Technological Innovations in Endodontic Surgery and Implant Dentistry

summary of the Ph.D. thesis

by

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Publications providing the basis of the thesis

I. ***Kiscsatári, R.;*** Nagy, E.; Szabó, M.; Braunitzer, G.; Piffkó, J.; Fráter, M.; Antal, M.Á. Comparison of the Three-Dimensional Accuracy of Guided Apicoectomy Performed with a Drill or a Trephine: An In Vitro Study. *Appl. Sci.* **2023**, *13*, 9642. **IF: 2.7**

II. Antal MA, ***Kiscsatári R***, Braunitzer G, Piffkó J, Varga E, Eliaz N. Assessment of a novel electrochemically deposited smart bioactive trabecular coating (SBTC®): a randomized controlled clinical trial. Head Face Med. 2024 Apr 16;20(1):24 **IF: 3.0**

Introduction

Modern medicine is greatly aided and supported by technological advancements, especially in computer-aided and/or computer-controlled, guided (or navigated) surgical interventions. It is increasingly common to consider the patient's unique anatomical conditions when planning surgical procedures or manufacturing specific surgical tools. This significantly enhances the accuracy of the procedure, improves short- and long-term success rates, prevents unnecessary tissue damage, and can sometimes reduce the risk of complications.

Understandably, digitally supported, guided surgical interventions are rapidly spreading across various surgical specialties. This is true in general surgery, orthopedic surgery, and even neurosurgery.

In the field of oral surgery, implantation and apical resection procedures specifically require a high degree of accuracy and minimal invasiveness. High precision and complication-free healing are crucial in these cases because these procedures often have both functional and aesthetic demands. Therefore, there is a strong need for predictability and meticulous planning in this area.

It is also crucial that the implants (in fact, artificial roots) achieve stable osseointegration and provide long-lasting good results.

Navigation allows for plan-accurate placement, which in itself can improve success rates. Additionally, however, there is ongoing experimentation with new implant surfaces that may further enhance the short- and long-term success of implantation procedures.

This thesis partially discusses a novel approach to statically guided apical resection *in vitro,* and partially presents the author's clinical experiences with a newly developed implant surface through a clinical trial.

Aims

The first study forming the basis of this thesis focused on the accuracy of static navigation in apical resection. In this rapidly developing field, only limited data has been published so far on whether the use of a standard straight drill (commonly referred to as a "pilot" drill in the literature) or a bone trephine achieves more accurate results in guided endodontic surgery. Our in vitro research investigated this question. *Our hypothesis was that there would be no significant difference between the two instruments when used with a static surgical guide.*

The second study focused on the surface treatment of dental implants. Among the various implant surface treatment options, additive procedures represent a rapidly developing area. Some of these surface treatments are widely available and have numerous known advantages and disadvantages, while newly developed solutions require thorough examination to map their properties, risks, and benefits. The aim of our clinical trial was to evaluate the suitability and safety of a new additive surface treatment for dental implants using NaOH-EDHAp (Sodium Hydroxide-Electrochemically Deposited Hydroxyapatite) coating, compared to a widely available commercial electrochemical surface treatment that combines magnesium hydroxide and hydroxyapatite. *Our hypothesis was that there would be no significant clinical difference between the two surface treatments.*

Materials and Methods

In the first study, we examined the accuracy of apical resection using pilot drills or bone trephines *in vitro* on extracted teeth. First, we created a master model in which the extracted teeth were embedded in methyl methacrylate in anatomically appropriate positions. A CBCT scan of this master model was taken using an i-CAT Next Generation device (Imaging Sciences-Kavi, Hatfield, PA, USA). Additionally, the model was scanned with a desktop scanner (Maestro 3D MDS400, AGE Solutions, Italy). The obtained DICOM and STL files were integrated into a specially developed surgical planning program (Smart Guide Software System, dicomLAB Dental Ltd., Szeged, Hungary) to create the surgical plan and the corresponding surgical guides. The guides were 3D printed (ProJet MD 3510, 3D Systems, SC, USA). Two surgical plans were made: in Plan A, the trephine drills were used on the right side, and the pilot drills were used on the left side; in Plan B, the arrangement was reversed. During the experiment, the drilling was performed on precise plaster replicas made from the master model, targeting the apical parts of the roots at a 90-degree angle to the tooth axis. After the holes were drilled, CBCT scans of the plaster models were taken. The resulting postoperative CBCT scans were compared to the preoperative plans using dedicated algorithms.

