Project Deliverable

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Abstract:

Aims
The aim of this deliverable was to report the clinical research that was performed in WP4 on the following applications: Implant planning, Impacted third molars, Impacted canines, Sinus grafting.

Materials and methods
For all studies a number of observers were confronted with 2D and 3D images they needed to assess. Also the surgeon responded to several questions, during surgery. A post-surgical questionnaire was filled in as well.

Both quantitative (measurements) and qualitative (multiple choice) questions were addressed.

Results
The result that can be generalised over the different clinical applications is the significant increase of the confidence of the observers in having enough information to start a treatment.

When planning implants, the implant chosen on CBCT was shorter than the implant chosen on 2D by the same observers. Moreover, surgical events could be better predicted based on CBCT images.

For the patient group in the current study on impacted third molars, we could not find significant differences in using 2D or CBCT images in surgical planning.

When planning impacted canine surgery, the division between oral and vestibular position could better be made with CBCT images than with 2D images, which directly influences the surgical approach and therefore efficiency. Moreover, the observers shifted in their treatment opinion from extraction to conservative treatment when confronted with CBCT images after the 2D images. Surgical events during canine surgery were better predicted with CBCT images. Finally, a scoring for treatment difficulty was used, where observers judged that a score > 1 required CBCT imaging.

There were no treatment planning differences between CBCT and 2D images for

sinus grafting procedures. The volume to be grafted could be well-planned before the surgical intervention using CBCT.

Conclusions

We can conclude from this work package that CBCT gives more confidence to surgeons before starting a treatment. Surgical events could be more easily predicted using CBCT imaging. This, in its turn, influences the efficiency and safety of the surgical intervention.

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1. The Context

1.1 SEDENTEXCT Aims and objectives

The aim of this project is the acquisition of the key information necessary for sound and scientifically based clinical use of dental Cone Beam Computed Tomography (CBCT). In order that safety and efficacy are assured and enhanced in the 'real world', the parallel aim is to use the information to develop evidence-based guidelines dealing with justification, optimisation and referral criteria and to provide a means of dissemination and training for users of CBCT. The objectives and methodology of the collaborative project are:

1. To develop evidence-based guidelines on use of CBCT in dentistry, including referral criteria, quality assurance guidelines and optimisation strategies. Guideline development will use systematic review and established methodology, involving stakeholder input.

2. To determine the level of patient dose in dental CBCT, paying special attention to paediatric dosimetry, and personnel dose.

3. To perform diagnostic accuracy studies for CBCT for key clinical applications in dentistry by use of in vitro and clinical studies.

4. To develop a quality assurance programme, including a tool/tools for quality assurance work (including a marketable quality assurance phantom) and to define exposure protocols for specific clinical applications.

5. To measure cost-effectiveness of important clinical uses of CBCT compared with traditional methods.

6. To conduct valorisation, including dissemination and training, activities via an 'open access' website.

At all points, stakeholder involvement will be intrinsic to study design.

1.2 Work package 4 (WP4) objectives

The overall aim of this work package is to assess diagnostic accuracy for CBCT for key clinical applications in dentistry. To achieve this goal, several sub-objectives needed to be reached:

1. To determine in vitro the segmentation, linear and/or diagnostic accuracy of various CBCT scanners versus MSCT (WP 4.1)
2. To assess the diagnostic accuracy of CBCT in an animal model (WP 4.2)
3. To determine the diagnostic accuracy of various CBCT scanners for specified clinical applications (WP 4.3)

1.3 Anticipated impact of the work

This section describes the impact of the work in this Work Package as anticipated at the start of the project.

The impact of the work that has been reached to date is the stimulation of discussions during congresses, consortium meetings and board meetings of several organisations. This directly affected the stakeholder group of the research community. We hope, with the publications ahead, to reach even more members of this group and to offer the members directions for further research on the topic.

The publications, to be submitted within the first half of 2011, are the first key performance indicator. As limited evidence existed for the diagnostic usefulness of CBCT, this is what we have tried to overcome for key clinical applications of CBCT in dentistry. Other than this, the results to date were presented at international conferences and research meetings.

Another key performance indicator would be the consensus amongst stakeholders on the rational use of CBCT. In this respect, a consensus meeting has been planned in May 2011 in Warsaw, between the European Association of Osseointegration (EAO), the SEDENTEXCT consortium, the European Academy of Dentomaxillofacial Radiology (EADMFR) and the Computer Aided Implantology Academy (CAIA). The meeting will deal with guidelines on preoperative imaging for implant placement and will be followed by other meetings on other applications of CBCT.

As such, with this clinical work package we hope to have contributed to guidelines for specific indications and stakeholder groups. This contribution should be spread to the national guidelines from radiation protection agencies and European guidelines specifying CBCT-users. Another impact this workpackage could have in the future is the decision on reimbursement of CBCT imaging for specific indications by social security.

Summary of expected impact:

Stakeholder(s)	**Impact**
Consortium partners	Continuing consultation among partners
Research community	Journal papers published Directions for future research
Oral & maxillofacial surgeons, dentists	CBCT optimisation & justification Guidelines
Patients	Protected due to scientific background. More informed
Manufacturers	Being aware of a justification need, also to be used in marketing
Social security	Reimbursement of specific indications justified by the workpackage work

1.4 Current state of the art

The current literature on clinical applications of CBCT is filled with case reports, non-systematic reviews and opinion led papers. There are few (*in vivo*) prospective diagnostic accuracy studies.

This being said, it is not obvious to perform diagnostic accuracy studies in this field of research. The use of randomised controlled clinical trials is not always feasible from an ethical point of view. Moreover, *in vivo* studies in radiology do not easily allow the use of gold standards. Therefore, the question in this type of research is whether it is better to use terms such as surgical and/or therapeutical outcome instead of diagnostic accuracy, which ends with the diagnosis.

A short overview is given below on the research context for each of the clinical applications studied in this work package.

1.4.1 Implant planning and placement

The preoperative planning of implant placement is one of the main categories for which clinicians turn to cone beam computed tomography (CBCT). A thorough evaluation of the receiving bone can be achieved with the technique. For certain more advanced procedures, the images can even be used additionally to manufacture surgical guides. In the past, when tomographic images and/or 3D reconstructions were deemed necessary, patients were often referred for multi slice spiral CT (MSCT). Although it was proven that the availability of 3D data allowed less complications to occur (Jacobs et al 1999a), a decision was not lightly taken, because of its impact: radiation dose, cost, practicalities. Alternatively linear or spiral tomography was applied, allowing some cross-sectional views but not more than a few slices (Bou Serhal et al 2000). With the availability of CBCT equipment, the decision to obtain a scan is carrying less weight, because of the lower radiation dose and extending availability of the equipment. Furthermore, the 3D volumetric dataset could allow a true planning of implant placement and even provide information on transfer to surgery (Vercruyssen et al 2008). This type of strategy has been demonstrated to be efficient, yet clear benefits of this planning over a conventional 2D planning has not been demonstrated. Although this might be evaluated via a true randomised controlled trial, implant surgery involves far too many patient-related and prosthetic-related variables to be able to have a proper control group.

To answer the question “Is it justified or necessary to obtain CBCT images for all or most of implant cases?” we have therefore performed a study on planning and surgical outcome of oral implant placement.

1.4.2 Impacted third molars

In previous studies, the prevalence of damage to the IAN during lower third molar surgery has been reported as varying from 0.4% (Sisk et al 1986) to 8.4% (Lopes et al 1995). Panoramic radiographs are most commonly used to describe the anatomic relationship between the IAN and the roots of the third molar teeth. Clinicians have suggested imaging features on panoramic radiographs to indicate an association with IAN injury (Kipp et al 1980, Sedaghatfar et al 2005). While a presurgical assessment should help in defining the location and relationship of impacted teeth, the radiological features for this have not been well identified with new diagnostic imaging procedures. In this regard, systematic review on the diagnostic efficacy of cone beam CT (CBCT) for impacted teeth and associated features showed that only a few studies were performed in this area (Horner et al 2009, Guerrero et al 2010). The number of studies that visibly define diagnostic accuracy criteria for CBCT was even sparser, with only two identified (Tantanapornkul et al 2007, Ghaeminia et al 2009).

The present study was conducted to compare the diagnostic accuracy of CBCT with that of panoramic radiography in assessing the mandibular canal before removal of impacted lower third molars.

1.4.3 Impacted canines

In case of delays in the course of eruption of canines, the role of radiological examination is to determine the presence of this tooth, its position and spatial context. Also, the radiological examination should help clinicians to assess the chances of normal eruption or making an adequate therapeutic plan to bring the canine tooth on the arcade.

Using CBCT to assess the position of the impacted canine, we can obtain a three-dimensional representation of the intraosseous canine position included in the virtual model of the dental arch. Chaushu et al, 2004, show that CBCT presents a clear benefit in the evaluation of impacted canines and recommend routine use of this method for patients requiring orthodontic treatment.

Most of the existing studies have compared the difference between conventional radiology and CBCT, showing that the latter is superior to conventional radiology for assessing the exact intraosseous position of the impacted canines (Walker et al 2005). Haney et al, 2010, evaluated the difference between sets of 2D and CBCT examinations, showing that there is a discrepancy between the two examinations in the assessment of both of the position of the impacted canine and the type of treatment chosen. Until now it is however not clear what the influence is of a correct assessment of the canine position on the management of impacted canines and on the prognosis after treatment.

Another important factor to be considered in treatment planning is the spatial context of impacted canines with adjacent teeth and the presence of external root resorptions. In the available literature, the accuracy for determining the relationship between impacted canines and the adjacent tooth is not well investigated with regard to the difference between CBCT and lateral skull radiography. Nor has it been done for the implications of determining this relationship for therapeutic management. Alqerban et al (2009) have shown high accuracy in *in vitro* studies comparing CBCT results to panoramic radiography in detecting external root resorption of adjacent lateral incisors next to the canines. In addition, Liedke et al (2009) showed that the accuracy of detecting external root resorptions did not differ significantly by varying voxel size. Although some studies have proven the benefit of CBCT in diagnosing root resorption, we are limited mostly to *in vitro* studies. It is now necessary to evaluate to what extent the (degree of) resorption of incisors influences the treatment of impacted canines.

The determining factors for the length of the treatment for orthodontic alignment has been investigated by several authors. Nieri et al (2010) make a correlation between the position of impacted canines, their angle, the distance from the plane of occlusion and duration of orthodontic treatment, using Bayesian network analysis. They show all of these factors to be significantly correlated. Fleming et al (2009) show that the major factor determining the duration of orthodontic alignment treatment is the distance between the canine tooth cusps and the maxillary midline, while the initial angle and the apex position of the canine does not significantly influence the length of the treatment. The above mentioned studies were conducted on canine position analyses using 2D X-ray analysis and models. In 2009, Kau et al. published a study attempting to estimate the prognosis in case of impacted canine treatment based on CBCT quantifying of the position of the apex and tip of the impacted canines. Based on this, a novel method of analysing impactions using cone beam imaging was proposed. This method utilizes the entire three views of a CBCT image.

A focus of research is needed on the three-dimensional measurement of impacted canine conditions (position, relation, ridge morphology). With an updated quantification of this condition, it might be possible to develop evidence-based treatment advice and/or a prognostic scale.

1.4.4 Sinus grafting

When there is insufficient bone in the upper jaw for dental implants to be placed, a sinus lift is recommended. A variety of filling materials and methods is possible for this procedure: autogenous bone graft or allogenic bone graft, with or without additional materials such as platelet-rich plasma to harden the bone or human-recombinant bone morphogenetic protein to stimulate bone formation. Regardless of the material or surgical technique used for a sinus lift, a preoperative clinical and radiological examination should take place for appropriate.

The preoperative radiologic examination allows the surgeon to measure accurately the dimensions of the existing bone and the morphology of the jaw and the maxillary sinus. Esposito et al (2010a and 2010b) conducted a Cochrane Review and concluded that it is still unclear when sinus lift procedures are necessary. Many studies show that short implants (5 mm) can successfully be loaded in maxillary bone with a residual height of 4 to 6 mm, but their long-term prognosis is still unclear. If sinus lift surgery is decided, it is necessary to evaluate the donor site and to estimate the volume of necessary bone graft.

For a sinus lift with autologous bone graft, the donor site needs to be assessed. The use of cross-sectional imaging is particularly useful to measure the size of the bone ridge from which the bone should be grafted. Several authors have shown the benefit of 3D imaging, in combination with dedicated software, to assess both donor site and the site to be elevated (Rodriguez-Recio et al 2010, Buyukkurt et al 2010, Arias-Irimia et al 2010).

Conditions that might be justified the routine use of CBCT in sinus lift planning are the detection of sinus mucosal inflammatory changes and sinus septa. The presence of sinus inflammation is an absolute contraindication for surgery. The presence of sinus septa can interfere with the sinus opening technique and predisposes to an increased risk of sinus mucosa perforation due to its adherence. Many studies have shown a high incidence of sinusal septa (Rosano et al 2010).

Although the previous mentioned studies are relevant to the use of CBCT in sinus lift surgery planning, the comparison between CBCT and conventional methods as such has not been made yet.

1.5 Deliverable D4.4

Deliverable D4.4 is the final deliverable of SEDENTEXCT Work Package 4. The objects of deliverable D4.4 are:

- To summarise earlier work
- To describe new work in this Work Package in the last period. The purpose of this work is to report the processed data of clinical research in WP4.
- To describe the possible impact of work in this Work Package
- To outline dissemination plans and possible future work

2. Earlier Work in WP4

WP4 began with a number of in vitro studies to evaluate the diagnostic accuracy of CBCT.

2.1 WP4.1

In WP4.1, skulls were used to evaluate the diagnostic accuracy of CBCT. WP4.1 dealt with three types of accuracy: segmentation accuracy, linear accuracy and diagnostic accuracy. These accuracy types were further investigated as follows (full report in Deliverable 4.2):

Segmentation accuracy

Surface: a methodology was developed to evaluate and compare the ability of CBCT to accurately provide 3D surface models of jaw bone.

Trabecular structure: a methodology was developed to evaluate and compare the ability of CBCT to provide an accurate description of trabecular bone.

