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Use and effectiveness of the Failure Modes and Effects Analysis (FMEA) for identification of potential errors and failures in the process of root canal treatment

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Abstract

Objectives: Root canal treatment (RCT) has high technical sensitivity, and many human procedural errors can compromise the success of treatment and well-being of patients. The failure modes and effects analysis (FMEA) is a risk assessment and management tool that ensures the safety of patient care by a systematic approach to failures. This study aimed to identify the potential errors and failures in the process of RCT using the FMEA.

Methods: This descriptive study evaluated the failure modes and their effects qualitatively and quantitatively using the FMEA methodology. For this purpose, a FMEA team was first established and the steps of RCT were described in a flowchart. Next, the potential errors and failures in each step were identified, and each failure mode was scored from 1 to 10, based on the severity of impact, likelihood of occurrence, and likelihood of detection. The three scores were multiplied to obtain the risk priority number (RPN). Corrective measures and preventive strategies were suggested for high-risk failure modes (RPN≥250).

Results: The FMEA identified 19 steps and 48 potential failures in the process of RCT. The maximum RPN in the process of RCT was assigned to file fracture in the root canal (RPN=324), apical extrusion of irrigating solution (RPN=320), and inappropriate or no rubber dam isolation (RPN=315).

Conclusion: The FMEA has high efficacy for detection and prioritization of improvable points in a complex dental procedure in a busy department such as the endodontics department.

Keywords: Dentistry; Endodontics; Failure Modes and Effects Analysis; Risk Priority Number; Patient Safety; Human Errors

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Introduction

Patient safety is a fundamental healthcare principle, which refers to prevention of any harm to patients during provision of healthcare services [1]. In order to ensure patient safety, it is imperative to identify the events that threaten the patient's health, analyze the process of occurrence of such events, and design and implement corrective strategies to improve the performance of the system [1].

The frequency of medical malpractice lawsuits, as a factor threatening the patient safety, has greatly increased in the recent years. According to the international reports, the frequency of medical malpractice lawsuits has been on the rise despite the great technological advances in diagnostic and

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treatment procedures. For instance, the percentage of physicians who had been sued at least once in the United States was 3-4% in 1970, 8% in 1972, 20% in 1980, and 25% in 1990 [2]. The dental profession is no exception to this rule and dentists may also be held civilly liable for their practice. In a study the dentists were found guilty in 44.3% of the lawsuit cases researched.

Endodontics was one of the most frequently involved specialty in the lawsuits analyzed, and was related to a high incidence of damages awarded to settle claims [3].

Among different dental specialties, endodontics includes various procedures with high technical sensitivity such as anesthesia, caries removal, working length determination, chemomechanical debridement of the root canal system, and root canal obturation. Inaccuracy and errors in any step of the procedures can compromise the patient's health [4,5]. Although errors in provision of dental care are expected to have lower morbidity and mortality rates than the medical errors, their prevention can increase patient satisfaction, decrease costs, increase credibility, and lower the stress level of both patients and dental care providers. Part of the errors than may occur in dental practice are related to human errors while another part is related to environmental conditions, quality of dental instruments and equipment, and the dental office setting, that would eventually compromise patient safety [6].

Evidence shows that analysis of human errors prior to their occurrence can prevent them to a great extent [7]. Moreover, risk assessment and risk management are gaining increasing popularity in many professions and industries in order to prevent or minimize the occurrence of errors and to increase the credibility and efficiency of the system in the current competitive market [8]. Implementation of error management techniques is an effective approach for detection and minimization of errors. Error management is an organized continuous process for identification, assessment and decision making about the risks and opportunities in a system, which would affect achieving the goals. At present, a great emphasis has been placed on error management as a key factor for ultimate success in achieving the organizational goals [9].

Several methods are available for risk assessment and error management. Some of them analyze errors prospectively and some retrospectively. The failure modes and effects analysis (FMEA), which is a prospective technique, is among the most valid and reliable techniques for risk management and prevention of errors in the healthcare systems according to the National Center for Patient Safety of the United States [5,10]. This technique was first used in the space industry in 1960, and is a qualitative and inductive method, and an organized tool and a completely cognitive preventive measure that operates based on team work. It is used for definition, identification, assessment, prevention, and elimination or control of potential failure modes and effects in a system, process, project or service, before the final product or service is received by the customer or client [11]. The main property of this technique is its ability in prediction of important errors and offering solutions to prevent their occurrence [10]. Its modified form is exclusively used for the healthcare systems, and offers a prospective systematic approach for identification and prevention of errors prior to their occurrence in healthcare

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organizations. The first application of this technique in the healthcare system dates back to 1990 when it was primarily applied for optimization of vital systems, production and development of medications, and prevention of pharmaceutical errors in the hospitals [12].

