Sains Malaysiana 53(5)(2024): 1201-1218
http://doi.org/10.17576/jsm-2024-5305-17

Developing A Temporary External Fixator (TEF) For Mandibular Reconstruction Using Two-Phase QFD And TRIZ Approach

(Pembangunan Peranti Penetap Luaran Sementara (TEF) untuk Pembinaan Semula Mandibel menggunakan Pendekatan QFD dan TRIZ Dua Fasa)

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Received: 14 August 2023/Accepted: 22 April 2024

ABSTRACT

A temporary external fixator (TEF) is a device used to bridge resection defects after sequestrectomy and before secondary mandibular reconstruction surgery. A well-designed TEF should be customizable and adjustable to accommodate individual patient needs. This study developed a TEF for mandibular reconstruction using the quality function deployment (QFD) and the theory of inventive problem-solving (TRIZ). Customer needs (CNs) were investigated from literature reviews and a survey. Subsequently, a questionnaire was developed, refined, and delivered to 22 experts to identify the essential principles of TEF. Afterwards, the QFD priorities were analyzed based on the acquired CNs and technical requirements (TRs), and the top priorities were found to be safety and adequate operational space. The guidelines for developing a TEF with TRIZ were established as follows: First, using carbon fiber epoxy composite and Ti-6Al-4V as the material for TEFs is recommended Second, permanent magnet should be inserted into the clamp lock bolts to prevent them from falling off during surgery. Last, replacing one Schanz screw with three Bicortical screws is recommended for the fixator pins. Additionally, it was also found that changing the screw size from 2.5–4.0 mm to 2.0–2.4 mm could reduce hole defects in the mandible.

Keywords: Mandibular reconstruction; quality function deployment; temporary external fixator; theory of inventive problem-solving

ABSTRAK

Penetap luaran sementara (TEF) adalah peranti yang digunakan selepas sekuestrektomi dan sebelum pembedahan kedua pembinaan semula mandibel untuk mengantara kelompangan kesan reseksi. Rekaan TEF yang baik haruslah boleh disesuaikan dan dilaraskan untuk memenuhi keperluan setiap pesakit. Kajian pembangunan TEF untuk pembinaan semula mandibel ini menggunakan kaedah penerapan ciri berkualiti (QFD) dan teori penyelesaian masalah inventif (TRIZ). Kaedah kajian yang digunakan untuk mengetahui keperluan pelanggan (CNs) adalah daripada tinjauan kepustakaan dan kaedah tinjauan. Satu set soal selidik kemudiannya dibangunkan, diperinci dan dihantar kepada 22 pakar untuk mengenal pasti prinsip penting TEF. Seterusnya, keutamaan QFD dianalisis berdasarkan CNs dan keperluan teknikal (TRs) tersebut. Keutamaan tertinggi adalah keselamatan dan ruang operasi yang mencukupi; oleh itu, garis panduan untuk membangunkan TEF melalui TRIZ telah ditetapkan. Pertama, adalah disyorkan untuk menggunakan komposit epoksi gentian karbon dan Ti-6Al-4V sebagai bahan untuk TEF. Kedua, magnet kekal hendaklah dimasukkan ke dalam bolt kunci pengapit untuk mengelakkannya daripada jatuh semasa pembedahan. Dan terakhir, disyorkan untuk menggantikan satu skru Schanz pada pin penetap dengan tiga skru mini. Kajian juga mendapati bahawa mengubah saiz skru dari 2.5–4.0 mm kepada 2.0-2.4 mm boleh mengurangkan kecacatan lubang di mandibel.

Kata kunci: Kaedah penerapan ciri berkualiti; pembinaan semula mandibel; penetap luaran sementara; teori penyelesaian masalah inventif

Introduction

The incidence rate of patients with jaw-related defects resulted from tumors, cancer, or motor vehicle accidents tends to increase annually (Odono, Brady & Urata 2019). Improper treatments and reconstructions usually lead to negative consequences, such as facial deformities, speech articulation, and difficulty chewing and swallowing. Therefore, a successful and effective mandibular reconstruction is crucial in enhancing the quality of life and social confidence of patients.

The usual approach to managing lower jaw injuries involves assessing the degree and extent of defect to the mandibular bone, which can be categorized into five levels that depend on the size and scope of the lesion (Brown et al. 2016). Hence, personalized treatment plans must be developed by oral and maxillofacial surgeons. The treatment of mandibular discontinuity defects presents a significant challenge. There are several methods for mandibular reconstruction, including the use of reconstruction plates with or without bone grafts, non-vascularized bone grafts, and microvascular free flaps (Peled et al. 2005).

Reconstructing the mandibular bone is crucial for patients who have had surgical removal of the jaw due to cancer or other diseases. Free tissue transplantation is one procedure used to re-build the jawbone; the most commonly used types are the fibular osteocutaneous free flap (FOFF), the scapular osteocutaneous free flap (SOFF), and the iliac crest osteocutaneous free flap (ICOFF) (Bak et al. 2010). These transplants have several advantages, including high success rates, minimal donor-site morbidity, and excellent functional and aesthetic outcomes. The successful implementation of these methods is supported by several devices and tools, such as microsurgical instruments, tissue expanders, and Computer-Aided Design and Manufacturing (CAD/CAM) systems for planning and performing the mandible reconstruction (Annino Jr. et al. 2022; Barr et al. 2020).

The length of hospitalization after mandibular reconstruction exhibits significant interindividual variability influenced by a multitude of factors. The length of stay was reported in a range of 10-55 days with an average of 23 days (Pamias-Romero et al. 2023). In addition, medical comorbidities, post-operative complications, and individual pain management requirements can substantially impact the duration of a patient's hospital stay. Virtual surgical planning (VSP) can decrease the time needed for surgery and the duration of hospital stay when CT scan data and 3D models are utilized. However, its high cost limits the extensive adoption of VSP (Ameerally & Hollows 2004). The cost per patient typically falls between US$3,000 and US$5,000 (Ameen et al. 2018).

