient-related outcomes of conventional protocols with computer-assisted implant planning and template-guided implant placement (CAIPP) protocols. Partially edentulous patients (N = 73) were assigned to either surgical planning based on two-dimensional radiographs and freehand implant placement (control; n = 26) or using three-dimensional computer-tomography data and implant placement using a tooth-supported surgical guide (test groups T1 [n = 24] and T2 [n = 23]). The two test groups differed from each other in digital data acquisition, software functionality, and the guide-manufacturing process. All surgeries were performed as open-flap procedures. Patient-related outcome measures were evaluated using questionnaires. Statistical tests were performed to investigate differences between treatment groups. Before treatment, 53% of patients in the control group and 83% of patients in the test groups (T1: 88%, T2: 78%) were satisfied with their group allocation. In the control group, 37% of patients favored CAIPP technology, while only 11% in the test groups would have preferred a conventional procedure. After treatment, 50% of patients in the control and 86% in the test groups (T1: 76%, T2: 94%) were satisfied with their allocation. Twenty-one percent of control-group patients favored the CAIPP treatment, while 6% of the test-group patients would have preferred a conventional treatment. The quality-of-life parameters during and after surgery did not show significant differences between groups. More postoperative discomfort was reported after longer and more-complex surgeries including guided bone regeneration and surgeries with two surgical sites. Generally, patients preferred computer-based technologies. No differences in the intra- and postoperative discomfort were observed compared to control protocols. More-extensive surgical procedures negatively affected the intra- and postoperative quality of life, irrespective of the treatment group allocation. Int J Periodontics Restorative Dent 2019;39:e99–e110. doi: 10.11607/prd.4145

In the recent past, the introduction of cone beam computed tomography (CBCT) improved the imaging possibilities in implant dentistry and subsequently introduced new treatment options.1–3 Improved software used to view CT-based radiographic data led to the development of computer-assisted implant planning and subsequently template-guided placement (CAIPP) protocols. Using specific computer software, the implant position can be simulated in a virtual environment given by the radiographic data set. This data can be used for ensuring production of surgical stents for instrument guidance during osteotomy and implant placement.

It has been assumed that CAIPP protocols offer several advantages over conventional techniques, including surgical interventions that are more accurate, faster, easier, and less traumatic,4–10 that should exceed possible disadvantages, such as radiation dose, infrastructural costs, and increased preoperative preparation time. A series of investigations analyzed in meta-analyses reported that CAIPP protocols had high accuracy, which has continued to increase over the past few years.11–13

However, there are limited evidence-based analyses of these theoretical benefits and possible limitations compared to conventional

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implant planning and placement protocols. A recent systematic review on clinical advantages of CAIPP identified seven articles focusing on patient-reported outcome measures (PROMs). Most of these studies included flapless procedures that were associated with lower postoperative discomfort and shorter duration of the surgeries compared to conventional or template-guided open-flap surgeries. However, in clinical settings, open-flap procedures are often indicated due to limited bone availability and the necessity for augmentation procedures. Data on patient-related outcomes using CAIPP in connection with open-flap procedures is scarce, and not all publications report consistent results. Therefore, the primary objective of the present study was to investigate whether CAIPP technology is superior to conventional planning and placement protocols regarding PROMs, including expectation, perception, intra- and postoperative morbidity when used in connection with open-flap procedures. The secondary objective was to identify additional surgery-related factors influencing PROMs.

Materials and Methods

The materials and methods including the study design, criteria for patient selection, materials and interventions have been described in detail in a previous publication. The study protocol was approved by the ethics review board of the University of Zurich (Kantonale Ethik-Kommission Zurich Ref. KEK-Zh-Nr. 2011-0020/5). In brief, 73 partially edentulous patients requiring implant therapy were included in this randomized controlled clinical trial. The residual dentition had to provide stable support for a radiographic and surgical guide and allow for a proper superimposition of digital scan models with radiographic data (see below). Patients were randomly allocated to one of three treatment groups. In all groups, a diagnostic wax-up of the tooth to be restored with an implant-supported reconstruction was performed after alginate impressions and cast-model production. In the control group (n = 26), the prosthetic wax-up was transferred into a tooth-supported acrylic radiographic stent, including a 5-mm-long metal tube in the center of the prospective reconstruction. A conventional panoramic radiograph was taken with the stent in situ, which was used together with photographs and other clinical data derived from a previous clinical examination for implant-position planning. On a light table, the future implant was drawn on an acetate foil. The dental technician then modified the radiographic stent into a surgical stent with a central access canal, preserving the outer contour of the prosthetic set-up for intrasurgical orientation. After flap elevation, freehand implant placement was performed, followed by a guided bone regeneration (GBR) procedure, if necessary.