FMEA aims to promote safety by preventing the occurrence of identified errors in a system and minimizing the unwanted consequences. This preventive and prospective approach allows identification and elimination of potential problems in an organization before they could impact on the system, services, and customers/clients [13]. Moreover, application of FMEA in the healthcare systems establishes a systematic attitude to promote patient safety. Evidence shows that FMEA can decrease the clinical risks of patients and identify and prioritize the improvable points of a process under implementation [14, 15]. Considering the high risk of procedural errors in the endodontics departments and the adverse consequences of such errors, this study sought to identify and prioritize the potential errors and failures in the process of root canal treatment (RCT) by the FMEA and offer corrective and safety measures for provision of services at the endodontics departments [16,17].

Methods

This descriptive study evaluated the failure modes and effects qualitatively and quantitatively using the FMEA methodology. The logic of this study was inductive, yielding practical results. The FMEA is a team-based, systematic and prospective approach to foresee and prevent problems that may arise in the production process or provision of services prior to their occurrence.

Hypothesis and Inclusion Criteria

This study questioned the possible high-risk errors and failure modes that can occur in the process of root canal treatment; the possibility of identifying and prioritizing risks and their causes, and the feasibility of suggesting and implementing preventive or corrective measures in each step.

The study was conducted in the Endodontics Department of the School of Dentistry, Shahid Beheshti University of Medical Sciences, Tehran, Iran, and focused on one main high-risk procedure done in this department, i.e. root canal treatment, between the years of 2019 and 2020.

Team Assembly

The FMEA team members consisted of 7 individuals that were purposefully chosen to be part of a Focus Discussion Group (FDG) [5]. The team consisted of two endodontists, one assistant from the endodontics department, one head nurse from the department, one clinic supervisor, one infection control personnel, and one quality control personnel of the specialty clinic (Table 1). In addition, 23 non-FMEA specialized endodontists, were selected as outside examiners to help identifying high risk procedures.

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Table 1. Members of the FMEA team

Order	Organizational ranking	Educational level	Work experience
1	Head of the department	Endodontist	7 years
2	Attending dental clinician	Endodontist	8 years
3	Assistant	BS of nursing	3 years
4	Head nurse	MS of nursing	5 years
5	Quality control personnel	BS of nursing	3 years
6	Clinic supervisor	BS of nursing	2 years
7	Quality control personnel	MS of healthcare service management	3 years

BS: Bachelor's degree; MS: Master's degree

Inter-examiner agreements

The team agreed to identify all root canal treatment steps, errors and failures, as well as implementing opportunities for improvement and correctional changes. Team members were allocated adequate time and resources to allow the process to be successful. The team leader (head of the department), who was skilled in team building, played a vital role in facilitating the various steps in the FMEA process, controlling the progress of the analysis, as well as assisting the team in applying a structured approach when identifying error causes and outlining necessary actions [6].

Data Collection

Data were collected through observation, questionnaires, and discussion group interviews by holding team sessions and meetings. The Eindhoven classification model (ECM) was used to find the root causes of errors.

In the next step, the FMEA team members defined the RCT procedural steps in a flowchart using the Visio software (Flowchart 1). The FMEA team members then identified and listed the possible procedural errors which may occur in every step of the process of RCT by brain storming, followed by determining the possible impacts of each error, and recorded them in a FMEA worksheet.