In terms of precision, accurate replication of a patient's bone shape and stabilization of healthy bones adjacent to the mandible can be achieved by applying advanced manufacturing technologies, such as 3D printing and biocompatible materials, including Titanium alloys (Ti-6Al-4V), after removing defects (Farrahshaida et al. 2017; Moiduddin et al. 2019; Nurul Nadiah, Abu Bakar & Ameyama 2023). A customized titanium alloy cranial implant offers durability, good fit, and aesthetic appeal. The Temporary External Fixator (TEF) demonstrably enhances the success rate of mandibular reconstruction through its multifaceted functionalities. It offers immediate stabilization, facilitating optimal healing and minimizing complications associated with delayed internal fixation. Moreover, TEF adjustable nature enables precise bone alignment, leading to superior functional and aesthetic outcomes compared to traditional methods. The positive impact of TEF extends beyond osseous consolidation, as evidenced by its documented contributions to infection control, improved joint mobility, improved flap survival and enhanced facial aesthetics (Braidy & Ziccardi 2009; Ung, Rocco & Deschler 2002; Vural & Yuen 2007). It is used before mandibulectomy to prevent the condyle head from shifting out of the neutral zone. The three-dimensional position of the lower jaw with the condyle in the glenoid fossa can be recreated using this device (Yin et al. 2019). A TEF comprises external rods, fixation pins, and connector rods. Some of the literature divides TEFs into three types: 1) structural metals made of titanium alloy or stainless steel rods, 2) hollow tubes filled with a special resin, and 3) arched structures made of titanium or stainless steel rod used as a framework for connecting the pins and the mandible (Braidy & Ziccardi 2009; Kazi et al. 2019; Marti-Flich et al. 2020). However, the clinical decision to utilize TEF necessitates a meticulous evaluation of individual patient factors and the specific complexities of the reconstruction. An example of a surgical operation using a TEF in mandibular reconstruction is shown in Figure 1.

A TEF is commonly utilized in mandibular reconstruction due to its several advantages. However, it still has limitations such as the risks of infection and hardware failure. These drawbacks can cause malunion or nonunion of the bone and may require additional surgical

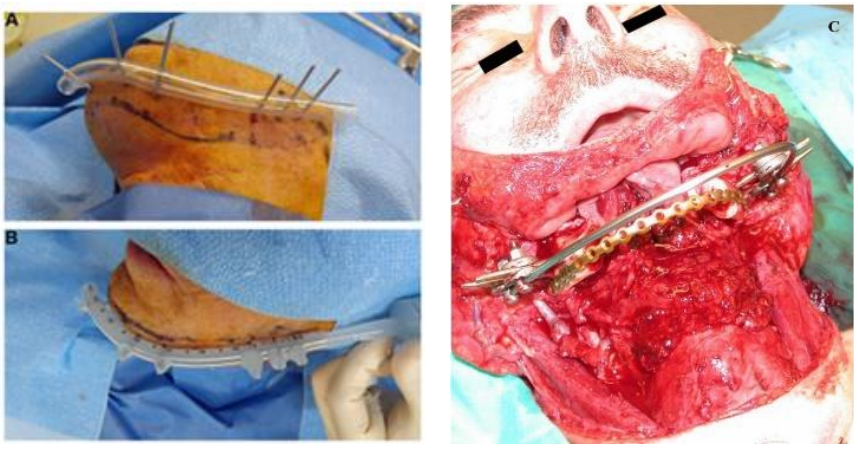

FIGURE 1. Surgical procedure that uses a temporary external fixator (TEF). (A) Before injection of self-curing resin, which will make the device rigid. (B) Proximal mandibular segments with an external fixator (Adapted from Marti-Flich et al. 2020) and (C) Proximal mandibular segments with external fixator and reconstruction plate *in situ* (Adapted from Ameerally & Hollows 2004)

interventions (Mohamed, Mepani & Sharma 2020). Therefore, improving TEF design by considering factors such as customer needs (CNs), stability, and flexibility is necessary to overcome these limitations. Quality function deployment (QFD) and the theory of inventive problem-solving (TRIZ) can assist in developing better-suited tools by analyzing CN, technical requirements, and design challenges.

In the engineering design process, the designer must ensure that the design contains essential customer-required functions before production. Certain engineering techniques have been established to perform this task. QFD is implemented to identify, express, and analyze the CNs and technical requirements (TRs) of a product by establishing house of quality (HoQ) models (Cornelius, Augustin & Sailer 2009). A study has shown that the healthcare industry in Tunisia used QFD to propose improvements in sterilizing procedures for maternity services, focusing on prioritization. QFD has also been applied to evaluate augmented reality (AR) head-mounted displays in operation simulation scenarios for maxillofacial surgery appliances. The method helped to identify CNs through quantitative argumentation. Another study at the Onofre Lopes Teaching Hospital in Brazil integrated QFD to identify and assess the main requirements of the operating room (Carpinello et al. 2021; Kammoun, Hachicha & Aljuaid 2021).

In 1946, the Russian inventor Genrich Altshuller and his colleagues developed TRIZ, an effective problem-solving tool for designers and engineers. This strategy process tackles innovative challenges by first identifying key needs (CNs) to define the problem space. TRIZ then helps eliminate contradictions between these needs and establish relevant innovation principles. Comprising 40 principles, TRIZ leverages a wealth of past successes by mapping them onto a 39×39 contradiction matrix, focusing on 39 common engineering parameters (Wang, Lee & Trappey 2017). TRIZ's unique strength relies on its five key elements: (1) systematic contradiction resolution; (2) a vast repository of patent-derived solutions; (3) an unwavering pursuit of ideality; (4) resourcefulness for efficient solutions; and (5) a demonstrably successful track record across diverse fields (Ghane et al. 2022). This potential combination allows users to tackle complex challenges and unlock transformative outcomes that go beyond conventional methods. Many researchers have integrated TRIZ-based contradiction analysis with QFD, leading to practical approaches and blueprints for successful service design (Melgoza et al. 2012).

