Endodontic Therapy at Different Stages in the Treatment of Avulsed Teeth: a Double Blind Randomized Controlled Clinical Trial

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Abstract

Objective To evaluate the outcomes of the teeth avulsed from alveolar bone in accidents for a 1 year follow up when endodontic root canal therapy was performed at different time points. **Materials and Methods** According to the inclusion criteria, 109 patients diagnosed with teeth avulsion due to accidents were enrolled at base-line and 103 patients finally completed follow-up in this trial. 115 teeth were firstly assigned to two groups according to storage condition. Then they were randomly assigned to one of two groups respectively. The teeth were treated with root canal therapy at different stages. All of patients were recalled at baseline, in the first, third month, sixth month and first year (end of follow-up) for clinical and radiological evaluation. **Results** 103 patients finally completed follow-up in this trial. As for periodontal healing, cases with before-replantation treatment were significantly more than post-replantation treatment in dry storage. On the contrary, more periodontal healing cases were obtained in ideal storage. In the first year after treatment, there was no difference of success rate between G21 and G22 ($P < 0.05$). Significant difference was found between G11 and G12 ($P < 0.05$). **Conclusion** In clinical practice, root canal therapy should be performed prior to replantation in dry storage condition for more than 60 minutes. In contrast, if not, root canal therapy could be postponed.

Background

Tooth avulsion, which is one of the most serious types of traumatic dental injuries caused by a fall, road traffic accident, sports injury and so on, is defined as a complete dislodgement of a tooth from the alveolar socket[1]. The maxillary central incisor is the most commonly avulsed permanent tooth. Several studies have reported that avulsion of permanent teeth accounts for approximately 5% of dental trauma for children and adolescents, which has a significant physiological and psychological impact on the quality of their life[2].

Tearing and displacement of the periodontal ligaments and supply of blood to the pulp was damaged once a tooth was extracted to occur[3]. Diangelis AJ stated that The vascular supply and root surface attachments can be preserved if the reimplantation was performed within 1 hour[4].

However, in most cases, the purpose is hardly achieved due to the long distance to the hospital, lack of awareness and knowledge of dealing with the emergency incident, severity of trauma or some other reasons[5]. As a result of it, an inevitable cell death in the avulsed tooth would lead to endodontic infection and root resorption by inflammatory, especially isolated tooth is kept in dry storage[6, 7]. Treatment should be undertaken aiming on eliminating the harmful products in the pulpal space. Consequently, in the event of pulp necrosis with apical periodontitis, a root canal therapy is usually required[8].

Until today, there is uncertainty, however, what is the best time point to initiate a clean-up of root canal. In a previous study, some investigators stated that the canal should be disinfected and filled with calcium hydroxide as soon as possible to establish a barrier in the apical portion of the root. On the other hand,

some studies have reported a good prognosis gained by root canal therapy one or two month after tooth avulsion. They emphasized that the toxic materials of medicine sealed in the root canal would leaks through apical foramina and have a negative effect of healing and reestablishing with periodontal ligament. Regarding this influencing factor, the problems also exists for the suitable medicine applied in root canal. What is more, further studies showed that, if involve root canal treatment had no effect on preventing the occurrence of infection and root replacement resorption[9].

When was the appropriate time point to take start root canal treatment still puzzles dentists in clinical practice. Even though some clinical case reports were found in previous documents, prospective clinical studies concerning comparing effectiveness between the two different time points to initiate root canal therapy are required[10, 11]. Thus, the aim of this clinical trial was to evaluate the success rate of replanted tooth cases to assess when to undertake root canal therapy for the better outcome of such cases. The null hypothesis that there is no difference in the clinical performance of avulsed teeth replantation regardless when to perform root canal therapy.

Materials And Methods

This was a double blind, randomized clinical trial and the study was conducted between May 2016 and September 2018. The research was conducted in full accordance with the World Medical Association Declaration of Helsinki. The project was evaluated and approved by the ethics committee of the Affiliated Huai'an Hospital of Xuzhou Medical University (HEYLL201813). It was designed in accordance with the 2010 CONSORT guidelines, and was registered at Chinese Clinical Trial Registry (identifier code: ChiCTR1900023744).

The aim of this study was to evaluate the endodontic performance of the teeth avulsed from alveolar bone in accidents for a 1 year follow up. Although participants were illuminated all the procedures they would be treated, which one kind of treatment allocated on each patient was not known by both participants and examiners. Operators were not blinded to treatment allocation.

