## *Summary at End of the Project, June 2011*

### 1.1 Project context and objectives

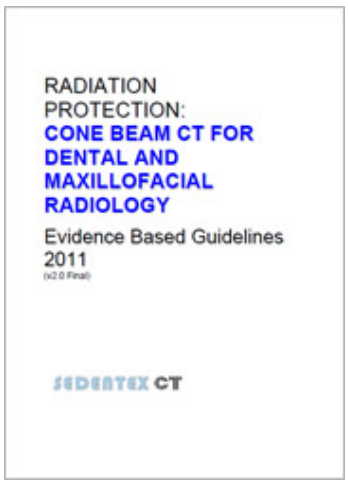
The SEDENTEXCT project (1 January 2008 – 30 June 2011) focused on enhanced safety and efficacy in the use of Cone Beam Computed Tomography (CBCT) in dental and maxillofacial radiology. In particular, the work plan aimed to find solutions to the challenge of a new x-ray imaging modality becoming available to the large community of dentists, medical physicists and other stakeholders in Europe. CBCT generates a higher x-ray dose than conventional radiographs, so it is important that it is used when clinically indicated and with the lowest dose consistent with appropriate image quality.

The project had a number of linked objectives:

- To develop evidence-based guidelines on the use of CBCT in dentistry, covering referral criteria, quality assurance and other optimisation strategies.
- To determine patient dose in CBCT, with an emphasis on paediatric dosimetry, and personnel dose.
- To perform diagnostic accuracy studies for CBCT in key clinical applications in dentistry.
- To develop a quality assurance (QA) programme, including the development of a tool/tools for QA and to define exposure protocols.
- To make an economic evaluation ("cost effectiveness" assessment) of CBCT compared with traditional methods of dental imaging.
- To conduct valorisation, both dissemination and training, activities via an open access website.

### 1.2 Work performed and results

**Figure 1: SEDENTEXCT Definitive Guidelines**




WP1 of SEDENTEXCT deals with evidence-based guideline development using systematic review. Its first externally visible output was the development of Provisional Guidelines on CBCT use in dentistry (May 2009). In the last year of the project, the WP1 team developed the Definitive Guidelines (May 2011). The development of the Guidelines was guided by the Basic Principles for Use of Cone Beam CT which resulted from a collaboration between SEDENTEXCT members and the European Academy of Dentomaxillofacial Radiology. The Definitive Guidelines (Figure 1) contain 58 recommendations in addition to the Basic Principles, covering (1) justification and referral criteria; (2) CBCT equipment factors in the reduction of radiation risk to patients; (3) quality standards and quality assurance; (4) staff protection; (5) economic evaluation; and (6) training. Examples of justification and referral criteria are provided in Table 1.

A Guideline Development Panel (GDP) was set up to oversee the work. The WP1 team extracted relevant papers on CBCT on a monthly basis throughout the project, and 583 publications and documents were identified by 31 March 2011. Initial screening excluded 144 of these, leaving 439 for further assessment. Critical appraisal of the literature was performed in duplicate, with any inter-assessor discrepancy being handled by further review by a third person. Following consideration by the GDP, the Guidelines underwent internal peer review within the project and assessment by independent external reviewers, as well as a Delphi process with members of the

European Academy of DentoMaxilloFacial Radiology (EADMFR). This resulted in the Definitive Guidelines v2.0, which were released in May 2011 and disseminated widely to the SEDENTEXCT mailing list.

**Table 1: Extract from SEDENTEXCT Guideline recommendations for justification and referral, showing the evidence grades (grades A,B,C,D are evidence-based (A=best); GP = Good Practice; BP = derived from the SEDENTEXCT Basic Principles; ED = derived from The Council of the European Union Directive 96/29/Euratom of 13 May 1996 or Council Directive 97/43/Euratom of 30 June 1997)**