The second study was a randomized controlled clinical trial involving 20 patients. Screened and eligible patients who expressed willingness to participate were randomly assigned to two groups. In Group A, the new type of surface-treated implant was placed on the left side, and the control implant (see surface treatments below) on the right side. In Group B, the arrangement was reversed. Subsequently, a preliminary CBCT scan was taken of the patient, regardless of the group, to be used for surgical planning. In this research, we also used the previously mentioned surgical planning software (SMART Guide, dicomLAB Dental, Szeged, Hungary). Based on the plan, the 3D printed surgical guides were created using a special plastic designed for this application (NextDent SG, 3D Systems, USA) with a ProJet MD 3510 printer (3D Systems, USA).

Regardless of surface treatment or randomization group, the implants were placed in the following positions: 32 to 35 (left side), 42 to 45 (right side). The following implant sizes were used: 3.75×11.5 mm ($n = 13$ in both groups) and 4.2×10 mm ($n = 7$ in both groups). The same participant always received the same implant size on both sides. All implants were of the P7D type from SGS Dental Holding (St. Gallen Switzerland), and were made of Ti6Al4V alloy. They were all grit-blasted with corundum (crystalline alumina), and just differed in their surface treatment – either SBTC® (smart bioactive trabecular coating, test group, bath concentration ×39, SGS Dental, Budapest, Hungary) or Bonit® (control group, DOT Medical Implant Solutions GmbH, Rostock, Germany).

Data Analysis

In the first study, the statistical analyses were performed in SPSS 23.0 (IBM, USA). Besides calculating the descriptive statistics (means, standard deviations, medians and 95% confidence intervals), multiple linear regression analyses and ANOVA were performed. In the multiple linear regression model, the following variables were defined as the predictor variables: plan version (A or B), position within the dental arch (according to the FDI system), instrument (drill or trephine) and the number of the specific plaster model in which the simulated surgeries were performed (1 to 6). DGD (distal global deviation = global deviation at the apex) and AD (angular deviation) were the dependent variables.

In the second study, the statistical analyses were performed using Jamovi 2.3.21 (The Jamovi Group) and SPSS 26.0 (IBM, USA). Categorical variables were presented as counts and relative percentages, while continuous variables were summarized with counts, means, 95% confidence intervals, medians, minimums, and maximums. To compare parameters related to the implants between the two randomization groups, the Kruskal-Wallis H test was employed. The results indicated no statistically significant differences, confirming the successful randomization process in effectively mitigating any potential influence of the surgeon's skill. For the primary outcome variable (implant stability over time), the assumption of normality was not met for all variables according to the Shapiro-Wilk test. Consequently, Friedman ANOVA along with Durbin-Conover post-hoc pairwise comparisons was utilized for the repeated measures analysis. Effect sizes, calculated using Kendall’s W, were also reported. Regarding bone level change over the entire 2-year observation period, it was assessed at four positions (as described above) for both study groups. As the assumption of normality was not met for all cases based on the Shapiro-Wilk test, the Kruskal-Wallis test was used to compare the two groups in terms of bone level change at these four positions. Lastly, the mean oral health-related quality of life scores across multiple appointments over time, as assessed with the OHIP-14 questionnaire, were compared using Friedman ANOVA with Durbin-Conover post-hoc pairwise comparisons.

Statistical significance was defined as $p < 0.05$ for all analyses.

The clinical trial was complete with a scanning electron microscopic (SEM) and X-ray photoelectron spectroscopic (XPS) studies of the implant surfaces, to characterize the novel surface in comparison with the control surface.

