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Gray X-Ray medical images encryption and decryption by chaotic algorithm

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ABSTRACT

The procedure for securely transferring encrypted images over the network so that an unauthorized user cannot decrypt them is by implementing strong algorithms that cannot be decrypted. There are different methods and multiple algorithms for encrypting and decrypting images. The most common way to encrypt images is the Chaotic Image System. The encryption key and decryption key are called the “symmetric key." In this research, a medical researcher found that the chaotic logistic encryption algorithm has a better effect on encrypting medical X-ray image information and hides the statistical properties of the original medical encryption. Several standards were used to measure image quality during and after encryption, and a comparison was made between them to obtain optimal values for encrypting the X-ray image. The correlation relationship between the adjacent pixels of both the original and the encrypted image was also measured at both values of the initial coefficients. The correlation relationship for the adjacent pixels in the original image was found to be strong. However, in the case of the encrypted image, it is sparse and has little correlation. Finally, in the case of the image in which encryption does not occur, the correlation relationship between adjacent pixels is similar to the original image. Several measurements were used in the research, such as Encryption Time (ET), Decryption Time (DT), and Information Entropy for the Original image (Eo).

Keywords: X-Ray Image Encryption, Decryption, Chaotic Logistic Encryption Algorithm, Histogram.

1. Introduction

Digital image processing is today the world's most significant and prominent domain. The web database integrates user data (Abu-Ein, 2023), including text and images. Improving security approaches and developing new algorithms are necessary for secure picture storage and transmission across networks. Cryptography aims to provide secure data transfer, ensuring information anonymity even in hostile environments. The field of cryptography has embraced a variety of strategies to counter assaults. This work presents an essential and efficient cryptography implementation. Chaos theory has significantly strengthened encryption techniques. This paper discusses chaotic cryptography (Ahmed, Hammood, Chisab, Al-Naji, et al., 2023; Ahmed, Hammood, Chisab, & Ismail, 2023; Masood et al., 2022). Telemedicine is an emerging domain that involves the remote delivery of medical services to patients, in which neither the patient nor the healthcare provider is physically collocated. Confidential patient information, including medical images, is transmitted via Internet or cellular network communication channels. An advanced healthcare system necessitates a streamlined framework that can securely store medical images, ensuring that only authorized users have access to them regardless of their location in the world. Most of the researchers' efforts have been devoted to developing computer-based approaches to enhance patient care. However, there has been a certain degree of latency in developing methods to attain the intended level of security for sensitive data in both storage systems and communication channels. One approach to safeguarding medical images in this circumstance is employing encryption schemes that render the images unusable for users who do not possess the corresponding encryption information (Bose et al., 2021; Mohamed, 2022; Zhang & Liu, 2023; Zhang et al., 2020). Decryption pertains to the inverse procedure through which encrypted data is regenerated into plain text, whereas encryption involves converting unencrypted data to encrypted data. The four primary objectives of cryptography are information authentication, confidentiality, integrity, and non-repudiation (Asgari-Chenaghlu et al., 2019; Mohsen et al., 2024). Before transmission over public networks, the raw data transforms into a representation devoid of additional information that renders it meaningless. Encryption is repeatedly recommended to guarantee the security of medical images within the healthcare sector. According to this scheme, the initial image is converted into a cypher image, thereby restricting access to its contents to authorized users only. Unauthorized users are thereby thwarted from accessing the data. Cryptography is widely utilized due to its substantial security advantages (Asgari-Chenaghlu et al., 2019).Images utilized in the medical domain are considered sensitive data within bio-information systems. In order to transmit images of this nature over a network, a secure encryption algorithm is indispensable. Over the past few decades, researchers have proposed numerous image encryption algorithms. The Data Encryption Standard algorithm is the earliest algorithm in use for encryption, and its cost computations require the least amount of time. Either symmetric or asymmetric algorithms can be utilized to encrypt images highly efficiently (Raman, 2016). Researchers encounter numerous obstacles when attempting to develop techniques that are impervious to assaults and practical. To accomplish this, sophisticated mathematical models and novel algorithms are implemented. Chaos refers to an unpredictable and pseudo-random motion that arises within a deterministic dynamical system due to its susceptibility to initial values and parameters. The investigation of chaos theory emerged from H. Poincare's 1913 examination of the three-body problem (Kumari et al., 2017). After extensive investigations, E. N. Lorenz introduced the Lorenz equation in 1963, the initial instance of a chaotic solution arising from a deterministic equation in a dissipative system (Rajoriya et al., 2018). In their 1975 paper "Period Three Implies Chaos," Tienyien Li and James A. Yorke coined the term "chaos" to denote this phenomenon (Hua & Zhou, 2017). Extensive research has been conducted in the years that followed on chaos-based cryptography, which has also entered the stage of practical application (Zhou et al., 2014). Chaotic systems demonstrate various captivating characteristics, such as their exactness, periodicity, and sensitivity to initial conditions and control parameters. Certain prerequisites for pseudo-random coding (i.e., chaotic) and cryptography apply to virtually any property (Mitra et al., 2006). A logistic map consisting of one and two dimensions generated the chaotic matrix. The encrypted image undergoes an XOR operation at each iteration, achieved via two-phase confusion and diffusion. Moreover, a color image derived from chaotic maps was presented. The aforementioned function is employed to produce pseudo-random sequences, which are subsequently utilized in an encryption

procedure comprising three distinct phases: "permutation," "diffusion," and "substitution." By modifying the values of image pixels during this phase, the position of the image's pixels is scrambled, and the connection between the encrypted and original image is confused (Özkaynak, 2015). The objective of this paper is thus to propose an image encryption algorithm based on chaos.

2. Chaotic Encryption and Decryption Process

Based on their temporal evolution, chaotic systems can be categorized as either discrete chaotic maps or continuous chaotic systems. A continuous chaotic system is characterized by a state that undergoes a continuous evolution over time, and its dynamical equations generally consist of a collection of differential equations. In contrast, a discrete chaotic map denotes a system in which the evolution of its state occurs discretely over time, and its dynamical equation is typically an iterative equation. (Faisal & Ameer, 2020; Hua & Zhou, 2017; Zhang & Liu, 2023).

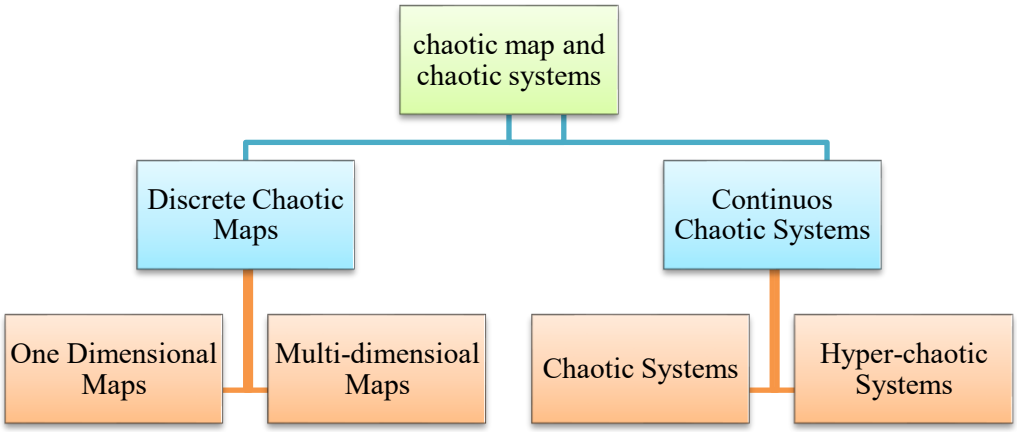

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Figure 1. Chaotic maps and systems classification (Zhang & Liu, 2023)

A discrete chaotic map represents a dynamic system characterized by time-varying discrete state variables. The discrete chaotic map is distinguished by its nonlinearity, sensitivity to initial conditions and parameters, and period multiplication (Zhang & Liu, 2023), demonstrating unpredictable and complex behavior over time. The evolution of state variables over time is typically governed by a set of ordinary or partial differential equations that characterize these systems. The state variables comprise physical attributes intrinsic to the investigated system (Zhang & Liu, 2023).

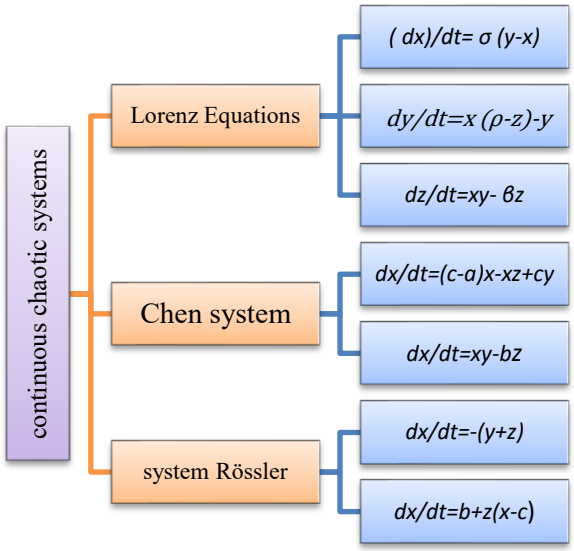


Figure 2. Examples of continuous chaotic systems and their mathematical define (Zhang & Liu, 2023)

A typical nonlinear iterative equation is as follows it ions:

$$X_{(K+1)} = U \times X_K \times (1 - X_K) \quad (1)$$

It is called the control parameter of logistic mapping for any k, where k is the iteration time step. Logistic mapping's dynamic behavior is highly dependent on the control parameter u. The system exhibits.

3. Proposed Algorithms

As illustrated in **Figures 3** and **4,** we proposed an encryption and decryption algorithm in this paper based on the logistic map and the chaotic system.

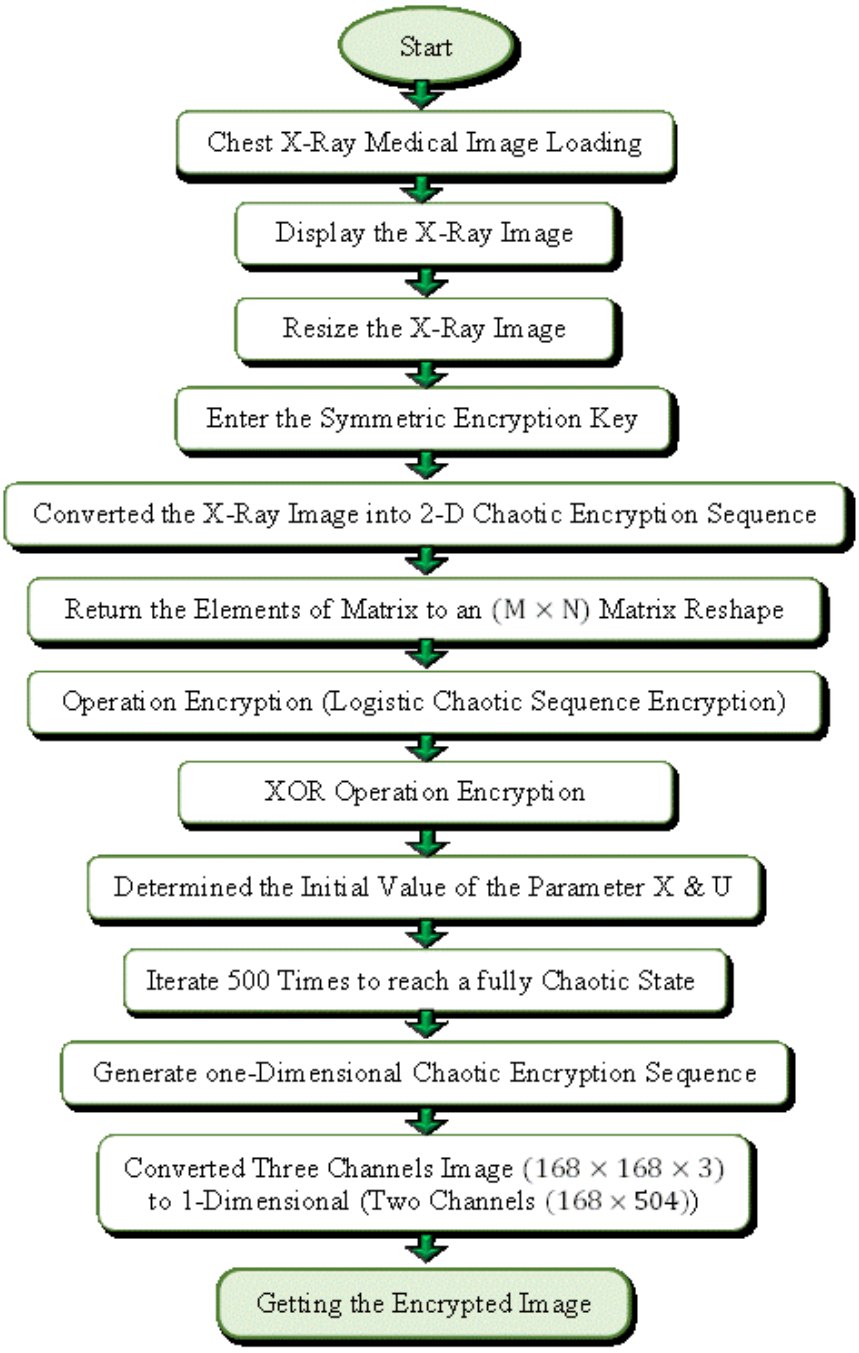


Figure 3. The Algorithm for image encryption

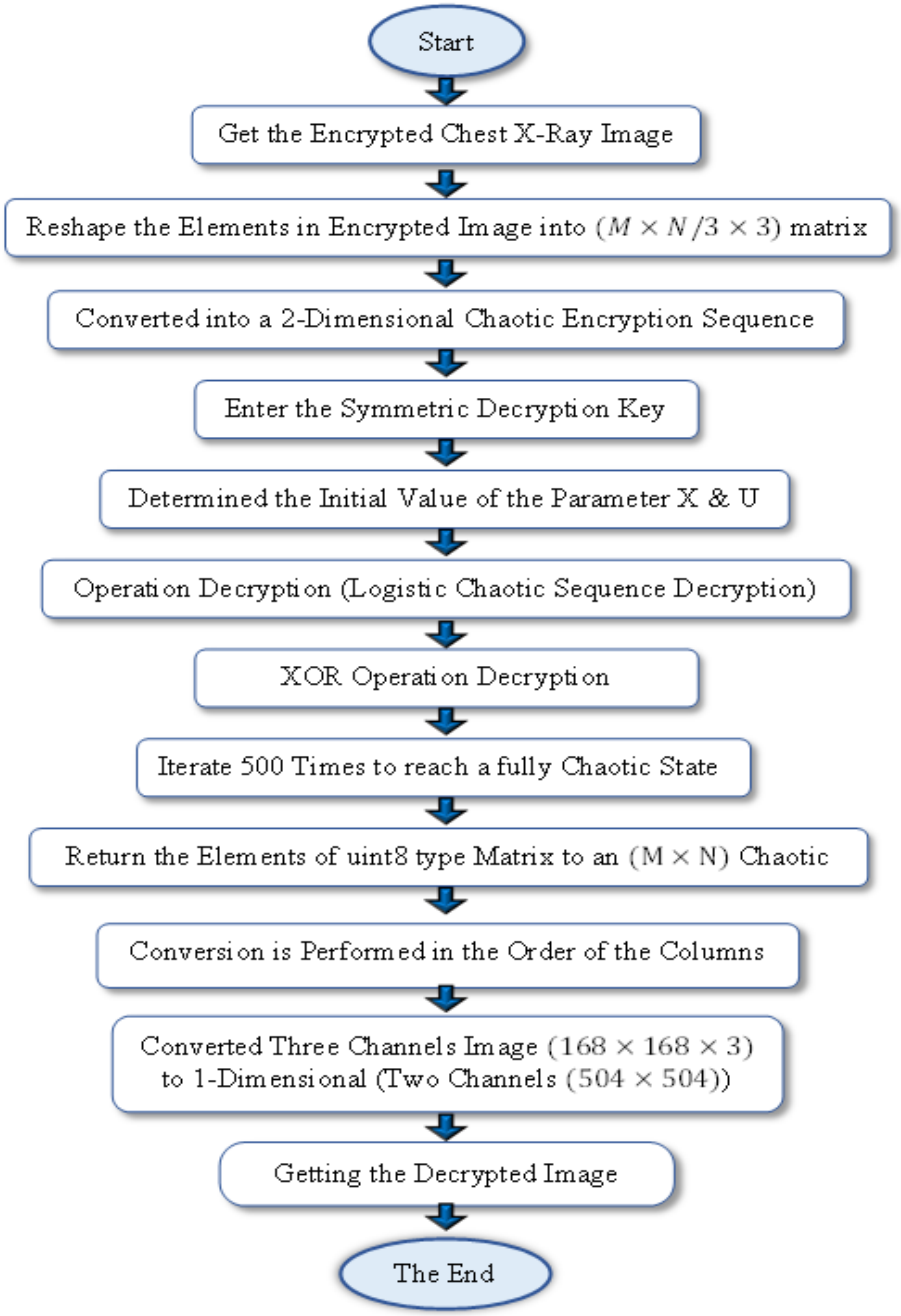


Figure 4. The Algorithm for image decryption

4. Image Acquisition

X-ray medical pictures make up the dataset of images utilized in the experiment. The pictures were provided by the Chest Diseases Center at Al-Hakim Hospital in Najaf and the Radiology Department of Al-Shamiya General Hospital in Diwaniyah. The dimensions picture (168 x 168) was used in our database. The data and numerical simulations were completed utilizing the MATLAB 2021a environment to confirm and demonstrate the viability and security of the suggested optical image encryption scheme. Using an Acer PC laptop running Windows 10 Pro 64-bit, including an Intel(R) Core (i5)-500U processor clocked at 2.5 GHz and 8.0GB of RAM.