Linear accuracy

Observers performed linear measurements on CBCT images taken at various image settings. We could not find performance differences for these various settings. This is an important results towards image quality – dose balance and thus towards CBCT justification and optimisation.

Diagnostic accuracy

The detection level for bone lesions with CBCT was investigated with an observer study. Detection levels varied for the six CBCTs tested. The lowest detection level was 0.175mm.

The detection level for root lesions (simulated root resorption) with CBCT was investigated with an observer study. The 6 CBCTs tested performed equally well.

2.2 WP4.2

In WP4.2, an *in vitro* animal study was used to evaluate diagnostic accuracy. WP4.2 dealt with the detection of bone lesions of different types in pig jaw bone. The results are described in short below and can be found in detail in Deliverable 4.1.

The aim of WP4.2 was to assess diagnostic accuracy for bone lesion identification in an animal model. This aim was addressed by two main studies.

The variables assessed in the first study were lesion size, tooth type, field of view (FOV) and cone beam CT. FOV did not seem to have an influence on accuracy. Lesion size was the clearest determinant of sensitivity, with CBCT system dependent detection thresholds. Accuracy was much higher in permanent teeth than in deciduous teeth.

In the second study, linear measurements of lesions of different size in different locations were assessed. Measurements were compared to microscopic measurements on the samples. Furthermore, CBCT images were compared to MSCT images. CBCT images were suitable for detection of sub-millimetre defects, while MSCT images were not. Linear measurements gave less measurement errors for CBCT images than for MSCT images, when compared to stereomicroscopy. Sensitivity was greater on CBCT examinations with a small FOV compared with medium or large FOV. CBCT could detect smaller bone defects than MSCT.

2.3 Output to date

The following presentations and publications were based on the above-mentioned research.

- Baçiut M, Hedesiu M, Baçiut G, Nackaerts O, Jacobs R, Horner K. The accuracy of CBCT in the assessment of artificially induced periapical bone lesions for deciduous and permanent teeth. Presented at the 17th International Congress of Dentomaxillofacial Radiology. 28 June - 02 July, 2009, Amsterdam, The Netherlands
- Hedesiu M, Baçiut M, Bran S, Nackaerts O, Jacobs R, Horner K. CBCT accuracy for detection and measurement of bone defects – a comparative study with stereomicroscopy as a gold standard. Presented at the 17th International Congress of Dentomaxillofacial Radiology. 28 June - 02 July, 2009, Amsterdam, The Netherlands
- Martens S, Guerrero ME, Nackaerts O, Jacobs R, Hedesiu M, Baciut M, Horner K. Radiographic detection of artificial bone lesions in an in vitro mandible. Presented at the 17th International Congress of Dentomaxillofacial Radiology. 28 June - 02 July, 2009, Amsterdam, The Netherlands
- Willems D, Van Bogaert P, Liang X, Pauwels R, Pattijn V, Dhoore E, Jacobs R. A comparative evaluation of CBCT vs MSCT for jaw bone model accuracy. Presented at the 17th International Congress of Dentomaxillofacial Radiology. 28 June - 02 July, 2009, Amsterdam, The Netherlands
- Nackaerts O, Oliveira C, Lambrichts I, Horner K, Jacobs R. Density and morphology of jaw bone assessed in 2D and 3D imaging methods. Presented at the 12th Congress of the European Academy of Dentomaxillofacial Radiology. June 2-5, 2010, Istanbul, Turkey.
- Alquerban A, Jacobs R, Nackaerts O, Fiews S, Willems G. A comparison of six cone beam computed tomography systems for the detection of simulated canine impaction-induced external root resorption in maxillary lateral incisors. Accepted for presentation at the 111th Congress of the American Association of Orthodontists. May 13-17, 2011, Chicago, USA
- Alquerban A et al. A comparison of six cone beam computed tomography systems for the detection of simulated canine impaction-induced external root

resorption in maxillary lateral incisors. *Publication ready for submission to American Journal of Orthodontics*

3. Work in the Final Period: Methodology

Sections 3, 4 and 5 of this deliverable report the work in WP4 in the last period. The purpose of this work is to report the processed data from clinical research in WP4. This section describes how the work was performed.

3.1 Bone quantification for preoperative planning of oral implant placement

Although the bone quantification work was reported in deliverable D4.3, it is included for convenience for the reader in this final deliverable on the clinical studies.

Fifty four patients (27 females, 27 males; mean (SD) age 51 (15) yrs) - were recruited at the Oral Imaging Center of K.U. Leuven and at the Department of Oral Radiology of “Iuliu Hatieganu University”, Cluj-Napoca. All patients were referred for imaging of the maxillofacial region in preparation for implant placement. Ethical approval for this study was obtained from the ethics committee at UZ KULeuven and the university of Cluj-Napoca, and informed consent was obtained from all patients. Only partially edentulous patients were included in the study. Imaging consisted of 2D (peri-apical radiographs and panoramic radiographs) and 3D imaging (CBCT scans). In Leuven, peri-apical radiographs were made with Minray (Soredex, Tuusula, Finland). In Cluj, panoramic radiographs were made with Instrumentarium OP100 (Soredex, Tuusula, Finland). The CBCT devices were Scanora 3D (Soredex, Tuusula, Finland) in Leuven and NewTom 3G (QR, Verona, Italy) in Cluj. Clinical settings, as recommended by the manufacturers, were used.

Six observers, all members of clinical university staff, participated in the study (5 maxillofacial surgeons and 1 dentomaxillofacial radiologist). With an interval of at least one month, the clinicians were asked to make an implant planning on the 2D and 3D image datasets respectively. A training session was organised for calibration and images were presented randomly. The software used for this planning in 2D and 3D was Digora (Soredex, Tuusula, Finland) and OnDemand 3D (Cybermed, Seoul, Korea) respectively.

The assessment form is attached as Appendix 1. Summarising this form, the observers needed to provide bone and implant properties and give an opinion on their confidence to perform surgery with the information available on the radiographs. For each observer the difference in planning decisions between 2D and 3D imaging was compared. Implants served as measurement units. To analyse the implant location on 2D and 3D planning, the McNemar test was used. For implant length and diameter, the distance between the planned implant and the nearest tooth/implant and the confidence levels, Wilcoxon’s test was used. For an answer to the question: “Can 2D and/or 3D predict complications during surgery?”, we used the X^2 test to compare proportions of agreement.

3.2 Presurgical assessment of tooth impaction – third molars

Forty five subjects (24 females, 21 males; mean (SD) age 25 (11) yrs), referred for surgical removal of impacted mandibular wisdom teeth to the Maxillofacial Surgery

Department of the University Hospitals Leuven were recruited. Ethical approval for this study was obtained from the ethics committee at UZ KULeuven, and informed consent was obtained from all patients. The exclusion criteria were both non riskful and too risky cases. The latter was assessed by a dentomaxillofacial radiology expert together with a maxillofacial surgeon. Cases at high risk were all referred for 3D CBCT diagnosis, and thus not included in the RCT to avoid bias. For the same reason, too simple cases, in which it was obviously sufficient to use panoramic images only (radiographic disconnection apices roots and canal, besides fully erupted wisdom teeth) were excluded.

Patients were randomly allocated to have either a panoramic radiograph or a CBCT scan. For panoramic radiography, a Cranex® Tome multifunctional unit (Soredex, Tuusula, Finland), was used. For CBCT imaging, Scanora® 3D (Soredex, Tuusula, Finland) was operated. A total of 54 impacted mandibular wisdom teeth in close relation to the mandibular canal were thus included with presurgical planning of third molar extraction and subsequent surgery being either CBCT- or panoramic-based. The intraoperative observations on the vicinity or relation of the mandibular canal to the wisdom tooth served as the gold standard for diagnostic accuracy. Radiologic observations were related to intraoperative data, reporting a variety of intraoperative measures on the local tooth-bone situation and any observed tooth-nerve contact and potential neurosensory disturbances.

During surgery, the surgeon observed whether the inferior alveolar nerve was exposed. The following variables were recorded in all patients: age, gender, the position of the third molar, development of the root, number of roots, root morphology, contact of the third molar to the second molar, and IAN (inferior alveolar nerve) exposure.

Seven days postoperative, the presence of dysesthesia was assessed. In the present study, neurosensory disturbances of the lip and chin were assessed before surgery and during the post-operative recall by measuring the function of the IAN with light touch sensation using the original Semmes-Weinstein Aesthesiometer® (Stoelting Company, Wood Dale, USA) device. To determine the threshold level the staircase method was applied and eight maximum and eight minimum values were recorded, as described by Jacobs et al (2002). The neurosensory testing of all patients was carried out by two calibrated investigators.

Three observers (postgraduate trainees in dentomaxillofacial radiology at the Oral Imaging Centre) evaluated all of the images independently. Images were viewed in a darkened room on a Dell Precision® 690 (1600x1200p). Two training sessions for calibration of the observers were organized prior to the final observations. The CBCT images were viewed with the OnDemand3D software (Cybermed Co, Seoul, Korea).

Appendix 2 shows the information that was collected for all patients on panoramic radiographs and CBCT images. In short, the following parameters were evaluated: the position of the IAN in relation to the third molar, development of the root, number of roots, and root morphology. For panoramic radiographs the following radiographic signs were assessed: interruption of the white line of the mandibular canal wall; radiolucent band; root deviation; narrowing of the mandibular canal; narrowing of the roots; superimposition of the roots. For the CBCT images, 2 items were determined:

thinning of the cortex by the root and/or the mandibular canal and the position of the IAN in relation to the tooth.

Predictive values of panoramic and CBCT findings were compared with the intraoperative observations. Fisher's exact and X^2 tests were used to assess the difference between both. P values less than .05 were considered statistically significant. Sensitivity, specificity, positive and negative predictive values, and accuracy of each imaging technique in predicting neurovascular bundle exposure were calculated. Kappa values were also calculated for inter- and intra-observer agreement.

3.3 Presurgical assessment of tooth impaction – canines

Thirty subjects (16 females, 14 males; mean (SD) age 25 (14) yrs) with impacted canines were recruited at the university hospital of Cluj-Napoca. In total, 39 impacted canines were evaluated (31 maxillary canines, 8 mandibular canines). The protocol of examination was approved by the ethics committee of UZ KULeuven and Cluj-Napoca University.

Inclusion criteria were the observation of impacted canines on a panoramic radiograph and following clinical examination, age over 11 years and the treating orthodontist's referral for CBCT examinations. Exclusion criteria were impacted canines associated with tumour processes, cleft palate, cranial deformities and bone lesions related to other diseases.

Panoramic radiographs were taken with Instrumentarium OP100 (Tuusula, Finland). The images were analysed with Digora software (Soredex, Tuusula, Finland). CBCT analyses were conducted using a NewTom 3G (QR, Verona, Italy). The images were analyzed with NNT software (ImageWorks, Elfmsford, NU, USA). Six examiners, 2 radiologists and 4 orthodontists were involved. Panoramic and CBCT images were anonymized and presented in random order to the examiners with a 6 weeks interval between the 2D and 3D images. The reference therapeutic decision for each case in this study was made by a specialist in orthognatic surgery and an orthodontist, based on clinical examination, a set of 2D radiographs, the CBCT examination and the study model. Together, they accomplished the therapeutic plan, and completed the case file of the patient. The protocol completed for each patient is added as Appendix 3. In short, the following parameters were observed for 2D and 3D images: observer's confidence in successful treatment, treatment options, canine position, resorption of neighbouring teeth roots and linear measurements. During surgery, comparable observations were made by the treating surgeon, as well as the registration of unexpected events. A short post-operative questionnaire asked the patient about pain, swelling and other complaints.
For statistical comparison, X^2 tests and contingency coefficients were used. Continuous data were analysed with the paired samples t-test. To evaluate the diagnostic accuracy of resorption, sensitivity and specificity were calculated.

3.4 Presurgical assessment and post-operative follow-up of sinus grafting procedures

Thirteen subjects (9 females, 4 males; mean (SD) age 50 (12) yrs) were examined prior to sinus grafting surgery using panoramic radiography and CBCT examination. Fourteen lateral upper maxilla were assessed for sinus lift planning. Eleven patients were postoperatively examined with CBCT after ridge augmentation.

Preoperative panoramic radiographs were taken with the Rotograph Plus (Imageworks, Elfmsford, NU, USA). Preoperative CBCT scans were made with Newtom 3G (QR, Verona, Italy). The images were assessed by 6 examiners: 1 radiologist and 5 specialists each with more than 5 years of experience in implant surgery.

The protocol for the image assessment is added as appendix 4. In short, preoperative image assessment included: choice of treatment, timing of implantation, level of confidence, surgeon's opinion on CBCT usefulness, sinus morphology, expectation of complications during surgery.

Other than the previous assessments, the accuracy of CBCT for sinus lift volume estimation was analysed for 11 patients. The observers measured size (height, diameter, length) and volume of the planned sinus lift.

Surgical and postoperative assessment included: type of treatment, planning deviation, time of surgery, intraoperative complications, clinical signs, postoperative size and volume of sinus lift using CBCT images. For the latter assessment (size and volume), two examiners (1 radiologist and one implant specialist) simulated the sinus lift deemed necessary using Surgicase 5.1 software (Materialise, Haasrode, Belgium).

X^2 tests (categorical data) and paired samples t-tests were used to evaluate the difference between 2D and 3D groups.

4. Work in the Final Period: Results

4.1 Bone quantification for preoperative planning of oral implant placement

Out of the 54 patients, 3 decided not to go through with implant surgery. The total number of patients was therefore reduced to 51. A total of 220 implant locations were evaluated.

Implant location

In an Excel table, one column was constructed with all answers on possible implant locations from all observers, based on 2D images. The second column contained the answers from all observers, based on 3D images. We found an agreement 92% of the cases and disagreement in 8%.

For more elaborate analysis, we performed the McNemar test. The results of this test for comparing the implant location based on 2D and 3D imaging are shown below for each observer separately. This test evaluates whether there is a different proportion of implants planned on 2D images, compared to 3D images.