The integration of QFD and TRIZ provides a framework to support innovation activities. Zhang, Yang and Liu (2014) has extended QFD into a two-phase House of Quality (HoQ) consisting of a product HoQ and a design HoQ to effectively apply this framework to radical innovations (RIs). TRIZ and QFD have recently been used to evaluate a hybrid manufacturing design process for direct open molds. This could reduce the production time, material usage, energy consumption, and waste generation (Yang et al. 2021). Similarly, TRIZ and QFD have been employed to improve the design of a tracheal stent. The resulting stent focused on CNs used integrating method to solve physical contradictions caused by the desired shape and material. The stent was then developed from the specific size needed to fit the trachea of the patient (Frizziero et al. 2018). Specifically, QFD and TRIZ offer a structured process for defining CNs and guiding product development, making them valuable tools for medical device innovation (Zhang et al. 2019).

This study introduced a user-centric approach utilizing the advantages of both operational principles and user requirements to design and develop more functional and cost-effective Temporary External Fixators (TEFs) for mandibular reconstruction. This user-centric approach prioritized the customer needs (CNs) and employed the combined methodologies of Quality Function Deployment (QFD) and Theory of Inventive Problem Solving (TRIZ) to ensure safety and biocompatibility of the TEFs, and desirable outcomes for both medical professionals and patients.

METHODOLOGY

A two-phase combination of QFD and TRIZ tools consisting of five steps was proposed to improve the design of TEF, and is shown in Figure 2. The description of five steps was as follows: Step 1: Intensive literature review on TEF - Identify the current design issues and establish the initial CNs of the product. Step 2: Expert survey - A questionnaire is developed and used to evaluate the priority TEF design principles. Data obtained from the questionnaire are tested for internal consistency and reliability. Factor analysis is then used to group CN components. Step 3: HoQ construction - Technical requirements are derived from the design issues and customer needs, and are used to construct the product HoQ. Step 4: Correlation matrix construction – The weighted score and priority ranking are determined by computing TRs, and are used to develop a Relationship matrix. Step 5: Conceptual design establishment - Contradictory TRs are identified and resolved using the 39 engineering parameters and 40 inventive solutions of TRIZ. The conceptual designs for the TEF are later determined by TRIZ and expert suggestions. The preliminary TEF conceptual designs are further developed and presented to clarify the specifications and implementation of individual parts.

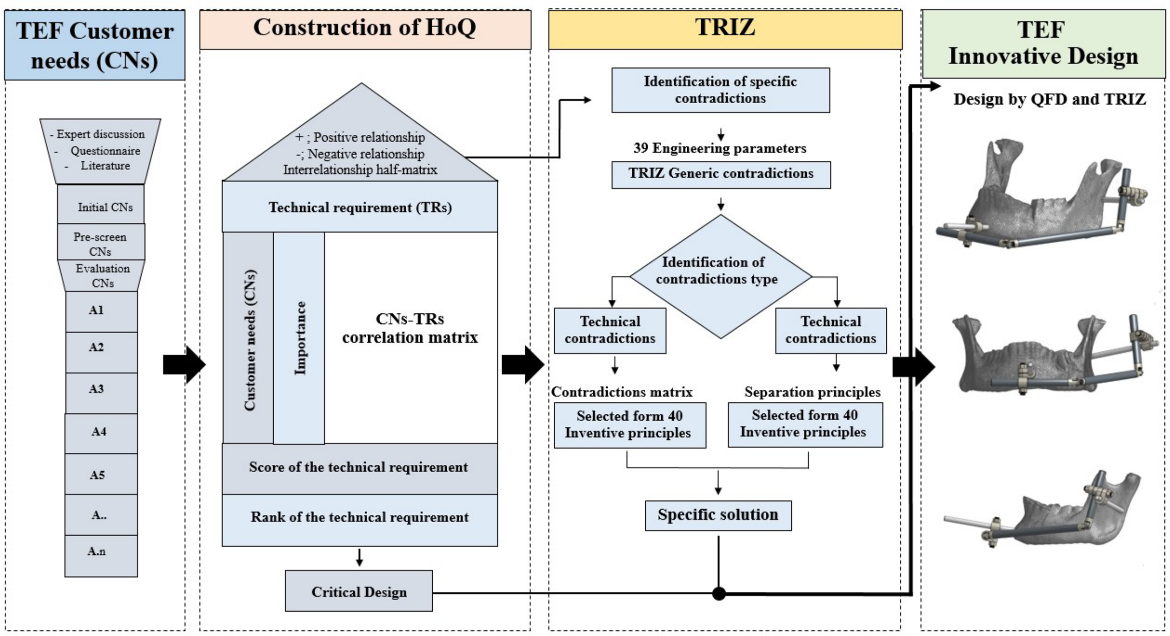

FIGURE 2. Research paradigm for TEF conceptual design

Customer needs (CNs) investigation

The first step in the research involved identifying the CNs through the literature review as shown in Table 1. CNs with similar characteristics were grouped together in the pre-screening stage to reduce the total number of CNs as shown in Table 2. The questionnaire was developed and underwent a reliability and validity test to ensure accuracy before being distributed to maxillofacial, manufacturing engineers, and relevant personnels. The collected feedback from the questionnaires was then used to further refine the CNs.