Figure 5. X-ray original image

5. The Experiential Results and Histogram Analysis

In order to simulate the proposed algorithm in MATLAB, a 168 x 168 standard grayscale X-ray image is selected as the basic image. Set the initial secret keys as follows: $p1 = 0.1, p2 = 0$. The encrypted X-ray image is depicted.

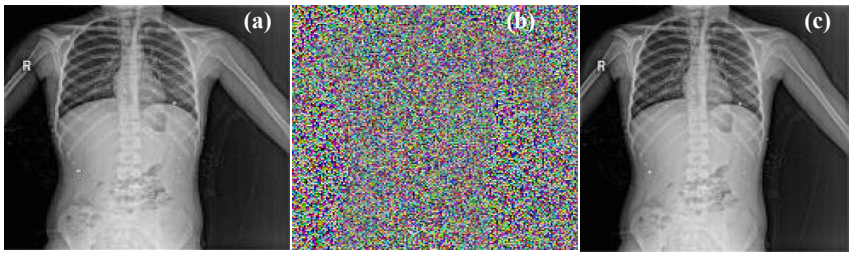


Figure 6. Medical image X-ray encryption using the chaotic method when X= 0.1; U = 4: (a) Original X-ray Image, (b) Encrypted X-ray Image, and (c) Decrypted X-ray Image

According to the outcomes of the investigations, the encrypted X-ray image differs significantly from the original. The encrypted and decrypted X-ray images do not disclose any information regarding the original X-ray image, as in **Figure 6**. In addition, the distribution of the encrypted X-ray image is uniform in the histogram. **Figure 8** demonstrates that the proposed encryption algorithm can effectively withstand statistical attacks.

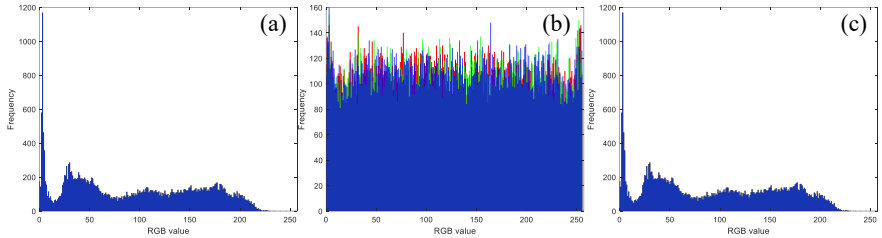


Figure 7. X-Ray Medical Image Histogram X= 0.1; U = 4: (a) Original X-Ray Medical Image Histogram, (b) Encrypted X-Ray Medical Image Histogram, and (c) Decrypted X-Ray Medical Image Histogram

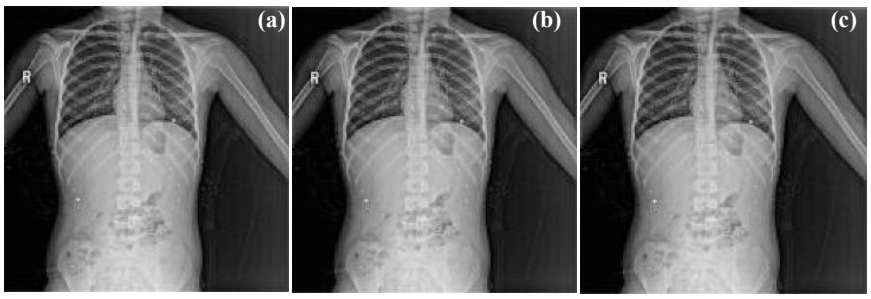


Figure 8. Medical image X-ray encryption using the chaotic method when X= 1; U = 1: (a) Original X-Ray Image, (b) Encrypted X-Ray Image, and (c) Decrypted X-Ray Image

According to the results of the investigations, the encrypted X-ray image does not differ from the original image. The encrypted X-ray images reveal any information related to the original X-ray image, as shown in **Figure 8**. The reason is that chaotic encryption works within a specific range represented by $(1 \leq U \leq 3.5699456)$ and $(0 < X \leq 1)$. In addition, the distribution of the encoded X-ray image is similar in histogram to the histogram of the original and recovered image. As shown in **Figure 9**, the proposed encryption algorithm can thus effectively resist statistical attacks within a specified range.

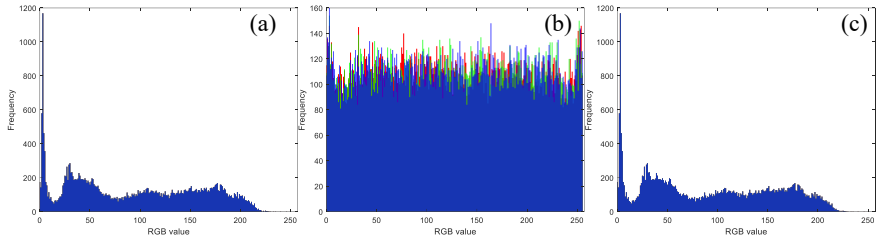


Figure 9. X-Ray Medical Image Histogram when X= 1; U = 1: (a) Original X-Ray Medical Image Histogram, (b) Encrypted X-Ray Medical Image Histogram, and (c) Decrypted X-ray Medical Image Histogram

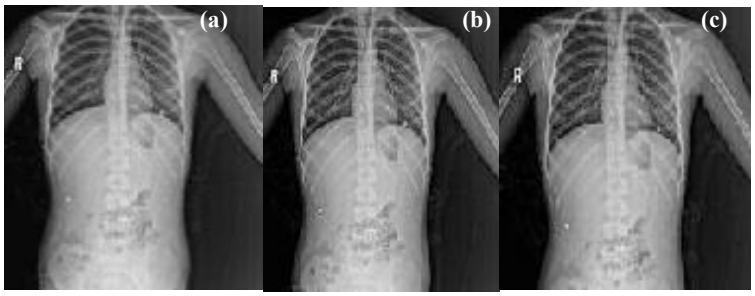


Figure 10. Gray Medical X-Ray Image with X= 0.1; U = 1: (a) Original X-Ray image, (b) Encrypted X-Ray image, and (c) Decrypted X-Ray image

According to the results of the investigations, the encrypted X-ray image does not differ from the original image. The encrypted X-ray images reveal any information related to the original X-ray image, as shown in **Figure 10**. The reason is that chaotic encryption works within a specific range represented by $(1 \leq U \leq 3.5699456)$ and $(0 < X \leq 1)$. In addition, the distribution of the encoded X-ray image is similar in histogram to the histogram of the original and recovered image. As shown in **Figure 11**, the proposed encryption algorithm can thus effectively resist statistical attacks within a specified range.

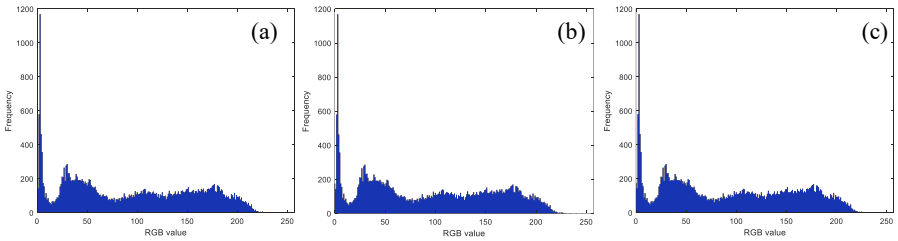


Figure 11. Gray Medical X-Ray Image histogram with X= 0.1; U = 1: (a) Original X-Ray image histogram, (b) Encrypted X-Ray image histogram, and (c) Decrypted X-Ray image histogram

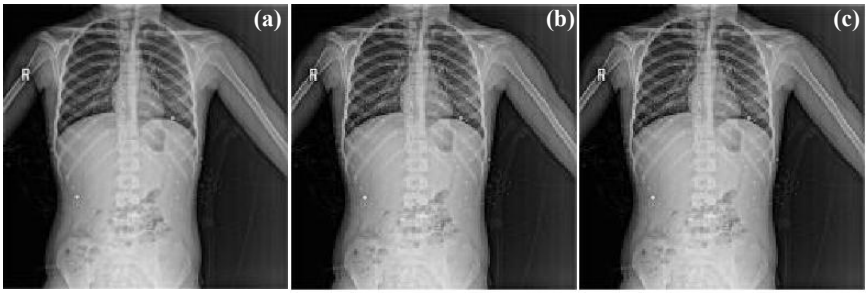


Figure 12. Gray Medical X-Ray Image with X= 1; U = 1: (a) Original X-Ray image, (b) Encrypted X-Ray image, and (c) Decrypted X-Ray image

According to the results of the investigations, the encrypted X-ray image does not differ from the original image. The encrypted X-ray images reveal any information related to the original X-ray image, as shown in **Figure 12**. The reason is that chaotic encryption works within a specific range represented by $(1 \leq U \leq 3.5699456)$ and $(0 < X \leq 1)$. In addition, the distribution of the encoded X-ray image is similar in histogram to the histogram of the original and recovered image. As shown in **Figure 13**, the proposed encryption algorithm can thus effectively resist statistical attacks within a specified range.

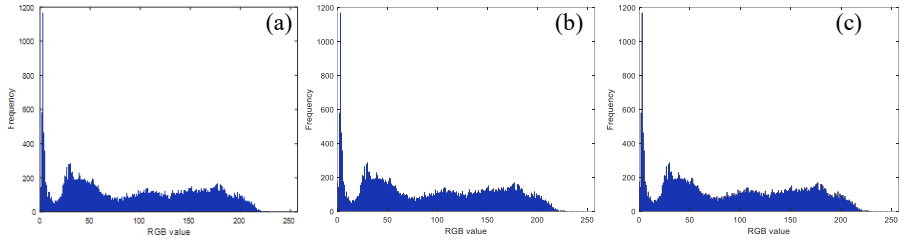


Figure 13. Gray Medical X-Ray Image histogram with X= 0.1; U = 1: (a) Original X-Ray image histogram, (b) Encrypted X-Ray image histogram, and (c) Decrypted X-Ray image histogram

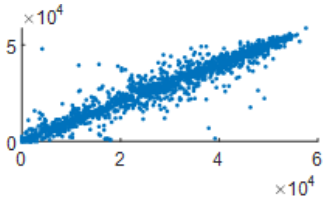
6. Results and Conclusions

This subsection provides an in-depth examination of the empirical analysis. As shown in **Table 1**, the X-ray image was encrypted using the chaotic encryption equation, and values were also used for the initial parameters outside the encryption range. The quality of the proposed algorithm was evaluated using the following image quality metrics:

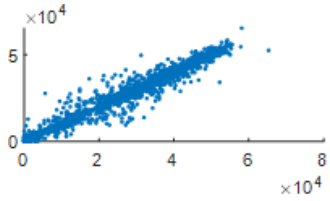
Table 1. Show some IQM values in two different values of X and U for medical images.

NO.	IQM	X=0.1, U=4	X=1,U=1	X=0.1,U=1	X=1, U=4	NO.	IQM	X=0.1, U=4	X=1, U=1	X=0.1,U=1	X=1, U=4
1.	ET	12.08	4.245	7.98	4.245	**10.**	CC1	1	1	1	1
2.	DT	7.599	3.624	8.079	3.624	**11.**	CC2	0.0067	1	1	1
3.	Eo	7.568828	7.56888	7.5688	7.568	**12.**	SNR1	37.857	37.85	37.85	37.8
4.	Ee	7.991998	7.56882	7.5688	7.568	**13.**	SNR2	37.857	37.85	37.85	37.8
5.	Ed	7.568828	7.56882	7.5688	7.568	**14.**	MD1	0	0	0	0
6.	NPCR	0.971	0	**0**	0	**15.**	MD2	227	0	0	0
7.	AV1	93.0489	93.0489	93.048	93	**16.**	EOD	0	0	0	0
8.	AV2	126.58822	93.0489	93.048	93	**17.**	EOE	1.37635	0	0	0
9.	AV3	93.0489	93.0489	93.048	93	**18.**	EDE	1.37635	0	0	0

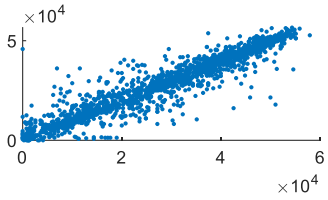
The correlation coefficients between the original and encrypted X-ray images are computed and presented in **Table 1**. The correlation coefficients for the original X-ray image are approximately one. In contrast, they approach zero for the encrypted X-ray image generated by the proposed algorithm, as in the following figures:



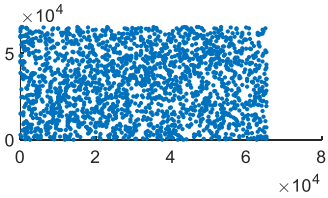
a. Horizontal correlation plot of two neighbouring pixels from the original X-ray picture



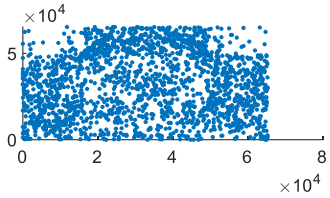
b. A vertical correlation map of two nearby X-ray original picture pixels



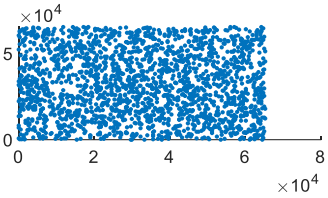
c. A diagonal correlation plot of two nearby X-ray original picture pixels



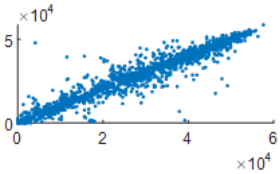
d. A horizontal correlation plot of two neighbouring X-ray encryption picture pixels $X = 0.1., U = 4$



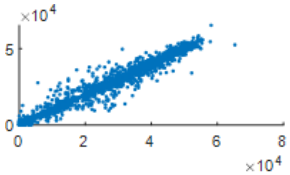
e. A Vertical correlation plot of two neighbouring X-ray encryption picture pixels $X = 0.1, U = 4$



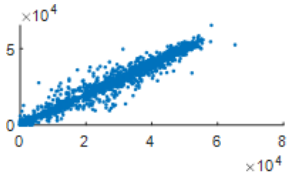
f. A diagonal correlation plot of two neighbouring X-ray encryption picture pixels $X = 0.1, U = 4$



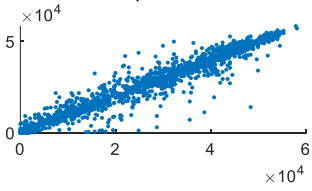
g. A horizontal correlation plot of two neighbouring X-ray encryption picture pixels $X = 1, U = 1$



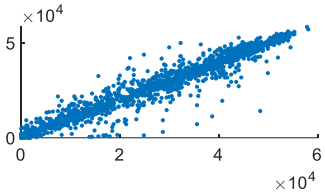
h. A Vertical correlation plot of two neighbouring X-ray encryption picture pixels $X = 1, U = 1$



i. A diagonal correlation plot of two neighbouring X-ray encryption picture pixels $X = 1, U = 1$

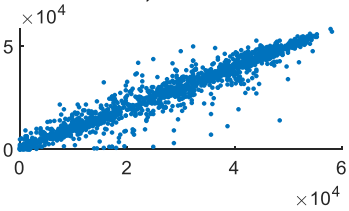


j. A horizontal correlation plot of two neighbouring X-ray encryption picture pixels $X = 0.1, U = 1$

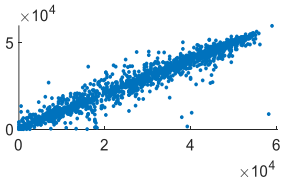


k. A Vertical correlation plot of two neighboring X-ray encryption picture pixels $X = 0.1, U = 1$

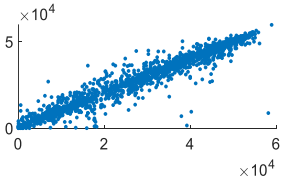
l.



