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## **Did malpractice claims for failed dental implants decrease after introduction of CBCT in Finland?**

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## **Abstract**

**Objectives.** To examine the role of cone beam computed tomography (CBCT) in preventing failures in implant treatment. We hypothesize that the number of malpractice claims related to dental implant treatment would decrease after the first CBCT device came available in 2002 in Finland.

**Material and Methods.** Data concerning malpractice claims related to dental implant treatment during the years 1997–2011 were collected from the Finnish Patient Insurance Centre (N = 330 subjects). We selected the cases that might have benefitted from the use of CBCT examination. These cases (n = 131) led to financial compensation due to permanent inferior alveolar nerve injury, improper implant position, or insufficient amount of bone for the implant. The annual total number of inserted dental implants, CBCT devices, and CBCT examinations in Finland were drawn from the national registers and used to estimate the impact of CBCT in preventing treatment failures.

**Results.** The most common reason for all failures (n = 268 implants) was an improper implant position (46.3%). The most common area of malpractices was upper front teeth (34%). We have noticed a fall in the rate of compensable malpractice cases concerning implant failure, simultaneously with CBCT technology emerging on the market.

**Conclusions.** There may be an association between the increasing availability of CBCT equipment and the reducing frequency of compensable malpractice claims.

**Clinical relevance.** It is possible that the use of CBCT may result in fewer compensable malpractice claims.

**Keywords:** cone-beam computed tomography; dental implant; injury; insurance; radiology

## **Introduction**

Cone beam computed tomography (CBCT) devices were developed for dentomaxillofacial imaging in the late 1990s [1, 2]. These devices allow accurate 3D imaging of hard tissues with a lower radiation dose, lower cost, and easier availability for dentists compared to multislice CT [3]. Panoramic and intraoral radiographies are still the dominant imaging methods in dentistry. In dental implantology, CBCT may offer vast therapeutic potential, including opportunities for surgical guidance and further prosthetic rehabilitation via computer-aided design/computer-aided manufacturing (CAD-CAM) solutions [4]. However, present knowledge on the impact of CBCT availability on treatment outcome and quality of care is still limited concerning implant treatments. Related to third molar surgery the introduction of CBCT did not decrease the number of nerve injuries [5].

The European Association for Osseointegration (EAO) and the International Congress of Oral Implantologists (ICOI) have published their recommendations for the use of diagnostic imaging in implant dentistry [6, 7]. For treatment planning, information on bone volume, structure and density, topography, and the relationship to important anatomical structures, such as nerves, vessels, roots, nasal floor, sinus cavities, and clinically relevant pathology are needed [6]. The use of CBCT is not recommended as a routine imaging technique for implant cases according to SEDENTEXCT provisional guidelines, which are officially published as European Guideline: Radiation Protection No. 172 [8].

If judged both clinically and by conventional radiological methods that there are relevant anatomical boundaries and adequate bone height and space, no additional imaging is required for implant placement [6]. The literature supports the use of CBCT particularly with regard to linear measurements, 3D evaluation of alveolar ridge topography, proximity to vital anatomical structures, and fabrication of surgical guides. CBCT is justified for cross-sectional imaging prior to implant placement as an alternative to existing cross-sectional techniques where the radiation dose is shown to be lower [8].

Complications occur occasionally in implant surgery [9], and they can be divided into three categories: inflammatory, prosthetic, and surgical complications [10]. Surgical complications can in turn be divided into i) treatment plan-related complications (incorrect angulation, improper implant location, lack of communication with dentist and surgeon or surgeon and patient), ii) anatomy-related complications (nerve injury, bleeding, cortical plate perforation, sinus membrane complications, devitalization of adjacent teeth), and iii) procedure-related

complications (mechanical complications, lack of primary stability, mandibular fracture, implant ingestion, and aspiration) [9].

The aim of this study was to determine whether the increase in availability of CBCT in Finland had an impact on the number of compensated malpractice decisions for implant treatment, namely inferior alveolar nerve (IAN) injury, improper implant position, or the lack of bone in the implanted area. Data used for this study originated from four national registers. Our hypothesis was that the proportion of compensated injuries related to dental implant treatments would decrease with increasing CBCT imaging possibilities.