	Obs1	Obs2	Obs3	Obs4	Obs5	Obs6
Difference in proportion	2.2%	9.0%	2.7%	0.5%	3.2%	2.2%
Confidence interval	1.94 to 5.14	3.15 to 12.87	0.58 to 3.58	4.27 to 5.16	2.63 to 8.32	0.44 to 2.23
p-value	0.39	0.003	0.13	1	0.33	0.13

Overall, there does not seem to be a difference between the choice of implant location based on 2D and on 3D images.

Implant length

In an Excel table, one column was constructed with all answers on implant length from all observers, based on 2D images. The second column contained the answers from all observers, based on 3D images. We found the same length in 31% of the cases. 41% of planned implants were longer on 2D and the remaining 27% was shorter on 2D planning.

The table below shows the results for the Wilcoxon test for paired samples. A positive difference in this context means that a longer implant was chosen based on the CBCT planning. A negative difference results from a shorter implant based on CBCT planning than the implant chosen based on a 2D planning.

	Obs1	Obs2	Obs3	Obs4	Obs5	Obs6
Median 2D_3D	12_12	12_12	11_10	11_10	11_12	11_10
Positive difference	16	15	37	40	103	23
Negative difference	24	30	106	102	39	65
p-value	0.23	0.03	<0.0001	<0.0001	<0.0001	<0.0001

Except for observer 1, all observers choose different implant lengths based on 2D and 3D images. Mostly, a shorter implant is chosen based on 3D images.

Implant diameter

In an Excel table, one column was constructed with all answers on implant diameter from all observers, based on 2D images. The second column contained the answers from all observers, based on 3D images. We found the same diameter in 52% of the cases. 22% of planned implants were more narrow on CBCT and the remaining 26% was wider on CBCT planning.

The table below shows the results for the Wilcoxon test for paired samples. A positive difference in this context means that a wider implant was chosen based on the CBCT planning. A negative difference results from a narrower implant based on CBCT planning than the implant chosen based on a 2D planning.

	Obs1	**Obs2**	**Obs3**	**Obs4**	**Obs5**	**Obs6**
Median 2D_3D	4.1_4.1	4.1_4.1	3.8_3.8	3.8_3.8	4_4.1	3.8_3.5
Positive difference	12	57	48	38	101	44
Negative difference	18	7	71	104	38	51
p-value	0.47	<0.0001	0.53	0.0001	0.003	0.05

Differences between implant diameters are present but very small. Based on these results, we cannot draw a general conclusion on the difference in implant diameter chosen based on 2D and 3D images.

Distance implant – neighbouring element

The table below shows the results for the Wilcoxon test for paired samples. A positive difference in this context means that the distance between the implant and its neighbouring element was higher on the CBCT planning than on 2D planning. The opposite is true for a negative difference.

	Obs1	Obs2	Obs3	Obs4	Obs5	Obs6
Median 2D_3D	6.8_7.23	6.4_6.29	6.3_7.2	6.4_6.42	5.9_5.6	5.19_5.80
Positive difference	74	61	87	78	57	70
Negative difference	61	78	58	67	83	57
p-value	0.12	0.07	0.0007	0.76	0.02	0.29

Differences are very small and not clinically relevant.

Surgeon's confidence

The tables below shows the results for the Wilcoxon test for paired samples. A positive difference in this context means that the rating for CBCT was higher than for 2D. The opposite is true for a negative difference.

For more convenient interpretation of the table, the question and answers are repeated below.

How confident are you that you can perform the implant surgery only with these images?
1=Very confident; 2=Confident; 3=No opinion; 4=Doubtful, unsure; 5=Very doubtful, unsure

	Obs1	**Obs2**	**Obs3**	**Obs4**	**Obs5**	**Obs6**
Median 2D_3D	3_2	4_2	2_2	3_2	3_2	3_2
Positive difference	0	0	6	15	32	35
Negative difference	100	130	84	79	86	53
p-value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.39

To analyse whether there was a different opinion, depending on the region of implant placement, we created the table below.

	Observers' confidence	
	2D	**3D**
Upper frontal	2.9	1.9
Upper central	3.4	2.2
Upper lateral	3.5	2.2
Lower frontal	3.3	1.8
Lower central	2.9	1.8
Lower lateral	3.0	1.7

The table shows the best results for the lower lateral area and the most insecure results for the upper lateral and upper central area of the mouth.

Surgical events

We calculated the agreement between the observers' opinion on uneventful surgery and the actual surgical report. Surgical events could be: dehiscence, fenestration, sinus perforation, mandibular canal perforation, malpositioning. For 2D images this agreement was 34% and for 3D images 54%. The X^2 test for the comparison of these proportions gave a p-value of 0.002.

4.2 Presurgical assessment of tooth impaction – third molars

Interobserver agreement was excellent for CBCT, showing a k-value of 0.7 for the bucco-lingual position of the mandibular canal, 0.86 for the position of the third molar, 0.67 for the root development and 0.68 for the number of roots. For panoramic images, agreement ranged from fair to excellent: 0.62 for the bucco-lingual position of the mandibular canal, 0.78 for the position of the third molar, 0.67 for the development of the root, 0.84 number of roots, 0.72 for the interruption of the white line, and 0.56 for superimposition of the root.

The IAN was exposed in 13 out of 54 extractions (24%). Post-operative dysesthesia occurred in 2 patients (4%). Both patients regained sensitivity within three months. Also, one patient reported postoperative taste disorders, which improved within one week. After third molar extractions, the IAN was exposed in 5 out of 7 cases showing a lingual mandibular canal location on pre-operative images. Thinning or perforation of the cortex could be seen on CBCT in 8 out of 10 teeth in which the inferior alveolar nerve was visible at the time of the surgical procedure (p=0.03).

None of the panoramic radiographic signs could statistically be associated with IAN exposure. The diagnostic accuracy of panoramic radiography and CBCT in predicting IAN exposure is given in the table below.

Technique	TP	TN	FN	FP	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
CBCT	10	5	0	12	100	29	46	100	56
Panoramic	3	6	0	18	100	25	14	100	36

TP: true-positive; TN: true-negative; FN: false-negative; FP: false-positive; PPV: positive predictive value; NPV: negative predictive value

In addition, radiologic observation results were related to the intraoperative data for each patient group. No significant differences were found between CBCT and panoramic radiographs in predicting canal and tooth properties. Both techniques allowed an equally good prediction of the position of the third molar. The 3D technique showed a slightly better result for the assessment of the root development, the number of roots and bifurcation of the tooth, but this result was not found to be statistically significant. Root morphology could not be predicted well on either imaging type.

4.3 Presurgical assessment of tooth impaction – canines

Canine position (qualitative): sagittal plane, axial plane, level of impaction

In the table below, an overview is given of the canine positions detected in panoramic images, CBCT images and during surgery.

Canine crown position in sagittal plane	**2D (%)**	**CBCT (%)**	**Surgery (%)**
central	15	22	18
oral	55	58	61
buccal	30	20	18
Canine crown position in axial plane	**2D (%)**	**CBCT (%)**	**Surgery (%)**
high	31	30	30
medium	20	40	44
low	52	34	27
Canine impaction level	**2D (%)**	**CBCT (%)**	**Surgery (%)**
partial eruption	6	17	16
soft tissue impaction	26	23	24
complete bone impaction	68	60	58

To assess the existing differences between the position of the canines assessed on panoramic radiographs and on CBCT, compared with the real position determined during surgery, a X^2 test was applied. The results show a strong correlation between 2D images and 3D images in the classification of the canine position compared to the position determined intraoperatively.

Differentiating a vestibular position from an oral position of the canine crown has great clinical importance: based on this position, the surgeon decides the best option for a surgical approach. Comparing panoramic and CBCT images for the classification of vestibular and oral position of the canines, we saw that 25% of the panoramic X-ray readings and 8.3% of the CBCT readings gave a reversed classification of the crown position compared to what was found during surgery: oral crown position classified on the images as vestibular and vice versa.

Canine relation to adjacent teeth

The analysis of the relationship of the impacted canine with the roots of adjacent teeth showed a predominance of direct or follicle contact with the lateral incisor, detectable on both 2D and 3D methods (Figure 1). The contacts were more frequently detected on CBCT examination compared with panoramic images: 38% and 29% respectively.

Comparing CBCT and panoramic radiographs in their respective ability to detect any direct (or follicle) contact, we found a statistically significant correlation between the two examination types for contact with the lateral incisor ($p<0.001$) but not for contact with the first premolar or the central incisor ($p=0.12$ and $p=0.23$ respectively).

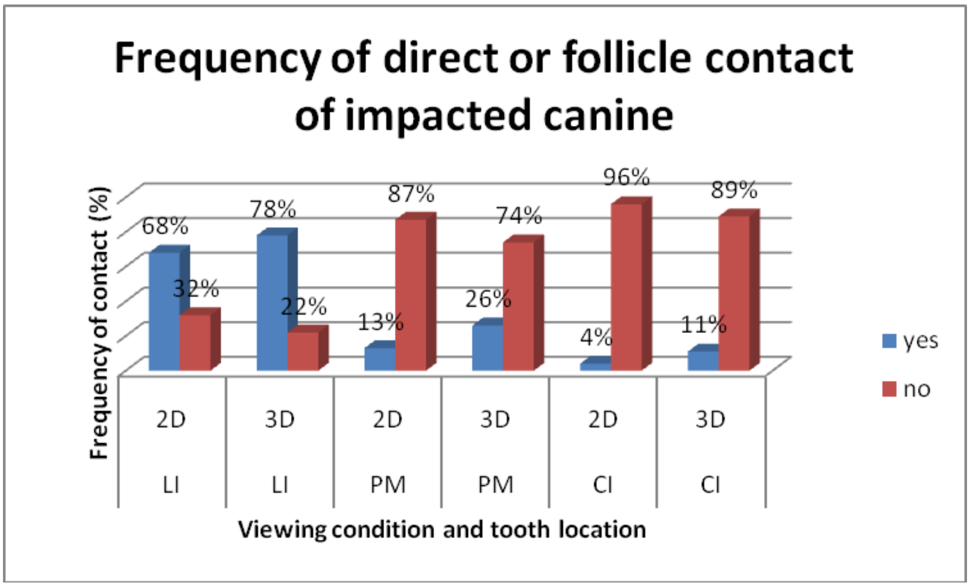

Figure 1: The frequency of impacted canine contacts with adjacent teeth
LI – lateral incisor, PM- first premolar, CI- central incisor

Root resorption

Root resorption was identified on CBCT in 10% of the observations. The sensitivity of 2D radiographs for root resorption identification was high when compared with CBCT (sensitivity was 0.9) and the probability of false negative results was very low (0.005). However, false positive probability was high for the 2D radiographs (0.7) (Table 1).

No root resorption that was identified on CBCT reached a level severe enough to change the therapeutic plan. In 5% of the cases the repositioning of the canines on the arch was performed without consequences and in the remaining 5% with root resorption of the lateral incisor, the impacted canine was extracted.

Table 1: Accuracy of 2D conventional radiography for root resorption using CBCT as reference examination

	Value	CI 95%
Prevalence	0.04	0.02 - 0.08
Sensitivity	0.90	0.54 - 0.99
Specificity	0.85	0.79 - 0.89
For any particular test result, the probability that it will be:		
Positive	0.18	0.13 - 0.24
Negative	0.81	0.75 - 0.86
For any particular positive test result, the probability that it is:		
True Positive	0.23	0.11 - 0.39
False Positive	0.76	0.60 - 0.88
For any particular negative test result, the probability that it is:		
True Negative	0.99	0.96 - 0.99
False Negative	0.005	0.0002 - 0.03

Treatment choice

Changes in the therapeutic plan occurred in 22% of the assessments after CBCT examination, more specifically the choice of treatment was more likely to be conservative (repositioning the canine) when CBCT images were used for the evaluation of the tooth. Going from 2D to 3D images, the percentage of decisions to extract the canine decreased by 6% and the percentage of decisions to reposition the canine on the arch increased by 6%. This shift in treatment decision could however not be proven statistically. During surgery, more canines were extracted than planned on 2D or 3D images (Figure 2).

Interexaminer variability of therapeutic planning was analyzed for the two types of imaging. Intraclass correlation coefficient showed that there was a good interrater agreement for both methods (ICC =0.7).

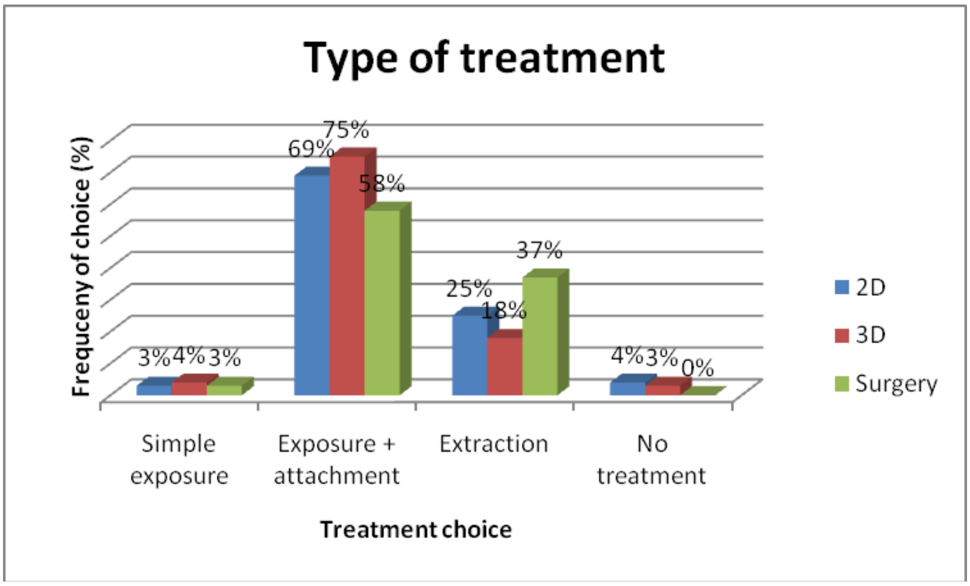

Figure 2: Type of treatment decided on panoramic radiograph, CBCT and during surgery

Confidence level

Examiners had high confidence on their therapy plan based on CBCT images (median 1) and only moderate confidence on their plan based on panoramic radiographs (median 4). This difference in confidence was statistically significant ($p<0.05$).