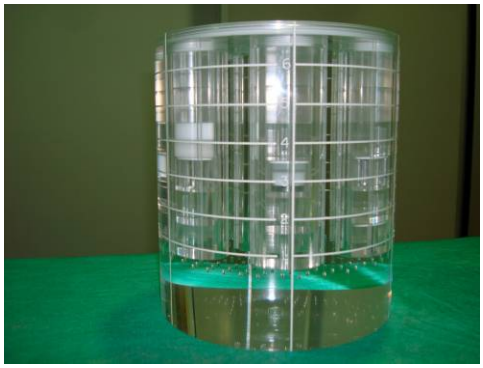
| | |
|---|---|
| *All CBCT examinations must be justified on an individual basis by demonstrating that the benefits to the patients outweigh the potential risks. CBCT examinations should potentially add new information to aid the patient's management* | ED BP |
| *When referring a patient for a CBCT examination, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the CBCT Practitioner to perform the Justification process* | ED BP |
| *CBCT should not be selected unless a history and clinical examination have been performed. "Routine" imaging is unacceptable practice* | ED BP |
| THE DEVELOPING DENTITION | |
| *For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is MSCT, CBCT may be preferred because of reduced radiation dose* | **GP** |
| *CBCT may be indicated for the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth) where the current imaging method of choice is conventional dental radiography and when the information cannot be obtained adequately by lower dose conventional (traditional) radiography* | **C** |
| *For the localised assessment of an impacted tooth (including consideration of resorption of an adjacent tooth), the smallest volume size compatible with the situation should be selected because of reduced radiation dose. The use of CBCT units offering only large volumes (craniofacial CBCT) requires very careful justification and is generally discouraged* | **GP BP** |

A major output from the CBCT dosimetry work (WP2) was the development of standardised dose indices for characterising dose distribution for CBCTs, allowing simple conversion of exposure protocols to the effective dose to the patient. Based on experimental results involving a wide range of CBCT devices and different dosimetry methods and phantoms (i.e. test objects), three different dose indices were defined. For the measurement of two of the proposed indices, a new customized cylindrical PMMA dosimetry phantom was created by partner Leeds Test Objects (LTO), which they are now marketing ("SEDENTEXCT DI"; www.leedstestobjects.com). The proposed dose indices were validated on a range of CBCT machines involving a large number of exposure protocols, varying all possible exposure factors (field of view size, kVp, mAs, rotation arc).

Computed methods may offer a less time-consuming alternative to phantoms for determining effective dose. Mathematical models were developed using the Monte Carlo N-Particle Transport Code (MCNP), to convert exposure settings to effective dose to the patient. A large number of CBCT devices and adult and paediatric phantoms were modelled on a validated Monte Carlo framework, and conversion factors were determined to obtain the effective dose from these simulations. Furthermore, the relationship between these simulated effective doses and the measured dose indices was investigated.
Another strand of the dosimetry work was the investigation of patient and staff dosages through *in vivo* measurements of skin doses and scatter dose measurements. *In vivo* skin dose measurements took place with 248 patients. The work covered a wide range of CBCT devices and

scanning protocols. It was seen that a considerable reduction in effective dose is possible when the FOV is limited to the area of diagnostic interest. This is particularly important for children, as they require smaller FOV sizes than adults in order to scan certain regions of interest. Scatter dose measurements from ten different CBCT models were performed, providing the x-ray dose at different distances from the isocentre of the CBCT device. Example calculations of the shielding requirements were offered and recommendations were made, which informed the Guidelines produced in WP1.

**Figure 2: SEDENTEXCT Quality Assurance phantom (marketed as SEDENTEXCT IQ; www.leedstestobjects.com)**



A Quality Assurance (QA) phantom (**Error! Reference source not found.**) and associated software was developed in WP3 in three cycles of development and testing, for use on a wide range of CBCT units and for an extensive range of image quality assessments. Each phase of testing informed improvements in the phantom or software, and the changes were incorporated into the design for the next round. The final QA phantom and the accompanying software for semi-automatic image evaluation of the phantom images were tested at five SEDENTEXCT partner sites. Partner LTO has begun commercial marketing of the phantom ("SEDENTEXCT IQ"; www.leedstestobjects.com).

A Quality Assurance (QA) procedure protocol was drawn up, comprising a generic part describing the implementation of a QA programme for CBCT ("QA Manual"), followed by a specific part describing the use of the SEDENTEXCT phantom and software used for running the tests in the generic QA protocol. The QA Manual specifies the necessary testing to ensure that all CBCT parameters remain in accordance with the standard operating protocol, resulting in images with diagnostic value without exposing the patient to unnecessary risk. The programme of equipment tests considers the performance of the X-ray tube and generator, patient dose, quantitative assessment of image quality and display screen performance. The QA Manual forms an appendix to the SEDENTEXCT Guidelines.