## Material and methods

Since 1987, the Finnish Patient Insurance Centre (FPIC) has handled claims for personal injury in medical care as well as decided when the patient is entitled for financial compensation. The FPIC register—the first register of our material—for dental implant patient cases was searched using the classification of treatments according to the Nordic Medico-Statistical Committee (Nomesco). The code for an implant placement was EBB10 and for the placement of additional implants EBB11. This coding system has been used at FPIC from the beginning of 1997. We therefore included the data concerning years 1997–2011 in this study. We analyzed the following malpractice claims: compensated cases of (i) permanent IAN injuries related to dental implant treatments, (ii) improper implant position, and (iii) insufficient amount of bone for the implant. The inclusion was based on the assumption that these faults could have been avoided or reduced by a 3-dimensional radiological investigation. Cases completed by the summer of 2014 were included. Local legislation stipulates that the final decision relating to nerve injury claims is not given until at least 2 years after the injury [11], and the complaint by the patient has to be made within 3 years after the injury. Due to these factors, we assumed that practically all decisions on the injuries that had occurred by 2011 were issued by summer 2014.

From the FPIC files we also recorded the gender and age of patient, the number of all inserted implants, the tooth area for each case, the type of failure, and pre-operative CBCT radiological examinations.

The National Institute for Health and Welfare (THL) maintains a register (the second register used for this study) of implant treatments in Finland, including the number of dental implants inserted annually. This voluntary register was established in 1994. The Finnish Medicines Agency first maintained it until 2009; since then THL has maintained the register. The number of inserted implants reported to the register was collected from the beginning of 1997 to the end of 2011.

The Radiation and Nuclear Safety Authority (STUK) keeps records (the third register used for this study) of all CBCT devices in Finland. Safety permission is compulsory for CBCT device use and it is given by STUK. In Finland, the first device was registered in 2002. The total number of CBCT devices in the STUK register in the years 2002–2011 was used for this study.

The Social Insurance Institution (KELA) (the fourth register used for this study) reimburses the cost of medical and dental treatment, including radiological examinations. According to the national Health Insurance Legislation,

reimbursement is paid for medical services obtained from private-sector providers. Concerning CBCT examinations, reimbursement has been paid since 2004. A referral for the imaging examination by a specialist dentist or physician is a prerequisite for reimbursement. The number of all CBCT examinations performed from 2004 to the end of 2011 (according to reimbursements made from the KELA register) was used for the analysis. The indication for the CBCT examination is not recorded by KELA.

Basic descriptive analysis was done with the Microsoft Excel spreadsheet program. A scatterplot with locally weighted smoothing (80% of points to fit) was created by using IBM SPSS Statistics version 20.

This study was carried out with the permission of FPIC. The national legislation required neither the approval by the ethical committee nor the patients' informed consents for this retrospective, register-based study without any patient intervention.

## Results

During the years 1997–2011 complaints related to dental implant care were recorded for 330 subjects. Of the 200 subjects who were entitled for compensation, 131 subjects met the inclusion criteria for this study (permanent IAN injuries, improper implant position, insufficient amount of bone, or combination of these injuries) (Fig. 1). The excluded cases were attributed to loss of implant, infection, lack of osseointegration, pain, implant fracture, and overloading. In addition, there were filed complaints for miscellaneous other reasons and a patient may have reported more than one complaint. Most of the subjects were women ( $n = 97$ , 74.0%). The mean age at the time of implantation was 52 years ( $SD \pm 14$ , range 15–85 years).

The 131 subjects had a total of 268 implants inserted during the operation leading to malpractice compensation (Table 1). Maltreatment was diagnosed from one or more implants per subject. The most common area of implantation was upper front teeth with one third of the malpractice claims derived from that area ( $n = 91$ , 34.0%). The most common reason for all failures related to these 268 implants was an improper implant position ( $n = 124$ , 46.3%).

During the years 1997–2011, a constant increase was evident in the registers in numbers of inserted implants, CBCT devices, and also examinations carried out with these devices (Fig. 2).

When the 131 compensated malpractice cases were plotted against the years 1997–2011, we observed that the number of injuries per procedure began to decrease from the year 2002 when the first CBCT device was registered in Finland (Fig. 3).

In our material, CBCT images had been obtained infrequently. CBCT examinations were not available until the year 2002. After that and to the end of the year 2011, a pre-operative CBCT examination was performed only in 12 cases (14%) of the compensated 84 cases: in two IAN injury cases and in 10 cases with improper implant position. There were no CT investigations done.



## **Discussion**

Supporting our hypothesis, the main result of the present study was that after the registration of the first CBCT device in Finland in the year 2002 the number of compensated malpractice claims related to implant treatment began to decrease. This association, however, may also have been affected by other confounders.

Possible explanations for the decrease could be the increasing experience of the operators and the use of proper, more sophisticated (surgical) techniques and the possible use of implant planning software. The total number of injuries can be anticipated to be higher than the number of claims issued to FPIC. The patients and operators may also make a deal and no malpractice claim is ever sent to the FPIC.