The sample size of this clinical trial was calculated based on the previous reported systematic review that the successful rate was 82% in replantation of avulsed teeth. Considering an α level of 0.05 and a power of 80% as a non-inferiority value, the sample size resulted in $n = 86$. Taking into consideration of 10% of the patients lost to follow-up, we finally set a sample size up to 110.

Eligible participants were enrolled from among patients who attended the Affiliated Huai'an Hospital of Xuzhou Medical University, seeking for treatment of tooth avulsion. All patient invited to participate as well as their parents in this clinical trial were informed of the procedure protocols, risks, and benefits and their right to self-determination regarding participation. A written consent was signed, and a copy was delivered to all participants.

The participants' inclusion criteria for this study were as follows: 1. both genders aged between 8 and 18 years. 2. permanent incisor with one root canal; 3. fully developed teeth with an extraoral time of 1hour; 4.

tooth without a history of root canal therapy and without porcelain restoration. 5. without fracture of alveolar; 6. patients and their parents signing agreement to the treatment protocol; 7. without trigeminal neuralgia and systemic disease[12].

Patients were excluded because of the following: 1. tooth without achieving good retention such as fracture of crown or root; 2. patients with periodontal disease; 3. poor compliance without subsequent visits; 4. can not build a good oral health habits after oral hygiene education; 5. history of esophageal reflux, gastrointestinal disorders, active asthma, decreased hepatic function, hemorrhagic disorders, or poorly controlled diabetes mellitus; 6. Pregnant or nursing[13].

Three operators (Wang SM, Shi XL and Shao P) were designated to perform the treatment procedures, who have at least master degree and more than five years of endodontic treatment experience. They were also previously calibrated by receiving the same clinical training in order to standardize the clinical treatment protocol for each group.

When patients attended our department, we picked up useful information about the time and place the trauma happened, the storage conditions and systemic disease. Their anamnesis, clinical examination, and radiographic examinations were evaluated to decide whether they meet the included criteria. Once they were enrolled in this trial, were randomly allocated into four groups. Under local infiltrative anesthesia with Articaine hydrochloride (an aqueous solution of 4% adrenaline with 1 : 100,000 adrenaline), the socket of all the teeth were gently rinsed with saline solution. Necrotic and dried periodontal ligament tissue were carefully sutured off the root surface with forceps. Then the follow steps were taken respectively for each group.

Firstly, the patients were assigned to two different groups (G1, G2) according to storage medium for transport of the tooth to the dentist. G1 consisted of those whose teeth was kept in ideal solution such as milk, Hanks balanced salt solution. The teeth in G2 were with dry storage. Subsequently, patients of each group were randomly allocated to two groups. Before each treatment, each patient was numbered randomly by computer before treatment. Random numbers which was integer multiples of 2 were treated by the first therapeutic schedule. Random numbers which was integer multiples of 2 remainder 1 were treated by the second therapeutic schedule. An investigator (Li FF) recorded the method of each patients. Considering the storage medium and therapeutic schedule, all the patients were contributed to four groups (G11, G12, G21, G22) and received one of the following endodontic protocols.

G11: Teeth in this group had been soaked in ideal solution and endodontic treatment was performed before replantation. Before excavating, the high-speed air-turbine handpiece (PA-S M4, NSK, Japan), was inspected to ensure that the water jets could be directly onto the burs. A no.702 cylindrical diamond bur was applied to excavated an access cavity[14]. A size 15 K-file was applied up to the apical foramen to establish a working length. The root canal were enlarged up to a size 40 K-file and then was irrigated 5 ml 2% NaOCl, sterilize saline and 1% hydrogen peroxide, alternate with 3 times. After that, a size 40 sterile paper points were used to dry the root canal[15].

A size 40 gutta-percha (Gapadent Dental Technologies of Beijing, China) cone as a main cone coated with cement was inserted into root canal by a working length. Accessory gutta-percha cone were inserted under lateral condensation with the a size 15-35 smooth file. A temporary coronal seal was made with glass ionomer (3M , Vitrebond™ Molar Easymix ,Landsberg am Lech, Germany) in the crown[16].

After all the aforementioned treatment is performed, the teeth were replanted gently into their socket with slight digital pressure, and the correct position of the replanted teeth were radiographically decided. A flexible splint with an composite resin is recommended to immobilize the teeth for 1 month. The splint should gain an appropriate degree of tightness in order not to interfere with a physiological movement of the teeth.