A number of studies have taken place in WP4 concerning the diagnostic accuracy of CBCT. The *in vitro* segmentation accuracy studies on the surface and trabecular structures collected data on the deviations of the three dimensional CBCT images from gold standard images from other imaging techniques. The linear accuracy studies measured distances between the dental cemento-enamel junction and bone in CBCT images and compared this with measurements in skulls. In the diagnostic accuracy studies, observers assessed the sensitivity of CBCT for detecting the presence of bone and root lesions.

*In vivo* diagnostic accuracy studies took place for the following clinical conditions: implants, impacted canines, impacted third molars and sinus grafting. For all these conditions, there was a significant increase in the confidence of the clinicians in “having enough information to start a treatment” when using CBCT compared with conventional means. Moreover, surgical adverse events could be better predicted based on the CBCT images. For implants, there was a significant difference between the use of CBCT and conventional radiographs in choosing implant length. The use of CBCT was seen to aid planning for impacted canine surgery, with more observers opting for conservative treatment when confronted with CBCT images after having seen conventional images first. There were no treatment planning differences between CBCT and conventional images for impacted third molars and sinus grafting procedures.

The cost analysis of CBCT took place in WP5 for three clinical situations (retained canines, lower wisdom teeth, pre-operative implant treatment) and was completed according to the protocol developed previously within the project. The work is significant because at the time of the study,

only one other paper existed on a health economics study in Dentistry. The work found that the cost per examination varied considerably between the four centres studied (Table 2).

**Table 2: Mean costs per CBCT examination at different centres. Direct costs = those incurred by the health care provider; indirect costs = those incurred by the patient**

| | Malmö Sweden | Vilnius Lithuania | Cluj-Napoca Romania | Leuven Belgium |
|---|---|---|---|---|
| Direct costs | 85.32€ | 52.58€ | 26.98€ | 18.75€ |
| Indirect costs | 93.14€ | 32.22€ | 63.31€ | 20.29€ |

Analysis of the health economics results in WP5 showed that there is no clear association between the estimated costs and the economic wellbeing of the country as measured by GDP per capita. Comparisons of costs between CBCT and conventional methods showed that examination with CBCT is always more costly, irrespectively of clinical situation. The main reasons for the differences in costs were: (1) the cost of the CBCT machine (newer machines are cheaper); (2) the cost of the additional space for the machine and those who work with the machine; (3) the volume of images performed, more images leading to a lower average cost; (4) the staff mix used to deliver the service (radiographers, radiologists, dental assistants; the staff types / levels used varied considerably between different institutions in the study) and (5) for patients, differences in the examination fee.

Work in WP5 on quantifying the benefits of CBCT in terms of additional diagnostic information took place for two clinical situations (retained canines and impacted lower wisdom teeth). The work showed that assessment of CBCT images made the radiologists significantly more confident in their assessments but that assessments of CBCT images took significantly longer time than assessments of radiographs from conventional methods, which affects the cost. The assessments by clinicians showed that they were also more confident in their decision when having access to CBCT images, although there was a wide range in confidence as well as in treatment decision between the clinicians. There was a change in treatment decision in 50% of the cases of planning for wisdom teeth to be removed.

The development of the SEDENTEXCT website www.sedentexct.eu in WP6 was informed by a Needs Analysis performed amongst stakeholders (dentists, medical physicists, equipment manufacturers and suppliers) to determine website content and methods of user assessment. The website was developed in three phases. The prototype website provided information about the project and basic functionality including a Drupal content management system which includes discussion forums and wiki functionality and a secure intranet for project partners, and the pre-definitive website included the initial population of the site with information about CBCT and development of a mechanism for providing three dimensional fly-throughs of CBCT images. The SEDENTEXCT Guidelines and national guidelines on CBCT are accessible via the home page, as are the SEDENTEXCT newsletters and Frequently Asked Questions for patients. The final definitive website included ten CBCT training modules,providing introductory materials for anyone with an interest in science, and suitable for undergraduate and post-graduate dentists and medical physicists and continuous professional development for dentists, as well as for the interested general public. Each of the ten modules comprises a PowerPoint with voiceover, some additional material encouraging active learning, and a set of assessment questions.