Although previous data did not result in a statistically significant number of changes to the therapeutic plan after evaluating CBCT images, examiners were asked whether the CBCT images had changed their therapy plan. Differences between 2D and CBCT treatment plans were found in 22% of the cases but the subjective impression of examiners was that CBCT examination changed their therapy plan in 48% of the cases (Table 2). This observation is important because it explains the higher degree of confidence when using CBCT images.

Table 2: Opinion of examiners about the change of treatment plan due to seeing CBCT images.

	Frequency	Percent
NO	119	52
YES	109	48

Confidence in the therapy plan was also influenced by the mesio-distal space and this confidence decreased more when the type of treatment was chosen on 2D radiological images (Figure 3).

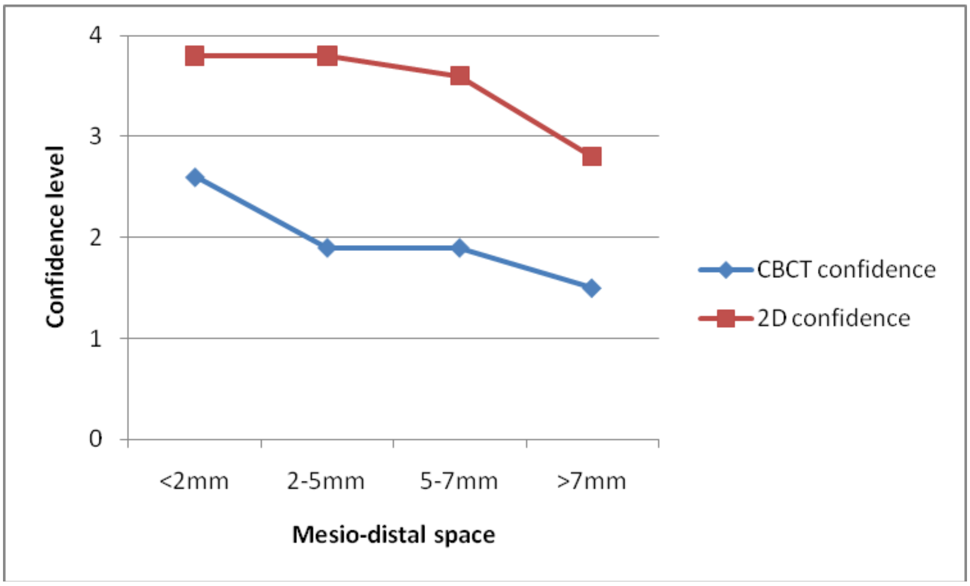

Figure 3: Mesio-distal space available and relation to confidence score
1=Very confident; 2=Confident; 3=No opinion; 4=Doubtful, unsure; 5=Very doubtful, unsure

Complication prediction

An overview of intraoperative complications is given in figure 4.

Complications occurred in 3% of the cases. The most common complication was “Contact of the drill with the canine root”. The X^2 test showed a statistically significant difference for the prediction of complications on both radiological methods compared to the actually occurring complications (Table 3).

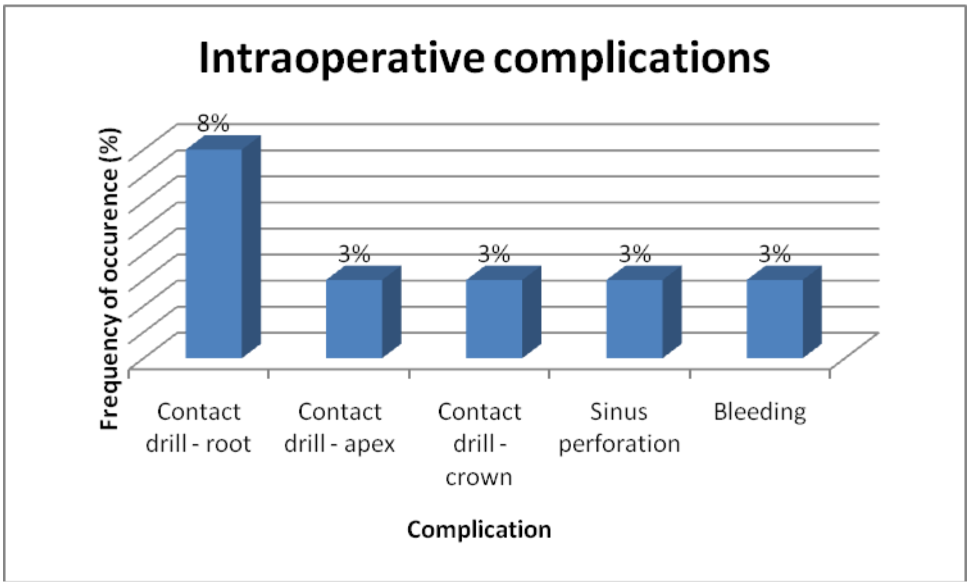

Figure 4: Frequency of intraoperative complications

Table 3: X^2 Tests for the difference between the complications predicted on 2D/CBCT compared and intraoperative complications

Complication 2D versus Surgery	
Pearson X^2	.05
Continuity Correction	.001
Complication CBCT versus Surgery	
Pearson X^2	.37
Continuity Correction	.19

Measurements on 2D and 3D

An overview of the measurement results is given in Table 4.

The mesio-distal space was measured from the distal face of lateral incisor to the mesial face of first premolar. The mean mesio-distal space on the alveolar crest measured intraoperatively was 5.5 ± 2.3mm. There were no statistically significant differences between the distance measured on 2D radiographs compared to the measurements on CBCT.

The tip position was measured by drawing the axis of the canine and measuring the distance from the tip of the crown of the impacted canine to the axis in a perpendicular direction. The mean distance was 5.6 ± 4.1mm on 2D images and 5.6 ± 4.0mm on CBCT. There were no statistically significant differences between the distance measured on 2D radiographs compared to the measurements on CBCT.

Apex position of the impacted canine was assessed by drawing a line through the ideal axis of the canine and measuring the distance from the apex of the impacted canine to this axis in a perpendicular direction. There were no statistically significant differences between the distance measured on 2D radiographs compared to the measurements on CBCT.

Table 4: Paired Samples Statistics for mean distances quantifying the canine position on 2D images and CBCT

	Mean	SD
2D mesio-distal space for the canine	5.22	3.12
CBCT mesio-distal space for the canine	5.35	3.07
Introperative mesio-distal space	5.48	2.32
2D Distance tip of canine to ideal axis	5.63	4.18
CBCT Distance tip of canine to ideal axis	5.69	4.08
2D Distance apex of canine to ideal axis	6.71	3.95
CBCT Distance apex of canine to ideal axis	6.73	4.16

Towards scoring treatment difficulty

The following parameters were used to determine a scale of treatment difficulty: mesio-distal space, distance tip of canine crown to ideal axis of canine, distance tip of canine to alveolar border and angle of the impacted canine with the midline.

Table 5: The score for radiological assessment of difficulty of orthodontic treatment

	MD space	Crown- ideal axis distance	Crown – alveolar border distance	Angle towards midline
Score 1 favorable	>7mm	0-3mm	Soft tissue impaction	0^0-15^0
Score 2 easy	5-7mm	3-5mm	Low position	15^0-30^0
Score 3 difficult	3-5mm	5-7mm	Medium	30^0-45^0
Score 4 very difficult	<3mm	>7mm	High	45^0-90^0

The examiners expressed their opinion about the usefulness of CBCT examination after their CBCT images assessment for each case. The difficulty score for each case was calculated based on the measurements performed on the CBCT images. Figure 5 shows that for score 1, the examiners generally assessed CBCT as useful but not necessary (83%). For score 2, CBCT was mostly found useful and necessary (50%). For 3 and 4, the CBCT was more often found mandatory than in the other difficulty categories (38% and 40% respectively).

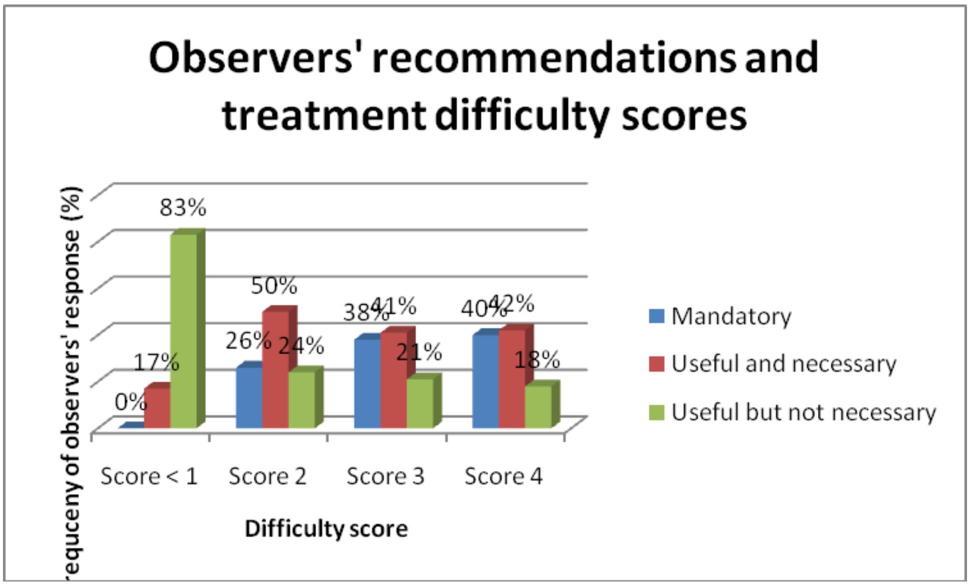

Figure 5: Observers' recommendations and treatment difficulty scores

4.4 Presurgical assessment and post-operative follow-up of sinus grafting procedures

4.4.1 2D vs 3D

Type of treatment

In most cases (96%) there was a concordance between the type of treatment established using panoramic images compared with the treatment chosen after CBCT images evaluation. The most frequent treatment option was a sinus lift with xenogenic bone graft. This choice was made in 82% of the cases. The CBCT images changed the surgeon's opinion regarding the type of treatment in 4% of the cases. Two "xenogenic bone graft" treatments that were planned using only panoramic radiographs were changed into "autologous bone graft" after CBCT examination, due to significant lack and low density of maxillary bone. In one case, the opinion changed from "no need for sinus lift" to "xenogenic bone graft" and delayed implantation. The surgeons opted for delayed implantation in 70% of the cases in both 2D and 3D planning. In only 2 cases an immediate implantation was changed for delayed implantation after having seen the CBCT images.

X^2 tests showed that there were no significant differences between the planning performed based on panoramic radiography compared with CBCT in terms of type of treatment or type of implantation. The contingency coefficient showed a good association between the type of treatment chosen based on panoramic radiographs and chosen based on CBCT images (Table 6) and for the type of implantation established on both imaging methods (Table 7) (Contingency coefficient >0.75)

Table 6: Concordance of the treatment planned using panoramic vs. CBCT images

Nominal by Nominal	Phi	1.587
	Cramer's V	.916
	Contingency Coefficient	.846

Table 7: Concordance of type of implantation using panoramic vs. CBCT images

Nominal by Nominal	Phi	1.214
	Cramer's V	.858
	Contingency Coefficient	.772

Confidence level

The Friedman test shows that there was a statistically significant difference between the examiners' level of confidence for planning the surgery using 2D radiographs or CBCT images. The mean score for the examiner confidence that the radiological images were giving them enough information to perform a treatment without complications was 3.5 for panoramic examination and 1.6 for CBCT. These results show a higher confidence for surgeons with CBCT images than with panoramic radiographs.

Sinus morphology (preoperative)

The assessment of sinus morphology using panoramic and CBCT did not show a significant difference between these two radiological methods (X^2 test Asymp. Sig >1). However, the results showed that 24% of sinus mucosal hypertrophy was not detected on panoramic radiographs and was visible only on CBCT examination. Also there was a 12% false positive result on the panoramic radiograph for sinus mucosal hypertrophy (Table 8). A percentage of 20% of sinus septa detected on CBCT examination were not mentioned by the examiners on the panoramic radiograph. Instead, there were 7% false-positive diagnoses for the presence of septa in maxillary sinus on panoramic radiographs (Table 9). Overview tables for diagnostic accuracy of sinus morphology with panoramic radiographs and CBCT are shown in table 10 and 11.

Table 8: Sinus mucosa hypertrophy – 2D vs. CBCT - Crosstabulation

Hypertrophy sinus mucosa		**CBCT**		**Total**
		no	**yes**	
2D	**no**	44	8	52
	yes	6	26	32
Total		50	34	84

Table 9: Presence of sinuses septa - 2D vs. CBCT - Crosstabulation

Intrasinusal septa		**Septa CBCT**		**Total**
		no	**yes**	
Septa 2D	**no**	64	3	67
	yes	5	12	17
Total		68	15	84

Table 10: the accuracy of panoramic radiography compared with CBCT for sinus mucosa hypertrophy diagnosis

	Estimated Value	**95% CI**	
		Lower Limit	**Upper Limit**
Prevalence	0.40	0.30	0.52
Sensitivity	0.76	0.58	0.89
Specificity	0.88	0.75	0.95
For any particular positive test result, the probability that it is:			
True Positive	0.81	0.63	0.92
False Positive	0.19	0.08	0.37
For any particular negative test result, the probability that it is:			
True Negative	0.85	0.71	0.93
False Negative	0.15	0.07	0.29

Table 11: The accuracy of panoramic radiography compared with CBCT for sinus septa diagnosis

	Estimated Value	**95% CI**	
		Lower Limit	**Upper Limit**
Prevalence	0.18	0.11	0.28
Sensitivity	0.8	0.51	0.95
Specificity	0.93	0.83	0.97
For any particular positive test result, the probability that it is:			
True Positive	0.71	0.44	0.89
False Positive	0.29	0.11	0.56
For any particular negative test result, the probability that it is:			
True Negative	0.96	0.87	0.99
False Negative	0.04	0.01	0.13

Usefulness

For 54% of sinus lift plannings, the examiners found that the preoperative CBCT exam was useful and necessary and even mandatory in 37% of cases. Only for 9% of the cases, the observers found that CBCT was useful but not absolutely necessary to be performed preoperatively.