Results

Results of the in vitro study

Regarding the *in vitro* study, the data of 86 procedures were analyzed. Of these, 39 (45.34%) were performed with a drill and 47 (54.65%) with a trephine. In the case of drill, DGD was 1.53 ± 0.51 mm, and AD was 3.32 ± 1.41°. In contrast, in the case of trephine, DGD was 1.31 ± 0.45 mm, and AD 3.5 ± 1.67°.

In terms of DGD, the multiple linear regression analysis indicated a moderately significant effect for the applied instrument ($\beta = -0.23$, $p= 0.036$). The rest of the predictors turned out not to have a significant effect on this parameter. DGD was 1.531 ± 0.510 mm (median: 1.45 mm, 95% CI: 1.366-1.697) for the pilot drills and 1.311 ± 0.456 mm (median: 1.33 mm, 95% CI: 1.177-1.446) for the trephines. The difference was moderately significant, as indicated ($F= 4.44$, $df=1$, $p= 0.038$, one-way ANOVA). The effect size was small ($f= 0.19$).

As for AD, the multiple linear regression analysis did not indicate a significant effect for any of the predictors. The mean AD was 3.323 ± 1.419° (median: 3.2°, 95% CI: 2.863-3.783) for the pilot drills and 3.500 ± 1.672° (median: 3.2°, 95% CI: 3.009-3.991) for the trephines. The difference was not significant.

Results of the clinical trial

20 participants enrolled in the study, all of whom completed the study per protocol. Among these participants, 14 were females (70%), 6 were males (30%). The average age was 67.3 years, with a standard deviation of 7.6 years.

Regarding the buccolingual stability measurements, a significant change between T1 (immediately after insertion) and T4 (2 years after insertion) was found for both the control ($\chi^2 = 50.1$, mean change: 8.25) and the test surfaces ($\chi^2 = 52.1$, mean change: 13.3). In both cases: df = 3, $p < 0.001$, Kendall's W = 0.835. The Durbin-Conover post-hoc analysis revealed that the change was significant between each time point. In the case of mesiodistal measurements, the same pattern was found. The change between T1 and T4 was significant for both the control ($\chi^2 = 51.3$, Kendall's $W = 0.855$, mean change: 7.90) and the test surfaces ($\chi^2 = 51.0$, Kendall's $W = 0.850$, mean change: 13.70). In both cases: $df = 3$, $p < 0.001$. The Durbin-Conover post-hoc analysis revealed that the change was significant between each time point.

Bone level changes over time were individually calculated for each participant in each study group. No statistically significant difference was found for any of the positions (buccal, lingual, mesial, distal).

It is evident that almost immediately after the delivery of the implant-retained prostheses, the patients experienced a significant improvement of oral-health related quality of life ($p < 0.001$, Friedman ANOVA with Durbin-Conover post-hoc pairwise comparisons), and the difference remained significant until the last appointment, with significant changes between the appointments. Neither adverse events nor implant loss were reported during the 2-year follow-up period.

Both XPS and SEM revealed characteristic differences between the test and control surfaces.

The SBTC® coating consisted of 55% hydroxyapatite and 45% octacalcium phosphate (OCP, atomic percentage). The analysis also revealed that the control coating consisted of magnesium hydroxide and hydroxyapatite. The magnesium hydroxide content ranged between 60% and 53%, with lower values observed deeper in the coating. In the SEM images, the differences between the surface structures were readily observable.

Conclusions and new results

From our studies, we draw the following conclusions, which we also consider as new scientific results of the dissertation:

1) Based on our in vitro study, we conclude that statically navigated apical resection, regardless of whether it is performed using a pilot drill or a trephine, provides a clinically acceptable level of accuracy. However, surgeries performed with a trephine are more accurate than those performed with a pilot drill.

2) Based on our randomized controlled clinical trial, we conclude that the new electrochemically deposited calcium phosphate coating (SBTC®) is a safe alternative to the widely used control surface, with similar ossification properties and identical bone level changes over time.

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