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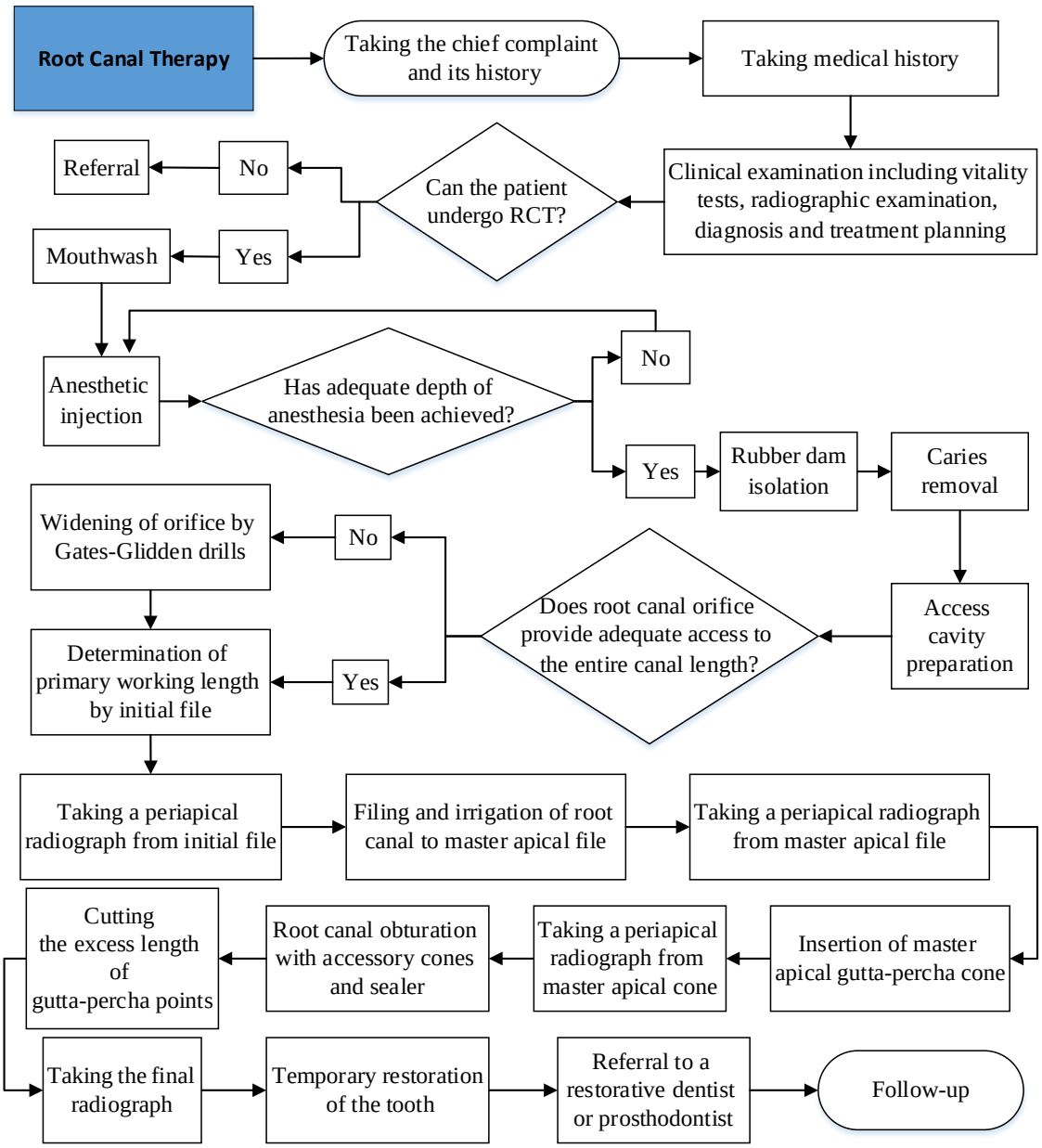
Flowchart 1. Procedural steps of RCT



Prioritizing errors and assigning RPN

In the FMEA, assessment of the sensitivity and significance of a risk is performed by assigning a numerical value to it, known as the risk priority number (RPN) [18]. Higher RPN of an error indicates higher risk for the system or its products [19]. Accordingly, the identified failure modes in the previous step were prioritized according to their RPN. The RPN is calculated by multiplying the scores assigned to the severity of impact (S), likelihood of occurrence (O), and likelihood of

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detection (D), which can be scored from 1 to 10 (Figure 1). Accordingly, considering the range of 1 < RPN < 1000, errors/failures with RPN ≥ 250 were classified as high-risk errors and entered the next level [20] (Figures 2 and 3).

After prioritizing the errors and calculation of their RPN, the root causes of high-risk errors were identified according to the ECM. In the ECM, the causes of errors are classified into two main categories of latent (technical and organizational errors) and apparent/active errors (human errors and other types).

Figure 1. Severity rating scale of failure modes

Severity Rating Scale of Failure Modes

Score	Severity of Effect
1	Slight annoyance—no injury to the patient or impact on the system
2	Slight danger—no injury to the patient
3, 4	Low to moderate danger—very minor or no injury to the patient
5, 6	Moderate danger—minor or no injury to the patient
7	Dangerous—minor to moderate injury to the patient
8, 9	Very dangerous—may result in major injury to the patient
10	Extremely dangerous—may cause death of the patient

Figure 2. Detection rating scale of failure modes

Detection Rating Scale of Failure Modes

Score	Probability of Detection
1	Certain—error will always be detected
2	Very high probability that error will be detected
3, 4	High probability of detection
5	Moderate chance that error will be detected
6, 7	Remote chance of detection only
8, 9	Remote or low likelihood of detection
10	No chance that error will be detected; no mechanism exists