4.4.2 CBCT accuracy for sinus lift volume estimation

Pair sample correlation showed that there was a statistically significant correlation between the volume of sinus lift planned using CBCT examination compared with the volume measured postoperatively (p=0.001) and that there was no significant difference between the values of these two volumes (p=0.22). The mean difference between the preoperative and postoperative volume was 0.24 +/- 0.67 cc with 95% CI [-0.16, 0.65] (Table 12).

In contrast, there were significant differences in the values of mesial-distal length of the estimated length of sinus lift compared with the length of performed sinus lift (p=0.005). Also, pre-operatively estimated height was not significantly correlated with the postoperative height of the sinus lift (p = 0.65).

Table 12: The difference between the volume and size of sinus lift planned using CBCT images compared with postoperative dimensions (Paired Samples Test)

	Paired Differences					t	p
	Mean	SD	SEM	95% CI			
				Lower	Upper		
volume-pre - volume-post	0.24	0.67	0.18	-0.16	0.65	1.30	0.22
H-pre - H-post	-1.88	3.40	0.94	-3.931	0.17	-1.99	0.07
L-pre - L-post	2.98	3.12	0.86	1.08	4.87	3.43	0.005
diam-pre - diam-post	-0.55	2.14	0.59	-1.84	0.74	-0.92	0.37

H = Height; L = Length; Diam = Diameter

4.4.3 The value of panoramic and CBCT examination in prediction of complications

Postoperative complications consisted in sinus infection (n=1), accidental perforation of the sinus mucosa (n=3) and dehiscence (n=1). Study results showed that neither the panoramic examination nor CBCT can be relied on to predict complications after sinus lift surgery. Their specificity in prediction of potential complications was 76% for conventional radiology and 73% for CBCT (Table 13 and 14).

Table 13: Complications estimated using panoramic radiography

	Estimated Value	95% CI	
		Lower Limit	Upper Limit
Prevalence	0.21	0.14	0.32
Sensitivity	0.72	0.46	0.89
Specificity	0.76	0.63	0.85
For any particular positive test result, the probability that it is:			
True Positive	0.45	0.27	0.64
False Positive	0.55	0.36	0.73
For any particular negative test result, the probability that it is:			
True Negative	0.91	0.79	0.97
False Negative	0.09	0.03	0.21

Table 14: Complications estimated using CBCT

	Estimated Value	95% CI	
		Lower Limit	Upper Limit
Prevalence	0.21	0.14	0.32
Sensitivity	0.56	0.31	0.78
Specificity	0.73	0.60	0.83
For any particular positive test result, the probability that it is:			
True Positive	0.36	0.19	0.56
False Positive	0.64	0.44	0.81
For any particular negative test result, the probability that it is:			
True Negative	0.86	0.73	0.93
False Negative	0.14	0.07	0.27

5. Work in the Final Period: Conclusions

5.1 Conclusions

5.1.1 Bone quantification for preoperative planning of oral implant placement

Implant location

The first step of implant planning is choosing the exact location of the future implant in the maxilla or mandible. Designating the right location on the alveolar crest is generally determined by the dimensions of the bone supposed to receive the implant. However this is not the only important factor. Of equal importance are the need for prosthetic rehabilitation and biomechanically balanced support depending on the type of treatment. Next to bone dimension, also bone quality is important (Ribeiro-Rotta et al 2010).

In the present study, only partially edentulous patients were included, which made the optimal location of the implant in many cases abundantly clear.

Our results showed that 92% of the implants had the same location on 2D and CBCT planning and only 8% of the implants had a different location in 2D and CBCT planning. For only one of the observers was there a statistically significant difference for the location of implants between their planning on 2D and CBCT.

In more complex cases, with large edentulous areas, the implant planning might target a fixed solution with a large number of crowns supported by the implants or, alternatively, a full prothesis placed on the implants. These options largely depend on the dimensions of healthy bone available as a basis for the implant, but also on a series of factors of a more subjective kind, such as the experience of the implantologist and the attitude of the patient versus one or the other therapeutic options. In the present study there were two situations with patients presenting large maxillary and mandibular edentulous areas, worsened by pronounced lateral resorption of the dental crest. In one of the cases, studied on 2D images, all examiners opted for the same implants, relying on a sinus lift to bring the crest to the desirable height. After having studied the CBCT images, three examiners changed their therapy plan, suggesting an overdenture solution for the entire maxillary area, reconsidering the number of the implants and their location. In another case two of the examiners chose the overdenture, based on the 2D planning, whereas based on the CBCT images, one more specialist gave up on the idea of a fixed solution, and decided for the overdenture option. Based on these examples, we assume that, for large edentulous areas, the choice of implant location or the therapeutical approach in general might well be influenced by the availability of 3D images. In the decision process, however, surgical experience and skills should not be underestimated as an important variable.

This might be explored in follow-up research involving edentulous patients and surgeons with and without (trainees) a specified years of experience.

Implant length

Our overall results revealed that only in 31% of implants, the implant lengths chosen by observers were the same on 2D planning as with CBCT planning. In 42% of the cases, the observers chose to place shorter implants based on CBCT images compared to 2D images. The remaining 27% stands for implants longer on CBCD planning than on 2D planning. The Wilcoxon test demonstrated a significant difference between the length of implants chosen on 2D images compared with the length planned on CBCT images in 5 out of 6 examiners. This might point to the importance of precise data on alveolar bone dimensions, to avoid damaging the mandibular canal of the maxillary sinus floor.

In these results we see a reflection of what can be found in the literature: Bone height, alveolar crest dimension and the identification of anatomically important structures can accurately be assessed on CBCT images (Fatemitabar et al 2010, Leung et al 2010, Lofthag-Hansen et al 2008).

The height of the alveolar crest can be estimated on a panoramic radiograph or on a periapical radiography as well. Estimating the proper implant length on these radiographs, based on the alveolar crest size, might be erroneous because of a pronounced angle of the alveolar crest or because of bone defects that are often invisible on the 2D images used. Another planning pitfall can be the mandibular canal, which is not always clear on 2D images, e.g. due to its lingual position (Mehra et al 2009). Nevertheless, Vazquez et al (2008) consider that panoramic radiography can be considered a safe pre-operative evaluation tool for routine implant placement in the posterior mandibular area under the condition that a safety margin of at least 2 mm is kept above the mandibular canal. The authors performed a study on the incidence of lesions involving the inferior alveolar nerve after placing implants relying only on panoramic radiography and a graduated implant scale provided by the implant manufacturer. Only in 2 cases out of 2584 there was permanent damage to the alveolar nerve (0.08%). Yet it should be mentioned that this problem was not objectivised by neurophysiologic testing and that these patient got a very simple implant treatment. Higher percentages, up to 17% of remaining altered sensation, were found by Abarca et al (2006) and Liang et al (2008).

Multiple factors influence the choice of implant length: the available height of alveolar bone and the angulation of the crest. Anyhow, reduced alveolar bone height does not necessarily impose a short implant because bone grafting can offer the extra height needed for an implant of optimal length. For some surgeons, the most important factor in implant planning is the length of the implant, which should guarantee stability, even if it means that a bone graft is required to obtain this. Other surgeons however, consider short implants satisfactory, e.g. in the (pre)molar area and are at ease to avoid in that way post-surgical risks introduced by the grafting procedure (Romeo et al 2010, Esposito et al 2010b). Evidently, the choice of the length of an implant is influenced by anatomical characteristics, but also by the surgeon’s personal opinion and experience and by the patient’s clinical condition. It is therefore difficult to get straightforward results on the difference between the implant length, based on 2D versus 3D planning. This finding coincides with the poor agreement in planning vs. surgery, found for both 2D and 3D preoperative planning, for the implant size (Jacobs et al 1999 a and b).

Implant diameter

Our overall results showed a concordance of diameter in 52% of implants (2D vs CBCT). In 22% of the cases, the observers chose to place more narrow implants based on CBCT images compared to 2D images. The remaining 26% stands for implants wider on CBCD planning than on 2D planning. The Wilcoxon test showed variable results for all observers: for 2 there was no difference in diameter on 2D and CBCT. For 2 the diameters were bigger on 2D planning and for 2 the diameters were smaller on 2D planning.

The implant diameter should be planned taking in consideration the alveolar crest width, height, angle and the consistency of the available bone. For an accurate planning of the implant diameter it is deemed necessary to use a radiological examination that provides a cross-sectional image. When using only 2D radiological methods, the surgeon needs additional information about the alveolar crest width, given by clinical examination. The implant diameter can also be influenced by bone density, for less mineralized bone requires wider diameters. CBCT examinations provide important information about bone density, whereas such information is less clear on 2D radiographies, and not assessable by clinical examinations.

Length, diameter and success rate

Cannizzaro et al (2009) established that the primary stability of short implants is comparable to that of longer implants only if the diameters were larger for short (8mm) implants. They found no difference for secondary stability.

Other authors however, believe that the amount of lost short implants is notably higher than the amount of lost long implants. Olate et al (2010) found no relation between early loss of implants and the osseous quality or implant diameter did find a difference between implant loss of short versus long implants. Cooper et al (2010) confirmed the latter by showing a higher risk of primary implant instability for short implants. Overall, it seems that larger implant diameter gives better primary stability and is associated with a higher surgical success rate (Krennmair et al 2010). Yet often it is necessary to use narrow implants, especially for replacing teeth in the incisive region or when the toothless area is narrow.

The success rate of the implants depends also on the degree of stress distribution within the alveolar bone. Anitua et al (2010) demonstrated that implant diameter has a more significant influence than implant length on stress distribution in alveolar bone and that the use of wider implants could reduce the stress in the bone surrounding the implant. For this reason, the use of short though wide implants could be a reasonable alternative in the case of limited residual ridge height.

Implant distance to neighbouring element

The distance from the implant to the adjacent teeth or implants should not be less than 2mm. Even for narrow edentulous spaces, this distance needs to be respected and sometimes it is not possible to place multiple implants in narrow spaces.

The Wilcoxon test for all observers for this parameter showed very small differences between 2D and CBCT planning ($\leq$ 1mm), which were only significant for one out of 6 observers.

Confidence score: "Are you confident that you can perform the implant surgery?"

As with convincement scores, the observers were all more confident about their therapeutic planning based on CBCT than the one based on 2D images.

The lowest confidence scores appeared in the upper lateral region, both for 2D and CBCT images. This might be explained by the higher risk and worse depiction of the maxillary area.

General conclusion on bone quantification for preoperative planning of oral implant placement

The difference in planning implants based on 2D and CBCT images appeared most clearly as a difference in the length of the implant and in the confidence of observers to perform surgery with the information available. It is important to use the available bone space in an optimal way, and the choices about the implants to be placed can be made with more confidence when the 'critical boundaries' can be assessed in all planes.

For the surgical procedure itself, efficiency and safety (avoiding complications) should be monitored and might be different based on different planning. It seems obvious that the more info *a priori* collected the more efficient the surgery can be. Indeed, this is what we found from a preliminary analysis, where any surgical event could be better predicted using 3D images. However, more in depth research on this is required to draw firm conclusions that can be generalised.

The comparison of implant planning based on 2D and 3D images is complicated, as a randomised controlled trial is hard to establish, considering that the required input for a rehabilitation with an implant-supported prosthesis exceeds by far the diagnostic information available on 2D or 3D images. The treatment outcome not only depends on the anatomical requirements and surgical challenges, yet also on the actual needs (fixed, removable), the existing therapeutic options, the aesthetic demands and antagonistic relations. In one and the same edentulous jaw, implants can be placed in a simple and routine way or in a very sophisticated and individualised way. The approach may be one-stage surgery and placement or multistage. Depending on the chosen pathways, imaging requirements may be different. The current protocol has attempted to highlight the differences in planning strategies and surgical preparations. All radiographical and non-radiographical requirements need to be integrated in the final treatment plan. This complex interplay hampers the use of a sound RCT design and hampers the selection of reference treatments or gold standards.

As a concluding note it should be said that the benefit of 3D imaging is related to 3D rendering making it possible to integrate data fully prior to surgery: in a well-performed pre-surgical planning, it is possible to integrate anatomical, pathological, biomechanical and esthetical aspects, which offers obvious advantages. In implant therapy, not only the surgical approach, yet an integrated approach is warranted, in contrast to e.g. wisdom tooth removal.

5.1.2 Presurgical assessment of tooth impaction – third molars

According to Tantanapornkul et al 2007, the mandibular canal was located inferior to the root in 64 of 142 teeth examined (45%), lingual to the root in 37 teeth (26%), buccal to the root in 36 teeth (25%), and interradicular in 5 teeth (4%). In the present study, we also found that the mandibular canal was most often positioned inferior, which is in accordance with those of other studies (Monaco et al 2004, Mahasantipiya et al 2005). This disagrees however with previous studies on the course of the mandibular canal which reported a predominantly buccal course (Kaeppler 2000, Tammisalo et al 1992, Maegawa et al 2003).

Dysesthesia caused by inferior alveolar nerve exposure during the surgical removal of impacted mandibular third molars can be prevented with an accurate preoperative prediction of neurovascular bundle exposure. We found 2 post-operative cases of dysesthesia. One occurred during surgery planned and performed based on CBCT: the mandibular canal was located lingual to the root and a loss of cortical lining of the mandibular canal was seen on the cross-sectional CBCT image. This result is in accordance with other studies (Ghaeminia et al 2009, Maegawa 2003). Maegawa el al (2003) have found that the rate at which the mandibular canal was in contact with the root surface (ie, disappearance of cortical bone around mandibular canal) is higher in lingual and inter-radicular roots positions. In addition, they stated that the IAN was more frequently exposed during third molar removal for these positions.

The findings of the present study are in disagreement with the study of Suomalainen et al 2010, where CBCT was more reliable in evaluating the number of mandibular third molar roots than panoramic radiography. In our study CBCT showed a slightly better result, but this trend was not found statistically significant. This can be explained by the fact that we only had two 3-rooted third molars in our sample due to our rather strict exclusion criteria. Differences in the number of roots and root morphology seem to exist in cases where the roots are difficult to diagnose, but larger samples are needed in order to draw meaningful conclusions.