Awareness of the SEDENTEXCT website was raised through successive SEDENTEXCT newsletters and through the formal launch at the SEDENTEXCT workshop in Leeds (March 2011). At the end of the project, the educational materials on the SEDENTEXCT website were transferred to EADMFR (http://www.eadmfr.info) for future maintenance and development of their content.

Scientific coordination, financial and administrative management took place as planned in the Description of Work (DoW). An email distribution list of key stakeholders was set up, providing

contact details for international and national professional bodies in dentistry and medical physics, radiation protection agencies, CBCT manufacturers, universities and others. The list supported systematic dissemination in the latter part of the project of the twice-yearly project newsletters, the SEDENTEXCT Guidelines, invitation to the SEDENTEXCT workshop in Leeds, and as a starting point for marketing activities for the SEDENTEXCT phantom. An independent Ethical Monitoring Committee ensured that appropriate ethical approvals had been achieved and remained current, and that procedures with regard to ethics were being followed.

## 1.3 Final project results and impact

SEDENTEXCT has generated a suite of outputs that enhance the safety and efficacy of CBCT to patients and staff in Europe and beyond, as well as enhancing the necessary evidence base and informing future research. Dentists, health care providers and third party payment agencies will gain a better understanding that will reduce inappropriate use of CBCT. The evidence-based Guidelines provide recommendations on the use of CBCT that can be expected to lead to improvements in patient and staff safety, through guiding dental professionals on whether to use of CBCT for different clinical conditions and factors to consider in reducing x-ray dosage. WP-MED, a body advising the EC on radiation protection issues, will consider the possibility of publishing the Guidelines in its official "Radiation Protection" publication series at its meeting in October 2011. The earlier Basic Principles and Provisional Guidelines have already influenced the development of national radiation protection guidelines for CBCT in the UK, Belgium, Norway and France, while countries outside Europe (Japan, Brazil) have contacted the project concerning translation into their languages.

SEDENTEXCT has provided important dosimetry data for a range of CBCT equipment, with a priority for paediatric dose measurement. The dose indices, using measurements performed in the field, allow a simple way of effective dose estimation that may be adopted by medical physicists. Such dosimetry data will also be a driver to manufacturers to reduce doses. The measurements and recommendations on personnel dose should be of importance to workers and in setting standards. A QA programme that is generally applicable to CBCT has been developed, key parts of which are the production of a marketable phantom and software for CBCT and the QA Manual. In terms of diagnostic accuracy, the project results give clinicians an accurate understanding of the diagnostic capabilities of CBCT compared with traditional techniques for key clinical situations. This information will have an impact on referral criteria and, it is hoped, will reduce inappropriate examinations of patients. The economic evaluation being performed in SEDENTEXCT is important in a wider radiological context than CBCT, as we have developed, for the first time, a methodology for economic evaluation of a dental diagnostic imaging technique.

The ‘valorisation’ of the project results, through a process of web-based dissemination and design of a training programme aimed at all stakeholders (dentists, medical physicists, industry and the public), provides lasting impact of the SEDENTEXCT project. The achievement of “adequate theoretical and practical training” for CBCT has been highlighted as important in raising standards; the freely accessible source of training that will be developed in SEDENTEXCT will make a significant contribution to this.

The project has disseminated its results in the research community, with six peer-reviewed papers being published or accepted for journal publication and 26 peer-reviewed presentations being g iven at international conferences in dental radiology and medical physics. A further five papers have been submitted to journals and 19 papers are in preparation.

SEDENTEX CT

***Contact details:***

Project Coordinator: Professor Keith Horner; keith.horner@manchester.ac.uk

***Partners***

The University of Manchester (UK) (Project Coordinator)
The National and Kapodistrian University of Athens (Greece)
"Iuliu Hatieganu" University of Medicine and Pharmacy in Cluj-Napoca (Romania)
Leeds Test Objects Ltd. (UK)
Katholieke Universiteit Leuven (Belgium)
Malmö University (Sweden)
Vilnius University (Lithuania)