Figure 3. Occurrence rating scale of failure modes

Occurrence Rating Scale of Failure Modes

Score	Probability of Occurrence
1	Remote—no known occurrence
2	Low probability—rare failures (yearly)
3, 4	Moderate probability—occasional failures (quarterly)
5, 6	Moderately high probability—monthly
7, 8	Very high probability—frequent (weekly)
9	Inevitable and predictable failure
10	Certain probability—daily, or every time

Identifying causes of error modes

Finally, according to the RPNs, possible failure or error causes were discussed and noted, and consequently, corrective and preventive measures were suggested for the high-risk failure modes. These measures, depending on the type of error/failure, focused on decreasing the severity of impact and rate of occurrence of errors/failures, and/or increasing the possibility of their detection.

Data analysis

The data was organized according to the FMEA principles and the process of RCT was defined step-by-step in a flowchart, and the failure modes and effects and their root causes were determined and listed in the FMEA worksheet. The procedures which had higher risks were prioritized using the

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Borda Function and the analyzed according to their Risk Priority Number (RPN).

Ethical measures

The patients' privacy was preserved and their personal information was protected in all steps of the study. Informed consent was attained from all patients.

Results

Nineteen steps and 48 potential errors/failures were identified and recorded for the RCT. Next, according to the respective tables for S, O and D, the FMEA team members individually scored each potential failure mode in several sessions, and the RPN of each failure mode was determined according to a 1-10 scale by multiplying the scores of S, O and D, and taking into account the ange of 1 < RPN < 1000 (Table 2).

In this study, RPN > 250 was considered high-risk and unacceptable in RCT [21]. Next, corrective measures were suggested for high-risk failure modes to prevent their occurrence, increase the likelihood of their detection, or decrease their impact in order to compile the details of process modification by focusing on the aforementioned three strategies. Totally, of the defined 19 steps and 48 identified errors, 12 errors were selected and categorized as high-risk, for which, corrective and preventive measures were suggested (Table 3).

One potential error was found in the process of taking the chief complaint and history of patient. Three potential errors were identified in the process of taking a medical history; among which, not asking the patient about the history of systemic diseases acquired the highest score with RPN=63.

Five errors were identified I the process of clinical examination, radiographic examination, diagnosis and treatment planning; among which, RCT of teeth with poor or hopeless periodontal prognosis was classified as a high-risk error (RPN=252). Six errors were identified in the process in anesthetic injection; among which, injection of unsafe doses of anesthetic agents containing vasoconstrictor in patients with contraindication (RPN=159), and injection of anesthetic agent in excessive amounts (RPN=158) acquired the maximum scores. Two errors were identified in the process of isolation; among which, inappropriate or no rubber dam isolation (RPN=315) was classified as a high-risk error. Six potential errors were identified in the process of removal of caries and previous restorations; among which, no reduction of unsupported cusps (RPN=275) was classified as a high-risk error. Three errors were identified in the process of access cavity preparation; among which, not finding additional root canals (RPN=271) was classified as a high-risk error. In the process of widening the root canal orifice, careless use of Gates-Glidden drills (RPN=288) was classified as a high-risk error. One error was identified in the process of primary working length determination by the initial file, and three errors were identified in the process of taking periapical radiograph from the initial file; among which, incorrect determination of root canal working length (RPN=211) acquired the highest score.

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Table 2. Primary FMEA worksheet for RCT