In the test groups, computer-assisted implant planning was applied. A diagnostic wax-up was performed with the same method as the control group. In test group 1 (T1, n = 24), a radiographic stent was manufactured by the dental technician based on the prosthetic wax-up. This acrylic stent included the future prosthetic reconstruction in a radiopaque material (barium-sulfate) that was mixed with acrylic material. After a CBCT scan of the patient wearing the radiographic stent, the prosthetic set-up appeared in the digital radiographic data set and allowed a virtual implant-position planning using anatomical and prosthetic information (Simplant, Dentsply Sirona). The digital data set, including the virtual implant position, was sent online together with a digital scan of a cast model to a guide-manufacturing center (Dentsply Sirona Implants in Leuven, Belgium). In this center, a stereolithographic surgical stent was designed and produced by means of computer-aided design/computer-assisted manufacturing (CAD/CAM). This guide was used during the subsequent surgical procedure for instrument guidance and implant placement.

In test group 2 (T2, n = 23), the same workflow was applied as in T1 except for a few modifications: No radiographic stent was produced for CBCT scanning. Instead, an optical scan of the wax-up was taken and the resulting digital surface model of the prosthetic set-up was superimposed in the planning software (SMOP, Swissmeda) using a best-fit algorithm on tooth surfaces. Another difference from T1 was that the surgical guide was produced by a 3D printer (Objet Eden260VS, Stratasys).
Treatment Perception and Preference of Conventional or CAIPP Workflows

Before any study-related interventions were performed, patients were provided with a standardized information document on the study and the different treatment protocols (see Appendix 1). At the following appointment, the perception of the treatment to be delivered was evaluated with a multiple-choice question: “Which treatment protocol would you prefer to receive?” Available answers were: computer-assisted protocol, conventional protocol, and no preference. The answer given by the patient had no influence on the group allocation.

The same question was asked again immediately after the implant surgery to evaluate the patient perception after the procedure.

Frequencies of answers at both time points were categorized according to treatment protocol.

Intraoperative Discomfort

Patients’ intraoperative comfort was evaluated with a questionnaire based partly on open-answer questions and partly on a 100-mm visual analogue scale (VAS). This questionnaire was completed by the patients immediately after surgery and included the following items:

Perceived Duration of the Surgical Procedure

VAS evaluation: A mark in the middle of the 100-mm VAS was used to represent patients’ experienced duration of the surgical procedure. Patients were asked to rate the duration as shorter than expected (by marking the 0- to 50-mm side) or longer than expected (by marking the 50- to 100-mm side).

Open-answer question: Patients were asked to respond to the question: “How long do you think the surgery lasted?” The answer was recorded as a number of minutes.

The true length of the surgical procedure was recorded and compared with the treatment duration perceived by the patient.

Perceived Symptomatology

VAS was used to evaluate patients’ perceived symptomatology at two time points:

Intraoperative Period

Intraoperative comfort: “Was the surgery uncomfortable?” Patients were expected to rate the degree of discomfort experienced during surgery. The left end of the VAS represented “very comfortable” and the right end “very uncomfortable.”

Intraoperative pain: “Was the surgery painful?” Patients were asked to rate the degree of pain experienced during surgery. The left end of the VAS represented “no pain” and the right end “extreme pain.”

Immediate Postoperative Period

“How much pain are you feeling at this moment?” Patients were requested to rate the amount of pain experienced immediately after surgery. The left end of the VAS represented “no pain” and the right end “extreme pain.”

Postoperative Morbidity

After surgery, a questionnaire was delivered evaluating the influence of the implant surgery on patients’ quality of life in the early postoperative period. This questionnaire was to be filled out daily during the first 7 postoperative days. A 100-mm VAS was used to quantify the answers. The following questions were asked:

“Please quantify the signs or symptoms you are suffering today.”