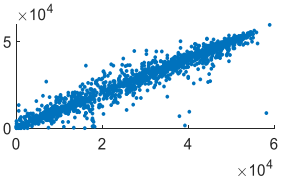
m. A diagonal correlation plot of two neighbouring X-ray encryption picture pixels $X = 0.1, U = 1$



n. A horizontal correlation plot of two neighbouring X-ray encryption picture pixels $X = 1, U = 4$



o. A horizontal correlation plot of two neighbouring X-ray encryption picture pixels $X = 1, U = 4$



p. A horizontal correlation plot of two neighbouring X-ray encryption picture pixels $X = 1, U = 4$

Figure 14. Plotting the correlation between two nearby X-ray medical images

7. Conclusion

More and more data will be accessible for research as medical image analysis techniques and imaging technologies develop. Therefore, it is vital to safeguard such photos. X-ray medical pictures are encrypted using a technique based on the chaotic logistic algorithm. Chaotic is among the most effective mathematical instruments for image analysis and cryptography because it possesses a particular structure. The capability of the chaotic is integrated with additional mathematical instruments. It can be inferred that image encryption and decryption techniques are highly secure and algorithmically chaotic. From **Table 1,** we notice that the value of Encryption time (ET), Decryption time (DT), Information Entropy for encryption image (E_e), Number of Pixel Change Rate (NPCR), Average Value of encryption image (AV2), Maximum Difference Index for encryption image (MD2), Entropy Differences (EOE, EDE) decreases when the values of the primary parameters move from the encoding range to outside the encryption range. At the same time, Correlation Coefficient Analysis (CC2) increases when the values move from the encryption range to outside the encryption range, and finally, Information Entropy (E_d), Average Value of the original image (AV1), Average Value of decryption image (AV3), Coefficient Analysis (CC1), Signal to Noise Ratio Index (SNR), Maximum Difference Index ($MD1$), Entropy Differences (EOD) that remain constant and do not change with any change. Initial parameter values from encryption range to out-of-range. It can be concluded that image encryption and decryption technology are very secure and algorithmically chaotic within the limits of chaotic encryption.

From **Figure 10**, we notice that in the encrypted image, the correlation between adjacent pixels is very weak, as the drawing is scattered, and this makes it impossible to know the information for the encrypted image, as the correlation coefficients are very weak, while in the original image, the pixels have a strong relationship, as they all share a single extension of the coefficient link. While the drawing of the Histogram shows the mismatch of the frequencies of the pixel values between the encrypted image and the original, and this indicates the efficiency of the encryption algorithm, the recovered image is identical to the original histogram image, and this is evidence of the success of the decryption algorithm.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Data Availability

No data was used for the research described in the article.

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A Leap for Medical Devices Regulation in India and its Comparison with United States and European Union Regulations

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ABSTRACT

The Indian medical devices sector is the sunrise sector and holds the potential to quickly become one of the top countries in the global medical devices market share. In the patient-centric era, this paper aims to comprehensively analyze medical device regulations in India and compare them horizontally with United States U.S. and European Union (EU) regulations. Data from open sources, such as reports, different search engines, etc., were considered for an in-depth analysis of the regulatory landscape in India, the US, and the EU. One of the significant comparative findings indicated that CE (European Conformity) is essential to EU regulation for ensuring medical devices' safety and effectiveness (efficacy). In contrast, notified bodies/central licensing authority (CLA) in India and U.S. Center for Medical Devices and Radiological Health (CDRH) perform the same. Variations in device classification, pre-market approval requirements, post-market surveillance, validity period, and quality management systems were also observed.

Despite significant developments in the medical devices rules (MDR)-2017, various challenges such as specific compliances for software as medical devices (SaMD), futuristic healthcare technologies regulations, and limited designated labs for performance evaluation of In-vitro diagnostics (IVD) medical devices, which needs to be addressed enabling multiple fold increment in the medical device market share. Recommendations include creating a unique quick response (QR) code for each medical device, creating a database of technical information on approved devices, and strengthening materiovigilance. These steps are essential to ensuring the quality and safety of medical devices and enhancing their competitiveness in the global market.

Keywords: Medical Device, Device Classification, Risk Assessment, Quality Management System, Medical Devices Rules.

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1. Introduction

The Global Harmonization Task Force 2012 (GHTF/SG1/N071:2012) defines a "Medical Device" and "*In-Vitro* Diagnostic (IVD) medical device" as follows: “Any instrument, apparatus, equipment, implant, machine, appliance, implant, consumables and disposables, reagents for in vitro use, software, material, or another similar or related article,. intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) as shown in Figure 1, and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but may be assisted in its intended function by such means (Force, 2012).

In recent years, the medical devices industry has experienced exponential growth globally after the emergence of corona virus disease 2019 (COVID-19), and it is still growing quickly. The world has shown a shift in behaviours, work culture, economy, and beyond due to the COVID-19 pandemic. Further, it has significantly raised the importance of manufacturing/importing medical devices or IVD as a key player in the prevention, diagnosis, treatment, monitoring, and management of all medical conditions, diseases, illnesses, interventions, and disabilities (see Figure 2).

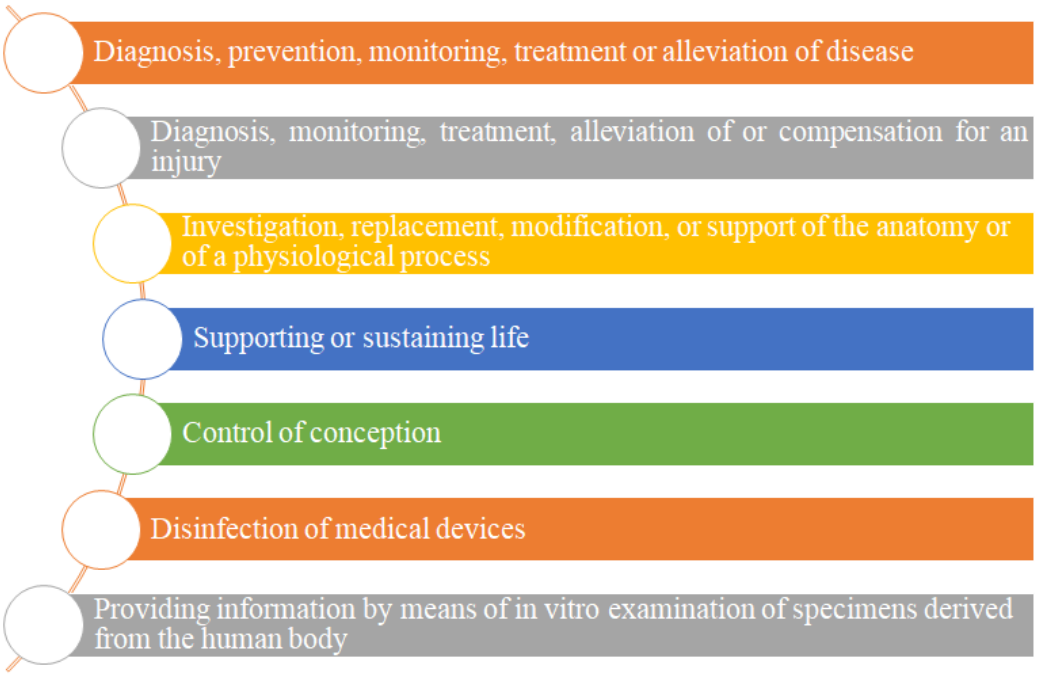

Figure 1. Graphical denotation of medical device and *in-vitro* diagnostic (IVD) medical devicedefinition

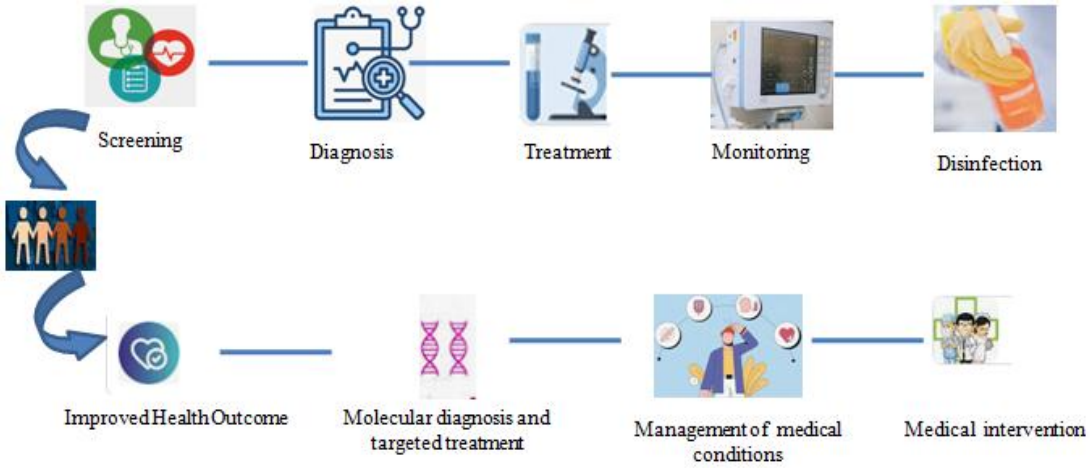

Figure 2. Medical devices as key players towards the goal of universal healthcare

1.1. Indian Medical Device Industry: Statistics Portrayal

The Indian medical devices industry, sharing the global medical device market of 1.65%, is a sunrise sector of $11 billion, growing steadily at a compound annual growth rate (CAGR) of 15% over the last 3 years (2020-2023). However, current medical market equipment is expected to record a 12.6 % CAGR from 2024 to 2033 (Customs market insights; India Medical Equipment Market 2024–2033, 2024). 2024, it is projected to reach $ 6 billion; by 2033, the valuation is anticipated to reach $17 billion (see Figure 3).

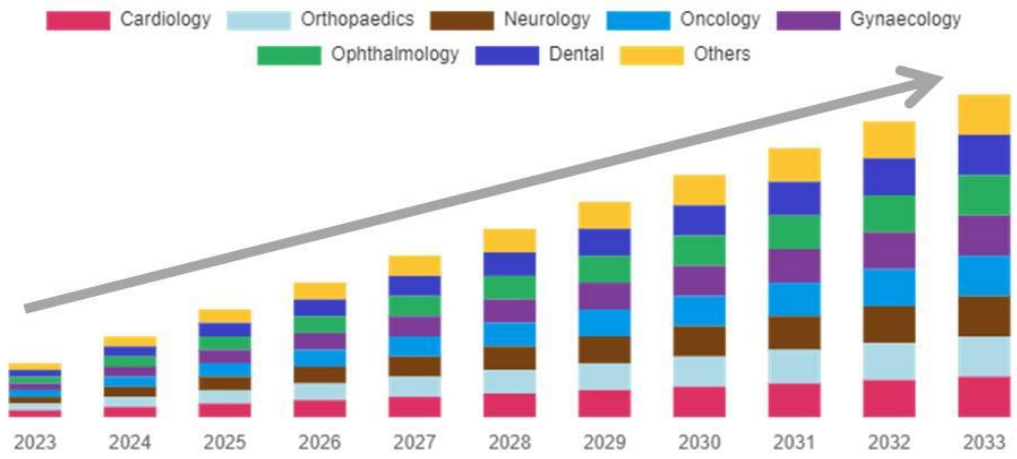

Figure 3. Indian Medical Equipment Market-current projection 2024-2033 by application (source: customs market insights India Medical Equipment Market 2024–2033 (*Customs market insights; India Medical Equipment Market 2024–2033*, 2024)

India is Asia's fourth largest medical device market, following Japan, China, and South Korea. It is among the top 20 global medical device markets (*Indian Medical Device Market, Annual Report* – 2022-2023). However, the sector faces a substantially high import dependency of 75-80% (see Figure 4). Moreover, India hosts approximately 750-800 domestic medical device manufacturers, which meet nearly 65% of the domestic market in disposable and consumable segments (*Boosting the Indian Medical Device Industry* 2023; *Note on Health and Pharmaceutical Sector. Invest India*, 2024).

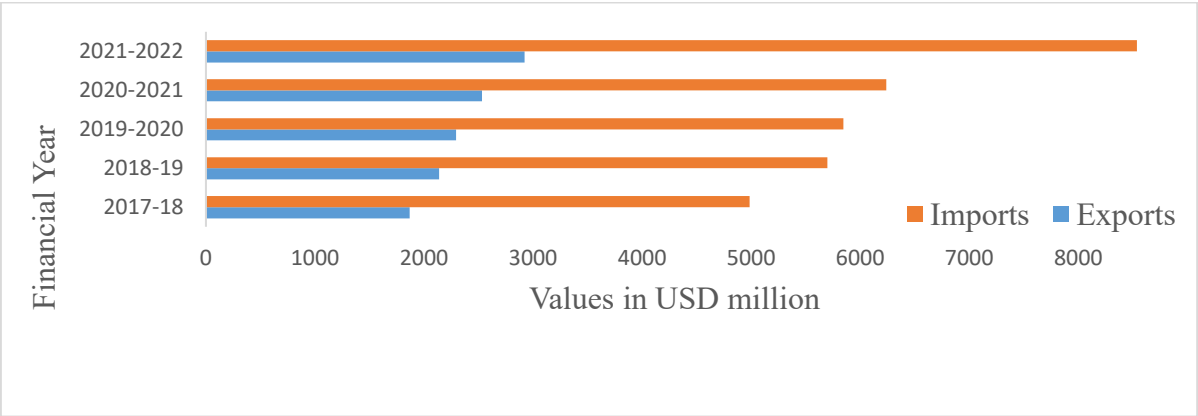

Figure 4. Exports and Import of Medical Devices in India (Source: Engineering Export Promotion Council of India-EEPC, India *(Final Report, Survey of Medical Devices Clusters,* 2023*)*

In particular, India remains immensely dependent on imports despite the significant presence of Indigenous manufacturing for higher-end medical diagnostics and testing products such as consumables and disposables, surgical instruments, implants, electronic equipment, and IVD reagents from the U.S., Germany, China, Singapore, and the Netherlands, which are the top

exporters of such devices to the country (*Final Report, Survey of Medical Devices Clusters,*, 2023; *India imports 80% of its requirement of medical devices: MoS Ashwini Choubey*, 2024) (see Figures. 5a and 5b).

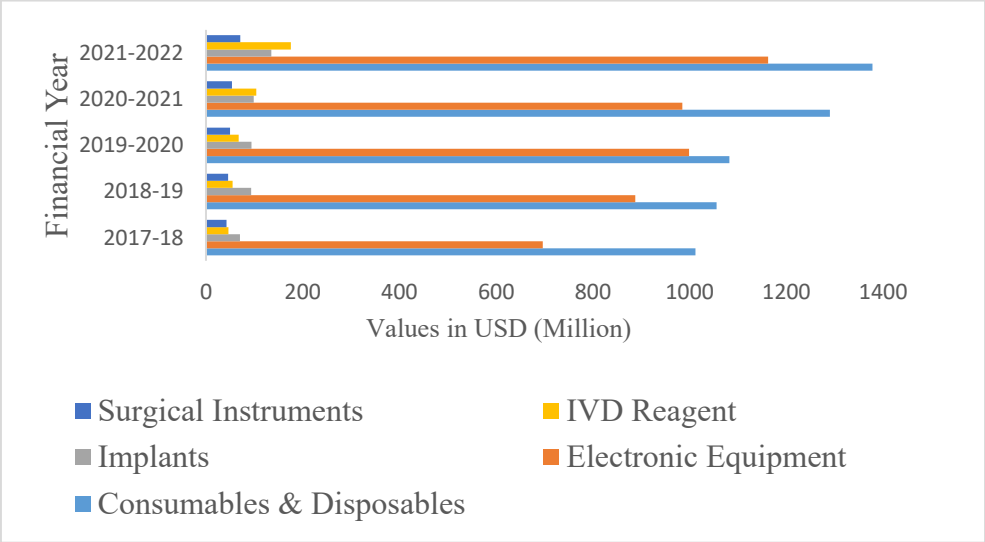

Figure 5a. Category Wise Export of Medical Devices (Source: Engineering Export Promotion Council of India-EEPC, India (*Final Report, Survey of Medical Devices Clusters*, 2023))

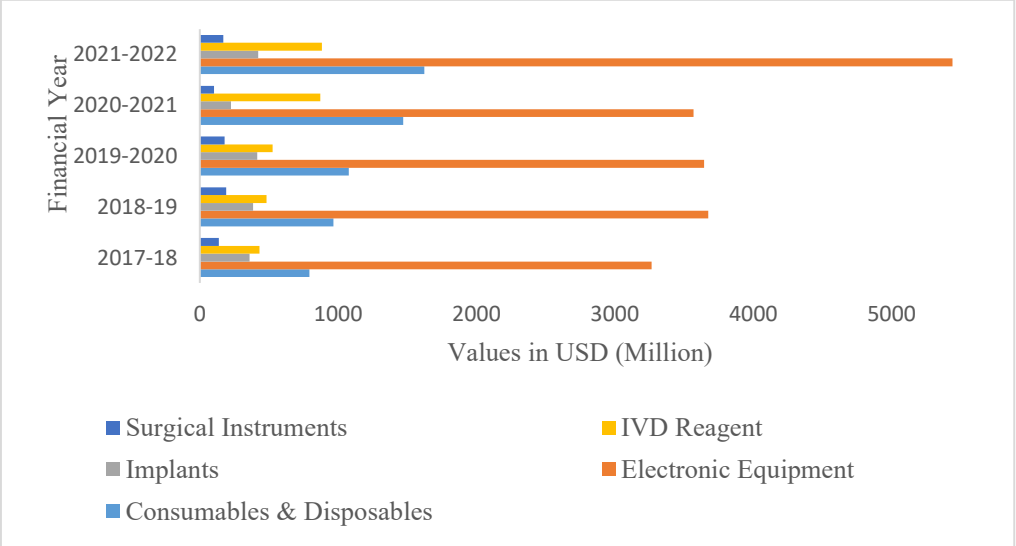

Figure 5b. Category Wise Import of Medical Devices (Source: Engineering Export Promotion Council of India-EEPC, India (*Final Report, Survey of Medical Devices Clusters*, 2023))

The market share of medical devices in India mainly comprises: a) medical instruments and appliances (market share of 34%), out of which 20% are Indigenous manufacturers, and 80% are importers, b) diagnostic imaging devices (market share of 31%), out of which 34% are indigenous manufacturers and 66% are importers c) consumables and implants (market share of 19%), out of which 50% are indigenous manufacturers and 50% are importers; and d) patient aids and others (market share of 16%), out of which 25% are indigenous manufacturers and 75% are importers *(Deloitte, NATHEALTH Medical devices making in India-a leap for Indian healthcare, 2016)* (see Figure 6).