Process steps	Modes of errors	Type of error	Impact of errors	Causes of errors	RPN
Taking patient complaint and history	Incorrect understanding of patient complaint and descriptions	Human, systematic	Treating the wrong tooth, incorrect treatment plan	Not allocating sufficient time by the dentist, crowded clinic, poor verbal communication with patient, poor sympathy with patient	56
Taking medical history	Not asking the patient about important systemic diseases	Human, systematic	Occurrence of cardiovascular or other systemic problems	Not allocating sufficient time by the dentist, crowded clinic, not adhering to the protocol regarding filling out the health questionnaire prior to the onset of treatment, shortage of human resources	63
	Not asking female patients whether they are pregnant	Human, systematic	Injury to the fetus	Inaccuracy of dentist, not adhering to the protocol regarding filling out the health questionnaire prior to the onset of treatment, shortage of human resources, no option regarding choosing a female dentist for female patients	56
	Not asking patients about their allergy history	Human, systematic	Risk of occurrence of allergic reactions in susceptible patients	Not allocating sufficient time by the dentist, crowded clinic, inaccuracy of dentist, not adhering to the protocol regarding filling out the health questionnaire prior to the onset of treatment, shortage of human resources	35
Clinical and radiographic examination, diagnosis and treatment planning	Diagnosis and treatment planning merely based on radiographic examination	Human	Treating the wrong tooth, incorrect treatment plan	Not allocating sufficient time by the dentist, inaccuracy of dentist	65
	Not requesting appropriate radiography	Human	Incorrect treatment plan	Inaccuracy of dentist, poor education and inexperience of dentist	56
	Excess request of radiography	Human	Excessive X-ray exposure, increased risk of cancer	Poor education and inexperience of dentist	36
	Root canal treatment of a tooth with poor or hopeless periodontal prognosis	Human, systematic	Progression of periodontal disease, mobility, necessitating later extraction	Not asking for periodontal consultation prior to RCT for periodontally compromised or suspected teeth	252
	RCT of complex root canals by a general dentist	Human, systematic	Abscess after RCT and treatment failure	Absence of an organizational treatment protocol	278
Local anesthesia administration	Injection of anesthetic agent containing vasoconstrictor in	Human	Development of cardiovascular complications	Not taking precise medical history, inaccuracy of dentist, poor education and inexperience of dentist	159

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	excessive amounts in a patient with contraindications				
	Not performing aspiration prior to anesthetic injection	Human	Entry of anesthetic agent into the bloodstream and subsequent development of cardiovascular problems, signs and symptoms of overdose	Not allocating sufficient time by the dentist, inaccuracy of dentist, poor education and inexperience of dentist	69
	Multiple insertions of needle into a highly vascularized area	Human	Rupture of vessel wall and development of hematoma	Inaccuracy of dentist, poor education and inexperience of dentist	93
	Excessive injection of anesthetic agent without taking into account the patient's weight	Human	Systemic toxicity (overdose)	Inaccuracy of dentist, poor education and inexperience of dentist	158
	Sudden change in direction of movement of needle in the tissue, precurving the needle in several points	Human	Fracture of needle in the tissue	Inaccuracy of dentist, poor education and inexperience of dentist	69
	Induction of long-term anesthesia for a short-duration procedure	Human	Development of traumatic ulcer due to soft tissue biting	Inaccuracy of dentist, poor education and inexperience of dentist	59
Isolation of the respective tooth	Improper or no rubber dam isolation	Human, systematic	Aspiration of dental instruments into the respiratory tract, traumatization of soft tissue or adjacent teeth, saliva leakage into the root canal, abscess formation	Inaccuracy of dentist, poor education and inexperience of dentist, absence of a clear treatment protocol	315
	Use of latex rubber dam in a patient allergic to latex	Human, systematic	Allergy in susceptible patients	Not asking the patient about history of allergy, inaccuracy of dentist, not adhering to the protocol regarding filling out the health questionnaire prior to the onset of treatment, shortage of medical equipment and instruments	211
Removal of caries and previous restoration	Carelessness in correct use of bur	Human, systematic	Traumatization of mucocutaneous surfaces or traumatizing the adjacent teeth with bur	Inaccuracy of dentist, inexperience of dentist, use of burs without protective guards	222

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	No irrigation during caries removal	Systematic	Thermal damage to enamel and dentin	Malfunction of medical equipment	196
	Application of uncontrolled force during caries removal, or excessive removal of tooth structure	Human	Irreparability of tooth crown, weakening of tooth structure and increased risk of tooth fracture	Inexperience of dentist	111
	Incomplete elimination of caries	Human	Development of secondary caries, requiring endodontic retreatment	Inaccuracy of dentist, inexperience of dentist	96
	Not reducing unsupported cusps	Human	Tooth fracture	Inexperience of dentist	275
	Not using face mask when removing old amalgam restoration with high-speed hand-piece	Human	Mercury vapor toxicity, increased risk of cancer	Inexperience of dentist	218
Access cavity preparation	Excessive removal of tooth structure	Human	Inability to ideally restore the crown, weakening of tooth structure, increased risk of fracture, tooth perforation	Inexperience of dentist	86
	Creating an undersized access cavity	Human	No straight path to the root canals	Inexperience of dentist	87
	Not finding additional root canals in molar teeth, particularly the second mesiobuccal canal in the maxillary molars and mid-mesial canal in the mandibular molars and mandibular lateral incisors	Human, systematic	Development of abscess after RCT, treatment failure	RCT of complicated cases by a general dentist, absence of an organizational treatment protocol	271
Orifice flaring if required	Careless use of Gates-Glidden drills	Human	Fracture of Gates-Glidden drills in the root canal, vertical root fracture	Poor education and inexperience of dentist	288
Primary working length determination by initial file	Incorrect working length determination	Human, systematic	Over-filling or under-filling	Inexperience of dentist, shortage of materials and equipment	211

