



Proactive Risk Assessment in Tooth Extraction: Evaluating the Impact of Failure Modes and Effects Analysis (FMEA)

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ABSTRACT

Objectives: Simple extraction is a routine dental procedure, yet numerous human and procedural errors can compromise treatment success and patient well-being. Failure Modes and Effects Analysis (FMEA) is a systematic risk assessment and management tool designed to enhance patient safety by identifying and addressing potential failures. This study aimed to identify potential errors and failures in the process of simple extraction using the FMEA methodology.

Methods: A descriptive study, using the mixed method, employed the FMEA framework to evaluate failure modes. An FMEA team was established, and the steps of simple extraction were outlined in a flowchart. Potential errors and failures at each step were identified and scored from 1 to 10 based on severity, occurrence, and detection likelihood. The Risk Priority Number (RPN) was calculated by multiplying these scores. Corrective and preventive strategies were proposed for high-risk failure modes (RPN \geq 200).

Results: The FMEA identified 23 failure modes in the simple extraction process. The highest RPN scores were associated with fractured tooth/root (RPN = 288), excessive bleeding (RPN = 225), inadequate pain management (RPN = 252), and postoperative infection (RPN = 225). These high-risk failure modes were prioritized for intervention. Mitigation strategies included staff training, standardized protocols, pre-operative assessments, and patient education.

Conclusion: The FMEA proved highly effective in detecting and prioritizing areas for improvement in a routine yet critical dental procedure such as simple extraction. By addressing high-risk failure modes, healthcare providers can enhance patient safety, reduce procedural errors, and improve treatment outcomes. This study underscores the value of FMEA as a proactive tool for risk management in busy outpatient departments.

Keywords: Extraction of tooth, Failure Modes and Effects Analysis, Risk Priority Number, Patient Safety

1. Introduction

While contemporary dental practice prioritizes the long-term maintenance of natural teeth, extractions remain a common procedure performed by dental professionals with varying levels of surgical expertise across diverse clinical settings. As Sambrook and Goss (2018) describe, exodontia is a frequently performed dental procedure encompassing a range of clinical scenarios. Successful execution of this procedure requires proficient practitioners to minimize patient discomfort. Regardless of the extraction classification as simple or surgical, a comprehensive approach to diagnosis, technique, and the anticipation of potential complications is paramount. Diagnostic procedures include a thorough review of the patient's medical history, a comprehensive clinical examination, and the acquisition of pre-extraction radiographs. Crucially, patient-specific factors beyond the tooth itself, such as systemic health status and any complex medical conditions, must be evaluated. This includes the effective management of medically compromised patients. Furthermore, localized factors, including but not limited to cemental hyperplasia and condensing osteitis, can introduce complexities to the extraction process. Therefore, it is essential that all practitioners who undertake dental extractions possess a thorough understanding of the fundamental principles governing this procedure to ensure both patient safety and treatment efficacy (Gadhia & Pepper, 2023).

While contemporary dentistry prioritizes tooth preservation, extractions are sometimes necessary (Gadhia & Pepper, 2023). Caries, especially when extensive, render teeth unrestorable and necessitate extraction (Broers et al., 2022). Similarly, pulpal/apical pathology is unresponsive to endodontic treatment, or when patients decline such treatment, often leads to extraction (Gadhia & Pepper, 2023). Severe periodontal disease, resulting in significant bone loss and tooth mobility, frequently requires extraction (Gadhia & Pepper, 2023). Non-restorable fractures (Aida et al., 2006), retained roots (Nayyar et al., 2015), and problematic supernumerary teeth (Garvey et al., 1999) are also common indications. Orthodontic treatment planning may include

extractions to create space (de Araújo & Caldas, 2019), as can pre-prosthetic considerations to improve denture fit (Fernández-Barrera et al., 2016). Teeth within mandibular fracture lines, posing infection or healing complications, are often extracted during fracture fixation (Taysi & Yildirim, 2015). Extraction may also be indicated for teeth associated with pathologies like cysts or malignancies (Nyimi et al., 2019) and prior to radiotherapy to mitigate the risk of osteoradionecrosis (Thorn et al., 2000).