- Swelling
- Hematoma
- Bleeding
- Nausea
- Bad taste

“Please quantify the average pain suffered today.”

“Please quantify the maximum pain suffered today.”

“Please quantify the overall influence the surgery had on your daily activities.”

Patients were also asked to indicate the amount of analgesic medication taken each postoperative day.
Statistical Analyses

For the treatment perception analysis, descriptive statistics robust summaries (median, minimum and maximum, and interquartile range) were calculated for non-normally distributed data. Data that followed a normal distribution were described with mean and standard deviation (SD). Differences in medians between treatment groups were investigated by nonparametric Kruskal-Wallis test. For post hoc tests, Bonferroni corrected ($P < 0.016 = 0.05/3$) Mann-Whitney test was used. Differences in means between treatment groups were investigated by analysis of variance (ANOVA) and Bonferroni post hoc test (Scheffé method). When additional predictors were evaluated, a multiple linear regression was considered.

Different tests were applied for intraoperative discomfort and postoperative morbidity. For the overall comparison of outcome development with time, repeated measures ANOVA tests were applied together with the Greenhouse-Geisser correction for the $P$ values. Other predictors besides treatment group were taken into consideration for the repeated measures ANOVA models.

Kruskal-Wallis test was used to investigate each time point separately in order to evaluate the differences between the three treatment groups. For post hoc tests, Bonferroni corrected ($P < 0.016 = 0.05/3$) Mann-Whitney test was applied.

To evaluate the influence of other binary predictors, a Mann-Whitney test for each time point was applied separately with a Bonferroni correction ($0.05/7 = 0.007$).

In order to contemplate other variables that could potentially influence patients’ intraoperative and postoperative periods, the study sample was split according to surgery duration, number of surgical sites, number of implants, need for GBR, location of the surgical site, and patient gender.

Results

A total of 73 patients were included in the present study: 26 in the control group, 24 in T1, and 23 in T2. Due to researcher- or patient-caused deviation from data-recording protocols, complete information was not provided for several evaluations. For the treatment perception evaluation, the data collection in the control group comprised 19 preoperative and 24 postoperative answers. Responses for the test groups were pooled together since the investigation inquired about the preference for computer-assisted implant placement as a whole. Thirty-five preoperative and 34 postoperative questionnaires were collected from the test study participants.

Intraoperative Discomfort and Perception of the Surgical Intervention Duration

For intraoperative discomfort and pain and immediate postoperative pain, no statistically significant differences between the three treatment groups were observed.

The mean (SD) total duration of surgery amounted to 93 (41) minutes in the control group, 110 (48) minutes in T1, and 130 (54) minutes in T2. The duration perceived by the patient was not significantly different from the recorded duration in any group: 93 (55) minutes, 107 (47) minutes, and 102 (41) minutes for the control group, T1, and T2, respectively.

In order to detect other variables that could potentially influence patients’ intraoperative and immediate postoperative periods, the study sample (all groups) was split according to surgery duration, number of surgical sites, number of implants, need for GBR, location of surgical site, and patient gender.

Treatment Perception and Preference of Conventional or CAIPP Workflows

Before treatment, 53% of patients in the control group and 83% of patients in the test groups (88% in T1 and 78% in T2) were satisfied with their group allocation. In the control group, 37% showed a preference in favor of computer-assisted technology, whereas only 11% of test-group patients (all in T2) would have preferred a conventional procedure. After treatment, 50% of patients in the control and 86% in the test groups (T1: 76%; T2: 94%) were satisfied with their allocation. Twenty-one percent of control-group patients favored a CAIPP treatment, while 6% of the test-group patients (all in T1) would have preferred a conventional treatment. Results from this portion of the study are shown in Table 1.
Longer surgeries were associated with more intraoperative discomfort ($P = .017$), more intraoperative pain ($P = .000$), and the perception of a longer duration of surgery ($P = .002$).

Surgeries involving two surgical sites with two separate flaps yielded higher levels of immediate postoperative pain than single-site surgeries ($P = .035$).

Surgeries in which more than one implant was placed and surgeries including GBR were associated with a longer perception of surgery duration ($P = .033$ and $P = .027$, respectively).