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Periapical radiography of initial file	Incorrect film positioning	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	59
	Under-exposure or over-exposure of the film	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	68
	Inappropriate film processing	Human, systematic	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist, shortage of materials and equipment	67
Filing and root canal irrigation to master apical file, followed by further filing and root canal debridement	Leakage of root canal irrigating solutions into the oral cavity	Human	Mucosal burning, liquid aspiration into the respiratory tract	Inexperience of dentist	211
	Inadequate filing and irrigation of root canal system	Human	Failure of RCT in long-term	Not allocating sufficient time by the dentist, inexperience of dentist	236
	File fracture in the root canal	Human, systematic	Abscess formation and failure of RCT in long-term	Inaccuracy of dentist, inexperience of dentist, multiple use of thin files, shortage of materials and equipment	324
	Apical extrusion of irrigating solution	Human, systematic	Hypochlorite accident	Inexperience of dentist, use of high-concentration hypochlorite, apical extrusion of irrigating solution	320
	Root canal transportation	Human	Apical perforation	Inexperience of dentist	170
	Ledge formation	Human	Perforation of external root surface	Inexperience of dentist	159
	Ignoring the danger zone	Human	Strip perforation	Poor education and inexperience of dentist	245
	Packing of debris in the root canal and obstruction of the main canal path	Human	Not accessing the entire working length and under-filling	Inexperience of dentist	244
	Changing the working length	Human	Over-filling or under-filling, failure of RCT in long-term	Inexperience of dentist	226

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Periapical radiography of master apical file	Improper film positioning	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	59
	Under-exposure or over-exposure of film	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	68
	Inappropriate film processing	Human, systematic	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist, shortage of dental materials and equipment	67
Placement of master apical gutta-percha cone	Selection of an undersized master apical cone	Human	Apical extrusion of gutta-percha, inappropriate apical seal, over-filling, failure of RCT in long-term	Poor education and inexperience of dentist	89
	Selection of an oversized master apical cone	Human	Under-filling of root canal, treatment failure in long-term	Poor education and inexperience of dentist	77
Periapical radiography of master apical cone	Inappropriate film positioning	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	59
	Under-exposure or over-exposure of film	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	68
	Inappropriate film processing	Human, systematic	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist, shortage of dental materials and equipment	67
Root canal obturation by insertion of accessory gutta-percha cones and sealer	Apical extrusion of sealer or accessory gutta-percha cones	Human	Infection, inflammatory reaction	Inexperience of dentist	236
	Application of excessive force by the spreader	Human	Vertical root fracture	Inexperience of dentist	288
	Root canal filling with inadequate density (void formation)	Human	Failure of RCT in long-term	Not allocating sufficient time by the dentist, inexperience of dentist	208
Cutting excess gutta-percha	Contact of hot endodontic plugger with the skin or mucosa	Human, systematic	Burning of skin and mucosa	Inaccuracy of dentist, inexperience of dentist, shortage of dental materials and equipment	265

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	Falling of the torch	Human, systematic	Fire	Inaccuracy of dentist, inexperience of dentist, unavailability of electronic devices for cutting of excess gutta-percha, shortage of dental materials and equipment	241
Final periapical radiography	Improper film positioning	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	59
	Under-exposure or over-exposure of film	Human	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist	68
	Inappropriate film processing	Human, systematic	Repeating radiography, over-exposure of patient, increased risk of cancer	Inexperience of dentist, shortage of dental materials and equipment	67
Temporary restoration	Carrying the filling material with the wrong instrument	Human, systematic	Contamination of filling material, waste of material	Inexperience of dentist, shortage of dental materials and equipment	56
	Over-filling of the access cavity with temporary restoration	Human	Temporomandibular disorders	Not allocating sufficient time by the dentist, inexperience of dentist,	69
	Poor retention of temporary restoration	Human	Early loss of temporary restoration, requiring replacement or necessitating endodontic retreatment	Inexperience of dentist	48
Referral to a restorative dentist or prosthodontist for final restoration	Not showing up for final restoration at an appropriate time	Human, systematic	Requiring endodontic retreatment, abscess formation	Negligence by patient, negligence by assistant, absence of an organizational protocol	252

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Table 3. Suggested measures for high-risk errors in the process of RCT