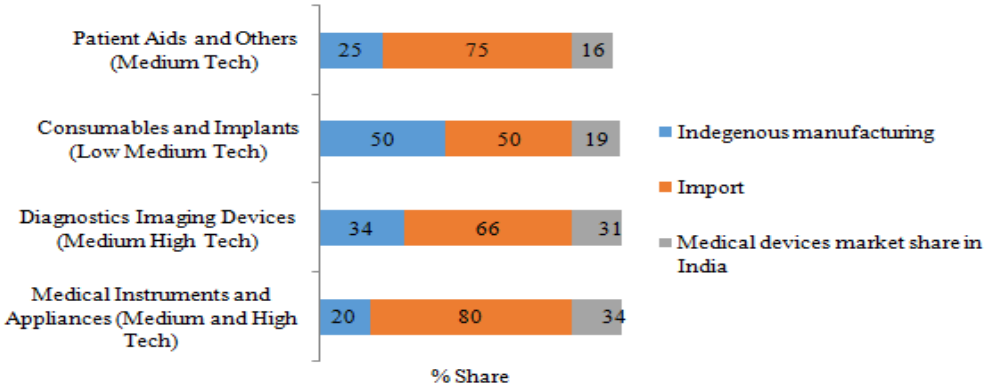

Figure 6. Market share (%) with respective manufacturing and importing of significant categories of medical devices in India (Source: Deloitte, Medical Devices Making in India - A Leap for Indian Healthcare (*Deloitte, NATHEALTH Medical devices making in India-a leap for Indian healthcare,* 2016))

Factors contributing to these imports' reliance include limitations in high-end technology, inadequate access to raw materials for manufacturing, and insufficient infrastructure and testing facilities to produce devices meeting an international standard. In response, efforts to reduce import dependency and foster self-reliance in the medical devices sector, Govt. of India has taken several flagship initiatives such as 'Make in India,' 'Start-up India,' 'Production Linked Incentive' (PLI), 'Foreign Direct Investment' (FDI) Scheme and setting up of 'Medical Devices Parks' which have catalysed investments and spurred innovation and new product development in the MedTech space. However, in the growing MedTech sector, more innovations are envisaged with every passing year by using advanced technologies like artificial intelligence (AI), machine learning (ML), internet of things (IoT), block chain, 5G, 3D printing in manufacturing medical devices such as smart wearable devices, implants, imaging devices, cardiovascular devices, and minimally invasive devices, etc., for which the regulatory compliances of medical devices are evolving, making a way ahead for comprehensive healthcare to all. Since medical device regulations are dynamic and vary from country to country, specific compliances are becoming increasingly stagnant worldwide.

The manuscript embarks a critical literature review of the regulatory framework's evolution governing medical devices, aiming to elucidate how pivotal changes have shaped the current regulatory landscape and influenced the medical devices industry in India. In addition, a brief comparison of the regulatory model specific to the EU and U.S. with India's counterpart is featured to thoroughly understand the regulatory approval across their geographic territories.

2. Importance of Stringent Medical Device Regulations

In numerous countries globally, the necessity for rigorous regulation emerged mainly to facilitate patients' access to high-quality, safe, and effective medical devices while preventing access to harmful items. Stringent medical device regulations are imperative due to the critical role these devices play in public healthcare, encompassing diagnosis, monitoring, and treatment. Ensuring that medical devices meet their intended use, are effective, and guarantee the safety of patients and operators is paramount. In this regard, reports of adverse incidents linked to faulty medical devices accentuate the necessity for rigorous regulations to enhance safety, quality, and design standards. Instances such as the faulty Acetabular Surface Replacement (ASR) hip implants from Johnson & Johnson in India, affecting thousands of patients due to metal degeneration and subsequent health complications, illustrate the risks associated with inadequate regulation *(innovation, J. J, 2010)*. Similarly, recalls of Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D) devices highlight the life-threatening consequences of premature device failures (*Medtronic Recalls Implantable Defibrillators, U.S. Food & Drug Administrator*, 2023). Recognising these safety concerns, the World Health Organization (WHO) has urged member states to establish guidelines for good manufacturing practices (GMP) and regulatory standards, as well as surveillance systems to ensure

the quality, safety, and efficacy of medical devices (*World Health Organization, Good Manufacturing Practices, Health products policy and standards*). With an estimated two million different types of medical devices on the global market, spanning over 7,000 generic device groups, diverse professionals are designing and supplying these devices (*Medical Devices, World Health Organization*). Hence, Stringent Regulation is essential to meet the medical community's and the public's needs, ensuring the safety and efficacy of devices used for medical purposes.

Moreover, it is understood that regulation of medical devices started relatively late in the 1960s and 1970s by observing the possibility of risks of micro-shocks from an electric current through the device (Contardi, 2019). Since then, demand for strict regulation legislation has come into the picture, and many countries have revamped their regulatory systems to support development or innovation and introduce preventive compliances to strengthen the medical device industry.

2.1. Regulatory Authority and Chronology of Medical Device Regulation in India

Medical device regulation in India is governed by the central and state Governments, which are accountable for enforcing the Act. The Central Drugs Standard Control Organization (CDSCO) serves as the principal Central Licensing Authority (CLA) and is overseen by the Drugs Controller General of India (DCGI). The State Licensing Authority (SLA), led by the State Drug Controller, collaborates with the CLA to develop policies and ensure consistent enforcement of regulations nationwide to protect citizens' lives.Significant technological developments in evolving Indian medical device regulation are herewith summarised (see Table 1).

Table1. Emergence of medical devices regulation in India

S.No	Major induction	Outcome	Reference
1	Inclusion under the Drugs and Cosmetics Act (DCA), 1940	Initially, medical devices were regulated as “drugs” under the DCA, 1940. On November 13th, 1982, an amendment to the DCA redefined “drugs” to include medical devices, subjecting them to the DCA's regulatory framework.	(*Act 68 of 1982: Drugs and Cosmetics*, 1982)
2	Introduction of requirements for manufacturing premises	On February 22, 1994, particular specifications for industrial facilities for the production of medical devices were announced.	(*Schedule M-III in Drugs and Cosmetics Rules, 1945 By Govt. of India Notification No. G.S.R. 109(E), w.e.f. 22.2*, 1994)
3	Guidelines for import/manufacture and clinical trials	On January 20, 2005, rules were issued for acquiring authorisation to import or manufacture novel pharmaceuticals and executing clinical studies. These regulations encompass medical devices categorised as "drugs."	(*Medical devices regulation in India: tracing its evolution to get cues on its future development*, 2020)
4	Notified medical device	The Health Ministry notified 10 sterile devices on October 6, 2005	(*S. O. 1468(E), (October 06, 2005)* 2012)
5	Sale, manufacture, and import of medical devices	On October 7, 2005, the Health Ministry delegated the DCGI the authority to sell, manufacture, and import the 10 notified devices. Subsequently, regulations for importing these 10 devices were implemented on March 1st, 2006.	(*Guidelines for import and manufacture of medical devices.* , 2018; *G.S.R. 627 (E), October 07, 2005, 2005*)

6	Proposal of Medical Devices Regulation Bill (MDRB), 2006	In 2006, the Ministry of Science and Technology proposed the MDRB 2006 to consolidate legislation concerning medical devices, establish the Medical Device Regulatory Authority of India (MDRA), and implement risk-based classification of medical devices.	(Updates on the Medical Device Regulations in India, September 1, 2009, Pacific Bridge Medical, U.S, 2009)
7	Introduction of Medical Devices Rules (MDR), 2017	Framed in conformity with the GHTF framework, the MDR 2017 classified medical devices based on risk and intended use, provided guidelines for licensing and clinical investigation and aimed to encourage Indigenous manufacturing of devices and implemented from January 1, 2018.	(Gazette of India notification, G. S. R. 78(E), January 31, 2017, 2017)
8	Draft Medical Devices (Safety, Efficacy, and Innovation) Bill, 2019	The proposed bill aimed at regulating all locally manufactured and imported medical devices, introducing fines and penalties for non-compliance, and emphasising the need for a national register of medical devices.	(*The Medical Devices Bill, explained*, 2019; "NITI Aayog plans to bring all medical devices under one regulatory regime," 2019)
9	Draft Bill for New Drugs, Medical Devices, and Cosmetics, 2022 July 8, 2022	Proposed to ensure the safety, effectiveness, and compliance with international standards of all drugs and cosmetics, including medical devices. It included provisions for setting up advisory boards, medical device testing facilities, mandatory registration of manufacturers, tax breaks for exports, and a single-window clearance system.	(New Drugs medical devices and cosmetics Bill,)
10	Approval of National Medical Devices (NMD) Policy, 2023 May 2, 2023	Aimed to providing a comprehensive framework for sustained growth and development of the medical device sector, focusing on regulatory streamlining, infrastructure development, R&D and innovation, investment attraction, and human resource development	(*National Medical Devices Policy*, 2023)
11	National Single Windom System (NSWS) January 1, 2024	NSWS Portal was developed independently from the existing Online System for Medical Devices portal for four applications (MD-1, MD-12, MD-16 and MD-39) under Medical Devices Rules 2017 and made life from January 1, 2024.	(*Launching of National Single Window System (NSWS) Portal*, 2024)
12	Periodic Safety Update Reports (PSUR) concerning marketing authorization. (MA) of medical devices/ IVD, March 19, 2024	Submission of online applications of PSURs w.r.t MA of Medical Devices/ In-vitro Devices has been functional through the online medical devices portal system.	(*Marketing Authorization of Medical devices: in vitro devices.*, 2024)

These developments underscore the evolving regulatory landscape in India, reflecting efforts to enhance the safety, quality, and accessibility of medical devices while fostering growth and innovation in the sector.

Since January 1, 2018, after MDR-2017 was operationalised across the country, different amendments have been formulated to facilitate ease of merchandising and availability of quality medical devices in India. (see Table 2). It is recommended by various stakeholders in the industry, manufacturers, healthcare providers, think tankers, policymakers, innovators, and start-ups, that all medical devices should be regulated in a phased manner to ensure that business continuity is not disrupted at all. Based on this recommendation, risk-based classification of the medical devices has been further categorised and notified, meaning that not all

medical devices follow the exact regulatory approval mechanism. For example, all non-sterile and non-measuring devices classified as class A medical devices are considered minimal risk and shall be registered (in both cases, either for manufacture or import) through an identified online portal established for the purpose (see Figure 10).

The Ministry of Health and Family Welfare, Government of India, has issued a notification to classify all medical devices as medications, as per S.O. 648 (E) dated 11.02.2020, under sub-clause (iv) of clause (b) of section 3 of the drugs and Cosmetics Act, 1940, effective from 01.04.2020 ("Gazette of India notification, S.O. 648(E)," 2020). In this regard, the CDSCO has issued G.S.R. 102 (E) dated 11.02.2020 to regulate medical devices in a phased approach. This ensures that business continuity remains unaffected by the licensing regime implementation, which commences on 01.10.2022 for class A and B medical devices and on 01.10.2023 for class C and D medical devices ("Gazette of India notification, G.S.R. 102 (E)," 2020). Before coming to the licensing regime on the date described above, sufficient time has been given to the manufacturer/importer to register their products (30 months for classes A and B and 42 months for classes C and D) so that they may ensure an uninterrupted supply of such medical devices across the country (See Table 3). The process of registration is a significantly simple process and subjective in nature. Once the application is submitted, the registration process will generate a file number, which must be included on the label before marketing.

Manufacturers and importers who fail to secure registration by October 1, 2022 (for classes A and B) and October 1, 2023 (for classes C and D) must either cease operations of the specified medical devices until they obtain the necessary registration or face potential penalties for violating the DCA and MDR. It has been determined that if an existing importer or manufacturer of Class A or Class B medical devices submits an application to the CLA or SLA for an import or manufacturing license under the provisions of MDR, 2017, on or before 30.09.2022, the application will be considered valid. The importer or manufacturer may persist in importing or manufacturing the specified devices for a maximum of six months from the issuance date of this order or until the CLA or SLA renders a decision on the application, whichever occurs first *(Central Drugs Standard Control Organization, Ministry of Health and Family Welfare notification number: F. No. 29/Misc/03/2022-DC (257), dated 30.09.2022 Regulation of all Class A & B Medical Devices under Licensing regime, w. e. f. 01.10.2022, as per G.S.R. 102(E) dated 11.02.2020)*

In the meantime, the CLA can use this period to build the necessary infrastructure and more notified bodies (earlier, only six notified bodies were approved till 31st July 2019, which is increased to 14 notified bodies by 15th Feb 2024 *(Central Drugs Standard Control Organization, Ministry of Health and Family Welfare notification number: F. No. 29/Misc/3/2017-DC (288),* List of notified bodies registered with CDSCO under MDR-2017 dated 31.07.2019; List of notified bodies available on the Online System for Medical Devices portal of CDSCO). Also, approval should be obtained to establish more medical device testing laboratories (MDTL) to carry out tests or evaluations of a particular medical device on behalf of the manufacturer. Presently, 61 MDTL labs have been registered with CDSCO to test different devices/reagents/IVDs as per the provision of MDR-2017 (*List of Testing Laboratories available on the Online System for Medical Devices portal of Central Drugs Standard Control Organization, Ministry of Health and Family Welfare*). This will enrich the device integrity in India and address critical issues such as notified bodies' capacity, compliance resources' availability, and potential delays in product certification.

Table 2. Brief Amendments in MDR-2017

S.No	Gazette Notification Number	Date of implement	Amendment Rules	Explanation	Reference
1	G.S.R. 729 (E)	1st August 2018	Medical Devices (Amendment) Rules, 2018	The manufacturer shall submit a performance evaluation report for in-vitro diagnostic medical devices to the SLA or CLA for the appropriate risk-based classification of MD/IVD.	(*The Gazette of India notification, G.S.R. 729 (E).* 2018)
2	G.S.R. 224 (E)	18th March, 2019	Medical Devices (Second Amendment) Rules, 2019	Modification of Environmental Requirements for the Production of Medical Devices Condom Annexure- A of the Fifth Schedule of MDR, 2017	(The Gazette of India notification, G.S.R. 224 (E). 2019)
3	G.S.R.787(E)	16th October, 2019	Medical Devices (Fifth Amendment) Rules, 2019	Testing laboratories of State and central governments shall be exempt from the necessity of accreditation by NABL for two years.	(Gazette of India notification, G.S.R. 787 (E). 2019)
4	G.S.R. 102 (E)	11th February, 2020	Medical Devices (Amendment) Rules, 2020	Expanded the 37 categories of notified medical devices within the scope of the DCA. All medical equipment, excluding these categories, must be registered with the CLA via a designated online portal commencing April 1, 2020.	(Gazette of India notification, G.S.R. 102 (E). 2020)
5	S.O. 648 (E)	11th February, 2020	Medical Devices Definition	Extended the definition of medical devices to include software, accessories, appliances, and others from April 1, 2020	(Gazette of India notification, S.O. 648 (E), 2020)
6	G.S.R. 918 (E).	31st December, 2021	Medical Devices (Amendment) Rules, 2021	Distinct apparatus Identification of all medical devices authorized for sale, distribution, or import (draft)	(Gazette of India notification, G.S.R. 918 (E). ," 2021)
7	G.S.R. 174 (E).	4th March, 2022	Medical Devices (Second Amendment) Rules, 2022	Include the United Kingdom in the list of territories that offer medical device importers the granting of an import license without undergoing clinical investigation.	(Gazette of India notification, G.S.R. 174 (E). 2022)
8	G.S.R. 356 (E).	18th May, 2022	Medical Devices (Third Amendment) Rules, 2022	Suspension and cancellation of licence	(Gazette of India notification, G.S.R. 356 (E), 2022)
9	G.S.R. 450 (E).	15th June, 2022	Medical Devices (Fourth Amendment) Rules, 2022	The Biological Safety (TSEs/BSE) Certificates are unnecessary if the source originates from an animal species in a specified country.	(Gazette of India notification, G.S.R. 450 (E). 2022)

10	G.S.R. 754 (E).	30th September, 2022	Medical Devices (Fifth Amendment) Rules, 2022	Registration certificate for the sale, stocking, exhibition, offering for sale, or distribution of medical devices in India, including in vitro diagnostic medical devices.	(Gazette of India notification, G.S.R. 754 (E). 2022)
11	G.S.R. 777 (E).	14th October, 2022	Medical Devices (Sixth Amendment) Rules, 2022	Exemption of non-sterile and non-measuring Class A medical devices from the licensing regime (registration required for manufacture/importation)	(Gazette of India notification, G.S.R. 777 (E). 2022)
12	G.S.R. 409(E).	2nd June, 2023	Medical Devices (Amendment) Rules, 2023	Creation of a state medical devices testing laboratory designated by the state government under sub-regulation (3) of rule 19 of MDR-2017	(Gazette of India notification, G.S.R. 409 (E). 2023)

Table 3. Timeline for the execution of medical devices regulation in India

Risks based classification	Voluntary registration	Mandatory registration	License regime	Reference
Class A and B	01.04.2020 to 30.09.2021	01.10.2021 to 30.09.2022	w.e.f. 01.10.2022	(Gazette of India notification, G.S.R. 102 (E), 2020)
Class C and D		01.10.2021 to 30.09.2023	w.e.f. 01.10.2023	
Class A medical devices (non-sterile and non-measuring)		14.10.2022 onwards	Exemption from licensing regime (only registration required for manufacture/import) w.e.f. 14.10.2022 to till date	(Gazette of India notification, G.S.R. 777 (E), 2022)
Class A medical devices (sterile and measuring)		Not applicable	w.e.f. 01.10.2022 comes into the licensing regime	(Gazette of India notification, G.S.R. 102 (E), 2020)

2.2. Classification of Medical Devices in India: Underlying Criteria and Risk Class

Based on the intended use of the device, associated risks, and other parameters outlined in the MDR-2017, the CLA of India classifies medical devices into four risk classes (see Figure 7), namely class A (further divided into non-sterile & non-measuring and sterile & measuring), B, C and D. The basic principles governing these classifications include the following:

- The purpose of the device.
- Combination devices/accessories/components.
- Software is classified in the same class as its associated device.
- Calibrators utilised with a reagent are categorised within the same classification as the reagent.
- Devices with numerous designated functions are categorised according to their primary function.
- If a device is designed for use in conjunction with another device, the categorisation rules shall be applied independently to each device.
- If disparate devices of varying classifications are amalgamated into a singular device or kit, the most rigorous regulations corresponding to the higher classification of the integrated device shall be enforced.