G12: Teeth in this group had been soaked in ideal solution and endodontic treatment was performed after replantation as described in G11.

G21: Teeth in this group had been kept with dry storage and endodontic treatment was performed before replantation as described in G11.

G22: Teeth in this group had been kept with dry storage and endodontic treatment was performed after replantation as described in G11.

Each tooth was labeled with a number and the protocols were recorded by a single researcher (Li FF). After endodontic and replantation protocols, Oral hygiene education sessions were conducted for the patients and their parents, who were requested to use soft food, to brush tooth with a soft toothbrush and to rinse the mouth with chlorhexidine twice a day. Clinical and radiographically evaluations were undertaken at baseline and in the first, third and sixth month. A single examiner (Hu XQ) was trained for each criterion, who did not know the therapeutic protocols for these patients.

The treatment was considered successful according to the following criteria: 1. patient without spontaneous pain; 2. color of the gingival was normal, no sinus tract; 3. no sensitive to percussion; 4. no loosening of the teeth or loosening at the Degree I; 4. radiological analysis demonstrated that radiolucent shadow around apex disappeared and there is no internal root resorption and external root resorption should be no more than 2 cm[17].

In the first month when patients attended our department, splinting was removed. If the teeth meet the successful criteria, they were restored permanently with light-cured resin composite. If not, teeth were avulsed. Patients would be under continuous supervision and appropriate treatment will be carried out if needed.

IBM SPSS-22 statistical package (IBM SPSS Statistics for Macintosh, Version 22.0; IBM, Armonk, NY) was used for the statistical analysis, and statistical significance was set at $P < 0.05$. The successful rate among the three groups were statistically and analyzed using Chi-square and significance was predetermined at $\alpha = 0.05$. Varies of root resorption in each group in the first year following-up were evaluated using t -test with a significance level of 5%.

Results

There were 115 replanted teeth from 109 patients in the clinical trial. Characteristics of the patients and the teeth are summarized in Table 1. There were 49 teeth in wet medium prior to replantation, as well as 66 in dry storage. They were allocated in G1 and G2 respectively. Figure 1 shows the flowchart containing all phases of the trial. At the end of the trial, 103 patients with 107 teeth were completed all the therapeutic procedure and they were evaluated. Only 6 patients and 8 teeth were excluded from the study because they were unable to comply with the follow-up.

In terms of mean change value of root resorption, significantly higher level in G2 was detected than in G1. Internal root resorption was not observed in G11 and G21, indicating that thorough disinfection would contribute to decrease the occurrence of internal root resorption. Varied root length at the first year in four groups were shown in Table 2. As for periodontal healing, cases with before-replantation treatment were significantly more than post-replantation treatment in dry storage. On the contrary, more periodontal healing cases were obtained in ideal storage.

In the first year after treatment, we compared the success rate among the four groups with statistical analysis. The outcome is shown in Table 3. In summary, there was significant difference between G1 and G2 after statistical analysis ($\chi^2=4.53$, $P<0.05$). At the same time, we compared the difference between G21 and G22, there was no difference between them ($\chi^2=0.16$, $P>0.05$). Significant difference was found between G11 and G12 ($\chi^2=5.45$, $P>0.05$).

Discussion

The prognosis of an avulsed tooth depends on many factors, such as extra-oral time, storage media and healing of periodontium[13]. Damage to periodontium is directly related to the long-term success of tooth replantation[18]. A strong relationship was found between periodontal ligament healing (PDL) and endodontic therapy by previous investigation[8, 19]. Pulpal revascularization occurred in only 7% of the replanted teeth and they all are found in the storage medium for less than 1 hour[20, 21]. Because tooth avulsion usually happens accidentally, there is no ideal medium to store the teeth. Therefore, pulp extirpation should be performed for most of cases[22, 23].

From the research of the previous literature, it is clear that a standardized protocol for the avulsed teeth is replantation. However, recommendations how to perform each step have not reached an agreement by endodontists. One of those controversies is when to perform root canal therapy. The recommendations of American Association of Endodontics (AAE) of dental trauma cases is that it is necessary to perform root canal therapy if the teeth are in extra-oral condition for more than one hour[10].