Based on our results, CBCT is not better than panoramic radiography in predicting IAN exposure for average cases of impacted third mandibular molars. Difficult cases will still require 3D. Flygare & Öhman (2009) recommended the use of CBCT for cases with two-dimensional radiographic evidence of an intimate relationship between the mandibular canal and the wisdom tooth, so that permanent nerve injuries following third molar removal may be avoided. The present RCT excluded those cases with an intimate relationship as these were directly referred for 3D CBCT radiographic planning. This decision strategy and recommendation is also in line with the observed lack of a significant difference between non-riskful cases planned with either 2D or 3D images in the present RCT.

Only two studies have reported the diagnostic accuracy of CBCT in predicting IAN exposure following third molar removal (Tantanpornkul et al 2007, Ghaeminia et al 2009). Tantanapornkul et al. Tantanpornkul et al (2007) reported a sensitivity of 93% and a specificity of 77%. This high sensitivity justifies CBCT where conventional radiographs suggest a close relationship between a mandibular third molar and the inferior dental canal. On the other hand, Ghaeminia et al. REF8 described a similar high sensitivity (96%) but a lower specificity (23%). The low specificity, described in the second study, might be explained by stricter selection criteria. Finally, Ghaeminia et al 2009 also showed that CBCT is not better than panoramic radiography in predicting IAN exposure in patients who are at high risk of IAN injury.

The value of a third dimension for pre-operative planning of impacted mandibular third molars has been stressed by numerous authors (Jhamb et al 2009, Maegawa et al 2003, Pawelzik et al 2002, Abrahams 2001, Smith et al 1997). More precise information when there is a close relationship between the impacted third molar and the inferior alveolar nerve, may simplify the surgical procedure and make it considerably safer. Additionally, the patient can receive more adequate information about the procedure and the associated risk.

5.1.3 Presurgical assessment of tooth impaction – canines

There are no statistically significant differences between panoramic and CBCT assessment of the impacted canine position when using surgical evaluation as reference standard. However, CBCT is more accurate than 2D conventional radiography to differentiate the buccal and oral position of an impacted canine and its impaction grade.

The cross-sectional reconstruction was considered mandatory by the examiners to determine the sagittal position (anteroposterior) position of the canine and the impaction level. The axial section proved to be most useful for the assessment of the canine relation to its neighbouring teeth.

The detection of ectopic canine relations and root resorption was different in CBCT and panoramic images. First grade resorptions did not influence the type of treatment chosen. Grade II or III resorptions however, may influence therapeutic decision as in these cases it might be necessary to perform an extraction or an intervention on the root level. Further studies are needed about assessments on CBCT and 2D radiographs that may influence the therapeutic plan in case of included teeth. For this, a clear distinction should be made between mild and advanced resorption.

No statistically significant difference between the treatment plan recommended after the evaluation of CBCT compared to assessment of conventional 2D images. The type of treatment has changed in 22% of the cases that were studied, reducing the number of planned canine extractions with 6%. We compared only the treatment plan based on 2D and/or 3D images. The surgery was performed by an independent surgeon and therefore a direct comparison between the treatment plans was not possible. Our goal in this treatment topic was to assess whether the treatment plan changes at all. A next step would be to evaluate this change for treating surgeons, and not only independent observers.

CBCT evaluation of impacted canines prior to surgery could reduce the number of extractions due to a better assessment of their position and their relation to the adjacent teeth, and through a greater degree of confidence about the therapy plan.

To be able to draw stronger conclusions on this hypothesis, a study with larger an more homogenous patient groups would be required.

The confidence of the examiners in their therapy plan based on the CBCT examination was significantly higher compared to the confidence related to 2D radiographic images.

None of the radiographic techniques used (2D radiographies or CBCT) could accurately predict complications. The most common intraoperative complication was contact of the drill with the canine root.

Based on a radiological examination, a difficulty score for orthodontic treatment can be calculated. In the current study, for a score >1, the observers considered a CBCT examination as necessary. It could be interesting to evaluate this scoring system more in depth in future research.

General conclusion on impacted canines

Based on the results of this study, CBCT is recommended in the following clinical situations:

- To define the <u>surgical access route</u>. A vestibular or oral crown position can more accurately be defined on CBCT images.
- To guide the direction of <u>orthodontic traction</u>. If the radiological appearance on the 2D image shows a direct relationship with the roots of adjacent teeth. This may interfere with the path of orthodontic treatment of the impacted canine. Many of the contact relations that are visible on conventional radiography are false positive (FP in the present study: 0.76).
- To determine if <u>root resorption</u> is present. If there are clinical and/or radiological signs suggestive for root resorption of adjacent teeth, and if these resorptions would require a specific treatment (resorption degree II or III).
- During orthodontic treatment when it is necessary to <u>differentiate</u> the pain due to mechanic traction or due to a iatrogenic resorption
- To choose optimal treatment in case of <u>doubt</u>, more specifically, when the treating dentist cannot decide between canine extraction or orthodontic treatment of the canine. The confidence degree of the examiners improved significantly with CBCT.
- Objective <u>scale of treatment difficulty</u>. A suggestion is made to use a scoring system, where, if the radiological score >1 or 2, a CBCT examination should be considered. The background and validation of this score should be elaborated in further research.

5.1.4 Presurgical assessment and post-operative follow-up of sinus grafting procedures

CBCT may change the planning in sinus lift treatment by bringing new detailed information through cross sectional images and 3D assessment of the region, but in the current study we found no statistically significant differences between 2D and CBCT planning. The surgeons' level of confidence was nevertheless higher in CBCT examination than in panoramic radiography.

Panoramic radiography can generate false positive and false negative results in detection of the sinuses mucosal hypertrophy and the presence of septa. Identification of preoperative sinus morphology is very important for performing sinus lift surgery since the existence of a preexisting sinus mucosa hypertrophy may predispose to inflammatory complications and it is a contraindication for surgery. The surgeon must know the existence of the septa to prevent accidents or intraoperative complications. Therefore, we conclude that although there were no statistic significant differences between panoramic radiography and CBCT for the assessment of sinus morphology, it is preferable to use CBCT for maxillary sinus preoperative evaluation.

Although there was no statistically significant differences between the type of treatment planning chosen or the sinus morphology assessment with panoramic radiography compared to the CBCT, surgeons have found that CBCT examination should be performed preoperatively in almost 2/3 of the cases. These results are consistent with the higher score of trust and confidence of the operator on the better results with CBCT images compared with 2D radiographic images.

Estimating the volume of sinus lift using CBCT images is more accurate compared to only estimating the size. Therefore CBCT is a superior examination because of the 3D planning possibility of sinus lift volume estimating comparing with 2D conventional imaging methods.

Complications are determined by a complex interaction of intraoperative factors and cannot be fully predicted by any radiological examination. The high level of confidence in CBCT images may however help to predict complications, much more than a panoramic radiograph may ever do.

General conclusion on sinus grafting

A CBCT examination may change the treatment plan for a sinus lift procedure: cross-sectional imaging can influence the choice of performing sinus lift, the time of implantation and the type of sinus lift. Sinus morphology, better visible on CBCT, is important in the prevention of postoperative complications and implant loss.

CBCT allows the estimation of bone graft volume using specialized software. This in its turn increases the accuracy of harvesting a bone graft in line with the estimated useful volume. A good planning of this harvesting reduces morbidity, traumatic surgery and the duration of the surgery.

CBCT increased the confidence in the treatment planning. The confidence level of surgeons was high when CBCT was used but weak in case of panoramic imaging. This in turn might lead to more efficient use of surgical time.

Further studies are needed to follow up the postoperative complications for sinus lift planned only with conventional radiological methods compared with those that were planned using cross-sectional imaging.

5.2 Implications for future work

Performing the clinical studies in this work package, we were able to draw a broad variety of conclusions on several clinical applications of CBCT use. At the very beginning of the process, we came across a boundary: to perform diagnostic accuracy studies, in the strict definition thereof, is not obvious with the type of data and applications we worked with. Indeed, diagnostic accuracy requires a gold standard. In an *in vivo* context, it is not always feasible to work with this principle. That is why, early in the process, we decided to focus on the comparison between 2D and 3D images as well as the surgical outcome. We feel it might be worth developing a scientifically sound approach for studies on the justification of the use of new radiological technology, a guide with research standards for scientists to follow when performing research in this area. As such, it would become also easier to compare previous research. This is quite laborious to date, due to the rather unsystematic approach of different authors.

Another general comment concerns the follow-up of patients. Within the framework of the current project, a long-term follow-up was not feasible. However, it is exactly this long-term follow-up that might distinguish the 2D from the 3D approach in a strong way. This goes most of all for the canine study, where the orthodontic and:or approach might show its implications only after the entire therapy process has been passed through.

Even though we feel that we have reached our goals as defined within this project, it seems advisable to work more in depth for each clinical application that was approached. A general advice in this would be to enlarge patient groups. More specific comments for each application follow below.

For what concerns the *implant study*, the results obtained in WP4.1, on trabecular bone segmentation, should be integrated in the analysis of bone quality when preparing surgery. The use of that information, combined with a long-term follow-up of implant patients, could lead to strong recommendations on pre-operative planning. Another point that deserves attention is the fact that study outcomes might depend strongly on the surgeon’s experience. Therefore it could be interesting to evaluate the results of surgeons with and without a number of years of experience. Another possibility of advanced research would be to opt for a clinical trial, within ethical constraints to distinguish between different technologies. However, the patient selected should in this case be very well defined and homogenous.

After the study on impacted third molars, we feel the patient group should have been larger to draw stronger conclusions. Currently, the results do not convince on a need of 3D imaging for preparing average cases of third molar impactions. In future research, the focus might be exactly on difficult cases and/or even on IAN exposures, to describe in detail the consequences of this exposure and to evaluate whether any occurred damage could have been prevented.

Inspired by the research on impacted canines and resorption of the neighbouring teeth and as a contribution to international guidelines, we feel it would be interesting to elaborate on difficulty scores for (orthodontic) treatment of impacted canines and assess, based on these scores, the need for advanced imaging. In this application we also found a major influence of the surgeon on the final treatment decision.

The sinus graft study could recruit only a limited number of patients. Therefore, further research should focus on larger patient groups. The goal of this future research should be to investigate whether complications can be predicted and/or through imaging. This is not indisputable based on the results collected to date.

6. Overall Work Package Conclusions

This section considers both the earlier work and the work in the final period, to draw conclusions regarding the SEDENTEXCT Guidelines and the overall impact of the work, and to summarise the implications for further work.

6.1 SEDENTEXCT Guidelines

For the SEDENTEXCT Guidelines, we will provide the most important findings from our clinical studies on implant placement, impacted canines and third molars and sinus graft procedures. In short, but to be elaborated to fit the WP1 requirements, we can conclude that in implant placement, 3D imaging is required. In the treatment of impacted third molars we could not find strong evidence for this. In the treatment of impacted canines, certain conditions do require the use of advanced imaging but we do need further research to evaluate the consequences for (orthodontic) treatment outcome. As a preliminary advice about sinus grafting procedures, we feel that the prediction of complications and the efficient use of bone grafts might be the most important indication for using cross-sectional imaging.

Other than the clinical results, we will, through thorough discussions with the WP1 lead scientists, provide a report on methodological challenges and how to face those challenges in future research.

6.2 Impact

To date, the work of this work package has stimulated discussions on the need of CBCT imaging in diagnostics. It has been presented at several congresses and during project meetings. Therefore, the dentomaxillofacial radiology community has been challenged to think about a justified and safe use of CBCT.

With the publications ahead, we expect to reach even more members of the stakeholder group, including CBCT manufacturers, and to offer the members of these groups directions for further research on the topic.

Key Performance Indicators:

The **publications**, to be submitted within the first half of 2011, are the first key performance indicator. As limited evidence existed for the diagnostic usefulness of CBCT, this is what we have tried to overcome for key clinical applications of CBCT in dentistry. Other than this, the results to date were presented at international conferences and research meetings.

Another key performance indicator is the **consensus** amongst stakeholders on the rational use of CBCT. In this respect, a consensus meeting has been planned in May 2011 in Warsaw, being a joint meeting between the European Association of Osseointegration (EAO), the SEDENTEXCT consortium, the European Academy of Dentomaxillofacial Radiology (EADMFR) and the Computer Aided Implantology Academy (CAIA). The meeting will deal with guidelines on preoperative imaging for implant placement. We expect this consensus meeting to be followed by other meetings on the other applications of CBCT, even beyond the end of the project.

Our contribution to the European Guidelines should be spread to the **national guidelines** from radiation protection agencies.

Another impact this work package could have in the future is the decision on **reimbursement** of CBCT imaging for specific indications by social security.

6.3 Roadmap

A major focus in future research would be to proceed with simulation-based research, for the standardisation of several variables. Currently, work is ongoing on this topic at the K.U. Leuven. This simulation-based research could facilitate the development of selection criteria for CBCT imaging in the different clinical applications: ideally, we should arrive at an individual indication- and patient-based optimisation. The focus here should be most importantly on paediatric doses and the lowering thereof.