High-risk failure modes	RPN	Suggested measures
Root canal treatment of a tooth with poor or hopeless periodontal prognosis	252	- Designing an organizational treatment protocol necessitating written periodontal consultation prior to RCT for periodontally compromised or suspected teeth - Holding continuing education courses for dental clinicians
Inappropriate or no rubber dam isolation	315	- Designing an organizational treatment protocol necessitating rubber dam isolation for RCT - Use of files with thread holes (at least for patients with poor cooperation)
No reduction of unsupported cusps	275	- Designing an organizational treatment protocol necessitating cusp reduction, and reduction of unsupported walls to prevent tooth fracture (depending on the tooth) - Holding continuing education courses for dental clinicians
Not finding additional root canals especially the second mesiobuccal canal in maxillary molars and mid-mesial canals in mandibular molars and mandibular lateral incisors	271	- Designing an organizational treatment protocol necessitating treatment of complex root canals exclusively by endodontists
Careless use of Gates-Glidden drills	288	- Holding continuing education courses for dental clinicians
File fracture in the root canal	324	- Holding continuing education courses for dental clinicians - Provision of high-quality files in the endodontics departments - Not using thin files for multiple teeth
Apical extrusion of irrigating solutions	320	- Holding continuing education courses for dental clinicians - Designing an organizational treatment protocol necessitating precise determination of the safe concentration of sodium hypochlorite for use in endodontics departments
Excessive force application by the spreader	288	- Holding continuing education courses for dental clinicians - Educating dental clinicians regarding controlled force application in use of spreader
Contact of hot plugger with the skin or mucosa	265	- Holding continuing education courses for dental clinicians - Use of rubber dam until the completion of RCT to protect the skin and mucosa
Not showing up in-time for final restoration of the tooth	252	- Raising awareness and informing the patients about the problems that may occur in case of not showing up for final restoration in-time, or nursing and following the patient by the assistant

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A total of 12 errors were identified in the process of taking a periapical radiograph from the master apical file, and continuation of filing and debridement of the root canal; among which, file fracture in the root canal (RPN=324) and apical extrusion of irrigating solutions (RPN=320) were classified as high-risk errors. A total of 8 errors were identified in the process of insertion of master apical cone, taking a periapical radiograph from it, and filling the rest of the root canal with accessory gutta-percha points and sealer; among which, excessive force application by the spreader resulting in a bend or deformation, or breakage of the spreader (RPN=288) was considered as a high-risk error. A total of 8 errors were identified in the process of cutting the excess end of gutta-percha points, taking the final radiograph, and temporary restoration of the tooth; among which, contact of hot endodontic plugger with the skin or mucosa (RPN=365) was classified as a high-risk error. In the process of patient referral to a restorative dentist or prosthodontist for final restoration of the tooth, not showing up in-time for final restoration (RPN=252) was classified as a high-risk error.

Discussion

In the recent years, many studies have focused on the human errors in high-risk dental fields due to their significant impact on health, costs, and quality of life of patients [7,22]. In this study, the FMEA was employed to identify errors related to RCT in the endodontics departments. Accordingly, the potential impacts and causes of errors were determined by the team members, and corrective strategies were suggested for high-risk errors.

According to the results of this study, file fracture in the root canal, apical extrusion of irrigating solutions, and inappropriate or no rubber dam isolation, acquired the maximum RPNs, and were classified as errors with maximum risk in the process of RCT.

Tzanetakis et al. [23] reported the prevalence of file fracture to be 1.83% and discussed that its occurrence had an inverse correlation with the experience level of dental clinicians, such that it had the highest frequency among dental students and lowest frequency among endodontists [23]. According to some studies, file fracture does not decrease the RCT prognosis [24,25]. However, some others believe that file fracture increases the risk of RCT failure [26,27]. McGuigan et al, [28] in their review study concluded that although file fracture does not increase the rate of endodontic treatment failure in cases without periapical disease, risk of endodontic failure increases following file fracture in teeth with a preexisting periapical lesion. Thus, they recommended attempts to remove the broken piece from the root canal.

Strategies suggested by the FMEA team in our study to minimize the occurrence of file fracture and decrease its RPN included continuing education courses for dental clinicians, and provision of high-quality files for the endodontics departments, as well as control over the number of usage of instruments. These strategies have been confirmed by a previous study as well [23]. For instance, evidence shows that higher education and training and greater experience decrease the occurrence of file fracture [23,28]. Also, McGuigan et al, [28] in their review study reported that type of alloy used by the manufacturer in the composition of files affects the frequency of file fracture, and use of high-quality files can minimize the occurrence of this adverse event [28].