1.1 Importance of FMEA in simple extraction

Patient safety, a cornerstone of healthcare, is defined as the prevention of harm to patients during the provision of care (Awhonn, 2015). A proactive approach to ensuring patient safety necessitates the identification of potential hazards, a thorough analysis of their occurrence, and the development and implementation of corrective measures to enhance system performance (Awhonn, 2015). The increasing incidence of medical malpractice litigation poses a substantial threat to patient safety. Despite significant progress in diagnostic and treatment modalities, international data reveal a consistent upward trend in malpractice claims. For instance, the percentage of US physicians facing litigation rose dramatically from 3-4% in 1970 to 25% in 1990 (Yamalik & Perea Pérez, 2012). 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.

Tooth extraction is widely considered a routine and uncomplicated procedure; however, any inaccuracies or mistakes during the process can significantly impact patient health (Thusu et al., 2012a). Although dental errors generally have lower morbidity and mortality rates compared to medical errors, preventing them can enhance patient satisfaction, lower costs, strengthen credibility, and reduce stress for both patients and dental professionals. Errors in dental practice may arise due to human factors, environmental influences, the quality of dental tools and equipment, as well as the overall dental office environment, all of which can jeopardize patient safety (Bailey et al., 2014). Studies suggest that anticipating and analyzing human errors before they occur can play a crucial role in their prevention (Chiozza & Ponzetti, 2009). Additionally, risk assessment and management are becoming increasingly essential across various fields and industries to minimize errors and improve system efficiency and credibility in an increasingly competitive market (De Wet et al., 2014). Employing error management techniques is an effective strategy for identifying and reducing errors. This approach involves a structured and continuous process of identifying, assessing, and making informed decisions about risks and opportunities within a system, ultimately influencing its success. In modern practice, error management is recognized as a key factor in achieving organizational objectives (Van Galen et al., 2016).

Various approaches exist for risk assessment and error management, with some focusing on prospective error analysis and others on retrospective evaluation. Among these methods, Failure Modes and Effects Analysis (FMEA) is a widely recognized prospective technique. According to the National Center for Patient Safety in the United States, FMEA is one of the most effective and reliable tools for risk management and error prevention in healthcare systems (Ierace, 2010).

Failure Mode and Effects Analysis (FMEA) facilitates continuous improvement in product and process quality and reliability, ultimately leading to increased customer satisfaction (Karim et al., 2008). As a widely adopted engineering technique, FMEA provides a structured approach for identifying, analyzing, and mitigating actual or potential failures, problems, and defects within the design or production/service process before the output reaches the customer (Stamatis, 2003).

Originating in the 1960s space program, FMEA is a qualitative, inductive, and team-based methodology serving as a proactive, cognitive preventive measure (Ramonia, 2012). A key strength of FMEA lies in its predictive capacity, enabling the anticipation of critical errors and the development of preventative solutions (Ierace, 2010). Adapted for healthcare, FMEA offers a prospective, systematic approach to error identification and prevention within healthcare organizations. Its initial healthcare applications, dating back to the 1990s, focused on optimizing critical systems, drug development and production, and preventing pharmaceutical errors in hospitals (Pemberton, 2014). FMEA's primary objective is to enhance safety by proactively preventing identified errors and minimizing their negative consequences. This prospective approach allows for the identification and elimination of potential problems before they impact the system, services, or patients (Black & Bowie, 2017). Furthermore, its application in healthcare fosters a systematic approach to promoting patient safety. Research indicates that FMEA can reduce clinical risks and identify areas for process improvement (Thusu et al., 2012b). Given the inherent risk of procedural errors associated with extractions and their potential adverse outcomes, this study aimed to utilize FMEA to identify and prioritize potential errors and failures in the extraction process and subsequently propose corrective and safety measures for service provision (Walji et al., 2020).

The FMEA process begins with the identification of potential failure modes (FMs) within the product, process, or system under analysis. For each identified FM, the FMEA team assigns scores to three risk factors (RFs): Occurrence (O), Severity (S), and Detection (D). These scores, representing the team's collective assessment, are then multiplied to calculate the Risk Priority Number (RPN). The RPN value directly correlates with the criticality of the failure mode; a higher RPN signifies a greater risk, while a lower RPN indicates a less critical failure mode.