Neither location of the surgical site nor patient gender showed a statistically significant influence on the intraoperative and immediate postoperative period.

Postoperative Morbidity

During the 1-week postoperative period, the three treatment protocols triggered similar postoperative findings according to the evaluation of the studied PROMs (Figs 1 to 4). No significant differences were found between groups.

In order to assess the level with which patients reported a range of symptoms, the data were pooled for the three treatment groups (as performed for peri-operative discomfort). A gradual reduction of the symptoms was observed from day 1 to day 7 ($P > .000$). Of all parameters studied, swelling was the only one that showed a peak on day 2 and then decreased gradually until day 7. For all other parameters, a gradual reduction was already observed on day 1 and continued throughout the 7 days. The values for bruising, bleeding, and nausea were low during the observation period. Pain, both average and maximum values, was higher during the first day and decreased gradually until day 4.

### Table 1 Patients’ Treatment Perceptions and Preference of Conventional or Computer-Assisted Workflow Before and After Treatment

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Test 1</th>
<th>Test 2</th>
<th>Global CAIPP</th>
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<tr>
<td></td>
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<tr>
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<td></td>
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<td>100</td>
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<tr>
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<tr>
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</tr>
</tbody>
</table>

CAIPP = computer-assisted implant planning and template-guided placement; global CAIPP = Combined Test 1 and Test 2 data.

Fig 1 Swelling (quantified by a 100-mm VAS) experienced by patients during the first postoperative week.
where it stabilized at a value close to zero. This coincided with the analgesic intake, which dropped at day 4 to a value close to zero and remained low.

The necessity of performing a simultaneous GBR procedure during the implant surgery had a significant impact on patients’ quality of life, irrespective of their group allocation. For the following variable, GBR patients experienced more postoperative symptoms than their non-GBR counterparts: mouth opening (days 3 and 4), speech (days 3 and 4), daily activities (days 3 to 5), social interaction (days 2 to 4), favorite activities (day 3), swelling (days 2 to 6), hematoma (day 2), nausea (day 3), average pain (days 3 and 4), maximum pain (day 2), overall influence on daily activities (days 2 to 5), and analgesic intake (days 2 to 6).
The number of surgical sites involved in the surgical procedure had a smaller influence than GBR procedures on the symptoms during the postoperative period. Cases with two surgical sites showed statistically significant differences regarding hematoma occurrence at day 1 and working interference during day 2 compared to patients with only one surgical site.

Surgery length again had a great influence on patient experiences during the postoperative period. Longer surgeries (> 100 minutes) had a greater adverse impact on: the patient’s chewing ability during days 2 to 6; mouth opening during days 1 to 6; speech during day 1; sleep during day 1; interference with daily activities during days 2 and 3; swelling during days 2 to 5; bruising at day 5; average pain suffered during days 2 and 4; maximum pain experienced at days 2 and 3; and analgesic intake during days 2 to 4.

Location of the surgical site had no influence on the patients’ quality of life.

Gender seemed to influence certain aspects of the postoperative period. Women had a greater impairment in the following parameters: mouth opening during days 5 and 6; sleep impairment at day 6; and overall impairment on daily activities at day 5.

Discussion

The results of the present study revealed that patients favor computer-assisted technology over conventional technology prior to and after therapeutic procedures, even if they have not directly experienced both workflows. However, during and after treatment, no significant differences in discomfort were observed, neither between the control and test groups, nor between T1 and T2. Factors like the duration of the surgical intervention, execution of GBR procedures, and presence of multiple surgical sites influenced the discomfort of the patients, and the nature of the technology applied (conventional or CAIPP) had no influence.

Treatment Perception and Preference of Conventional or CAIPP Workflows

Patients’ preference for computer-assisted technology has been observed in a series of investigations.
in the medical field. It has been demonstrated in a recent study that the acceptance of computers being used by the physician is high and that 63% of the patients believe that the quality of the treatment is improved by the use of a computer (19% unsure, 14% disagree). High levels of patient acceptance (94%) have also been shown for tablet computers used by physicians. In another study, the use of computers during patient-physician communication significantly increased patient satisfaction.