TABLE 1. Summary of literature review for CNs

CNs	Research findings	References
Simple locking mechanism	The TEF is employed in the treatment of mandible fractures. It has been determined to be easily adjustable, simple, convenient, and time-saving. Additionally, the outcomes demonstrate positive results in terms of occlusion, facial contour, and overall functionality	Alencar et al. (2018); Hihara et al. (2019); Yin et al. (2019)
Fixation	The TEF is employed to stabilize and align during the reconstruction process. An integral aspect of its effectiveness lies in the use of pins or screws for fixation in the bone and the application of a rigid frame	You et al. (1994); Amaro et al. (2020), Ameerally & Hollows (2004); Braidy & Ziccardi (2009); Cornelius, Augustin & Sailer (2009); Ho, Brown & Shaw (2013); Shen et al. (2017)
Biocompatibility	Due to their excellent biocompatibility, Titanium alloy (Ti6Al4V) and stainless steel (316L) are used for medical device production	Manam et al. (2017); Alaneme et al. (2022); Basat, Estrella & Magdaluyo (2020); Tümer et al. (2020)
Safety	The mandibulectomy utilizes External Fixation (EF) as a safe method, as supported by a research report that effectively highlights the potential to enhance outcomes. This approach is crucial for providing stability during segmental mandibulectomy	Gibbons, Mackenzie & Breederveld (2011); Shen et al. (2017); Kazi et al. (2019)
Functionality	Research has been conducted on TEF because it stabilizes and aligns. It is used in conjunction with other equipment to enhance the procedural capabilities, such as a surgical guide, positioning tools, and drilling guides	Funayama et al. (2017); Patel et al. (2019); Louvrier et al. (2020)
Flexibility	A universal TEF designed for various mandibular anatomical applications. The device is reusable, reducing costs, and ensuring swift availability in urgent situations	Hihara et al. (2019); Riccio et al. (2021)
Operation space	The TEF provides a more expansive operative area, enhancing the ease of performing flap inset. It is crucial for stability and facilitates the overall surgical process	Ung, Rocco & Deschler (2002); Kazi et al. (2019)
Reusability	The reusable TEF device in mandibular reconstruction is cost-effective for suitable urgent situations and has various universal applications, making it a versatile and economical choice in such scenarios	Chaus et al. (2014); Alencar et al. (2018); Riccio et al. (2021)

Questionnaire development and validation for customer needs survey

The relative importance of various equipment factors was assessed through a five-point Likert scale questionnaire (Tortorella et al. 2022). The questionnaire addressed four domains including: participant information, the perceived importance of fundamental equipment features, the perceived importance of technical characteristics, and suggestions for future equipment development. Content validity of the questionnaire was assessed in two stages. First, posteriori content validation using the Index of Item Objective Congruence (IOC) by three experts (Grant & Davis 1997). The Scale-level Content Validity Index (S-CVI) score of 0.91, exceeding the accepted threshold of 0.80 (Lynn 1986; Polit & Beck 2006), confirmed strong concordance with intended learning objectives. Second, reliability test with 30 undergraduate participants, and the subsequent analysis yielded a Cronbach's alpha (α) of 0.87, demonstrating adequate internal consistency and the questionnaire's suitability for collecting data on these factors.

To assess the impact of integrating quality function deployment (QFD) and theory of inventive problem solving (TRIZ) on device innovation, the questionnaire was administered to a purposive sample of 22 experts in product development. The questionnaire focused on gauging the perceived level of innovation achieved in devices where these methodologies were concurrently employed. The returned questionnaires provided valuable data on significant CNs, including equipment usability, device limitations, and the consequences of not using such equipment in mandibular reconstruction. The questionnaire results provided insights into the needs and requirements of users, which helped aid the design process of the TEF device. Overall, this approach ensured that the TEF design was user-centered and met the requirements of the users.

Expert background

The experts involved in this study were either in healthcare services or medical device development. Their fields of expertise include oral and maxillofacial surgery (42.86%), industrial and manufacturing engineering (38.10%), mechanical design engineering (9.52%), and occupational health and safety (4.67%). On average, these professionals had 11.14 ± 4.70 years of work experience. All of them held a doctorate in their field of study.

Twenty-two experts participated in the study provided data of customer needs through the questionnaire to establish the relative priority of TEF principles. The questionnaire used a Likert rating scale with five points to obtain the relative importance ratings of CNs. Internal consistency reliability and factor analysis with varimax rotation were conducted to classify the CNs using IBM SPSS Statistics version 28.0 software (IBM Corp., Armonk, NY, USA).

TABLE 2. Combined and eliminated CNs in the pre-screening process

No.	CNs of TEF	Definition
1	Simple locking mechanism	A locked coupling clamp between the external bar rod and the fixable pin can easily and securely fasten without slipping
2	Fixation	Fixator pins should secure and stabilize the mandible during the osteotomy procedure and be compatible with 2.0–2.4 mm bicortical screws
3	Safety	To increase corrosion resistance, devices should be made from medical grade metal with proper biocompatibility and surface finishing
4	Functionality	Allow the attachment of an additional item, such as a cutting or drilling guide. Easy maintenance
5	Flexibility	Accommodate various mandible sizes with an adjustable distance between the clamp lock and fixation point on the mandible
6	Operation space	Allow a sufficient distance between the TEF external rods and the mandibular bone for operation on the defective bone
7	Reusability	Reusable, can be cleaned via sterilization
8	Lightweight	Lightweight, compact, and made of minimal components

Conversion of customer needs (CNs) into technical requirements (TRs)

After strategically eliminating and combining customer needs (CNs) based on insights from the literature review, the refined set of critical customer needs underwent further refinement (Chan & Wu 2002). This refinement process included the elimination of certain CNs and the creation of combinations, such as safety, flexibility, and reusability. The meticulous process aimed to translate these refined CNs into precise technical specifications for the target engineering feature. Subsequently, a correlation matrix within the House of Quality (HoQ) was employed to analyze the refined CNs and identify their interrelationships, ultimately leading to the derivation of Technical Requirements (TRs).

The technical requirements (TRs) were defined by carefully considering the specific steps and demands of the osteotomy procedure. Pre-operative planning plays a pivotal role in this process, as it establishes the optimal TEF angle to align precisely with the intended osteotomy site. This meticulous alignment ensures precise intraoperative bone resection and stable fixation during surgery. Following complete tumor resection, the TEF's crucial function is to stabilize the mandible and secure it to the reconstruction plate (Yin et al. 2019). These detailed specifications and functionalities, arising directly from the surgical workflow, guided the selection of necessary components and manufacturing specifications.