2. Methods

This descriptive study used the FMEA methodology to assess the failure modes and impacts both qualitatively and quantitatively. This study used inductive logic that produced useful outcomes. The FMEA is a collaborative, methodical, and forward-looking technique that anticipates and avoids issues before they happen in the manufacturing process or service delivery.

This study questioned the possible high-risk errors and failure modes that can occur in the process of extraction; 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 out-patient Department of a secondary care hospital, in Sri Lanka and focused on one main high-risk procedure done in this department, from January 2024 to January 2025.

2.1 FMEA team formation and data collection

Twelve skilled and knowledgeable dental surgeons were enlisted to establish an FMEA team, which was the first step in the FMEA of simple procedures. They all consented to participate in the study after being informed of its objectives. Each member of the team has eight to fifteen years of work experience and a Bachelor of Dental Surgery (BDS) degree. Following multiple meetings with them, a total of 23 possible extraction FMs were found; they are listed in Figure 1.

Figure 1: Potential failure modes (FM) of extraction



2.2 Setting error priorities and allocating RPN

A risk's sensitivity and significance are evaluated in the FMEA by giving it a numerical value called the risk priority number (RPN). An error's larger RPN denotes a bigger risk to the system or its output. As a result, the failure modes that were discovered in the preceding stage were ranked in order of RPN. The severity of impact (S), likelihood of occurrence (O), and likelihood of detection (D) scores—which range from 1 to 10—are multiplied to determine the RPN (Yazdani et al., 2022). Therefore, mistakes/failures with $RPN > 200$ were categorized as high-risk errors, taking into account the range of $1 < RPN < 1000$. The main causes of high-risk errors were found after the errors were prioritized and their RPN was calculated.

Figure 2: Severity rating scale of FM

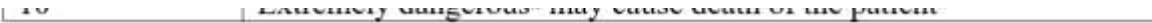


Figure 3: Detection rating scale of FM



Figure 4: Occurrence rating scale of FM



2.3 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, focus on decreasing the severity of impact and rate of occurrence of errors/failures, and/or increasing the possibility of their detection.

3. Results

According to the scale, a score was prepared for the errors identified in the extraction process. For each failure mode (FM), a score was assigned based on the severity of the effect, the probability of occurrence, and the likelihood of detection. Then, multiply these three scores to get a Risk Priority Number (RPN) (Table 1).

Table 1: RPN scores for extraction process steps

1. Pre-Procedure Errors

Step	Mode of Error	Causes of Error	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
Patient Identification	Incorrect patient identification	- Miscommunication between staff - Lack of proper verification protocols	8	2	2	32
Consent	Failure to obtain proper consent	- Rushed process - Inadequate explanation of risks and benefits	7	3	3	63
Medical History Review	Inadequate medical history review	- Patient not revealed - Staff not asking detailed questions	9	4	4	144

Step	Mode of Error	Causes of Error	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
Sterilization	Improper sterilization	- Inadequate sterilization protocols - Use of expired or contaminated tools	10	2	3	60
Diagnosis	Misdiagnosis of tooth to be extracted	- Poor clinical examination - Inadequate radiographs or imaging	8	3	4	96
Equipment	Insufficient equipment	- Poor inventory management - Lack of backup tools	7	4	5	140
Personnel	Lack of trained personnel	- Inadequate staffing - Lack of ongoing training for staff	9	3	4	108

2. Intra-Operative Errors

Step	Mode of Error	Causes of Error	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
Anesthesia	Inadequate local anesthesia	- Incorrect dosage - Poor injection technique	7	5	5	175
Injection Site	Injecting into the wrong place	- Lack of anatomical knowledge - Poor visualization of the area	8	4	4	128
Injection Technique	Wrong injection technique	- Inadequate training - Rushed procedure	7	5	5	175
Tooth/Root Fracture	Fractured tooth/root	- Excessive force - Poor extraction technique	8	6	6	288
Bleeding	Excessive bleeding	- Underlying patient conditions (e.g., bleeding disorders) - Trauma during extraction	9	5	5	225
Tissue Injury	Injury to soft/hard tissue	- Poor technique - Lack of attention to surrounding structures	8	5	5	200
Instrument Breakage	Instrument breakage	- Use of low-quality instruments - Excessive force	7	4	5	140
Patient Cooperation	Poor patient cooperation	- Anxiety or fear - Lack of patient education	6	7	6	252
Allergic Reaction	Allergic reaction	- Failure to review patient allergies - Use of inappropriate anesthetics	10	3	4	120
Documentation	Poor documentation	- Rushed procedure - Lack of standardized documentation protocols	5	6	7	210