In dentistry, a dental multimedia system for administrative, information, visualization, and educational purposes has been evaluated in a multicenter set-up. Patient satisfaction dramatically increased from visits one to three, with levels of excellent satisfaction amounting to 39.1% (visit 1), 69.5% (visit 2), and 78.2% (visit 3). Using the computer-based information system, patients particularly appreciated the improved level of understanding and expectation of the prosthodontic procedures compared to traditional communication patterns.

In therapeutic procedures, the use of computer-based technology has also been compared with conventional impressions. Patients’ perception, treatment comfort and effectiveness, and clinical outcomes were evaluated. Overall discomfort was rated significantly lower by the patients when using digital optical scanning (VAS: 59 ± 38 for conventional, 90 ± 18 for digital). Similar findings were reported in another comparative investigation that revealed a mean (SD) patient convenience level of 78.6 (14.0) in favor of a digital intraoral scanner compared to 53.6 (15.4) for conventional impressions.

In the present study, the percentage of participants satisfied with their study group allocation prior to treatment was greater in T1 and T2 than in the control group. This fact could be interpreted as a positive opinion of computer-based technology by patients. No information is available in the literature regarding preoperative patient perception of CAIPP protocols. However, outside the dental field, research suggests that, for certain customers, innovation has a positive influence on their product perception. New technologies are not only evaluated from both functional and symbolic aspects and are usually rated as better than older technologies. In the present study, patients received a standard information sheet to avoid any operator subjectivity during protocol information. However, the information the patients knew before seeking treatment (media, colleagues) cannot be standardized and may have influenced the treatment preference.

After treatment, the percentage of participants satisfied with their allocation remained stable in the control group with respect to the pretreatment evaluation (before: 53%; after: 50%). The percentage willing to have undergone a CAIPP protocol decreased by 16% to 21%, while the undecided percentage increased by 18% to 29%. This development could be interpreted as patients perceiving the conventional treatment protocol as a positive experience, as fewer patients would have preferred another protocol and more patients were undecided with their preference. The undecided participants may have been satisfied with the conventional treatment but still considered the CAIPP option a positive alternative. Still, 21% of patients in the control group would have preferred having been treated by computer-assisted protocols, which reinforces the idea that patients perceived CAIPP protocols positively. Since no significant peri- or postoperative complications occurred in the control group, and other patient-related parameters evaluated did not differ between groups, the change in the attitude cannot be attributed to medical reasons. Another possible factor influencing the patients’ treatment experience is the therapist, who also contributes to the patients’ perception. Furthermore, the exact nature of the intervention is of importance. This was demonstrated in a study that compared patients’ postoperative treatment perception of conventional and CAIPP protocols with a questionnaire completed at 1 day postsurgery. The conventional group received an open-flap approach while the CAIPP group consisted of a flapless mucosa-supported, guided surgery. Patients in the CAIPP group were more willing to repeat the surgical procedure and would recommend it more intensely to a friend than those in the conventional group. This perception may be linked to the fact that patients in the CAIPP group had less postoperative pain and swelling due to the flapless surgical procedure. In the present investigations, conventional

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implant-site surgeries. Other indica-
tors of surgical invasiveness, such as
the number of implants placed or
performance of GBR, did not influ-
ence intrasurgical symptoms but led
to the surgery to be perceived as
longer-lasting. Surgery invasiveness
and duration, together with other
factors including the patient’s anxi-
ety level, anesthetic efficacy, and
operator skills, have been shown to
influence the level of intraoperative
pain and comfort.26–30