At the same time, the guidelines from the International Association of Dental Trauma (IADT) suggests endodontic treatment can be performed prior to tooth replantation under certain conditions such as closed apex and extroral dry time more than 60 minutes[24]. In a similar study by Sardana D et al., they carried out extraoral endodontic treatment and restoration of the access cavity with Glass ionomer

cement before replantation with a 3-year follow-up. Periodic evaluation in the third year showed that replanted tooth remain in a stable functional position and with an acceptable replacement resorption[22]. In an *in vivo* study by Andreasen et al, they found extra-oral root filling lead to more replacement resorption but less inflammatory resorption in the teeth of monkey[8].

Taking into account that some outcomes of the study are based on laboratorial test, it is known that laboratorial outcome do not always reflect clinical practice. Case report and clinical trial with small sample size also fail in persuasiveness and strong evidence. In this way, clinical trial with an adequate sample size and appropriate statistical method is still the most trustable way to evaluate the prognosis of different protocol[25]. According to the existing guideline, the indication for endodontic therapy is that teeth are in extroral condition for more than 60 minutes because the survival rate of dental pulp is higher within 60 minutes. In order to avoiding the bias of these teeth with opportunity of revascularization, we only selected avulsed teeth for more than 60 minutes. Although the teeth should be stored in special storage, in many cases, many parents did not have the awareness[23, 26]. Thus, we divided these teeth into different groups.

Inflammatory and replacement resorption play a fundamental role in healing of periodontal ligament[27]. The inflammatory reaction was mainly caused by toxic products from necrotic pulp tissue. Extraoral endodontic therapy eliminates the bacteria and necrosis pulp, thus preventing the infection from root canal. On the basis of this consideration, endodontic therapy should be performed as early as possible. But it is not commonly accepted by a number of dentists and researchers for the following reasons. On the other hand, they think early remove of dental pulp could damage the remain alive pulp to support the blood to periodontal ligament[28]. Postponed replantation also has negative effects on periodontal ligament healing due to prolonged extraoral periods. In an animal experiment by Schwartz O et al, a slightly higher successful rate of replanted teeth with postponed endodontic therapy[29].

In the present clinical trial, we obtain an absolutely contrary outcomes in different storage. A possible explanation is that pulp contamination could be more serious in dry storage condition. Entirely removing the necrosis pulp and sealing the apical foramina is an inevitable way in order to avoiding inflammatory resorption. Although there was no significantly differences in G11 and G12 according to the success rate, it is not mean we can perform endodontic therapy at any time point when avulsed tooth was in dry storage. Because incidence of root resorption in G11 was significant lower than G12, we are inclined to perform endodontic therapy as soon as possible if tooth is in dry storage.

Additionally, for the root resorption, there was a significant difference between two different storage condition at the 1-year follow-up, regardless when to perform endodontic therapy. G11 and G12 showed a better clinical performance, which is a completely contrary outcome. We can consider endodontic therapy timepoint could not be the determining factor[30]. This result is in accordance with some other researches which highlight the importance of storage condition[31, 32].

Additionally, all intervention procedures were performed by three well trained operator, who had been practicing physician for more than five years. Additionally, to avoid the effect of operator on the result,

they were previously calibrated in a clinical training and randomly assigned to each patient. Moreover, participants were also selected according to specific and clear criteria. Interference by different operator and subjectivity selecting patients were avoided. On the other hand, one of the main limitations of the study included short follow-up period (1 year). Previous studies show root resorption does not become obvious until the sixth month. But recent research of Lima TF et al found root resorption according to cone beam computed tomography and periapical radiography[33]. Therefore, we believe additional outcomes could be observed with a longer follow-up period.

Conclusion

From this study, we conclude that emphasis on correctly storage of an avulsed tooth should be made for all teachers, patients, children and even dentists for good prognosis. In clinical practice, root canal therapy should be performed prior to replantation in dry storage condition for more than 60 minutes. In contrast, if not, root canal therapy could be postponed.

Declarations

Ethics approval and consent to participate: The project was evaluated and approved by the ethics committee of the Affiliated Huai'an Hospital of Xuzhou Medical University (HEYLL201813).

Consent for publication: Not applicable

Availability of data and material: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests

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Authors' contributions: In this clinic trial, there are mainly five dentist and doctor contributing to the study. Shengming Wang, Fangfang Li and Xiaoqing Hu conceived and designed the clinic trial. Shengming Wang, Xiaoqing Hu, Zhiqing Luo, and Peng Shao performed the experiments. The data was analyzed by Fangfang Li and then the paper was finally wrote by Shengming Wang, Fangfang Li.

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