These principles guarantee the precise categorisation of medical devices according to their intended use and related dangers, enabling suitable regulatory control and ensuring patient safety.

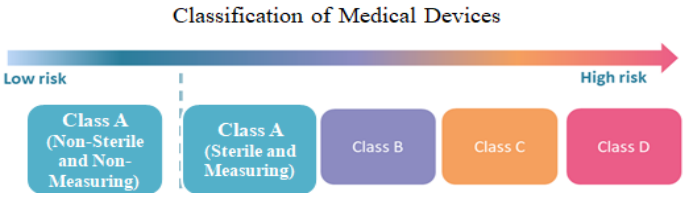

Figure 7. Risk-based Classification of Medical Devices

2.3. Regulatory Approval of Medical Devices in India: Manufacture and Import

Each unique category of medical devices adheres to a designated regulatory pathway, guaranteeing suitable approvals and compliance with safety and quality criteria during the registration procedure. The SLA will issue a manufacturing or loan license to produce notified Class A (sterile and measuring) and Class B devices. In contrast, the CLA will issue the manufacturing or loan licenses for Class C and Class D devices. (see Figure 8a, 8bi, 8bii). These licenses possess perpetual validity unless suspended, cancelled, or renewed, contingent upon the payment of the license retention fee before the expiration of five years from the date of issuance. No assessment of the quality management system by a registered notified body for the manufacturing site is required before issuing a manufacturing license or loan license to sell or distribute Class A medical devices (excluding non-sterile and non-measuring devices).According to the stipulations of MDR-2017 (Sub Rule 4 (i and ii) of Rule 20), an audit of the manufacturing site is not a compulsory prerequisite for the issuance of a manufacture or loan license for the sale or distribution of Class A medical devices (excluding non-sterile and non-measuring devices) ("G. S. R. 78(E), January 31, 2017," 2017). A quality management system (QMS) audit of a class A device manufacturing site (excluding non-sterile and non-measuring devices) is mandated by the registered notified body as outlined in the third schedule of MDR-2017 and must be conducted within one hundred and twenty days from the date the state licensing authority issued the license. Furthermore, mandatory registration for class A devices (non-sterile and non-measuring) necessitates the submission of a declaration from the manufacturer affirming that the proposed device adheres to the essential principle's checklists for safety and performance and complies with the relevant standards applicable to such devices. This self-explanatory endeavor addresses potential health risks, emphasizing risk management, design controls, and corrective and preventive actions (CAPA) to ensure patient safety is never compromised in any clinical setting. At its discretion, the relevant licensing authority may cancel or suspend the registration number, either entirely or for specific medical devices if malpractice is reported or if the applicant fails to adhere to any provisions of these regulations.

Conversely, for Class B medical devices, the manufacturing site must adhere to the QMS criteria outlined in the fifth schedule, and a registered notified body must verify this compliance through an audit prior to the issuance of a license. Furthermore, CLA will conduct an inspection of the manufacturing site following the assessment of necessary documentation for Class C and D, in accordance with Chapter IV, manufacture of medical devices for sale or distribution, MDR-2017.
Firstly, an applicant can apply for a test license for manufacturing a small quantity of medical devices for the purpose of clinical investigation, test, evaluation, examination, demonstration, or training to make three consecutive test batches (in case both or either predicate devices are available or not in India) with a validity of three years. It is noted that if there is no predicate device available in India against the proposed device, meaning that it comes under the scope of investigational medical devices, the applicant/innovator can initiate the regulatory approval by applying test license (MD-12) application followed by clinical investigation (MD-22); permission to manufacture (MD-26) and commercial manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device (see Figure 8bi). On the other hand, if

predicate devices are earlier approved in India against the proposed device, the applicant can directly apply for the test license (MD-12) followed by a manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device (see Figure 8bii). Moreover, import licenses of Class A (sterile and measuring), Class B, Class C and Class D have been granted from CLA with perpetual (see Figure 9). Despite that Class A devices (non-sterile and non-measuring), registration is solely required for manufacturing and import on the online portal of medical devices, as depicted in Figure 10.



Figure 8a. Role of SLA and CLA to grant manufacturing medical devices

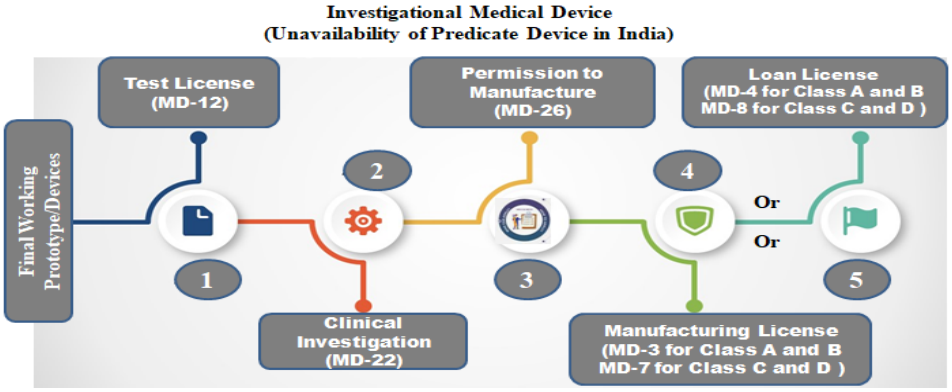

Figure 8bi. Workflow of sequence of the application for the grant of manufacturing/loan license of all medical devices (other than Class A non-sterile and non-measuring) in India. If there is no predicate device available in India against the proposed device, meaning that it comes under the scope of investigational medical devices, the applicant/innovator can initiate the regulatory approval by applying test license (MD-12) application followed by a clinical investigation (MD-22); permission to manufacture (MD-26) and commercial manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device

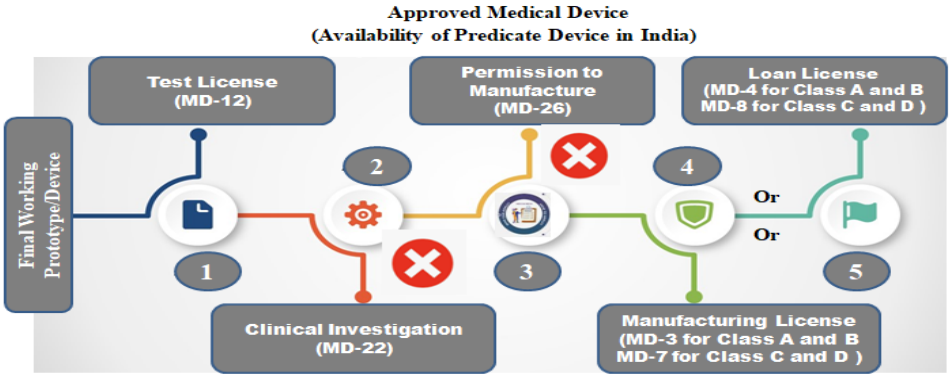

Figure 8bii. The sequence of the application for the grant of manufacturing/loan licenseof approved devices in India. If the proposed devices are earlier approved in India, the applicant can directly apply for the test license (MD-12) followed by a manufacturing/loan license application (MD-3/MD-4 or MD-7/MD-8) based on the risk-based classification of the proposed device. In this regard, there is no requirement to get the application for clinical investigation (MD-22) and permission to manufacture (MD-26), which is indicated with a red Cross mark

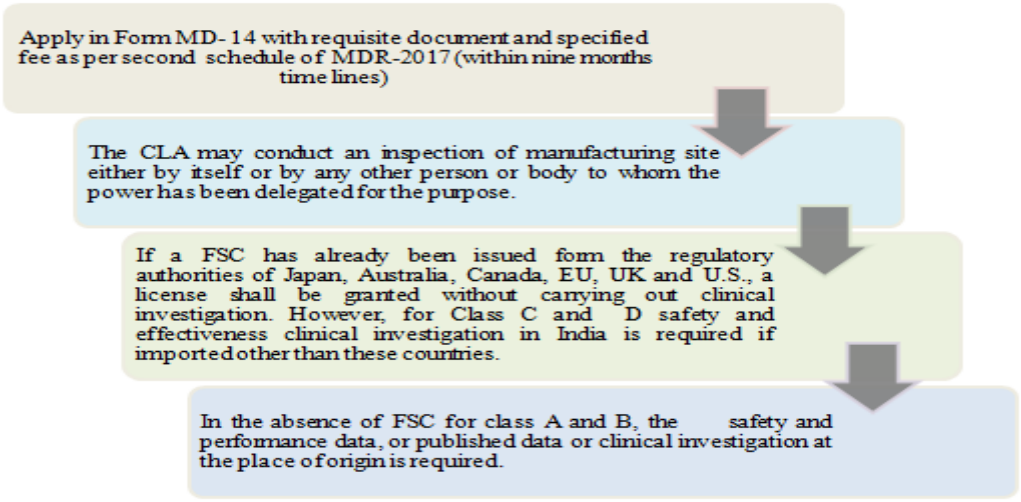

Figure 9. Schematic representation of approval of import license of medical devices (other than Class A non-sterile and non-measuring) in India

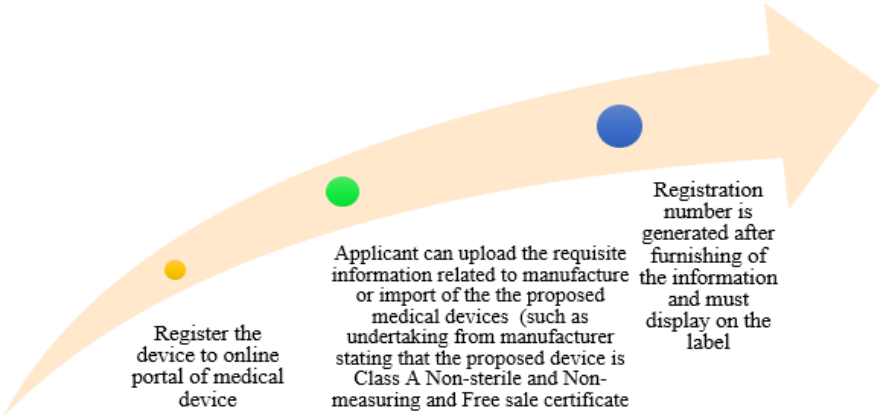

Figure 10. Illustration of the registration process of Class A (non-sterile and non-measuring) medical devices in India for the purpose of manufacturing and import into India

2.4. Regulatory Pathway for Conducting Clinical Investigation of Medical Device

A clinical investigation is a sequence of events involved in running a clinical trial or a research study that states the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct, and record keeping of the study. Clinical investigation is mandatory for manufacturing the investigational medical device (class A -sterile and measuring, B, C, and D) and importing the medical device (class A -sterile and measuring, B, C, and D) from countries other than the U.S, UK, Japan, EU, Australia, and Canada, the applicant can submit form MD-22 to the CLA, along with the necessary information listed in the seventh schedule of the MDR-2017.Upon receipt of the requisite requirements, including Institutional Ethics Committee (IEC) approval and clinical study plan, the CLA may grant permission in Form MD-23 (based on the subject expert committee recommendation), allowing the clinical investigation to commence. In addition, the clinical investigation must be registered with the clinical trial registry of India (CTRI) before enrolling participants, and the first participant must be enrolled within one year of grant permission.

However, without carrying out clinical investigation, the import license for all risk-based classified medical devices (other than class A non-sterile and non-measuring)from the U.S, UK, Japan, EU, Australia, and Canada may be granted based on the fact that the proposed device had been marketed for at least two years in these countries. CLA is satisfied with the data of safety, performance, and pharmacovigilance of the device (see Table 4). These studies are essential for obtaining regulatory approval

of the device. Applicants must submit annual status reports on each clinical investigation to the CLA detailing the ongoing, completed, or terminated status of the study.

Table 4. Condition for conducting the clinical investigation of medical device

Medical Device	Purpose	Clinical Investigation	Condition
based risk-based classified Medical Devices (other than Class A – non-sterile and non-measuring)	Manufacture	Mandatory	Investigational medical device (No predicate device available)
		Not applicable	Subsequent equivalent predicate device (demonstrate concerning intended use, design, types of specimens, materials of construction,and technological characteristics underlying the working principle) available in India
	Import	Waive off	▪ Medical Devicesimported from countries U.S, UK, Japan, EU, Australia, and Canada ▪ Remain marketed for at least two years in these countries ▪ CLA is satisfied with the data on the safety, performance and pharmacovigilance of the device
		Mandatory	Medical devices approved and marketed in other than the U.S, UK, Japan, EU, Australia, and Canada.
			Investigational medical devices

Further, there are two types of clinical investigations conducted for medical devices, namely:

1. **Pilot Clinical Investigation:** A pilot clinical investigation is an initial study conducted on a small group of patients to gather specific information about the device before initiating the pivotal clinical study. It is exploratory and aims to assess feasibility, evaluate preliminary device performance, examine eligibility criteria, ascertain possible harm, study device mechanism, and validate outcome measures or surrogate outcomes. Pilot studies do not provide support for specific therapeutic claims but are crucial for informing the design and conduct of subsequent pivotal studies.
2. **Pivotal Clinical Investigation:** Pivotal clinical investigations are definitive or confirmatory studies conducted in a larger population to gather evidence supporting the safety and effectiveness of the medical device intended for use and conclusive. Pivotal studies are conducted following pilot investigations and must demonstrate the safety and effectiveness of the device in the intended Indian patient population.

2.5. Post Marketing Surveillance (PMS) Reporting in India

PMS is a continuous process of monitoring and collecting data (containing both complaints and adverse events) on the safety and performance of medical devices after being released to the market. The document provides a proactive and systematic process for manufacturers to collect and analyse post-market data in terms of reporting procedures for AE (adverse events) complaints received, SUSAR (Serious Unexpected Suspected Adverse Reactions) reports, PSUR (Periodic Safety Update Report), CAPA and FSCA (Field Safety Corrective Action).

ISO 20416:2020 is an international standard for Post-Market Surveillance (PMS), aligning with ISO 13485, which emphasizes quality criteria for medical devices, and ISO 14971, which primarily addresses safety, security, and risk connected with the use of medical devices. The manufacturer or importer of the investigational medical device (MD-27 or MD-29 holder) is permitted

to submit the Periodic Safety Update Report (PSUR) to the competent licensing authority i.e., CLA from the date of the device's market launch. This report must be submitted biannually for the initial two years, followed by annual submissions for the subsequent two years.

MD-27/MD-29 holders can conduct post-marketing clinical investigations for testing the safety and performance, which covers the two significant reporting such as:

i. CAPA: It is a system that all medical device companies must establish to identify quality-related concerns, examine their core causes, and execute remedial and preventative steps to prevent recurrence. The five principles of the CAPA technique are: a) Detection (issue identification), b) Investigation and root cause analysis, c) Proposed correction, d) Implementation, and e)Verification of effectiveness.

ii. FSCA: It is a measure that manufacturers may undertake for technical or medical justifications to mitigate or diminish the risk of severe occurrences, including fatalities, associated with the use of a medical device that has been commercialized.