Hypochlorite accident is among the oldest complications of RCT [29]. Rowland et al. [30] performed a literature review on this topic and concluded that its prevalence is highly variable. Leakage of sodium hypochlorite into the periapical tissues can cause hemolysis, prevent the migration of neutrophils, and damage the endothelial cells and fibroblasts [31]. The toxic effects of sodium hypochlorite are due to

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its alkaline nature and hypertonicity, which can cause oxidation of proteins and lipid membranes [31]. Patients often experience excruciating pain, and their clinical examination reveals ecchymosis, hematoma, swelling, and temporary paresthesia (with a lower prevalence rate) [32]. Pain and swelling may last for 1-4 months [33,34], and healing of injured mucosa may take up to 2 months [35]. Also, hypochlorite accident can even cause irreversible complications such as fibrosis and unesthetic scarring [36,37]. Obviously, educating dental clinicians regarding the use of other irrigating solutions such as saline or chlorhexidine, or use of diluted sodium hypochlorite, and delivary of irrigating solutions only in the root canal environment, by use of 30 G needles either with open-ended or side-vented cannulas, while moving inside the root canal with a plunger force of 10–40 N, can decrease the occurrence of hypochlorite accident [19,29,47]. Futhermore, the hypochlorite accident may be due to operator malpractice or negligence.

Over 140 years have passed since the introduction of rubber dam as an effective isolation tool in dentistry [38]. During this time period, its application has been technically simplified, and it is widely used by dental clinicians in restorative dentistry, endodontics, periodontics and pedodontics [39]. According to Madarati et al, [18] use of rubber dam alone can serve as an independent factor in prevention of many dental complications, particularly in endodontics [18]. However, evidence shows that still a lot of dental clinicians do not routinely use rubber dam isolation in RCT due to a number of reasons such as poor compliance and acceptance by patients, time required for its installation, related costs, and not receiving adequate instruction about its use and its difficult installation [40]. Not using rubber dam can cause cross-contamination, prevent ideal irrigation of root canal, adversely affect the treatment results, and increase the risk of swallowing or aspiration of dental materials and instruments [41]. Thus, use of rubber dam is imperative as a standard of care, and is an integral part of the organizational treatment protocols in many universities and dental clinics worldwide [42-45]. In addition, during the coronavirus disease (COVID-19) outbreak, as aerosols and airborne particles can easily be generated during endodontic treatment, the use of personal protective barriers and rubber dam is recommended at the dental office [48].

The current results well indicated that a large portion of root causes of the most important potential errors in the process of RCT are due to inexperience, poor education, and lack of scientific knowledge of dental clinicians. Ghasemi et al. [46] reported that the majority of errors performed by post-graduate students of endodontics were procedural errors due to their inexperience, inadequate skills, outdated scientific information, imbalance between the number of patients and attending endodontists, and inefficacy and inadequacy of the protocols and guidelines. Accordingly, they suggested the inclusion of a separate course on human errors as part of dental curricula.

The FMEA identifies and prioritizes the potential errors in a prospective manner. Retrospective review of studies regarding the common procedural errors in the process of RCT revealed that the potential risks classified as high-risk by FMEA were all among the commonly reported, important, and challenging errors in the field of endodontics. This finding highlights the factuality and efficacy of FMEA and further confirms its credibility for accurate detection of errors and risks in the process of RCT. It appears that adherence to the corrective and preventive measures in a logical time period can decrease the risk of such errors in the respective organizations/institutions. Clearly, after the termination of this time period, re-implementation of FMEA in the respective organizations/institutions and calculation of RPN of the potential errors can reveal the efficacy of corrective and preventive measures and indicate the quality of their implementation [29].

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Conclusion

According to the current results, identification of potential errors in the process of RCT, detection of high-risk (unacceptable) errors, finding their root causes, and offering corrective measures to prevent their occurrence all indicated the high efficacy of FMEA for identification, assessment, prioritization, and analysis of errors in endodontics departments. Moreover, combining group interviews with FMEA, identifying the framework of errors, designing comprehensive tables for the severity of impact, rate of occurrence, and rate of detection of errors, and finding the root causes of high-risk errors by using the RCA in this study decreased the effects of some limitations of the FMEA such as its time consuming nature and high dependence of the results on team participation of individuals, and consequently increased its efficacy. However, the efficacy of this approach in implementation of corrective measures was not tested in this study, and requires an implementation time period and further studies in this respect.

Conflicts of interest

The authors declare no competing interest.

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