The conversion of CNs to TRs was a crucial process which ensured that the design of TEFs met the necessary TRs for effective mandibular reconstruction. The remaining critical customer needs were categorized by function, intended use or impact on the final product, to highlight the focused attention on individual sets of technical challenges. Additionally, the use of the HoQ aided in identifying potential conflicts between different TRs; therefore, the conflicts could be resolved before device production. The resulting TRs are presented in Table 3. According to the translation of technical requirements (TRs) from customer needs (CNs), the succeeding phase involved the construction of a relationship matrix. The matrix acted as a critical bridge, effectively aligning customer desires with engineering possibilities. A team of experts meticulously evaluated how individual customer requirements were impacted by specific technical features and the degree of that impact. These relationships were typically denoted by the symbols with three distinct levels of strength: weak, medium, and strong. Which are then translated into a standardized rating scale, commonly employing a point system such as 1-3-9 or 1-5-9 (Carpinello et al. 2021; Jia & Bai 2011; Roy, Ray & Pradhan 2014).

TABLE 3. The technical requirements (TRs) derived from the conversion of customer needs (CNs)

No.	CNs of TEF	Technical requirements (TRs)
A1	Simple locking mechanism	B1. Clamp lock should be easily fastened
		B2. Clamp lock surface should be knurled for easy handling
		B3. Clamp lock parts should not loosen during surgery
		B4. TEF connectors should rotate along two degrees of freedom (DOFs) to adjust between the ramus and the angle of the mandible
A2	Fixation	B5. TEF should possess adequate strength to achieve a minimum stiffness of 220 N/mm
		B6. Pin fixator should accommodate 2.0–2.4 mm screws
		B7. Pin fixator should have rotational resistance
A3	Safety	B8. Biocompatible metals, such as Ti-6Al-4V or 316L, should be used for TEF fabrication
		B9. TEF should have a surface finish that resists corrosion
		B10. Schanz pins, which are 2.5–4.0 mm, should be replaced with Bicortical screws sized 2.0–2.4 mm to reduce the incidence of hole defects in the mandibular process
A4	Functionality	B11. TEF should be able to align with the mandibular during the osteotomy process
		B12. TEF can also be used together with cutting and drilling guides
A5	Flexibility	B13. Size adjustment of TEF should be allowed, e.g., by a sliding clamp lock on the external rod
A6	Operation space	B14. The device should provide sufficient operational clearance between the TEF and the mandible for convenient use during surgical procedures
A7	Reusability	B15. TEF can be reused after autoclave sterilization
A8	Lightweight	B16. TEF should be made from a lightweight alloy or composite

RESULTS AND DISCUSSION

The initial CNs were categorized into two components with a criterion of eigenvalue greater than one. The internal consistency reliability of CNs was tested with Cronbach's coefficient (α). The findings showed that the Cronbach's and Kaiser-Meyer-Olkin (KMO) value in the study was 0.758 and 0.567, respectively, indicating an acceptable consistency. In general, an α value greater than 0.7 indicates high reliability (Zhang, Yang & Liu 2014). In our case, each factor loading was equal to or greater than 0.5. Hence, the construct validity is supported by factor loading (McChesney et al. 2022). The component of the factor analysis in the CNs is shown in Table 4.

After performing factor analysis with varimax rotation using IBM SPSS V.28, the CNs were classified into two main categories with eight sub-categories. The initial CN categories and the results of the internal consistency reliability test are tabulated in Table 5. The corrected item total correlation results showed that all CNs exceeded the cutoff threshold of 0.2 (Streiner, Norman & Cairney 2015).

TABLE 4. Component of the Factor Analysis in customer needs (CNs)

No.	Customer needs (CNs)	Component	
		1	2
1.	3.Safety	0.873	
2.	8.Lightweight	0.816	
3.	1.Simple locking mechanism	0.804	
4.	2.Fixation	0.780	
5.	6.Operation space		0.863
6.	7.Reusability		0.879
7.	4.Functionality		0.615
8.	5.Flexibility		0.513

TABLE 5. The initial category of each CN was determined through a test of internal consistency reliability and rotated factor loading

Category	Rank	CN of TEF	22 experts		Corrected item total correlation	Alpha, if item deleted	Alpha with all items
			Mean	SD			
1. The TEF operation needs	1	3. Safety	4.64	0.848	0.349	0.746	0.848
	6	8. Lightweight	4.09	0.750	0.519	0.720	
	3	1. Simple locking mechanism	4.55	0.596	0.634	0.707	
	4	2. Fixation	4.23	0.685	0.715	0.686	
2. The TEF specification needs	2	6. Operation space	4.59	0.503	0.242	0.762	0.665
	8	7. Reusability	3.68	0.995	0.352	0.764	
	7	4. Functionality	3.73	0.767	0.528	0.718	
	5	5. Flexibility	4.18	0.664	0.369	0.746	

Establishing the relation matrix and priority of technical requirements (TRs)

In order to ensure the establishment of reliable weighing in the HoQ matrix, we assembled a carefully chosen group of experienced and proficient experts, each possessing over five years of expertise. Six individuals were randomly selected from both groups to participate in the evaluation of the relationship between CNs and TRs. Their diverse backgrounds, including industrial and manufacturing engineers alongside maxillofacial specialists, complemented each other and provided nuanced assessments of relationships within the matrix. The value t_{mn} in the matrix represents the correlation between the m-th TR and the n-th technical measure.

The scoring system presented in Table 6 effectively encapsulates the nuanced connections within the matrix (Fung et al. 2002). The score was in a range of 0-9, where 9 indicated 'Strong relationship', 3 indicated 'Medium relationship', 1 indicated 'Weak relationship', and 0 indicated 'not relevant'. These assessments are conducted by the experts who considered various aspects such as customer needs, technical viability, and design integrity (Purushothaman & Ahmad 2022; Singh & Agrawal 2022). For instance, when considering the relationship between A1 (Simple locking mechanism) and B1 (Clamp lock), where the clamp lock should be easily fastened, it became evident that the two components were interrelated and mutually impactful. Therefore, a score level of "9" was assigned indicating a high correlation. On the other hand, the relationship between A2 (Fixation) and B2 (Clamp lock surface) involved the recommendation that the clamp lock surface should be knurled for easy handling. In this case, there was no discernible relationship or influence between the two factors, and thus the score level of '0' was assigned.