The PSUR submission of investigational medical devices (approved for manufacturing or import in India) requires the documents (Checklist for PSUR Submission of New Medical Devices approved for Manufacturing or Import in India). Moreover, to sustain a better risk-benefit ratio of medical devices, the Government of India (Indian Pharmacopoeia Commission) has approved the commencement of the materiovigilance programme of India (MvPI). MvPI aims to systematically collect data on medical device-related adverse events and scientifically analyze them to aid in regulatory decisions and recommendations on the safe use of medical devices (see Figure 11). Sixteen medical devices have been recalled from the Indian market since the MvPI was launched, and many more are under systematic review (Product Recall, CDSCO). The medical device-associated adverse events (MDAE) under the aegis of MvPI create awareness among healthcare professionals about the importance of MDAE reporting in India.

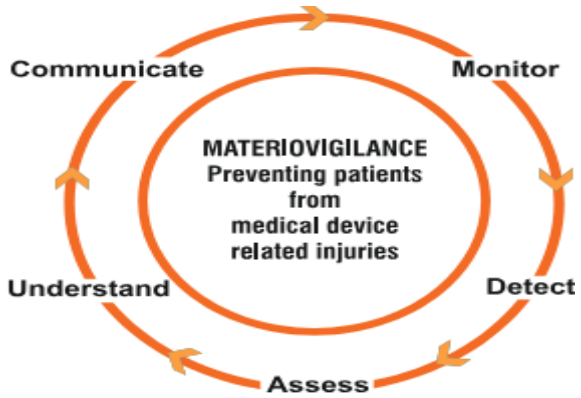

Figure 11. MvPI, evidence-based recommendations on the safety of medical devices

3. Comparative Insight of Regulatory Approval: Legislative Landscape and Historical Development in the U.S. and EU

The comprehensive regulatory approval process is intricate, multistep, and region-specific and requires critical assessments by the competent authority. It is also a metaphorical ‘valley of death’ in which most products fail to fulfil the regulatory pathways before being commercially marketed. Each country has stringent regulatory compliances to safeguard and elevate healthcare end users by assuring medical devices' safety, efficacy, and quality. An in-depth analysis of the regulatory landscape governing medical devices in India regulated by the Indian Apex body, namely CDSCO, with a focus on comparing it with the regulatory frameworks in the European Union-Medical Device Regulation (EU-MDR) and the United States-Food and Drug

Administration (U.S.-FDA) in terms of device classification, pre-market approval requirements, post-market surveillance, and quality management systems.

3. 1. Chronology of Medical Device Regulation in the U.S

The historical development of medical device regulation in the USA has been framed (see Figure 12). These legislative milestones reflect the evolution of medical device regulation in the USA, aiming to include risk-based classification of all medical devices, post-market surveillance, improvements in the premarket reviews system, and certification of facilities for ensuring the safety, effectiveness, and quality of medical devices throughout their lifecycle (A History of Medical Device Regulation & Oversight in the United States; Medical Device & Diagnostics).

3.2. Chronology of Medical Device Regulation in the European Union

The evolution of medical device regulation in the EU reflects the commitment to ensuring medical device safety, quality, and performance while promoting innovation and competitiveness in the healthcare industry. The chronology of medical device regulation in the EU can be outlined as follows, with significant milestones as per European Commission Medical Devices Directives (European Commission Medical Devices Directives) (see Figure 13a and 13b).

1. European Economic Community (EEC) Directives (1970s-1990s): The first directives related to medical devices were introduced by the EEC in the 1970s, focusing on specific product categories such as implants, active implantable medical devices, and in vitro diagnostic medical devices. These directives aimed to establish common standards for safety and performance across member states.
2. Medical Devices Directives (MDD) (1990s-2010s): The MDD comprised three directives: the Active Implantable Medical Devices Directive (AIMDD), the Medical Devices Directive (MDD), and the In Vitro Diagnostic Medical Devices Directive (IVDD). These directives harmonised regulations for medical devices within the EU and established the CE marking process for market approval.
3. Revision and Amendment of MDD (2010s): In response to technological advancements and concerns about the effectiveness of the existing regulatory framework, the EU began revising and amending the MDD. This led to the introduction of the Medical Devices Regulation (MDR) and the IVDR in 2017.
4. Medical Devices Regulation (MDR) (2017): The MDR replaced the MDD and introduced more stringent requirements for approving, manufacturing, and marketing medical devices in the EU. It expanded the scope of regulation to include certain products that were previously unregulated or considered low-risk, such as software and aesthetic devices. The MDR also established stricter conformity assessment procedures and increased transparency and traceability requirements.
5. In Vitro Diagnostic Medical Devices Regulation (IVDR) (2017): The IVDR replaced the IVDD and introduced similar enhancements to the regulatory framework for in vitro diagnostic medical devices. It imposed stricter requirements for clinical evidence, performance evaluation, and post-market surveillance to ensure the safety and effectiveness of these devices.
6. Transition Period (2017-2021): Following the adoption of the MDR and IVDR, a transition period was established to allow manufacturers and other stakeholders to adapt to the new regulatory requirements. During this period, devices could continue to be placed on the market under the existing directives, but they would eventually need to comply with the new regulations.

7. Implementation (2021 and beyond): The transition period for the MDR ended on May 26, 2021, marking the full implementation of the regulation. Manufacturers must now comply with the MDR's requirements for all new devices seeking market approval or renewal of existing certifications. The IVDR's transition period is set to end in May 2022.

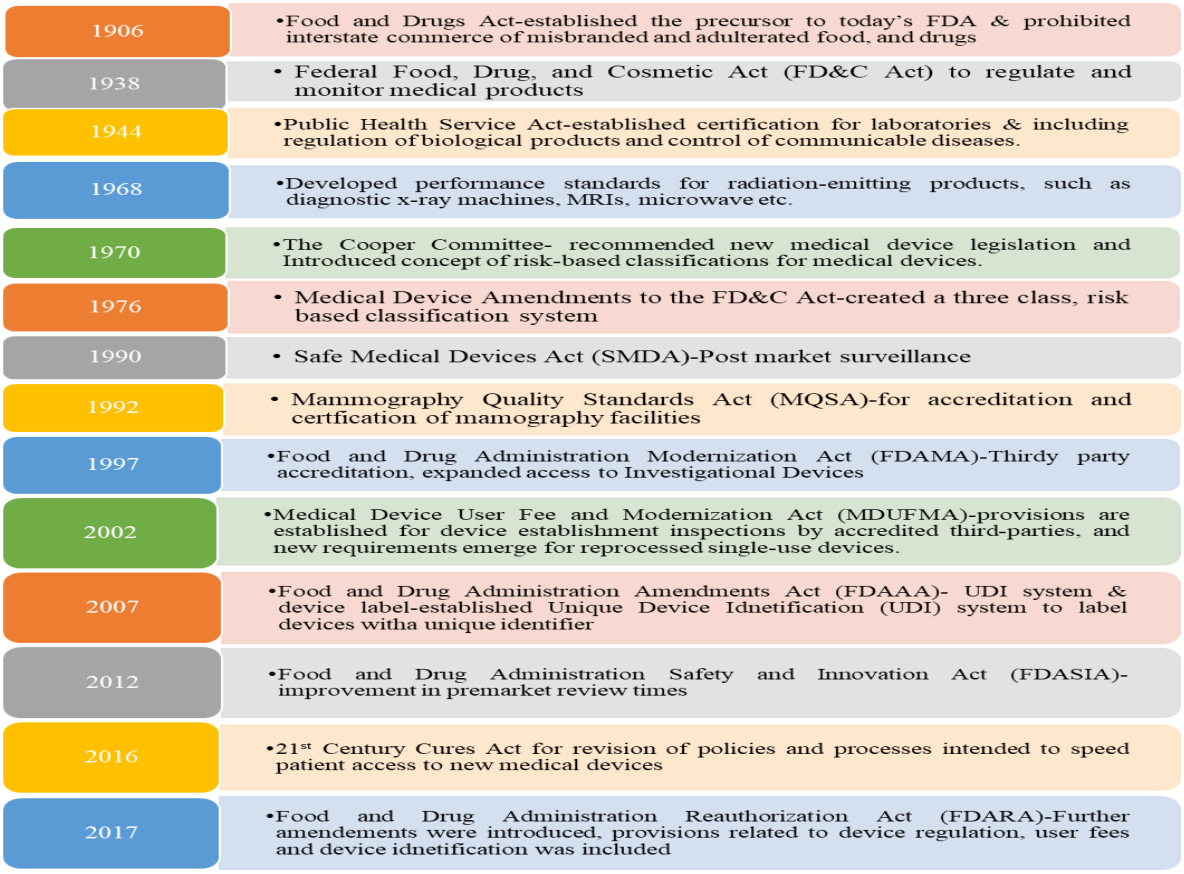

Figure 12. Chronology of medical device legislation in the U.S.

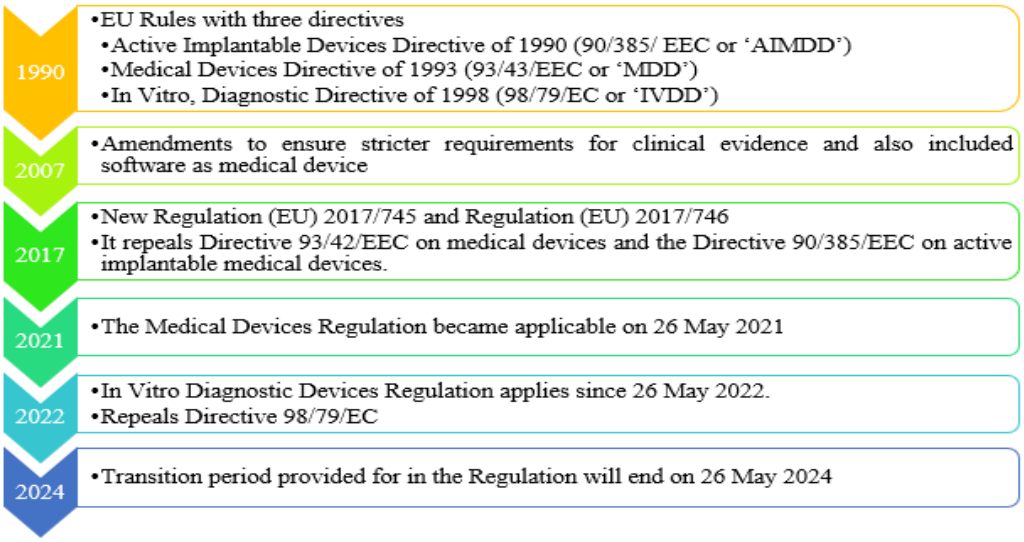

Figure 13a: Chronology of medical device legislation in EU

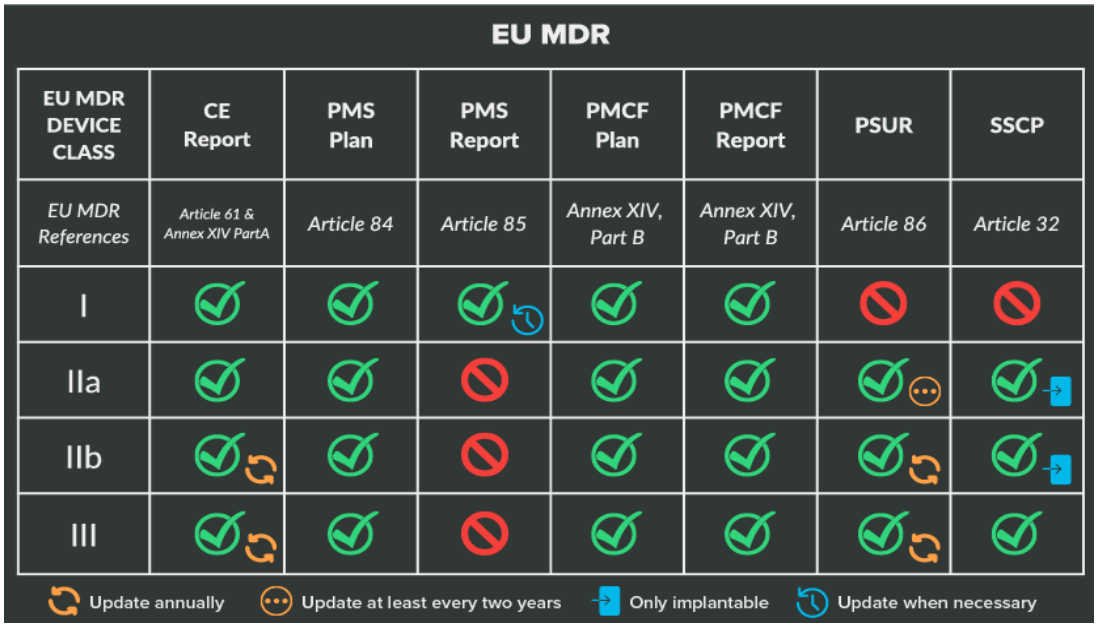

Figure 13b. Major compliances of EU MDR for all risk-based classification of medical devices

3.3. Assessment of Distinctness of International Medical Device Regulation: USA versus EU

A comparative description has been summarized (see Table 5) to overview the legal and regulatory requirements in the EU and the US to place a medical device on the market. There are many similarities but significant differences in the requirements concerning clinical evidence and post-market surveillance in the two regions.

Table 5: Resemblance and Differences of USA and EU Medical Device Regulation

Point of Comparison	India	USA	EU
Regulatory body	Directorate General of Health Services, MoH&FW, DCGI under CDSCO	FDA, Department of Health and Human Services	EMA & Registration authorities (RA) of Member State
Assisting bodies	CLA for Class C & Class D Medical Devices, SLA for Class A & Class B medical devices	CDRH-FDA	NCA-EMA
Regulation act/Guidelines	MDR-2017 Through the Drugs & Cosmetics Act 1940	Federal Food Drug and Cosmetic Act (FD & C Act); Food and Drug Administration Safety and Innovation Act 21 CFR Parts 800-1299	Regulation (EU) 2017/745 for medical devices Regulation (EU) 2017/746 for IVDs
Classes of medical devices	Four (Class A, B, C & D)	Three (Class I, Class II and Class III	Four (Class I, IIa, IIb & III)
Standards making body	BIS/ ISO/ IEC	U.S. FDA	ESO such as: CEN, CENELEC, ETSI
QMS or Applicable standards (mandatory)	ISO 13485:2016	QSR 21CFR Part 820 (Similar to ISO13485:2016 but not same)	ISO 13485 or as per applicable in 94/42/EEC Regulation (EC) No 765/2008

Assessment of technical data	Notified bodies under CDSCO	CDRH	CE marking of conformity
Language	English	English	Official union language as determined by member state
Submission format	Electronic through Online System for Medical Devices portal	Electronic using CDRH Portal - eSTAR.	Electronic

4. Discussion

Since 1st January 2018, when Indian medical device regulations came into existence, it went through dedicated deliberation among the healthcare authorities and different stakeholders to adopt a holistic approach for including medical devices/diagnostics falling in the category of low-risk to high-risk, under license regime, while maintaining high standards of quality, tolerability, and effectiveness. Futuristic healthcare innovations like wearables, telemedicine, multiplex pathogenic kits, drug-eluting patches, breath analyser-based diagnostic techniques, immersive technologies (such as Virtual Reality (VR), Augmented Reality (AR), Mixed Reality (MR), and Extended Reality (XR)) based diagnostics primarily using on surgery and anatomy-related subjects against particular disease/conditions, organoid bioprinting technology that uses 3D printing to create tissue models that mimic the structure and function of human organs, Volatile Organic Chemicals (VOCs) based detection of specific cancer, Nanoscale Point of Care (POC)/Point Of Detection (POD) device, drug delivery system and others are emerging and accordingly MDR is evolving. Such dynamic technological progress has led to a transformative surge in medical device regulation, propelling the rise of new and innovative medical devices. Presently, no specific regulation addresses these futuristic technologies-based medical devices. However, clinical decision-making tools using Artificial Intelligence (AI), Machine Learning (ML), and Internet of Things (IoT) algorithms have highlighted the urgency of devising new regulations to address the transformation. Accordingly, an amendment in the MDR, 2017 was introduced under gazette notification S.O. 648 (E) for extending the scope of medical devices, including software-integrated medical devices/Software as Medical Devices (SaMD) in the regulatory regime ("Gazette of India notification, S.O. 648(E)," 2020). Considering clinicians are highly dependent on SaMD for diagnosing, preventing, monitoring, and treating diseases, it is extremely important to have compliance with standards and statutory guidelines that are still evolving.

During Covid-19 onwards, CDCSO issued a notification regarding risk-based classification of medical devices pertaining to Personal Protective Equipment (PPE), masks (2-ply, 3-ply, surgical, N-95), RNA and DNA extraction kits, viral transport media, viral reagents, liquid chemical sterilant/high-level disinfectants, rapid antigen/antibody-based and RT-PCR kits for testing of Covid-19to facilitate import, manufacture, sale and distribution and clinical investigation for effective pandemic management. The results of this spotlight are that till 20.06.2022, 262 IVD kits have been approved, out of which 102 kits are indigenously manufactured (*PCR Kits approved for testing of Covid-19* 2022). Earlier, India broadly relied on the import of PPE and masks. However, it is the outcome of the regulatory initiative that India has become the second-largest manufacturer of PPE in the world within a short period, and more than 600 companies in India are certified to produce PPEs today, whose global market worth is expected to be over $92.5 billion by 2025 (*Investment Opportunities in Textiles and Apparel Textiles and Apparel*; *Textiles Committee* 2020). On the other hand, IVD kits for diagnosis of COVID-19 have been processed as a high priority for accelerated approval for marketing in India to support companies that are either developing the kits or importing the existing ones already approved by the U.S. FDA or EMA. Data requirements for clinical performance evaluation may be abbreviated, deferred, or waived on a case-to-case basis depending on the type and nature of diagnostics kits, existing data on the product, and evidence of available clinical performance evaluation data of such kits in the country of origin. Moreover, applications to

manufacture/import such IVD kits for testing, evaluation, and further use in performance evaluation may be processed on priority within seven working days. Many CDSCO-designated labs have been updated to conduct a performance evaluation of such IVD kits during the Covid-19 health emergency without compromising the quality of the products in India.