3. Post-Operative Errors

Step	Mode of Error	Causes of Error	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
Infection	Infection	- Poor sterilization - Inadequate post-operative care	9	5	5	225

Step	Mode of Error	Causes of Error	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
Medication Interaction	Medication interaction	- Failure to review patient medications - Prescribing contraindicated drugs	8	4	5	160
Pain Management	Inadequate pain management	-Under-prescription of analgesics - Lack of follow-up	7	6	6	252
Post-Extraction Instructions	Failure to give post-extraction instructions	- Rushed discharge - Lack of written instructions	6	5	5	150
Hemostasis	Delayed or absent hemostasis	- Underlying patient conditions - Inadequate post-operative care	8	5	5	200
Infection	Infection	- Poor wound care - Patient non-compliance with instructions	9	5	5	225

Table 2: Summary of RPN scores for extraction process steps

SR no.	Failure Mode (FM)	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
1	Incorrect patient identification	8	2	2	32
2	Failure to obtain proper consent	7	3	3	63
3	Inadequate medical history review	9	4	4	144
4	Improper sterilization	10	2	3	60
5	Misdiagnosis of tooth to be extracted	8	3	4	96
6	Insufficient equipment	7	4	5	140
7	Lack of trained personnel	9	3	4	108
8	Inadequate local anesthesia	7	5	5	175
9	Injecting into the wrong place	8	4	4	128
10	Wrong injection technique	7	5	5	175
11	Fractured tooth/ root	8	6	6	288
12	Excessive bleeding	9	5	5	225
13	Injury to the soft/hard tissue	8	5	5	200
14	Instrument breakage	7	4	5	140
15	Poor patient cooperation	6	7	6	252
16	Allergic reaction	10	3	4	120
17	Poor documentation	5	6	7	210
18	Infection	9	5	5	225
19	Medication interaction	8	4	5	160
20	Inadequate pain management	7	6	6	252
21	Failure to give post-extraction instructions	6	5	5	150
22	Delayed or absent hemostasis	8	5	5	200

SR no.	Failure Mode (FM)	Severity (S)	Occurrence (O)	Detection (D)	RPN (S × O × D)
23	Infection	9	5	5	225

3.1 Risk Interpretation of Failure Modes

The identified failure modes are categorized into three primary stages of the extraction process: Pre-Procedure, Intra-Procedure, and Post-Procedure failures.

The analysis reveals several critical areas for intervention. Fractured tooth/root (RPN 288) emerges as the highest risk due to its combination of severity, relatively frequent occurrence, and the difficulty of immediate detection. Similarly, poor patient cooperation (RPN 252) and inadequate pain management (RPN 252) represent significant risks. While patient cooperation may not be the most severe issue, its frequency and the challenges it presents contribute to a high RPN. Inadequate pain management, although not always life-threatening, is a common and impactful concern. Excessive bleeding (RPN 225), infection (RPN 225, listed twice, likely pre- and post-extraction), injury to soft/hard tissue (RPN 200), and delayed or absent haemostasis (RPN 200) also pose substantial risks. These findings underscore the need for targeted interventions, including enhanced protocols for managing uncooperative patients, improved pain management strategies, meticulous surgical techniques to minimize fractures and tissue damage, rigorous infection control measures, and comprehensive pre-operative assessment and planning. While failure modes with lower RPNs, such as incorrect patient identification (RPN 32), are not negligible, the FMEA prioritizes efforts on the highest-impact areas. It is crucial to acknowledge that FMEA relies on subjective scoring; therefore, consistent application of the methodology is essential for reliable risk comparison within the tooth extraction process.