The assigned scores were derived from the assessments conducted by a panel of experts, whereby the ratings assigned by six experts ascertain the scores for each relationship pair. The number of selectors at each level was divided by the total number. The acceptance is depending upon the average value exceeding 0.67. If the calculated average fell below this predetermined threshold, the matter was reassessed. This iterative process continued until each relationship underwent a comprehensive evaluation. The diverse perspectives within the panel guaranteed thorough consideration, and effectively addressing both customer satisfaction and technical robustness.

$$\mathrm{T} = \begin{pmatrix} t_{11} & \cdots & t_{1n} \\ \vdots & \ddots & \vdots \\ t_{m1} & \cdots & t_{mn} \end{pmatrix}, (m = 1,2,\cdots,8;\ n = 1,2,\cdots,16) \quad (1)$$

T = correlation matrix

To determine the priority rankings of the TRs, the weight score of each technical measure was multiplied by the corresponding value in the relationship matrix. These products were then summed to obtain a weighted score for each requirement. Equation (2) was then used to determine the weighted scores for the 16 TRs. The %Relative is a percentage of individual CNs score to the total score. It indicated critical design attributes that could improve customer satisfaction. The resulting values of these parameters are as shown in Table 7.

$$B_n = \sum_{k=1}^{8} [A_m \times T_{mn}], (n = 1,2,\cdots,16) \quad (2)$$

B_n: n-th weighted score of technical measure, A_m: m-th weight of TR.

TABLE 6. Relation matrix of customer needs (CNs) and technical requirements (TRs)

	IMP	B1	B2	B3	B4	B5	B6	B7	B8	B9	B10	B11	B12	B13	B14	B15	B16
A1.	4.62	9	3	9	3	3	1	1	0	0	1	0	0	0	0	1	1
A2.	4.52	3	0	1	9	9	9	9	0	0	1	9	3	3	3	0	0
A3.	4.19	1	1	9	0	9	9	9	9	9	9	9	1	1	1	9	0
A4.	4.57	0	0	1	3	0	3	0	0	0	3	3	9	9	9	3	0
A5.	4.19	3	0	0	3	3	3	3	9	3	1	9	3	9	3	9	0
A6.	3.71	3	1	0	3	1	0	1	0	0	9	0	0	3	9	0	0
A7.	3.71	1	0	0	0	1	0	0	9	9	0	0	0	0	0	9	3
A8.	3.62	0	0	0	0	0	0	0	1	0	9	0	0	0	0	0	9

A: Customer needs (CNs), B: Technical requirements (TRs)

TABLE 7. Weighted scores and priority rankings of technical requirements (TRs)

Technical Requirement (TR)	Weighted Score	priority rankings	%Relative
B1 Clamp lock should be easily fastened	87.77	12	5.75
B2 Clamp lock surface should be knurled for easy handling	22.75	16	1.49
B3 Clamp lock parts should not loosen during surgery	90.16	10	5.90
B4 TEF connectors should rotate along two DOFs for adjusting between the ramus and the angle of the mandible	88.68	11	5.80
B5 The TEF should possess adequate strength to achieve a minimum stiffness of 220 N/mm	113.61	5	7.44
B6 Pin fixator should accommodate 2.0–2.4 mm bicortical screws	107.51	6	7.04
B7 Pin fixator should have rotational resistance	100.95	9	6.61
B8 Biocompatible metals, such as Ti-6Al-4V or 316L, should be used for TEF fabrication	115.58	4	7.57
B9 TEFs should have a surface finish that resists corrosion	86.73	13	5.68
B10 Schanz pins with a sized of 2.5-4.0 mm, should be replaced with 2.0–2.4 mm mini-screws to reduce the incidence of hole defects in the mandibular	140.13	1	9.17
B11 TEF can align the mandibular during the osteotomy process	128.13	2	8.39
B12 TEF can also be used as cutting and drilling guides	63.15	14	4.13
B13 Size adjustment of TEF should be allowed, e.g., by a sliding clamp lock on the external rod	102.00	8	6.68
B14 The device should provide sufficient operational clearance between the TEF and the mandible for convenient use during surgical procedures	104.28	7	6.83
B15 TEF can be reused after autoclave sterilization	127.52	3	8.35
B16 TEF should be made from lightweight alloy or composite	48.77	15	3.19

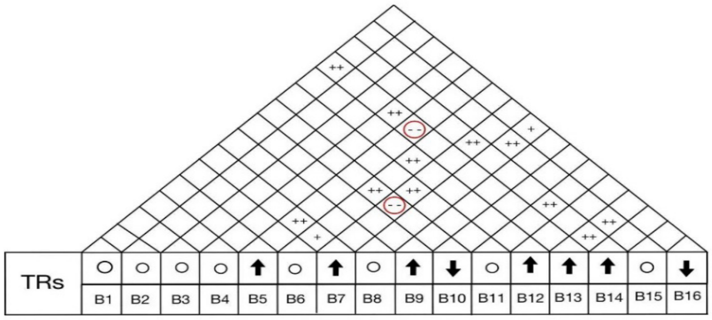

FIGURE 4. Correlation triangle (Roof of HoQ)

Figure 4 illustrates a visual depiction of the Roof of the House of Quality framework, often denoted as the Correlation Triangle. The figure shows the intricate interconnections among the TRs integrated into a QFD. These TRs were classified into four levels based on their relationships: Strong positive correlation (++), Weak positive correlation (+), Weak negative correlation (-), and Strong negative correlation (--) (Singh & Agrawal 2022).

According to the evaluation of the relationship between the TRs, two pairs of the requirements had a negative relationship. Specifically, TR B7, which specified that rotation resistance was necessary, contradicted the TR B10, which emphasized the significance of a small fixation pin. This contradiction occurred because the size of the pin was directly related to the action force caused by mandibulectomy. Additionally, TR B5, which described the need for the main body of the TEF to have sufficient stiffness to resist the load, conflicted with TR B13, which showed the importance of adjustable rod size. The negative relationships between the technical requirements were addressed through contradiction analysis to generate the new solutions using TRIZ.