Hence, recognising the myriad instruments affecting individual and animal health, the government must extend regulations to this rapidly evolving realm, as a handful of medical devices are currently regulated only.

5. Conclusions

The review delves into the dynamic landscape of the Indian medical device market statistics, legislative changes, and government initiatives to significantly increase the manufacture of medical devices. Indian regulators have transitioned from a flexible, need-based approach to a systematic and stringent regulatory framework aimed at ensuring the effectiveness and safety of medical devices. Despite having huge import dependency, India has made significant strides, ranking fourth in Asia while maintaining high standards of quality, safety, and efficacy. Further, a comparative analysis of the regulation processes for medical devices in India, the US, and the EU highlights variations in terms of CE marking, risk-based classification, validity period, post-market surveillance, traceability and other conditions and specifications that adhere to ensure that products are made at par with global standards. As a part of a comprehensive strategy towards strengthening the healthcare system in India in alignment with the vision of Viksit Bharat 2047 (Develop India 2047), the introduction of medical devices (Amendment) rules in 2020 towards more stringent regulations is a welcome move in this direction. Conformity to these regulations will ensure that products are made at par with international quality.

In parallel, some recommendations have been proposed, such as creating a comprehensive database for information on all recalled medical devices. This could also be the next important step for ensuring patient safety. Similarly, creating a QR code-unique to a particular medical device/IVD, conveying necessary information on the nature, date, and validity of applicable license (manufacturing/import), intended use, instructions for use (IFU), etc. will be a critical step towards traceability of medical devices in the long run. Additionally, establishing a database with information on all devices approved so far (predicate devices), along with their technical details, will be highly beneficial to the innovators working in the MedTech innovation space so that innovators can smoothly enforce the regulatory directive. To achieve success, it is also necessary to consolidate the enforcement mechanism called materiovigilance, which is used for identifying, collecting, reporting, and analyzing adverse events associated with medical devices to improve patient safety by preventing the recurrence of adverse events.

Further, all concerned stakeholders and knowledge partners shall work closely together with the regulator as a public-private partnership (PPP) model so that it will address and mitigate the challenges faced by innovators. In this view, the government has introduced a dedicated public relations office (PRO) with a mandate to act as an interface catalyser between the regulator and its stakeholders, including the general public, for the exchange and dissemination of information to foster the disposal of grievances, provide complete details regarding regulatory prerequisites for the commercialisation of products, clarification about MDR and handholding assistance to investors in various phases of the business life cycle as per the existing focus on the "Invest India/Make in India initiative". This initiative demonstrates the government's commitment to enabling quality medical device manufacture in India and positioning the country as a global hub for medical devices that are reliable and trustworthy.

Author Contributions

The manuscript is conceptualized and formulated by several authors with their specific contributions. Garima Singhal and Aarti Sahu conducted an extensive literature review to gather relevant information on medical device regulations in India, the

United States, and the European Union. Their work involved identifying existing frameworks and understanding gaps in the current landscape.

Deepak Kumar Gupta, **Meeta Mukherjee Verma**, and **Jyoti Batra** contributed significantly to the core content of the regulatory framework, discussed key challenges, and highlighted current systems' drawbacks and potential strategies and solutions to address these issues effectively.

Rupak Kumar and **Suchita Markan** played a crucial role in shaping the paper's overall framework and conceptualization. They were also responsible for the meticulous proofreading of the manuscript, ensuring clarity, coherence, and academic rigor throughout the paper.

Conflicts of Interest

The authors declare that the review was comparatively analyzed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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List of Abbreviations

MoH&FW: Ministry of Health and Family Welfare; **DCGI:** Drugs Controller General of India; **PMA:** Premarket Approval; **CDSCO:** Central Drugs Standard Control Organisation; **NCA:** National Competent Authorities; **IVD:** In-vitro Diagnostics; **EMA:**European Medicines Agency; **CDRH:** Centre for Devices and Radiological Health; **QR:** Quick Response**;** **FDA:** Food and Drug Administration; **FSC:** Free Sale Certificate; **ESO:** European Standards Organization; **CEN:** European Committee for Standardization; **CENELEC:** European Committee for Electrotechnical Standardization **ETSI:** European Telecommunications Standards Institute; **BIS:** Bureau of Indian Standards; **ISO:** International Organization for Standardization; **IEC:** International Electrotechnical Commission; **CDRH:** Centre for Medical Devices and Radiological ; **PMA:** Post Market Approval ; **PMS:** Post Market Surveillance; **PSUR:** Periodic Safety Update Report; **CLA:** Central Licensing Authority; **SLA:** State Licensing Authorities; **PMSR:** Post Market Surveillance Report; **PMCI:** Post Market Clinical Investigation;**MDR:** Medical Device Regulation; **PMCF:** Post-market clinical follow-up; **CER:** Clinical Evaluation Report; **PER:** Performance Evaluation Report; **PAS:** Post-Approval Studies; **AE:** Adverse events; **MvPI:** Materiovigilance Programme of India; Health; **QSR:** Quality System Regulation; **QMS:** Quality Management System **TSE:** Transmissible Spongiform Encephalopathies; **BSE:** Bovine Spongiform Encephalopathy;**NABL:** National Accreditation Board for Testing and Calibration Laboratories; **MD:** Medical Device; **DCA:** Drug and Cosmetic Act; **CE:** ConformitéEuropéenne or European conformity; **PMCF:** Post-Market Clinical Follow; **SSCP:** Summary of safety and clinical performance.

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Antimicrobial Sensitivity on the Seed Extracts of *Combretum Micranthum* (kinkheliba) on Some Bacteria of Public Health Importance

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ABSTRACT

This study explores the antimicrobial effects of seed extracts from *Combretum micranthum* against two bacterial pathogens: *Staphylococcus aureus* and *Escherichia coli.* The extracts were prepared using methanol and water, and their antibacterial properties were assessed in vitro using the agar diffusion method. A phytochemical analysis revealed the presence of resins, alkaloids, saponins, and tannins in the extracts. The methanolic extract demonstrated notable antibacterial activity, inhibiting *S. aureus* with a 17 mm zone of inhibition and *E. coli* with a 20 mm zone of inhibition. In contrast, the aqueous extract only exhibited antibacterial effects against *S. aureus* (8 mm inhibition zone) and had no impact on *E. coli.* These results indicate that *Combretum micranthum* seeds may serve as a potential source of antibacterial agents for treating bacterial infections. Further research is needed to identify and isolate the specific active compounds responsible for these antimicrobial properties.

Keywords: *Combretum micranthum*, Antimicrobial activity, Phytochemical analysis, *E.coli*.

1. Introduction

In recent years, ethnobotanical studies have gained significant global attention due to the increasing reliance on traditional medicine, especially plant-based remedies. The World Health Organization (WHO) reports that 80% of the population in developing countries primarily depends on traditional medicine, often involving medicinal plants. In Cameroon, while traditional medicine remains a cornerstone of healthcare, its integration into the formal health system is hindered by organizational challenges (Nkongmeneck et al., 2007; Snigdha et al., 2024).For centuries, people have utilized herbal remedies for various ailments, and contemporary advancements in phytochemical analysis have facilitated the identification and characterization of bioactive compounds with potential therapeutic applications (Adejuwon et al., 2011; Adekunle et al., 2009). The screening of higher plants for medicinal purposes represents a significant endeavor in the ongoing quest for novel, safer, and more efficacious drugs to combat pathogenic bacteria. *Combretum micranthum*, a member of the Combretaceae family, is a plant species widely employed in traditional medicine to treat a diverse range of ailments, including gastrointestinal disorders, fever, and colic. Medicinal plants offer a compelling alternative to synthetic drugs, often mitigating adverse side effects while demonstrating efficacy in treating infectious diseases. Numerous studies have identified bioactive compounds within plants that exhibit potent antimicrobial activity. Some traditional remedies have even yielded compounds effective against antibiotic-resistant bacterial strains. This study aims to investigate the antimicrobial properties of C. micranthum seed extract against a panel of clinically relevant bacteria. Infectious diseases are the most dreaded human ailments globally, resulting in approximately 50,000 fatalities daily (Akeem et al., 2012; Osonwa et al., 2012; Tanwieh et al., 2024; Taura et al., 2009). The incidence of antibiotic-resistant bacteria is increasing (Akeem et al., 2012; Osonwa et al., 2012). The emergence of resistance to novel antibiotic compounds by bacteria responsible for the majority of infectious illnesses has exacerbated the problem. Over the past three decades, pharmaceutical companies have developed new antibiotics (3rd Generation). Nonetheless, these antibiotics remain ineffective in inhibiting the proliferation of several bacteria, particularly those with the potential to acquire resistance. Consequently, the researcher intends to investigate the antimicrobial sensitivity of C. micranthum seed extract against several microorganisms of public health significance. In this study, we screened *Combretum micranthum* for antibacterial medicine and determinate the phytochemical content.

2. Experimental part

2. 1. Materials

The seed of *Combretum micranthum* was harvested in a food market in dry form and ground to a powder in the Bamenda North West region in April 2019. After weighing the powder form of the seed, the extraction was done shaking intermittently for 24h. The extraction was filtered with Whatman No.1 filter paper, put into Petri dishes, and allowed to evaporate to dryness in the incubator at 50 °C.

2. 2. Test Organisms

2. 2. 1. Isolation and purification of *Staphylococcus. aureus*

A pus specimen was first collected from an infected wound, inoculated on nutrient agar, and incubated for 18 hours. After gram staining and the colonies' growth, a distinct colony of gram-positive cocci was picked and subcultured on nutrient agar and incubated aerobically at 37 °C for 24 hours for a purity test. Catalase and coagulase tests were then performed to confirm that the cocci were *Staphylococcus aureus*.

2. 2. 2. Isolation and purification of *Escherichia coli*

A specimen of slaughtered pigs (faeces) was collected in Bamenda II, inoculated on MacConkey agar, and incubated for 24 hours. After gram staining, the colonies' growth (pink in colour) and a distinct colony of the gram-negative rod were picked and subcultured on MAC and incubated aerobically at 37 °C for 24 hours for the purity test. The presence of pink colonies when subcultured and the lactose-fermenting colonies was observed to confirm that it is Escherichia coli.

2. 2. 3. Inoculum standardization

Standard bacterial cultures (*S. aureus* and *E. coli*) were prepared by sub-culturing a loopful of each bacteria into 10ml sterile peptone water and incubating overnight at 37 ^{0}C.

2. 3. Geographical Distribution of *Combretum micranthum*

Combretum micranthum belongs to the *Combretaceae* family, which consists of 18 genera. It is a highly regarded medicinal plant in Africa, with roots, barks, seeds, fruits, and leaves being used. It grows with annual rainfall between 300 and 1500 mm and at altitudes from sea level to 1000 mm. *Combretum* is a very large genus, comprising about 250 species and distributed worldwide in the tropics and subtropics. About 140 species occur in tropical Africa, and 20 are endemic to Madagascar (Schmelzer & Gurib-Fakim, 2008). In Africa, it is widespread in the savanna zone of West Africa (Burkhill, 1985). The flowers are usually bisexual and are borne as auxiliary clusters on scaly stalks. The fruits are small and scaly, while the leaves are dorsoventrally or rarely centric with short stalk. The leaves turn green to orange over time and are useful in herbal medicine (Watson & Dallwitz, 1991). The plant is very drought- and fire-resistant; it's a browse plant for cattle and is of some importance for forage during the dry season in northern Nigeria.

- **Botanical classification**
  - **Kingdom**: Plantae
  - **Order**: Myrtales
  - **Family**: Combretaceae
  - **Genus**: Combretum
  - **Species**: *Combretum micranthum*



Figure 1. picture of *Combretum micranthum* fruit that contain s



Figure 2. Picture of *Combretum micranthum* tree

2. 4. Extraction

2. 4. 1. Aqueous Extraction

100g of the powdered seed was weighed and put into a flask/bottle, and 800 ml of distilled water was added, mixed, and shaken intermittently for 24 hours. The materials were then filtered using Whartman No1 filter paper, and the filtrates were distributed into three separate clean, sterile dishes and were evaporated to dryness in the incubator at 50°C.

2. 4. 2. Alcoholic Extraction

100 g of the powdered seed was weighed and deposited in a clean and sterile bottle/flask, and 800 mL of methanol was added. The bottle was shaken intermittently for 24 hours. The materials were subsequently filtered with Whartman No1 filter paper, and the filtrates were allocated into three distinct clean, sterile dishes and evaporated to dryness in an incubator at 50°C.

2. 5. Antimicrobial Sensitivity Assay

The antimicrobial assay was conducted utilizing the agar well diffusion technique. (Habamu et al., 2010; Perez, 1990). Wells measuring 4mm in diameter were created in MHA plates using sterilized radio antennas. The examined organisms in sterile peptone water were introduced onto the media in each section of the three wells. Two wells were filled with 0.1 ml of the extract. 1 mg/ml of Doxycycline was added to the third well and functioned as a control. The plates were pre-incubated for 15 minutes to facilitate extract diffusion prior to overnight incubation at 37°C. The diameter of the clean zone was quantified in ml utilizing a ruler.

2. 6. Phytochemical Screening

The seed powder of *Combretum micranthum* (Kinkeliba) served as the sample for qualitative phytochemical screening of resins, alkaloids, saponins, tannins, glycosides, and flavonoids, adhering to the standard protocols outlined by (Evans, 1997) and (Fon et al., 2009).

- **Detection of Resins**

1 g of seed powder was incorporated into 4 ml of boiling ethanol. The solution was passed through Whatman No1 filter paper, and the filtrate was diluted with 4 ml of 1% aqueous HCl, after which the degree of coloring was measured. The emergence of a dense resinous precipitate signified the existence of resins (Evans, 2009).

- **Detection of Alkaloids**

1g of seed powder was stirred with 10 ml of 2N HCl in a steam bath. This was filtered, and 1 ml of the filtrate was tested with a few drops of Wagner's reagent. The formation of a precipitate after 15-20 min indicated the presence of alkaloids.

- **Detection of Saponins**

1g of seed powder was stirred with 10 ml of distilled water in a test tube. After heating and filtration, agitation must be applied; the appearance of a persistent foam indicates the presence of saponins.

➢ **Detection of Tannins**

1 g of seed powder was stirred with 10 ml of boiling distilled water. The filtrate was subjected to filtration, followed by the addition of a few drops of 6% Ferric Chloride. The appearance of deep green coloration indicated the presence of tannins. The subsequent portion of the filtrate was treated with several ml of iodine solution. The emergence of a subtle bluish hue validated the existence of tannins (Evans, 2009).

➢ **Detection of Glycosides**

1 g of seed powder was stirred with 10 ml of boiling distilled water. The filtrate was subjected to hydrolysis with 2 ml using a few drops of strong HCl, followed by the addition of a few drops of ammonium solution to achieve alkalinity. Five drops of this solution were incorporated into 2 ml of Fehling qualitative reagents and subsequently heated to boiling. The emergence of a reddish-brown precipitate signifies the existence of glycosides (Evans, 2009).

➢ **Detection of Flavonoids**

1 g of the seed powder was dissolved in 2 ml of weak sodium hydroxide. A little quantity of concentrated H_2SO_4 was subsequently introduced. The loss of color signified the presence of flavonoids (Evans, 2009).

3. Results

Table 1. Results of phytochemical analysis of *Combretum micranthum*.

Phytochemicals	Abundance
Resins	+
Alkaloids	++
Saponins	+++
Tannins	++
Glycoside	_
Flavonoids	_

-: absent, +: present but trace, ++: present but less abundant, +++: present abundant

Table 1 shows the types of phytochemicals present in *Combretum micranthum* seeds. The highest being saponins and the least glycosides and flavonoids.

Table 2. Sensitivity testing to determine the zone of inhibition in mm

	Staphylococcus aureus	Escherichia coli
Control (doxycycline)	Sensitive (Ø=20mm)	Sensitive (Ø=20mm)
Methanolic extraction	Sensitive (Ø=17mm)	Sensitive (Ø=20mm)
Aqueous extraction	Sensitive (Ø=8mm)	Resistant

Ø=diameter of inhibition of growth

Table 2 shows that *E. coli* was resistant to aqueous extraction and sensitive to methanolic extraction, while *S. aureus* was sensitive to all extracts.