6.4 Future dissemination

International conferences

- SEDENTEXCT workshop at the British Society of Dentomaxillofacial Radiology meeting, 31 March 2011, Leeds, UK
- American Association of Orthodontists. 13-17 May 2011, Chicago, USA*
- Chinese Society for Dentomaxillofacial Radiology. 22-23 May 2011, Dalian, China*
- International Association of Dentomaxillofacial Radiology. 25-29 May 2011, Hiroshima, Japan*

**Dissemination at these conferences is not financed by SEDENTEXCT.*

Planned publications

Title or topic	Journal targeted	Phase
Topic: Segmentation accuracy – Surface analysis *Title*: Comparative study evaluating surface analysis with CBCT and µCT.	- Oral Surg, Oral Med, Oral Pathol, Oral Radiol & Endo	In draft
Topic: Segmentation accuracy – Trabecular bone analysis *Title*: Comparative study evaluating trabecular bone analysis with CBCT and µCT	- Not known	In draft
Topic: Linear accuracy *Title*: The influence of CBCT exposure parameters on periodontal bone measurements: *in vitro* accuracy	- European Radiology	Ready for submission

Title or topic	**Journal targeted**	**Phase**
Topic: Impacted canines *in vitro* *Title:* A comparison of Six CBCT Systems for the Detection of Simulated Canine Impaction-Induced External Root Resorption in Maxillary Lateral Incisors	- American Journal of Orthodontics	Ready for submission
Topic: Diagnostic accuracy – Animal study *Title:* Diagnostic accuracy of CBCT in the detection of bone lesions in pig jaws	- Dentomaxillofacial radiology	In draft
Topic: Diagnostic accuracy – Implants	- European Journal of Oral Implantology	In draft
Topic: Diagnostic accuracy – Impacted 3^{rd} molars	- Clinical Oral Investigations	Ready for submission
Topic: Diagnostic accuracy – Impacted canines *in vivo*	- European Journal of Orthodontics	/
Topic: Diagnostic accuracy – Sinus lift	- Dentomaxillofacial Radiology	/

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Appendix

The following appendix provides the questionnaires used in the work described in this deliverable.

SEDENTEX CT

WP 4.3.1

PATIENT INFORMATION

Patient name ______________________________

Male/Female ______________________________

Patient study ID (initials) ______________________________

Date of birth ______________________________

Grafting procedure before implant placement? ☐ Yes ☐ No

Date of implant placement ______________________________

Surgeon ______________________________

△ Please add implant location (1.2, 1.4, …) every time when applicable (measurements).

PRE-OPERATIVE EVALUATION

PLANNING ON PERI-APICAL RADIOGRAPH IN DIGORA

Questions

1. On a scale of 0-5, how <u>convinced</u> are you that these 2D images will give you enough information to perform a surgery without complications?

   1= Very convinced/confident; 2= Convinced/confident; 3= No opinion
   4= Doubtful/unsure; 5= Very doubtful/unsure

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2. On a scale of 0-5, how <u>confident</u> are you that you can perform the implant surgery only with 2D images?

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

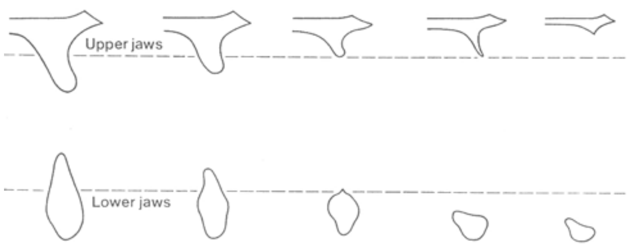
3. What type of implant would you choose?

   ____

4. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4

5. Jaw shape



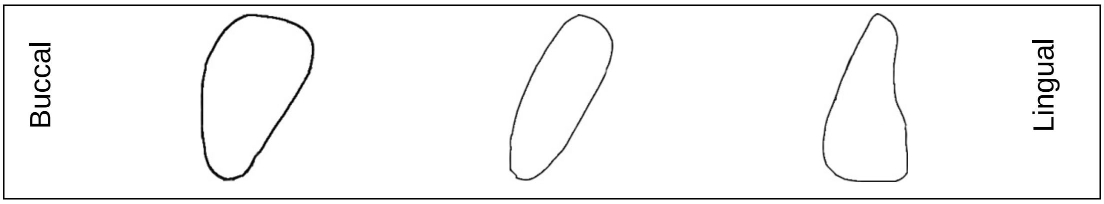
   Upper jaw: ☐ A ☐ B ☐ C ☐ D ☐ E
   Lower jaw: ☐ A ☐ B ☐ C ☐ D ☐ E

6. Trabecular bone quality

   ☐ Dense homogeneous ☐ Heterogeneous ☐ Sparse homogeneous

Ob ID ______________ Pat ID ______________ Date ______________

7. Bone morphology



☐ Type I ☐ Type II ☐ Type III

8. Is there any bone pathology visible? ☐ Yes ☐ No

   If yes, specify ______________________________

9. Is there a need for a bone augmentation procedure? ☐ Yes ☐ No
10. Do you expect good primary stability? ☐ Yes ☐ No
11. Do you expect uneventful surgery? ☐ Yes ☐ No

Measurements

1. Implant length ______________________________
2. Implant diameter ______________________________
3. Distance implant midline and adjacent tooth (or implant) midline ____________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) <u>and</u> M (mesial) or D (distal). E.g. TD, ID, TM, …
4. Angulation implant midline and adjacent tooth (or implant) midline ____________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) <u>and</u> M (mesial) or D (distal). E.g. TD, ID, TM, …

PLANNING ON CBCT IN ONDEMAND

Questions

1. On a scale of 0-5, how convinced are you that these 3D images will give you enough information to perform a surgery without complications?

   1= Very convinced/confident; 2= Convinced/confident; 3= No opinion
   4= Doubtful/unsure; 5= Very doubtful/unsure

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2. On a scale of 0-5, After evaluating these CBCT images, how confident are you that you can perform the implant surgery?

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

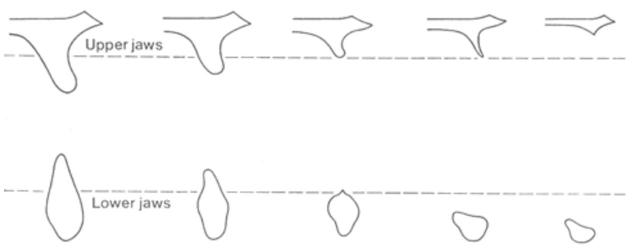
3. What type of implant would you choose?

   ____

4. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4

5. Jaw shape

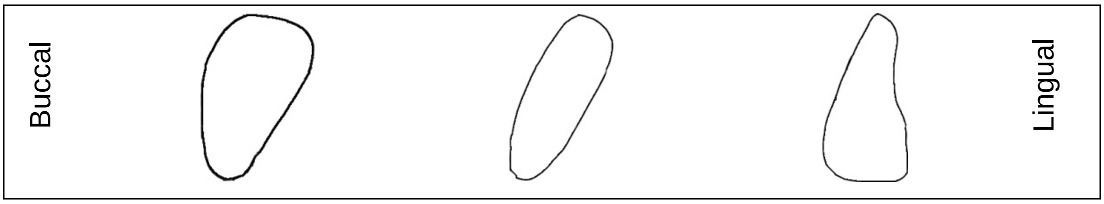


   Upper jaw: ☐ A ☐ B ☐ C ☐ D ☐ E
   Lower jaw: ☐ A ☐ B ☐ C ☐ D ☐ E

6. Trabecular bone quality

   ☐ Dense homogeneous ☐ Heterogeneous ☐ Sparse homogeneous

7. Bone morphology



☐ Type I ☐ Type II ☐ Type III

8. Is there any bone pathology visible? ☐ Yes ☐ No

   If yes, specify ______________________________

9. Is there a need for a bone augmentation procedure? ☐ Yes ☐ No
10. Do you expect good primary stability? ☐ Yes ☐ No
11. Do you expect uneventful surgery? ☐ Yes ☐ No

Measurements

1. Implant length ______________________________
2. Implant diameter ______________________________
3. Distance implant midline and adjacent tooth (or implant) midline____________________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …
4. Angulation implant midline and adjacent tooth (or implant) midline _____________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …

PERI-OPERATIVE EVALUATION

PERI-APICAL RADIOGRAPH WITH PIN

Measurements

1. Distance pin midline and midline adjacent tooth (or implant) ___________________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …
2. Angulation pin midline and adjacent tooth (or pin/implant) midline _____________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …

SURGICAL FILE

Questions

1. Time of surgery (from first cut) ______________________________________
2. Implant type ______________________________________
3. Implant length ______________________________________
4. Implant diameter ______________________________________
5. Surgical events
   - Deviation from the planned procedure: implant (type), bone graft,…?

     ☐ Yes ☐ No

     If yes, specify ______________________________________

     ____

     ____
   - Dehiscence? ☐ Yes ☐ No
   - Fenestration? ☐ Yes ☐ No
   - Suboptimal primary stability? ☐ Yes ☐ No Remark: __________________

     ____
   - Mandibular canal perforation (LJ)? ☐ Yes ☐ No
   - Sinus perforation (UJ)? ☐ Yes ☐ No
   - Malpositioning (according to biomechanical / aesthetic requirements)?

     ☐ Yes ☐ No

Remarks ______________________________________

____

SURGEON'S OPINION

Questions

1. Did the diagnostic system, CBCT, provide you with diagnostic information that you did not have otherwise?
   ☐ Yes ☐ No
2. Did your surgical approach change because of the diagnostic information your received through the CBCT images?
   ☐ Yes ☐ No
3. Would you use this diagnostic system again for similar treatment conditions?
   ☐ Yes ☐ No
4. Comments: ______________________________

   ____

   ____

POST-OPERATIVE EVALUATION

PERI-APICAL OR PANORAMIC RADIOGRAPH WITH IMPLANT

Measurements

1. Distance implant midline and adjacent tooth (or implant) midline ________________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …
2. Angulation implant midline and adjacent tooth (or implant) midline ______________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …

PATIENT FILE

Questions

1. Pain — Duration medication: ______________________ days

   Duration sensation: ______________________ days
2. Neurosensory disturbances? ☐ Yes ☐ No

   If yes, specify ____

   ____

   ____

   Duration ____
3. Blue spots duration ____
4. Swelling duration ____
5. TMJ pain after surgery ☐ Yes ☐ No

CAST

Measurements

1. Distance implant midline and adjacent tooth (or implant) midline ________________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …
2. Angulation implant midline and adjacent tooth (or implant) midline ______________

   △ Select adjacent: 1. Closest proximity 2. Mesial.

   Mark T (tooth) or I (implant) and M (mesial) or D (distal). E.g. TD, ID, TM, …

INSTRUCTIONS FOR THE PANORAMIC IMAGES

1) Postition

Options:		Number for this option:
Vertical		1
Horizontal		2
Distoangular		3
Mesioangular		4
Transverse position		5
Inversion of the tooth		6

2) Contact 2nd Molar

Options	Number
Contact	1
No contact	2

3) Root Development

Options	Number
Complete developmen	1
1/2 of the root	2
2/3 of the root	3
1/4 of the root	4

4) Number of roots

Options	Number
One	1
Two	2
Three	3
Four	4

5) Root Morfology

Options	Number
	1
	2
	3
	4
	5
	6
	7
	8
	9

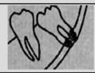
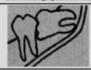
6) Bifurcation

Options	Number
Middle third	1
Apical third	2
None	3

7) Neurovascular bundle exposure

Options:	Number for this option:
Present	1
Absent	2

8) Canal

Options	Number	
Not in contact	0	
Loss of cortex of canal	1	
Bifid and dark apices of the root	2	
Change in mandibular canal direction	3	
Root narrowing	4	
Increased radiolucent band of the root(s)	5	
Contact mandibular canal	6	
Mandibular canal narrowing	7	
Root deviation (dilaceration)	8	
Superimposition of the root(s)	9	

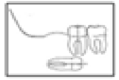
9) Associated pathology

Options	Number
None	0
caries	1
odontogenic infection	2
Periodontal disease	3
cyst/tumor	4
tooth fracture	5
mandibular fracture	6

Next page: enlargement of the images

INSTRUCTIONS FOR THE CBCT IMAGES

1) Postition

Options:		*Number for this option:*
Vertical		1
Horizontal		2
Distoangular		3
Mesioangular		4
Transverse position		5
Inversion of the tooth		6

2) Contact 2nd Molar

Options	*Number*
Contact	1
No contact	2

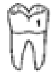
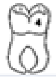
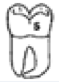
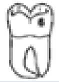
3) Root Development

Options	*Number*
Complete developmen	1
1/2 of the root	2
2/3 of the root	3
1/4 of the root	4

4) Number of roots

Options	*Number*
One	1
Two	2
Three	3
Four	4

5) Root Morfology

Options	*Number*
	1
	2
	3
	4
	5
	6
	7
	8
	9

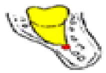
6) Bifurcation

Options	*Number*
Middle third	1
Apical third	2
None	3

7) Neurovascular bundle exposure

Options:	*Number for this option:*
Present	1
Absent	2

8) A. Position of the canal to the 3M mesial root

Options / *Number*	Lingual	Interradicular	Buccal	Inferior
Contact	 1	 2	 3	 4
No contact	 5	 6	 7	 8

B. Position of the canal to the 3M distal root

	Lingual	Interradicular	Buccal	Inferior
Contact	 9	 10	 11	 12
No contact	 13	 14	 15	 16

9) Lingual cortex

Options	*Number*
Normal	0
Thining	1
Perforation	2

10) Associated pathology

Options	*Number*
None	0
caries	1
odontogenic infection	2
Periodontal disease	3
cyst/tumor	4
tooth fracture	5
mandibular fracture	6

WP 4.3.2- 4.3.3

PATIENT INFORMATION

Patient name ______________________________

Male/Female ______________________________

Patient study ID (initials) ______________________________

Date of birth ______________________________

Orthodontist ______________________________

Date of surgery on the canine ______________________________

Surgeon ______________________________

PRE-OPERATIVE EVALUATION

PLANNING WITH "CONVENTIONAL METHOD"

2D RX (SELECT): OPG, TELERAD, AXIAL OF PALATE, PERIAPICAL AND CAST

Questions

1. On a scale of 0-5, how convinced are you that these 2D images + cast will give you enough information to perform a complete treatment without complications?

   1= Very convinced/confident; 2= Convinced/confident; 3= No opinion
   4= Doubtful/unsure; 5= Very doubtful/unsure

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2. On a scale of 0-5, how confident are you that you can perform the canine treatment only with 2D images + cast?

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

3. What type of treatment would you choose?

   ☐ Simple surgical exposure of canine ☐ Surgical exposure with attachment (bracket/chain) ☐ Canine extraction ☐ No treatment

   In case of surgical exposure: ☐ Open technique ☐ Closed technique

   Type of incision…………………………………………………….