TRIZ-based design alternate creation

This phase involved generating TR alternatives through the TRIZ major tools and contradiction analysis. TR contradictions were the negative relationships between pairs of TRs that can be transformed into 39 engineering parameters. These contradictions could be resolved with the help of a contradiction matrix (Wang, Lee & Trappey 2017; Zhang, Yang & Liu 2014). In our case, the identified contradictions were resolved using the separation principles. Additionally, some recommended inventive principles among the 40 inventive principles were determined and used to select the most effective solutions for product and practical issues (El-Haik & Mekki 2008; Kang, Ng & Liew 2022). This approach, based on TRIZ, enhanced the design attributes of the TEF by addressing the contradictions in TR specifications and identifying inventive principles. The results of improving the contradicting TRs using the 40 fundamental inventive principles are listed in Table 8.

The resolution to the contradiction between the TRs B7 and B10 could be found in engineering parameters 8 and 13 from the 39 invention solutions. This solution involved fixing the pins and utilizing composite materials. Additional solutions extracted from the 40 fundamental inventive principles could be applied to further enhance the solution, such as principle 28, replacing the mechanical system; principle 34, rejection, regeneration, discarding, and recovering; principle 35, changing parameters; and principle 40, the use of composite materials. To resolve the contradictions between TRs B5 and B13, the solutions could be found in engineering parameters 14 and 35 from the 39 invention solutions. For further improvement, principles 3 (local quality), 6 (multifunctionality), 32 (changing color), and 35 (change of parameter) obtained from the 40 fundamental inventive principles could be implemented.

Concept generation and preliminary assessment

The way of resolution in the TRIZ process was a method used to rectify the contradiction of TRs. The TEF was improved according to TRs for the structure, working function, and manufacturing process. The 'TRIZ Separation Principles', based on a specific criterion, were used in the TEF product design (Kang, Ng & Liew 2022), and are shown in Table 9.

The inventive solution was determined after the contradiction TRs were analyzed using the 40 fundamental inventive principles. The following inventive solution was obtained through TRIZ. The summary of the resolution for the TEF from TRIZ analysis, which was discussed in the 40 fundamental inventive principles and expert maxillofacial deliberation on the suitability of the specifications for medical devices, is shown in Table 10.

TABLE 8. Contradicting TRs improved through 40 fundamental inventive principles

TRs	39 Engineering Parameters	40 Fundamental inventive principles solution
B7 (Worsening)	13 Stability of the object's composition	28, 34, 35, 40
B10 (Improving)	8 Volume of the stationary object	
B5 (Worsening)	14 Strength	3, 6, 32, 35
B13 (Improving)	35 Adaptability	

TABLE 9. Inventive principles and ways of resolution for technical requirements (TRs)

Problem	40 Fundamental inventive principles	Way of resolution
B7, B10	28 Mechanics substitution	C1 Use magnets to interact with the object
	34 Discarding and recovering	C2 Make portions of an object that have fulfilled their functions go away
	35 Parameter change	C3 Change the degree of flexibility
	40 Composite materials	C4 Change the TEF from homogeneous to composite materials
B5, B13	3 Local quality	C5 Make each part of an object fulfill a different and useful function
	6 Multifunctionality	C6 Make a part perform multiple functions
	32 Changing color	C7 Change the color of an object or its external environment
	35 Parameter change	C3/C8 Change the degree of flexibility

TABLE 10. Summary data for the TEF parts specification

Part	Concept by TRIZ	The TEF parts specification
Main frame	Replace homogeneous metal with composite material	Adjusting the size of the main frame involves sliding the coupling camp lock in the axial direction of the rods, which are made of composite materials for weight reduction and high strength
Coupling clamp lock	Use magnets to interact with the object, change the color of an object or its external environment	To prevent slipping during picking up and locking the position of the coupling clamp lock, 1) increasing the strength of the magnet to make it more difficult for the object to fall out during surgery and 2) adding knurling on the surface of the workpiece to provide a better grip
Fixation pins	Make portions of an object that have fulfilled their functions go away, make each part of an object fulfill a different and useful function, and make a part perform multiple functions	Pin fixation parts in contact with the mandible are designed as additional custom cutting guides for mandibulectomy to fit each patient. The pins are positioned in a way that can resist torsional force from the mandibular during the reconstruction process

Specifications and implementations of the TEF components were developed using the data obtained from QFD and TRIZ analysis, and represented using 3D-model prototypes generated from the software CAD Onshape (Onshape Inc, Boston, MA, USA). The resulting design consisted of four parts namely the external frame, connector rod joint, fixation pin, and clamp lock. Carbon composite and a biocompatible metal (Ti-6Al-4V) were suggested to fabricate the external rod, as shown in Figure 5. During a mandibulectomy, this temporary external fixation could help stabilize the reconstruction process (Ameen et al. 2018).

The TEF connector rod joint used in the TEF external rod allowed the adjustment of the mandible angle between the inferior border of the mandibular body and the posterior border of the ramus. The mandibular angle typically ranged from 124.1–125.6° in males and 125.8–132.0° in females (Shaw et al. 2011). The newly designed connector composite rod joint had two degrees of freedom (DOFs) to accommodate the TEF angle as shown in Figure 6.

The fixation pins are essential components of a TEF that stabilize the connection between the external rod and the mandibular body. The surgical approach may vary depending on the location of the fracture, but the underlying principles are universal. First, it is best to insert percutaneous pins into the 'safe zones' of the mandible while avoiding tooth roots, developing teeth, the inferior alveolar canal, the facial artery and vein, and the major vein of the face. The safe zones are located along the inferior and posterior borders of the mandibular symphysis, body, and ramus (Ao Foundation 2022; Marti-Flich et al. 2020). The fixation pin is designed to resist rotation force during the operation. To achieve this, an increased number (3) screws are used to secure it to the mandible to increase the resistance to displacement (Pereira-Filho et al. 2013), using 2.0–2.4 mm bicortical screws for normal maxillofacial cases (De Mello-Filho et al. 2013; You et al. 1994). Bone drilling is necessary for installing the Titanium alloy plates into the segmental bone. However, the drilling process generates heat that can potentially cause thermal necrosis of the bone. To minimize this risk, an internal gas cooling method is used to manage the temperature rise (Shakouri, Haghighi Hassanalideh & Fotuhi 2021). The new design for the TEF fixation pins is presented in Figure 7.