The number of claims with compensation among women substantially exceeded that of men (74% vs. 26%). Similar findings have been reported in studies concerning other dental treatments [5, 12-14]. This phenomenon is explained by women's greater general interest in dental health and use of services [15].

Clinical examination gives only limited information of bony structures. In the compensated cases, CBCT examination had seldom been done preoperatively, although many patients could have benefitted from it. Panoramic tomography provides a rough estimate on the vertical amount of bone, but it does not provide any information regarding the thickness or the 3-dimensional position of the alveolar ridge. In addition, horizontal measurements on panoramic radiographs are unreliable due to distortion and overlapping [3]. (CB)CT scans can be utilized not only for planning implant size, location, and vector of placement, but also to identify and avoid the mandibular canal [9]. Proper measurements, the use of implant-planning software, and the use of surgical guides are tools for planning the ideal implant placement.

Implant angulation and location are also determinants for implant success. Implants placed merely on the basis of available bone often result in poor esthetic outcomes as well as in long-term biomechanical instability [9]. The upper frontal area is especially prone to complications resulting from insufficient amount of bone leading to improper implant position [16-18]. A history of trauma to the anterior maxillary region or dental infection leading to tooth loss cause the most advanced cases of bone resorption in the anterior maxillary region [17]. In addition, this region is esthetically very demanding and patients most likely pay attention to even minor complications or failures in this area.

During the years 2004-2008 and according to the national statistics, the number of implants inserted in the upper premolar and the lower first molar regions were constantly higher than the number of implants inserted in the upper incisor region [21]. It is unlikely that there were significant differences between national statistics and our study, and therefore, it is difficult to explain our finding that upper incisor region was the most common place for malpractice. It is probably a question of aesthetics.

Limitations of the present study include the reliability of the registers. Official registers in Finland are regulated by laws and acts promoting their reliability, but they still may hold some uncertainty. We know that there is some discrepancy in the number of the inserted implants reported to THL in comparison to those reported to KELA [19]. According to THL in 2012 only 77% of implants reported to KELA were reported to THL. One reason for the difference may be that the information is sent to THL even one year or more after the operation. Also, the operation date is not always reported to THL, and in the KELA register the day of payment is reported instead of the operation date. Nevertheless, we decided to use THL register because this system has been in constant use during the study period. It is noteworthy that related to the complaints of subjects with several implants it was not always possible to identify from the FPIC register the particular implant in question.

Reimbursement of CBCT examinations requires a referral for the imaging examination by a specialist dentist or physician, which may lead to an underestimation of the number of CBCT examinations done in the private sector. It is worth mentioning that the KELA register reflects the situation in the private sector only.

KELA does not register the indication for the CBCT examination. In a previous study we showed, however that, at a proportion of 49%, planning of dental implant placement is a very typical indication for CBCT examinations in Finland [20].

The introduction of new technology is often expensive, and little is known about the true patient outcome and benefits [22]. Our before-after introduction of CBCT in Finland study is observational and not as accurate as a rigorous randomised trial, and it has a weak accountability for temporal changes. We recognise the limitations as well as the fact that the results in our study might overestimate the benefits of the introduction of CBCT. However, this kind of studies are needed as new technology tends to disseminate quickly, even before accuracy and therapeutic impact are completely evaluated.

In conclusion, over the same period of time we can observe an increasing availability of CBCT systems and a fall in the rate of compensable malpractice claims. The availability of CBCT may explain the results only in part, and

a direct cause-effect relationship cannot be established based on our observational study. It may be especially beneficial to obtain CBCT from the upper frontal area of the dentition with high aesthetic demands. With regard to the reported IAN injuries, the use of CBCT was scarce and it is plausible that more patients would have benefitted from preoperative CBCT use.

### **Compliance with Ethical Standards**

Conflict of interests: Authors declare that they have no conflict of interest.

Funding: This work was supported by the Finnish Association of Women Dentists (A.S.) and Radiological Society of Finland (A.S.).

Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent: For this type of study, formal consent is not required.