3.2 Mitigation strategies for the high-risk FM

A Failure Modes and Effects Analysis (FMEA) conducted on the tooth extraction process identified several critical failure modes with high-risk Priority Numbers (RPNs), necessitating targeted mitigation strategies. The highest RPN was associated with fractured tooth/root (288), emphasizing the need for meticulous pre-operative radiographic evaluation (including CBCT when indicated) and clinical assessment to identify anatomical variations and potential weaknesses. Intraoperative strategies include atraumatic extraction techniques, judicious use of instruments, and sectioning of multi-rooted teeth when necessary. Continuous training and education for dental professionals on advanced extraction techniques are also crucial. Poor patient cooperation (RPN 252) necessitates a multi-faceted approach, including pre-operative communication to establish rapport and address anxieties, offering anxiolysis or sedation when appropriate, and employing behavior management techniques during the procedure. Inadequate pain management (RPN 252) requires a comprehensive strategy encompassing pre-emptive analgesia with appropriate local anesthetics and vasoconstrictors, considering pre-operative NSAIDs, utilizing regional anesthesia techniques, and providing thorough post-operative pain management instructions and prescriptions. For excessive bleeding (RPN 225), a meticulous review of the patient's medical history for bleeding disorders or anticoagulant medications is essential. Surgical technique should prioritize gentle tissue handling and minimize trauma. Hemostatic agents should be readily available. Infection (RPN 225, pre- and post-extraction) necessitates strict adherence to sterilization protocols, aseptic technique, and consideration of prophylactic antibiotics in high-risk patients. Post-operative instructions regarding oral hygiene are crucial. To mitigate injury to soft/hard tissue (RPN 200), careful instrumentation, appropriate retraction, and thorough pre-operative planning are essential. Finally, for delayed or absent haemostasis (RPN 200), a thorough medical history, meticulous surgical technique, and readily available hemostatic agents are required. Post-operative instructions should include guidance on managing minor bleeding. These evidence-based mitigation strategies, implemented systematically and subject to ongoing review and refinement, aim to minimize the occurrence of these critical failure modes, thereby enhancing patient safety and optimizing outcomes in tooth extraction procedures.

In the process of dental extractions, where precision meets patient care, the stakes are high, and the margin for error is slim. The failure modes with RPN scores exceeding 200—ranging from fractured teeth and excessive bleeding to inadequate pain management and post-operative infections—highlight the critical areas where even the smallest misstep can lead to significant consequences. However, these challenges are not insurmountable. By embracing a proactive approach—rooted in rigorous training, standardized protocols, and patient-centered care—we can transform potential pitfalls into opportunities for excellence.

Imagine a scenario where every extraction is not just a procedure but a seamless experience: patients are calm and informed, staff are skilled and confident, and complications are anticipated and managed with precision. This vision is within reach. Through continuous education, meticulous planning, and a commitment to innovation, we can elevate the standard of care, ensuring that every patient leaves not just with a treated tooth, but with trust in the system and a smile on their face.

In the end, the journey toward safer and more effective extractions is not just about avoiding errors—it's about building a foundation of trust, expertise, and compassion that resonates far beyond the dental chair. An effort to make every extraction a testament to the harmony of skill, care, and dedication, where the only thing left behind is relief and the promise of better oral health.

In conclusion, the analysis of failure modes in simple extraction procedures within an outpatient department reveals critical areas of risk, particularly those with RPN scores exceeding 200. These high-risk failure modes—such as fractured teeth, excessive bleeding, inadequate pain management, and post-operative infections—underscore the need for systematic and evidence-based interventions to enhance patient safety and procedural outcomes. By addressing these risks through targeted mitigation strategies, including rigorous staff training, standardized protocols, and comprehensive pre-and post-operative care, healthcare providers can significantly reduce the likelihood of adverse events. The implementation of these strategies not only minimizes

procedural errors but also fosters a culture of continuous improvement and accountability within the clinical setting. Furthermore, integrating patient education and engagement into the care process ensures that individuals are well-informed and actively participate in their treatment, thereby reducing anxiety and improving compliance. This holistic approach aligns with the principles of patient-centered care and evidence-based practice, which are fundamental to modern healthcare delivery. Ultimately, the goal is to transform these identified risks into opportunities for enhancing clinical excellence. By prioritizing safety, efficiency, and patient satisfaction, healthcare providers can achieve optimal outcomes in extraction procedures, reinforcing trust in the healthcare system and advancing the overall quality of care. This academic perspective emphasizes the importance of proactive risk management and the continuous pursuit of excellence in clinical practice.

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