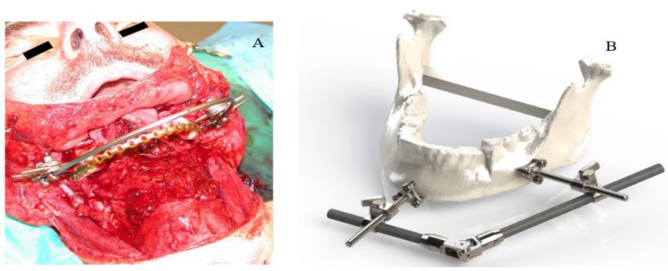

FIGURE 5. A. The proximal mandibular segments with external fixation and reconstruction plate *in situ* (Adapted from Ameerally & Hollows 2004).
B. A novel temporary external fixation Design leveraging integrated QFD and TRIZ

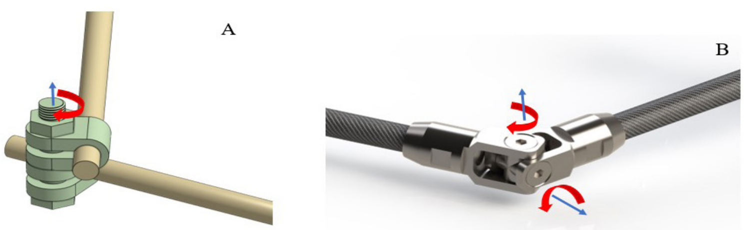

FIGURE 6. A. Type 1 external fixator connector rod with one DOF.
B. Newly designed type 2 connector rod with a universal joint and two DOFs

A clamp lock is a device used to secure the external rod and fixation pin. It requires the ability to slide along the rod to adjust its position during surgery. This device can be made from Ti-6Al-4V composite material. The new clamp lock design can rotate on the lower hub, which supports pins at different angles. The locking mechanism is based on a screw-clamping principle with a lever to rotate the two hubs with a gap of approximately 1.5 mm. This clamp lock design was developed using the 40 fundamental inventive principles. A magnet has been added to the clamp locks to prevent them from falling off during assembly. The newly designed clamp lock is illustrated in Figure 8.

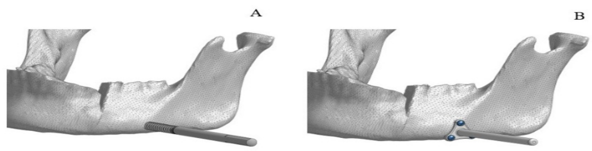

FIGURE 7. A. Schanz screw-type mandible fixation pin. B. Newly designed mandible fixation pins with the Anti-rotation feature

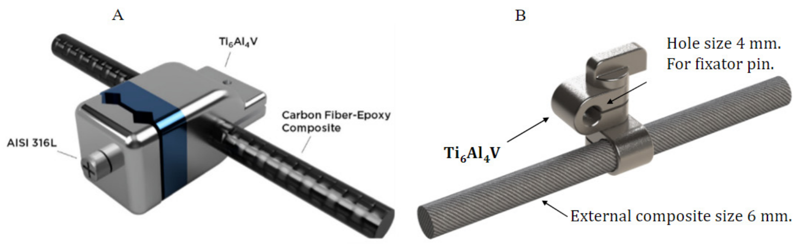

FIGURE 8. The temporary external fixator connectors A. Rendered design of external fixator for metacarpal fractures and the materials for each part as well as (Adapted from Basat, Estrella & Magdaluyo 2020). B. Newly designed clamp lock for securing external composite and fixation pin

Conclusion

This study aimed to address the limitations of existing temporary external fixators (TEFs) used in mandibular reconstruction. The main limitations included bulky pins, insufficient stability, and lack of adjustability of the TEFs. The research employed a two-phase Quality Function Deployment (QFD) and TRIZ methodology with the extensive data collection, including literature review and a survey of 22 experts, to identify key customer needs (CNs) and convert these needs into technical requirements (TRs). The survey results indicated that the top priorities identified through QFD analysis were safety, adequate operational space, and improved patient comfort. A novel design of TEF was successfully developed according to the prioritized user needs, and the designed TEFs could offer significant improvements in these key areas. The resulting design incorporated several key improvements over traditional TEFs, as follows: 1) Reduced pin sizes (from 2.5 - 4.0 mm to 2.0 - 2.4 mm) to minimize bone hole defects. 2) Augmenting the number of screw fixation points demonstrably enhances mandibular stability against rotational forces. However, meticulous placement within designated safe zones remains paramount for patient safety. 3) Adjustable angles and distance provide greater flexibility and Individualized Customization for Patients, addressing concerns about inadequate operational space and lack of adjustability. 4) The addition of a Permanent magnet retention mechanism to the clamp lock part eliminates the risk of accidental detachment.

However, there are still challenges to be comprehensively investigated for the extensive adoption of the newly designed TEFs. Two crucial inadequacies are necessary to be fulfilled: the absence of robust clinical confirmatory testing and a lack of comprehensive biomechanical testing, including finite element analysis (FEA).

ACKNOWLEDGMENTS

This research was partially supported by the Research and Graduate Studies, Khon Kaen University, and The National Science and Technology Development Agency (NSTDA) of the Royal Thai Government. The authors would also like to thank the Department of Industrial Engineering, Faculty of Engineering, Khon Kaen University, the Dental Department, Sakon Nakhon Hospital, and the Faculty of Sciences and Engineering, Kasetsart University.

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