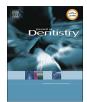
## ARTICLE IN PRESS

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# Crown therapy in young individuals with amelogenesis imperfecta: Long term follow-up of a randomized controlled trial

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ARTICLE INFO	A B S T R A C T
<i>Keywords:</i> Ceramics Clinical outcomes Enamel mineralization Patient outcomes Pediatric dentistry Restorative dentistry	<i>Objectives</i> : Amelogenesis imperfecta (AI) is a rare, genetically determined defect in enamel mineralization. Several problems are associated with AI: hypersensitivity, wear, restorations requiring replacement, gingivitis, aesthetic problems, and social avoidance. We conducted a randomized controlled trial of crown therapy in young individuals with AI showing excellent results. This study reports results from a long-term-follow-up with focus on quality, longevity and adverse events. <i>Methods:</i> The RCT included 27 patients (aged 11–22 years) with severe AI in need of crown therapy and used a split-mouth technique. After placing 119 Procera <sup>*</sup> crowns and 108 IPS e.max Press crowns following randomization, we assessed longevity, quality, adverse events, and tooth sensitivity and calculated survival rates and success rates. <i>Results:</i> We followed the original 227 crowns for 4.3–7.4 years (mean 5.5 ± 0.8). In all, 79% (193) crowns were followed for at least 5 years. The survival rate was 99.6% and the success rate, 94.7%; 95% of the crowns had excellent or acceptable quality. Due to suboptimal marginal integrity, 4% of the crowns required adjustment. Sensitivity problems decreased after crown therapy (p < 0.001). All adverse events occurred in patients aged 19–23 years and involved apical periodontitis (3% of teeth); all but two events were related to dental trauma in the actual tooth. <i>Conclusions:</i> Ceramic crown therapy in adolescents and young adults with severe forms of AI show excellent survival and success rates and longevity with few adverse events.

#### 1. Introduction

Amelogenesis imperfecta (AI) is a rare, genetically determined defect in enamel mineralization. In most severely affected patients, teeth exhibit rapid loss or fractures of the enamel as well as alterations in enamel thickness and color; changed tooth shape; an open bite; and tooth impaction [1,2]. Several problems are associated with AI, including hypersensitivity, problems in masticatory function, gingivitis, restorations requiring replacement during the whole lifetime, and negative aesthetic effects due to abnormal tooth shape and color [3–6]. Patients with AI report significantly higher levels of social avoidance and distress than subjects without the condition; they also report a social impact on education, job satisfaction, and family building [3,7–10]. Current guidelines recommend postponing prosthetic therapy in children and adolescents until adulthood [5,10–12]. Although replacements of many restorations are anticipated, resin composite restorations are still recommended in young patients with AI [5,10,11,13]. A study of the quality of restorative treatment found that longevity of composite resin restorations was significantly shorter in patients with AI compared to controls and in particular shorter for the hypomaturated/ hypomineralized forms [4]. We have previously reported a high success rate of crown therapy in young patients with AI [14]. After 2 years, 97% of both Procera with zirconia coping and IPS e.max Press crowns had excellent or acceptable quality [14]. Anusavice has recommended 5-year follow-ups of ceramic crown therapy [15] in order to allow a wider range of possible adverse outcomes to be detected. The present study compared the long-term survival of IPS e.max

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Press crowns and Procera crowns with zirconia copings in young individuals with AI through routine recalls after 4.3–7.4 years; the study also closely monitored adverse events and reasons of failure.

#### 2. Materials and methods

The Regional Ethics Review Board in Uppsala (Daybook number 2008/108) approved the study. It followed the Declaration of Helsinki guidelines and is a single-center, double-blind, randomized controlled trial with a split-mouth design. The study was conducted at the Centre for Oral Rehabilitation, Department of Pediatric Dentistry, Falun, Sweden, and is registered at www.controlled-trials.com: ISRCTN70438627.

From May 2009 to March 2012, we enrolled the patients with AI who had been referred to the Department of Pediatric Dentistry in Dalarna County, Sweden. Each patient received oral and written information, and patients and their parents signed informed-consent forms. To be included, patients needed a clinically verified AI diagnosis, confirmed by an anamnestic family history or histological examination. We excluded patients with fluorosis, molar incisor hypomineralization, other oral developmental disturbances, systemic disorders, and patients who were unable to provide informed consent. Of the primary study sample of 82 patients with AI (40 boys and 42 girls aged 6-25 years), 27 patients (12 boys and 15 girls, aged 11-22 years) needed prosthetic therapy. All of the patients selected for prosthetic therapy agreed to participate in the study. Following the classification system of Sundell and Koch [16], 15 patients were diagnosed with hypoplastic AI and 12 with hypomineralized/ hypomatured AI. In cases of mixed forms of AI, we recorded the most dominant form. All teeth were vital at the start of crown therapy. The flow-chart in Fig. 1 shows patient selection and randomization, and follow-up examinations. Details regarding randomization can be found in a previous paper [14].

#### 2.1. Protocol

All cases followed the same protocol: The clinical examination included a family history to exclude possible differential diagnoses and childhood diseases [17]. Caries [18], gingival bleeding on mesial and distal surfaces (recorded before and after therapy) on the teeth selected for crown therapy [19], previous trauma history, quality of restoration [20–22] and endodontic diagnoses [23] were then assessed. The examination also included a panoramic radiograph if none was available. We recorded tooth sensitivity for the entire dentition on a visual analogue scale (VAS), letting the patient estimate sensitivity problems by marking with a pen on a 100-mm line. [24,25]. An orthodontic consultation was done if we anticipated future problems with the occlusal curve, or other problems.

The treatment procedure was carefully explained to the patient and parent. Oral hygiene instructions, cooperation control and injection training were performed. After an expectation period of three month cooperation of oral hygiene was controlled and the decision for making crowns or not and if nitrous oxygen should be used, was finally set with the absolute focus on patients own wishes. As the crown therapy followed tooth eruption pattern, front teeth 12–22 often were treated with crown therapy before full eruption of canines and premolars was present.

The patients were given paracetamol 1 h before treatment and ibuprofen in combination with paracetamol throughout the rest of the day. Sedation with nitrous oxygen was offered to all patients, and 18 accepted. Local anesthesia was given using Xylocaine dental (20 mg/ml lidocaine hydrochloride + 12.5  $\mu$ g/ml adrenalin). We also covered unanesthetized teeth with fluoride varnish during crown preparation. Two types of burs were used, both with a rounded top: Parmax 12 212 A and Parmax 9 209 A (from Parmax AB). For tooth preparation, a high-speed turbine was used; we removed as little tooth substance as possible, without reducing the recommended thickness of the porcelain

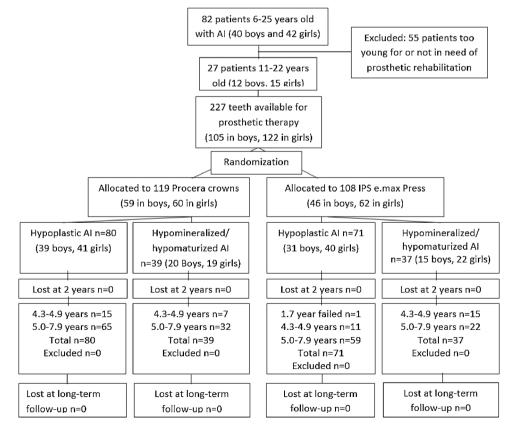


Fig. 1. Flowchart showing patient selection and randomization, and follow-up examinations (AI, amelogenesis imperfecta).

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