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Figure captions

**Fig. 1** Distribution of compensated malpractice claims related to implant surgery during the years 1997–2011 meeting the inclusion criteria of this study (n = 131 cases)

**Fig. 2** The number of implants inserted annually in Finland and reported to the THL's register during the years 1997–2011, the number of new CBCT devices in the register of STUK and the number of annual CBCT examinations reimbursed by KELA. The first CBCT device was registered in year 2002 and the reimbursements by KELA started year 2004

**Fig. 3** Annual rate of compensated malpractice claims (permanent IAN injuries, improper implant position, insufficient amount of bone or combination of these injuries) related to the total number of inserted implants in Finland. A scatterplot with locally weighted smoothing (80% of points to fit)



Figure 1

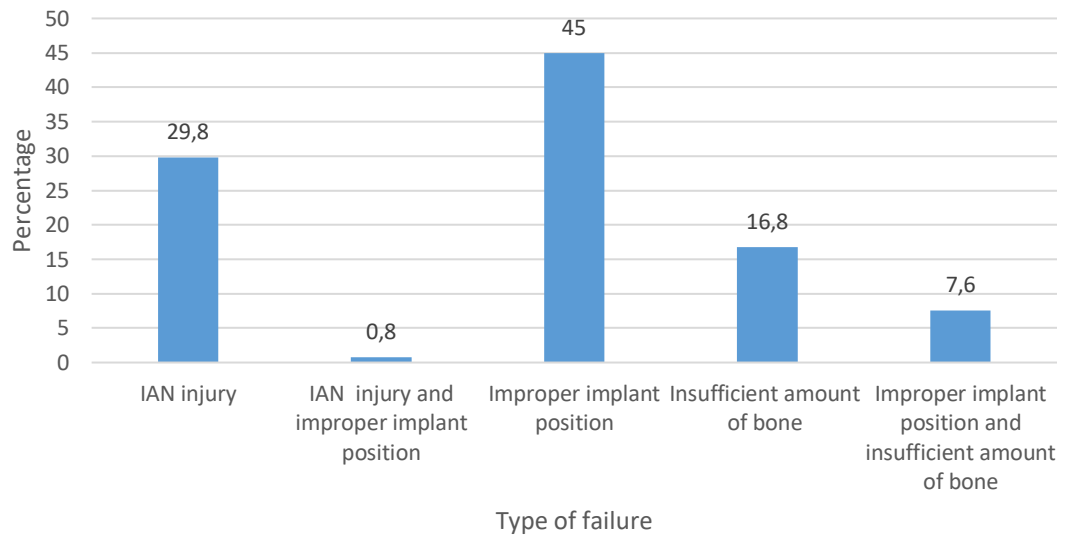


Figure 2

