Summary
This thesis focuses on possibilities to reduce the dose and thereby the carcinogenic risk of orthodontic X-rays. The probability of a tumour developing is dependent on the X-ray dose.

The radiation dose to the patient of an orthodontic lateral cephalogram (Ceph) and its consequential risk is relatively low. Because many children undergo orthodontic treatment, and during the course of this treatment usually one or more Cephs are made, the consequential collective X-ray burden is considerable, resulting in an increase of the incidence of cancer in the population. For this reason it is worthwhile to investigate measures to lower the radiation dose of Cephs, even this dose being already comparatively low.

To avoid unnecessary exposure of the population to ionising irradiation, the International Commission on Radiological Protection (ICRP) has developed a framework of radiological protection principles that has been incorporated into clinical guidelines. This framework comprises amongst other the ALARA (‘as low as reasonably achievable’) dose principle. This principle leads the clinician to choose exposure parameters and to limit the field of view to the area where the diagnostic information is to be found. On Cephs a large area above the skull base contains no diagnostic information as well as an area below the mandible, where the radiosensitive thyroid gland is found. This has lead to development of a thyroid collar and collimators that shield the area above the skull base and below the mandible. For different reasons these protective measures did not become widely utilized although theoretically they reduce the dose to the patient by more than 50%. It can be hypothesized that instead of trying to collimate the two regions with one device, it would be more feasible to shield them with two different devices.

Therefore in Chapter 2 of this thesis an anatomically-formed cranial collimator (ACC) for the area above and behind the skull base for lateral cephalography is introduced. An outline for this collimator was established in such a way that it collimates a maximal area with only a remote chance of blocking anatomical structures that are of diagnostic interest. It was designed to be fixed to the ear post of the cephalostat between the X-ray generator and the head of the patient. In Chapter 3 of this thesis the ACC was tested in an observer study evaluating 100 Cephs made with the ACC. The results showed that there was minimal interference of the ACC on the diagnostic value of the cephalography, while reducing the irradiated area of the patient by almost one third.

According to clinical guidelines, shielding the thyroid from the primary beam in lateral cephalography is mandatory, unless it interferes with the depiction of structures of diagnostic interest. When a thyroid collar is used for this purpose it has been shown that the bodies of the cervical vertebrae below C2 are not depicted. The depiction of these cervical vertebrae assists orthodontic clinicians in calculating the maturation index which in turn can help to choose the optimal timing for orthodontic treatment. Therefore in Chapter 4 the design of a thyroid shielding device, referred to as cephalographic thyroid protector (CTP), is presented which leaves the cervical vertebrae depicted. In this chapter a phantom dose study is presented that quantifies the dose reduction to the patient when using ACC and CTP. It appeared that the use of these two devices results in a dose reduction of almost 60%. The CTP achieved a dose reduction which is comparable to the classic thyroid shield.

In regards to the different exposure protocols, in the dose study of Chapter 4 we
encountered difficulties in reporting correct confidence intervals around our calculated values. It is important to report the correct confidence intervals and therefore the use of statistical software was explored to correctly assess the RE in the dose measurement experiment. In Chapter 5 of this thesis the use of statistical software R (R version 3.0.2; The R Foundation for Statistical Computing, Vienna, Austria) for this purpose is described. This software was used to introduce RE around the measurement values on the basis of Monte Carlo simulation while performing multiple calculation cycles. This proved a viable way to correctly assess RE and to make credible statements about the statistical significance of the differences found between exposure protocols. The method of software simulation also appeared to be useful for power analysis when designing a phantom dose research protocol. This method can also be used for any other exposure modality than Ceph.

Achieving almost 60% dose reduction in cephalography by ACC and CTP might seem a sensible way of complying with the ALARA principle. But the dose level of a Ceph is already low; so does it make sense to lower this already low dose when social and economical factors are taken into consideration? To answer this question, in Chapter 6 we looked for methods to perform a cost-utility analysis (CUA). In a CUA one has to compare the value of the dose reduction with that of the costs, by expressing both in the same quantity. We explored three different methods of approaching the CUA comparing them on the basis of criteria of coherence and adaptability. One method, the time-for-time method, proved to be the most suitable in terms of coherence and adaptability. This method expresses both the dose reduction and its financial costs in an amount of time for comparison. It appeared to be possible to calculate with a simple formula how many times the dose reducing devices have to be used before they become cost effective:

$$n = \frac{c \cdot f}{\text{GNI}_c \cdot \Delta S_v \cdot \text{RF}_{\text{adj}} \cdot \text{LLT/SE}_{\text{adj}}}$$

where $n$ is the minimum number of uses; $c$ is the monetary cost of the device; $f$ is the factor of his/her life an average person spends working; GNI$_c$ is the gross national income per capita; $\Delta S_v$ is the amount of dose reduction per exposure; RF$_{\text{adj}}$ is the risk factor adjusted for the specific patient population; and LLT/SE$_{\text{adj}}$ is the lost life time per stochastic effect adjusted for the specific patient population. When the dose-reducing devices ACC and CTP presented in Chapter 2, 3 and 4 are evaluated using the CUA it can be concluded that the devices are cost-effective when used more than 200 to 600 hundred times. This number seems quite realistic, given the typical life cycle of orthodontic equipment in the orthodontic office.

The use of this method is not limited to dental dose reducing measures. The conclusions that can be drawn from this thesis are:

- With two devices (ACC and CTP) the radiation dose in orthodontic lateral cephalography can be reduced by almost 60% without losing diagnostic information.
- The results of phantom dose studies can be given with credible confidence intervals when Monte Carlo simulation is used for the assessment of the RE in statistical software.
- It is possible to make a well-founded statement about the minimum number of uses of a dose reducing measure before it becomes cost-effective, using a simple formula.
- The ACC and CTP are cost-effective after a realistic number of 200 to 600 uses, according to this formula.
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