   Type of access…………………………………………………….

4. Do you expect complications?

   ☐ Yes ☐ No

5. Type of impaction

   ☐ Partial eruption ☐ Soft tissue impaction ☐ Complete bone impaction

6. Canine position

Oblique	Horizontal	Transversal	Reverse
☐ 1	☐ 2	☐ 3	☐ 4

7. Canine crown position in saggital plane

Vestibular	Palatal	Close to the crest line
☐ 1	☐ 2	☐ 3

Ob ID _______________ Pat ID _______________ Date _______________

8. Canine crown position in axial plane
   - ☐ High (near to the apex of lateral incisor = apical 1/3)
   - ☐ Medium (near to the middle of the root of lateral incisor = medial 1/3)
   - ☐ Low (near to the cement enamel junction= coronal 1/3)
9. Relationship with nearby teeth (multiple options are possible)
   - ☐ No contact with nearby teeth
   - ☐ Direct contact with lateral incisor
   - ☐ Direct contact with first premolar
   - ☐ Direct contact with central incisor
   - ☐ Direct contact with primary canine
   - ☐ Follicle contact with lateral incisor
   - ☐ Follicle contact with first premolar
   - ☐ Follicle contact with central incisor
   - ☐ Follicle contact with primary canine
10. Resorption of nearby teeth
    - ☐ Root resorption of lateral incisor Degree………………………………….
    - ☐ Root resorption of first premolar Degree………………………………….
    - ☐ Root resorption of central incisor Degree………………………………….
11. Canine apex position in axial plane from the ideal position

Mesial	Distal	Middle
☐ 1	☐ 2	☐ 3

Measurements

12. Canine root length ____
13. Crown diameter ____
14. Distance tip of canine to axis of ideal place of canine __________________________
15. Distance apex of canine to axis of ideal place of canine ________________________
16. Distance from lateral incisor to first premolar
    (mesio-distal space for the canine)
    On radiograph ____
    On cast ____
17. Size of canine follicle ____

PLANNING WITH CBCT

Questions

1. On a scale of 0-5, how <u>convinced</u> are you that these 3D images will give you enough information to perform a complete treatment without complications?

   1= Very convinced/confident; 2= Convinced/confident; 3= No opinion
   4= Doubtful/unsure; 5= Very doubtful/unsure

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

2. On a scale of 0-5, how <u>confident</u> are you that you can perform the canine treatment only with 3D images?

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

3. What type of treatment would you choose?

   ☐ Simple surgical exposure of canine ☐ Surgical exposure with attachment (bracket/chain) ☐ Canine extraction ☐ No treatment

   In case of surgical exposure: ☐ Open technique ☐ Closed technique

   Type of incision……………………………………………………

   Type of access……………………………………………………….

4. Do you expect complications?

   ☐ Yes ☐ No

5. Type of impaction

   ☐ Partial eruption ☐ Soft tissue impaction ☐ Complete bone impaction

6. Canine position

Oblique	Horizontal	Transversal	Reverse
☐ 1	☐ 2	☐ 3	☐ 4

7. Canine crown position in saggital plane

Vestibular	Palatal	Close to the crest line
☐ 1	☐ 2	☐ 3

8. Canine crown position in axial plane

   ☐ High (near to the apex of lateral incisor = apical 1/3)

   ☐ Medium (near to the middle of the root of lateral incisor = medial 1/3)

   ☐ Low (near to the cement enamel junction= coronal 1/3)

9. Relationship with nearby teeth (multiple options are possible)

☐ No contact with nearby teeth
☐ Direct contact with lateral incisor
☐ Direct contact with first premolar
☐ Direct contact with central incisor
☐ Direct contact with primary canine
☐ Follicle contact with lateral incisor
☐ Follicle contact with first premolar
☐ Follicle contact with central incisor
☐ Follicle contact with primary canine

10. Resorption of nearby teeth

☐ Root resorption of lateral incisor Degree……………………………………
☐ Root resorption of first premolar Degree……………………………………
☐ Root resorption of central incisor Degree……………………………………

11. Canine apex position in axial plane from the ideal position

Mesial	Distal	Middle
☐ 1	☐ 2	☐ 3

Measurements

12. Canine root length ______________________________________
13. Crown diameter ______________________________________
14. Distance tip of canine to axis of ideal place of canine ________________________
15. Distance apex of canine to axis of ideal place of canine ______________________
16. Distance from lateral incisor to first premolar ______________________________
(mesio-distal space for the canine)
17. Size of canine follicle ______________________________________

PERI-OPERATIVE EVALUATION

SURGICAL FILE

Questions

1. Time of surgery (from first cut) ____
2. What type of treatment was chosen?

   ☐ Simple surgical exposure of canine ☐ Surgical exposure with attachment (bracket/chain) ☐ Canine extraction ☐ No treatment

   In case of surgical exposure: ☐ Open technique ☐ Closed technique

   Type of incision……………………………………………………….

   Type of access…………………………………………………….….

3. Type of impaction

   ☐ Partial eruption ☐ Soft tissue impaction ☐ Complete bone impaction

4. Canine position

Oblique	Horizontal	Transversal	Reverse
☐ 1	☐ 2	☐ 3	☐ 4

5. Canine crown position in saggital plane

Vestibular	Palatal	Close to the crest line
☐ 1	☐ 2	☐ 3

6. Canine crown position in axial plane

   ☐ High (near to the apex of lateral incisor = apical 1/3)

   ☐ Medium (near to the middle of the root of lateral incisor = medial 1/3)

   ☐ Low (near to the cement enamel junction of lateral incisor = coronal 1/3)

7. Relationship with nearby teeth (multiple options are possible)

   ☐ No contact with nearby teeth

   ☐ Direct contact with lateral incisor

   ☐ Direct contact with first premolar

   ☐ Direct contact with central incisor

   ☐ Direct contact with primary canine

☐ Follicle contact with lateral incisor

☐ Follicle contact with first premolar

☐ Follicle contact with central incisor

☐ Follicle contact with primary canine

8. Resorption of nearby teeth

☐ Root resorption of lateral incisor Degree…………………………………

☐ Root resorption of first premolar Degree…………………………………

☐ Root resorption of central incisor Degree…………………………………

9. Canine apex position in axial plane from the ideal position

Mesial	Distal	Middle
☐ 1	☐ 2	☐ 3

10. Canine length (in case of extraction)____________________________

11. Crown of canine diameter (in case of extraction) ____________________

12. Surgical events and/or complications
    - Deviation from the planned procedure: exposure / extraction?

      ☐ Yes ☐ No

      If yes, specify ____________________________
      ____
      ____
    - Hitting with the drill the root of canine? ☐ Yes ☐ No
    - Hitting with the drill the apex of canine? ☐ Yes ☐ No
    - Hitting with the drill the crown of canine? ☐ Yes ☐ No
    - Sinus perforation? ☐ Yes ☐ No
    - Nasal fossa perforation? ☐ Yes ☐ No
    - Other ____________________________

SURGEON'S OPINION

Questions

1. Did the diagnostic system, CBCT, provide you with diagnostic information that you did not have otherwise?

   ☐ Yes ☐ No

2. Did your surgical approach change because of the diagnostic information your received through the CBCT images?

   ☐ Yes ☐ No

3. Would you use this diagnostic system again for similar treatment conditions?

   ☐ Yes ☐ No

4. Comments: ______________________________________

   ____

   ____

POST-OPERATIVE EVALUATION

PATIENT FILE

Questions

1. Pain — Duration medication: ____________________ days

   Duration sensation: ____________________ days

2. Swelling duration ____________________________________
3. Infection duration (if applicable) ____________________________________
4. TMJ pain after surgery ☐ Yes ☐ No

SEDENTEX CT

WP 4.3.4

PATIENT INFORMATION

Patient name ________________________________

Male/Female ________________________________

Patient study ID (initials) ________________________________

Date of birth ________________________________

Date of surgery ________________________________

Surgeon ________________________________

SEDENTEX CT

WP 4.3.4

PRE-OPERATIVE EVALUATION

PRE-OPERATIVE PLANNING WITH "CONVENTIONAL METHOD"

2D RX (SELECT): OPG, TELERAD, AXIAL OF PALATE, PERIAPICAL

Questions

1. On a scale of 0-5, how confident are you that you can perform the treatment only with 2D images? 1= Very confident; 2= Confident; 3= No opinion; 4= Doubtful/unsure; 5= Very doubtful/unsure

   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
2. What type of treatment would you choose?

   ☐ Simple sinus lift with no graft ☐ Sinus lift with xenogenic bone graft ☐ Sinus lift with own bone graft ☐ No treatment

   Type of incision……………………………………………………….

   Type of access………………………………………………………..
3. Do you expect complications?

   ☐ Yes ☐ No
4. What type of implant would you choose?

   ____
5. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4
6. Jaw shape

   Upper jaw: ☐ A ☐ B ☐ C ☐ D ☐ E
7. Trabecular bone quality

   ☐ Dense homogeneous ☐ Heterogeneous ☐ Sparse homogeneous
8. Is there any bone pathology visible? ☐ Yes ☐ No

   If yes, specify ______________________________________

9. Is there a need for a bone augmentation procedure? ☐ Yes ☐ No
10. Do you expect good primary stability? ☐ Yes ☐ No
11. Do you expect uneventful surgery? ☐ Yes ☐ No

Measurements

12. Bone height (minimum) ______________________________

    From alveolar crest to the sinus floor

PRE-OPERATIVE PLANNING WITH CBCT

Questions

1. On a scale of 0-5, how confident are you that you can perform the treatment only with 3D images? 1= Very convinced/confident; 2= Convinced/confident; 3= No opinion
   4= Doubtful/unsure; 5= Very doubtful/unsure
   ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
2. What type of treatment would you choose?
   ☐ Simple sinus lift with no graft ☐ Sinus lift with xenogenic bone graft ☐ Sinus lift with own bone graft ☐ No treatment
   Type of incision……………………………………………………….
   Type of access……………………………………………………….
3. Do you expect complications?
   ☐ Yes ☐ No
4. What type of implant would you choose?

   ____
5. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4
6. Jaw shape

   Upper jaw: ☐ A ☐ B ☐ C ☐ D ☐ E
7. Trabecular bone quality
   ☐ Dense homogeneous ☐ Heterogeneous ☐ Sparse homogeneous

WP 4.3.4

8. Is there any bone pathology visible? ☐ Yes ☐ No

   If yes, specify ______________________________

9. Is there a need for a bone augmentation procedure? ☐ Yes ☐ No
10. Do you expect good primary stability? ☐ Yes ☐ No
11. Do you expect uneventful surgery? ☐ Yes ☐ No

Measurements

12. Bone height (minimum)

    From alveolar crest to the sinus floor

13. Sinus volume ____________________
14. Sinus mucosa thickness ____________________

WP 4.3.4

PERI-OPERATIVE EVALUATION

SURGICAL FILE

Questions

1. Time of surgery (from first cut) ______________________________
2. What type of treatment was chosen?

   ☐ Simple sinus lift with no graft ☐ Sinus lift with xenogenic bone graft ☐ Sinus lift with own bone graft ☐ No treatment

   Type of incision ______________________________

   Type of access ______________________________
3. Bone height (minimum) ______________________________

   From alveolar crest to the sinus floor
4. Sinus volume ____________________
5. Sinus mucosa thickness ____________________
6. Volume of bone graft ____________________

   (for granules the weight, for own bone volume)
7. Surgical events and/or complications
   - Deviation from the planned procedure?

     ☐ Yes ☐ No

     If yes, specify ______________________________

     ____

     ____
   - Sinus opening? ☐ Yes ☐ No
   - Dehiscence ☐ Yes ☐ No
   - Other ______________________________

WP 4.3.4

SURGEON'S OPINION

Questions

1. Did the diagnostic system, CBCT, provide you with diagnostic information that you did not have otherwise?

   ☐ Yes ☐ No

2. Did your surgical approach change because of the diagnostic information your received through the CBCT images?

   ☐ Yes ☐ No

3. Would you use this diagnostic system again for similar treatment conditions?

   ☐ Yes ☐ No

4. Comments: ______________________________________

   ____

   ____

WP 4.3.4

POST-OPERATIVE EVALUATION

PATIENT FILE

Questions

1. Pain — Duration medication: ____________________ days
   Duration sensation: _____________________ days
2. Swelling duration ____________________________________
3. Infection duration (if applicable) ____________________________________
4. TMJ pain after surgery ☐ Yes ☐ No

EVALUATION ON 2D IMAGES – IMMEDIATELY AFTER SURGERY

Questions

1. What type of treatment was chosen?
   ☐ Simple sinus lift with no graft ☐ Sinus lift with xenogenic bone graft ☐ Sinus lift with own bone graft ☐ No treatment
2. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4
3. Trabecular bone quality
   ☐ Dense homogeneous ☐ Heterogeneous ☐ Sparse homogeneous
4. Is there any bone pathology visible? ☐ Yes ☐ No
   If yes, specify ____________________________________

Measurements

5. Bone graft volume ____________________________________
6. Sinus volume ________________________

EVALUATION ON 2D IMAGES – 6 MONTHS AFTER SURGERY

1. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4

SEDENTEX CT

WP 4.3.4

Measurements

2. Bone graft volume ______________________
3. Sinus volume ______________________

EVALUATION ON CBCT – IMMEDIATELY AFTER SURGERY

Questions

1. What type of treatment was chosen?

   ☐ Simple sinus lift with no graft ☐ Sinus lift with xenogenic bone graft ☐ Sinus lift with own bone graft ☐ No treatment

2. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4

3. Trabecular bone quality

   ☐ Dense homogeneous ☐ Heterogeneous ☐ Sparse homogeneous

4. Is there any bone pathology visible? ☐ Yes ☐ No

   If yes, specify ______________________

Measurements

5. Bone graft volume ______________________
6. Sinus volume ______________________

EVALUATION ON CBCT – 6 MONTHS AFTER SURGERY

1. Bone quality

   ☐ 1 ☐ 2 ☐ 3 ☐ 4

Measurements

2. Bone graft volume ______________________
3. Sinus volume ______________________

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