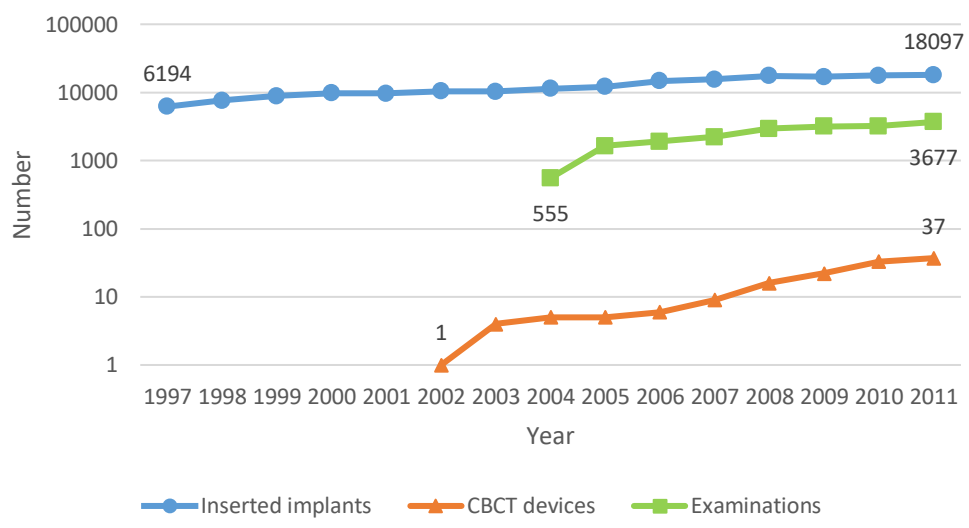


Figure 3

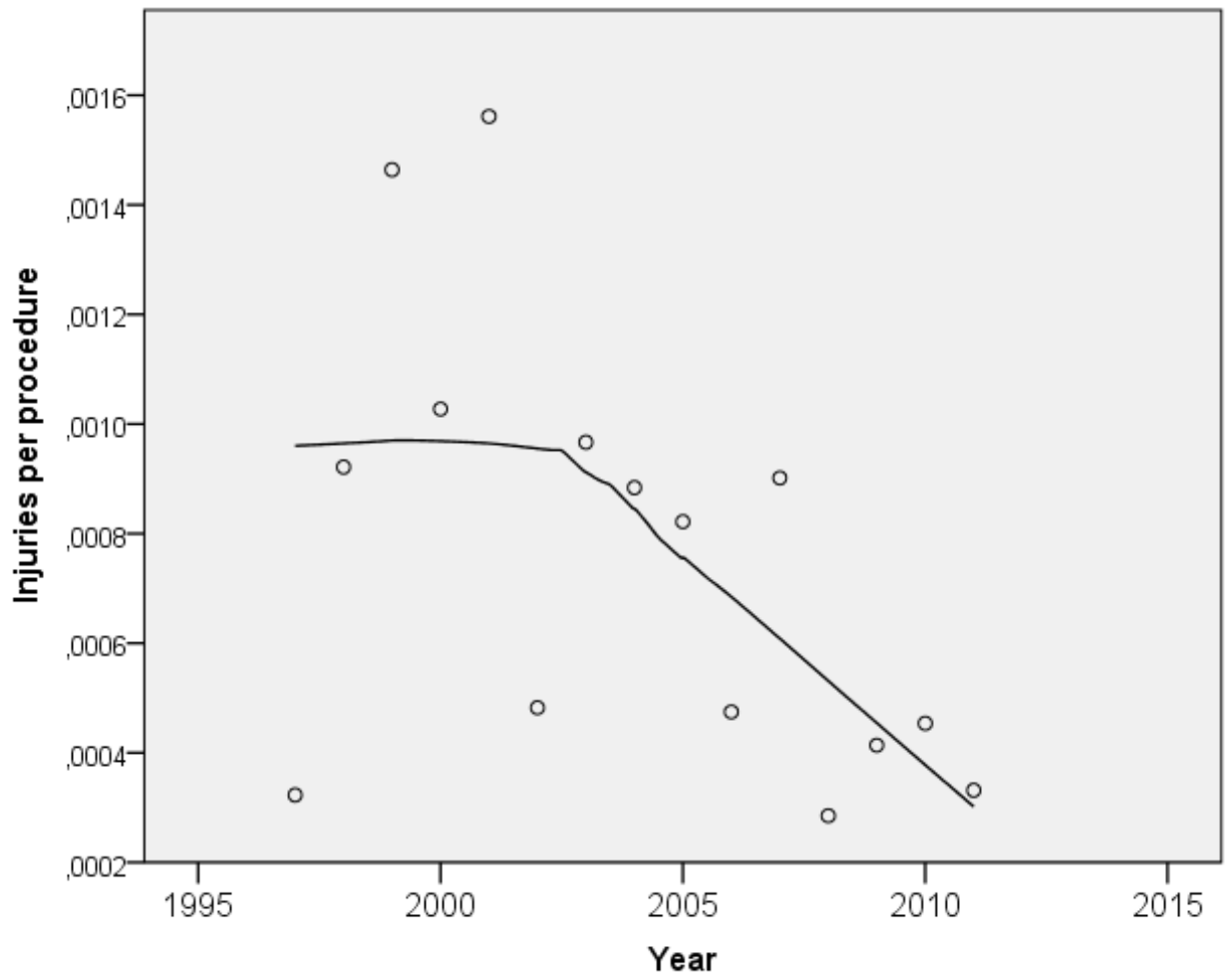


Table 1. Distribution of the 268 implants according to diagnosis of failure by area of implantation.

Area of implantation	Inferior alveolar nerve injury, n=66 [%]	Improper implant position, n=124 [%]	Insufficient amount of bone, n=56 [%]	Improper implant position combined with insufficient amount of bone, n=22 [%]	Number of implants (% of all)
Upper frontals	0 [0]	47 [37.9]	31 [55.4]	13 [59.1]	91 (34.0 %)
Upper premolars	0 [0]	28* [22.6]	18 [32.1]	4 [18.2]	50 (18.7 %)
Upper molars	0 [0]	10 [8.1]	4 [7.1]	0 [0]	14 (5.2 %)
Lower frontals	9 [13.6]	11 [8.9]	1 [1.8]	0 [0]	21 (7.8 %)
Lower premolars	26 [39.4]	9 [7.3]	2 [3.6]	4 [18.2]	41 (15.3 %)
Lower molars	31* [47.0]	19 [15.3]	0 [0]	1 [4.5]	51 (19.0 %)
<b>Total</b>	24.6 %	46.3 %	20.9 %	8.2 %	268 (100 %)

\* = one patient received compensation for two implants: one with IAN injury and the other with improper implant position