The effect of the surgery on pa-
tients’ quality of life was mostly felt
during the first 4 postoperative days.
Signs and symptoms peaked on day
1 for most of the variables studied
(except for swelling, which peaked
on day 2) and decreased gradually
thereafter. Treatment duration and
surgical invasiveness significantly
influenced patients’ quality of life.
Longer surgeries and those needing
a GBR procedure caused greater
swelling and pain levels during the
first 3 to 4 postoperative days and
significantly impaired chewing and
mouth opening abilities of patients
across groups. These symptoms
could be responsible for the daily
activity impairment reported during
the first 5 postoperative days. In a
recent study confirming the present
results, the necessity of GBR pro-
cedures impacted patient discom-
fort in terms of swelling and pain.31
Implant-placement surgeries using
two CAIPP and one conventional
protocol in completely edentulous
patients were analyzed for differ-
ces in surgery duration and pa-
tient discomfort in another clinical
study.10 The guided implant-place-
ment procedures involved either a
flapless mucosa-supported single-
stent approach or an open-flap
bone-supported multiple-stent ap-
proach and an open-flap free-hand
control. The flapless single-stent
guided protocol allowed shorter
and less-invasive surgeries than in
the other two open-flap groups,
which resulted in less swelling, pain,
and analgesic intake during the
postoperative period. These results
point out that shorter and less-inva-
sive surgeries have a positive impact
on patients’ postoperative peri-
dods. A flapless approach has been
shown to be favorable in terms of
postoperative discomfort, which has
been confirmed by several other
studies.8–10 However, in many im-
plant treatments, insufficient bone
is present, which renders a flapless
approach impossible. That is why,
to reduce the heterogeneity of the
study sample, only treatments using
an open-flap approach were includ-
ed in the present study.

According to the results of the
present study, the use of CAIPP
techniques used in conjunction with
open-flap procedures in partially
edentulous patients in T1 and T2
did not influence patients’ discom-
fort during the intraoperative or
postoperative periods compared to
the control group’s conventional
implant planning and placement.

However, certain limitations are
present in this investigation. For in-
stance, regarding the evaluation of
the patients’ preference of the two
treatment techniques (CAIPP and
conventional), it would be ideal to
have both approaches used in the
same patients to allow for a direct
comparison. However, the recruit-
ment of suitable subjects is rather
dificult. Moreover, the study population exhibited some heterogeneity in terms of site location, complexity of the intervention, additional procedures like GBR, and different therapists. These circumstances hamper a strict comparison of the surgical approach applied in the study groups and its effect on patients’ quality of life. Despite these limitations, the selected study population well reflects the majority of patients seeking implant therapy in clinical practice.

Conclusions

Patients manifested an improved treatment perception of CAIPP protocols over conventional protocols before and after treatment. Overall, no statistically significant differences were observed between groups for intraoperative and postoperative quality of life parameters. Independently of the group allocation, the surgery influenced patients’ quality of life mostly during the first 4 postoperative days. Signs and symptoms peaked on day 1 for most of the variables studied and decreased gradually thereafter. Regarding open-flap surgeries, the duration of surgery or execution of GBR procedures had a greater impact on symptoms during the postoperative period than the conventional or CAIPP nature of the implantation protocol used.

Acknowledgments

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References

Appendix I: Patient Study Information Document  
(Translated from German)

1. Conventional protocols

The standard implant planning and placement protocol used for decades implies a preliminary clinical evaluation and a two-dimensional X-ray exam. This radiograph is then viewed on a light viewer where bone measurements can be performed. This allows the dentist to determine the position of the implants taking into account anatomical structures, such as bone height availability, nerves, etc.

In a second step, a tunnel is drilled into the bone and an implant is inserted fee-hand. The drilling instruments and implant are directed by the operator’s hand. The surgeon transfers the planned position into the patient’s mouth with the help of preoperative x-rays and a surgical stent that is prepared by the laboratory technician.

The advantages of this procedure are good long-term success rates, relative simplicity, cost efficiency and reduced x-ray exposure.

Among the disadvantages are the two-dimensional X-ray examinations, which don’t allow the assessment of bone width at the implantation area, and the fact that the position of the implant is heavily dependent on manual skill of the surgeon, since there is no guidance of the drilling instruments.

2. Computer-assisted technology

With the development of the computer implant planning and placement protocols it is possible to plan preoperatively the optimal implant position using 3-D x-rays (digital volume tomogram, DVT) and computer software programs. The bone morphology can be studied three-dimensionally, allowing to measure bone height and width. The implant surgery is simulated before the actual intervention, which allows detecting possible difficulties such as bone insufficiency.

Based on the virtual planning, a drilling template is produced industrially to fully guide the drilling instruments and implant into the patient’s mouth.

The advantages from this protocol are the three-dimensional bone evaluation, preoperative virtual implant planning and the instrument guidance given by the surgical stent.

The disadvantages comprise higher costs and the higher x-ray exposure levels. Further advantages and disadvantages of these two methods are currently investigated in our clinic. Your contribution will help us to better evaluate the value of these two methods.

Please select which of the two methods would you prefer.