Figure 3. Mueller Hinton agar showing clear zone of inhibition of growth by the extracts. (*E.coli)*



Figure 4. Mueller Hinton agar shows clear zone of inhibition of growth by the extracts.(*S.aureus*)

4. Discussion

The aqueous and methanol extracts of *Combretum micranthum* seed inhibited *Staphylococcus aureus and Escherichia coli.* These results are similar to those obtained on the stem bark (Akeem et al., 2012), leaves (Osonwa et al., 2012), and roots (Taura et al., 2009). The phytochemical analysis indicated the existence of bioactive substances with in vitro antibacterial properties. The results indicated the existence of bioactive substances such as resins, saponins, tannins, and alkaloids. Nonetheless, it is shown that the plant composition is contingent upon the geographical origin. (Rao & Rout, 2003). Tannins were present but in fewer amounts, approximately similar to works done on the leaves (Karou et al., 2005) and stem bark (Akeem et al., 2012). Herbs containing tannins have been reported to aid in treating inflamed or ulcerated tissues, as well as intestinal disorders like diarrhea and dysentery (Parekh & Chanda, 2007). Tannins are also known to exhibit bacteriostatic or bactericidal effects against Staphylococcus aureus (Chung et al., 1998). This study found a high presence of alkaloids, which contrasts with previous research on the leaves (Osonwa et al., 2012) and stem bark (Akeem et al., 2012), where this compound was absent. Alkaloids have been associated with antimicrobial, antidiarrheal, and anthelmintic properties (Tiwari et al., 2011). Additionally, saponins were detected in high amounts, while resin was present only in trace quantities.

5. Conclusion

This investigation has enabled us to ascertain the antibacterial susceptibility of C. micranthum seed extract against some bacterial pathogens (*S. aureus and E. coli*).The methanol extracts eradicated the bacteria entirely, although the aqueous extract had a moderate antimicrobial activity.

The findings from these experiments indicate that the seed extracts of Combretum micranthum demonstrate antimicrobial sensitivity against the selected isolates, with the exception of *E. coli*, which exhibited resistance to aqueous extraction.Phytochemical substances found in plants that possess antibacterial effects include resins, saponins, tannins, and alkaloids.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Data Availability

No data was used for the research described in the article.

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A new approach for studying plaster beam bending based on DISS Algerian (nano-short-bio-fibres)

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ABSTRACT

Construction materials, particularly plaster (gips), are crucial in civil engineering and architecture. Due to their durability, it is essential to use durable materials. A Berber plant, a renewable and persistent plant, has been chosen to improve the mechanical properties of plaster (gips). The PIGGOT rule of homogenization was used to determine the properties of the total set, with plaster as the matrix and DISS (Scrip) as the reinforcement. A high-order mathematical model was established to study the bending of a new bio-beam using local materials, resulting in the birth of the beam. The results show that the deflection of the bio-plaster beam decreases with an increase in the nano-short-fibre fraction of DISS (Scrip). The main objective is to reinforce plaster and reduce flexion by utilizing the effect of short fibres to enhance shear performance. Another goal is to minimize the flexion of plaster beams. Additionally, this approach aims to introduce innovation in the field of construction and civil engineering while promoting the use of biological substitutes in this sector. This study will be conducted analytically through homogenization and analysing the non-local flexure of beams rather than experimentally.

Keywords: The plaster, Mechanical properties, PIGGOT (homogenization), Deflexion, Bio-beam.

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1. Introduction

Plaster (gips) is a traditional construction material that consolidates in water, taking various forms such as beams, plates, and panels. It is also used as a wall coating or bonding agent between bricks in masonry. Recently, significant progress has been made in improving this material, with several studies exploring its properties and performance. Plaster is obtained by dehydrating gypsum ($CaSO_4 \cdot 2H_2O$), a hydrated calcium sulfate, to form anhydrite ($CaSO_4$). In recent research, experimental results have studied and validated steel-reinforced plaster boards for paving structures, though adjustments may be necessary depending on reinforcement or anchoring configurations (Karni & Karni, 1995). Plaster coatings with lightweight aggregates impregnated with phase-change materials (PCM) have significantly reduced building energy consumption, with maximum savings of 293.8 kWh (Wadee et al., 2023; Wang et al., 2023). Adding recycled plastic and glass to plaster coatings has increased the strength and density of plaster beams, improving their brittle behaviour (Boukert et al., 2019). Furthermore, research on lime-based plasters has demonstrated high compressive strength and proposed mathematical models to predict their behaviour (Abdullah & Sichani, 2009; Rahimzadeh et al., 2022). Flash calcination of gypsum has led to the development of new plaster composite particles with unique properties, such as maintaining γ-anhydrite in humid conditions, unlike traditional plaster (Berenger et al., 2015). Studies have shown significant strength loss above 500°C for plaster exposed to high temperatures, with complete loss of strength for some plaster types at higher temperatures (Mohammed, 2010; Yaqoob, 2019). Incorporating recycled materials like PET and sawdust into lightweight plaster boards has yielded optimal thermal insulation and mechanical strength (Ali et al., 2015). Adding kaolin and metakaolin has also shown positive effects, increasing the compressive strength of plaster (Fahih et al., 2005). In addition, polymer coatings have improved the strength of plaster beams, reducing the risk of rupture under high loads (Saurav & Porter, 2018). On the theoretical side, non-local continuum theories, such as Eringen's non-local elasticity theory, have been used to analyse the response of nanostructures, specifically nanobeams, accounting for size effects at the nanoscale (Sayyad & Ghugal, 2021; Sayyad et al., 2023). Higher-order deformation models have been proposed to simulate the behaviour of plaster beams reinforced with short fibres, using Piggot's homogenisation rule to treat these materials as isotropic. Timoshenko's works have validated this model. Timoshenko has many statistical studies that address the issue of flexure (Timoshenko & Gere, 2012). Arbabi improves methods through non-local analysis by enhancing the Timoshenko model (Arbabi, 1991) and forms the basis of this study on the bending behaviour of plaster beams, validated by a mathematical model with advanced deformation functions and homogenisation via Piggot (Sayyad & Ghugal, 2021; Sayyad et al., 2023). It is noted that the plaster and gypsum are the exact definition, but the **DISS** is a plant material often found in regions bordering the Mediterranean. This Berberian plant grows in the Berber world, which signifies a random world. The word "Berber" comes from the language of the Algerian population and refers to a forest plant. This study focuses on non-local flexure but does not address long-term control or durability effects. The idea stems from ancient constructions in the Bous region, where this plant was frequently used in old buildings. For this reason, the goal is to analyse the non-local effect on plaster beams, considering the adhesion between fibres and plaster particles, which generates a significant shear effect.

2. Model Mathematics

2. 1. Homogenization

The Piggot rule (Piggott, 1981; Piggott, 2002) for homogenisation remains highly relevant and is still utilised for homogenising materials reinforced with short fibres, despite the advancements made in the works of (TKAYANAGI 1 & 2) (Jamalzadeh et al., 2018; Zare & Rhee, 2020). Recent studies, such as those by (MARIANNA RINALDI et al.) (Rinaldi et al., 2023), have applied the original Piggot rule to investigate the performance of a 3D-printed material made from polyether-ether-ketone (PEEK) reinforced with short carbon nanotube fibres (nano short fibres of CNTs). This highlights the continued validity of the Piggot rule up to 2023. However, it is important to note that the theory's applicability assumes that the matrix material is

relatively weak. The difference in the elastic properties between the matrix and the reinforcement is insignificant, making the rule applicable in such scenarios. When ζ_d is the ratio between the maximum fibre diameter and the particles diameters of the ultimate plaster grains, and λ_l is the ratio between the maximum fibre length and the minimum length fibre of the reinforcing fibres. $E_{\text{hom}}^{P\&D}$ is the module of young homogeneous. $E_P; E_D$ are the module of young of Plaster and the DISS respectively, $\upsilon_{\text{hom}}^{P\&D}; \nu_P; \nu_D$ are the ratio Poisson of homogeneous, Plaster and the DISS respectively and the same goes for other factors, such as volume fraction V_D and shear modulus $G_{\text{hom}}^{P\&D}$.

$$E_{\text{hom}}^{P\&D} = (\frac{1}{5} V_D \times \zeta_d \times \lambda_l \times E_D) + (V_P \times E_P) ....(a)$$

$$\zeta_d = \frac{D_{f\max}^D}{D_{p\max}^P} ...(b) ..... \lambda_l == \frac{L_{f\max}^D}{L_{f\min}^D} ....(c) ..... V_P + V_D = 1 ....(d) \qquad \text{Eq.01}$$

$$\upsilon_{\text{hom}}^{P\&D} = \nu_P \times V_P + \nu_D \times V_D ....(e) ..... G_{\text{hom}}^{P\&D} = \frac{E_{\text{hom}}^{P\&D}}{2(1+\upsilon_{\text{hom}}^{P\&D})} ....(f)$$

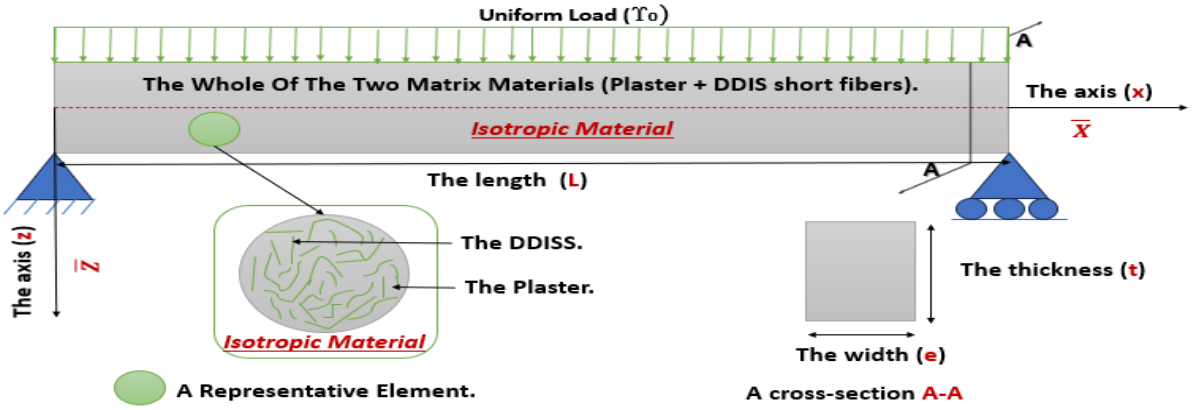


Figure 1. Presentation of the beam is considered isotropic (Plaster reinforced by the nano-short fibers) with uniform loading.

2. 2. Bending beam

The kinematics of isotropic beam is written as presented below:

$$\overline{X}(x,z,d) = \overline{x_0}(x,d) - z \times \frac{\partial \overline{z_0}}{\partial x} + \chi(z) \times \psi(x,d) ..... \overline{Z}(x,z,d) = \overline{z_0}(x,d). \qquad \text{Eq.02}$$

$\overline{X}$ and $\overline{Z}$ are the axial and transverse displacement respectively in x and z directions where the x axis confused on the neutral axis), and ψ is the shear slope. $\overline{x_0}$ and $\overline{z_0}$ are the displacement in any position.

$$\Omega_x = \frac{\partial \overline{Z}}{\partial x} = \Omega_x^0 + z \times \mathrm{P}_x^b + \chi(z) \times \mathrm{P}_x^s. \qquad \text{Eq.03}$$

$$\wp_{xz} = \frac{\partial \overline{Z}}{\partial z} + \frac{\partial \overline{X}}{\partial x} = \delta(z) \times \wp_{xz}^0.$$

Where:

$$\Omega_x^0 = \frac{\partial \overline{x_0}}{\partial x}; \mathrm{P}_x^b = -\frac{\partial^2 \overline{x_0}}{\partial x^2}; \mathrm{P}_x^s = \frac{\partial \psi}{\partial x}; \wp_{xz}^0 = \psi.$$

$$\chi(z) = \frac{3}{8} \times z + \frac{41 \times z^3}{30 \times t^2} - \frac{1}{2} \times t \times \arctan(\frac{z}{t}). \qquad \text{Eq.04}$$

$$\delta(z) = 1 - \frac{\partial \chi(z)}{\partial z}.$$

For the bending of a beam, the normal and the tangential stress are as follows:

$$\sigma_x = E_{\text{hom}}^{P\&D} \times (\Omega_x^0 + z \times \mathrm{P}_x^b + \mathrm{P}_x^s \times \chi(z)).....\tau_{xz} = \frac{E_{\text{hom}}^{P\&D}}{2 \times (1 + \upsilon_{\text{hom}}^{P\&D})} \times \delta(z) \times \wp_{xz}^0 . \quad \text{Eq.05}$$

Where $E_{\text{hom}}^{P\&D}$ and $\upsilon_{\text{hom}}^{P\&D}$ are the elastic modulus and Poisson's ratio of a homogeneous plaster beam reinforced by short DISS fibres are determined after homogenization as an isotropic beam.

Hamilton's principle determines equilibrium equations, considering the initial during (**d_i**) and the final during (**d_f**).

$$\int_{d_i}^{d_f} (\delta \mathrm{H} - \delta \mathrm{P}) dt = 0.....\delta \mathrm{H} = e \int_0^L \int_{-\frac{t}{2}}^{\frac{t}{2}} (\sigma_x \delta \Omega_x + \tau_{xz} \delta \wp_{xz}) dz dx.$$

$$\delta \mathrm{H} = \int_0^L (F_r^x \delta \Omega_x^0 + M_r^b \delta \mathrm{P}_x^b - M_r^s \delta \mathrm{P}_x^s + \Re' \wp_{xz}^0).....\delta \mathrm{P} = \int_0^L (\Upsilon(x) \delta w) dx. \quad \text{Eq.06}$$

We note that $\Upsilon(x)$ is the loading applied to the beam studied. $(F_r^x ; M_r^b ; M_r^s ; \Re')$ are the resulting forces and moments obtained by the thickness (z= $\{-\frac{t}{2}$ to $\frac{t}{2}\}$).

$$F_r^x = e \int_{\frac{-t}{2}}^{\frac{t}{2}} 1 \times \sigma_x dz = \bar{A}_{st} \times \Omega_x^0 + \bar{B}_{st} \times z \times \mathrm{P}_x^b + \bar{C}_{st} \times \mathrm{P}_x^s \times \chi(z).....M_r^b = e \int_{\frac{-t}{2}}^{\frac{t}{2}} z \times \sigma_x dz = \bar{B}_{st} \times \Omega_x^0 + \bar{C}_{st} \times z \times \mathrm{P}_x^b + \bar{E}_{st} \times \mathrm{P}_x^s \times \chi(z).$$

$$M_r^s = e \int_{\frac{-t}{2}}^{\frac{t}{2}} z \times \chi(x) \times \sigma_x dz = \bar{C}_{st} \times \Omega_x^0 + \bar{E}_{st} \times z \times \mathrm{P}_x^b + \bar{F}_{st} \times \mathrm{P}_x^s \times \chi(z).....\Re' = e \int_{\frac{-t}{2}}^{\frac{t}{2}} \delta(x) \times \tau_{xy} dz = \bar{G}_{st} \times \wp_{xz}^0 . \quad \text{Eq.07}$$

$(\bar{A}_{st} ; \bar{B}_{st} ; \bar{C}_{st} ; \bar{D}_{st} ; \bar{E}_{st} ; \bar{F}_{st} ; \bar{G}_{st})$ are the stiffness coefficients; where:

$$\bar{A}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} 1 \times E_{\text{hom}}^{P\&D} dz..... \bar{B}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} z \times E_{\text{hom}}^{P\&D} dz.$$

$$\bar{C}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} \chi(z) \times E_{\text{hom}}^{P\&D} dz..... \bar{D}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} z^2 \times E_{\text{hom}}^{P\&D} dz.$$

$$\bar{E}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} z \times \chi(z) \times E_{\text{hom}}^{P\&D} dz..... \bar{F}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} \chi^2(z) \times E_{\text{hom}}^{P\&D} dz. \quad \text{Eq.08}$$

$$\bar{G}_{st} = e \int_{\frac{-t}{2}}^{\frac{t}{2}} \delta^2(z) \times E_{\text{hom}}^{P\&D} dz.$$

We replace equations N° (7 and 8) into equation N°(6) and replace all the parameters. To obtain the equilibrium equations, we find the following:

$$\delta\overline{x_0}:\frac{\partial F_r^x}{\partial x}=0.....\delta\overline{x_0}:\bar{A}\frac{\partial^2\overline{x_0}}{\partial x^2}-\bar{B}\frac{\partial^3\overline{z_0}}{\partial x^3}+\bar{C}\frac{\partial^2\psi}{\partial x^2}=0.$$
$$\delta\overline{z_0}:\frac{\partial M_r^b}{\partial x^2}+\Upsilon=0.....\delta\overline{z_0}:-\bar{B}\frac{\partial^3\overline{x_0}}{\partial x^3}+\bar{D}\frac{\partial^3\overline{z_0}}{\partial x^3}-\bar{E}\frac{\partial^3\psi}{\partial x^3}+\Upsilon(x)=0. \quad \text{Eq.09}$$
$$\delta\psi:\frac{\partial M_r^s}{\partial x}-\Re^{'}=0.....\delta\psi:\bar{C}\frac{\partial^2\overline{x_0}}{\partial x^2}-\bar{E}\frac{\partial^3\overline{z_0}}{\partial x^3}+\bar{F}\frac{\partial^2\overline{\psi}}{\partial x^2}+\bar{G}\times\psi=0.$$

Applying the boundary conditions of a beam supports when **x=0** and **x=L**.

$$\overline{x_0}=\overline{Z}=M_r^b=M_r^s=0. \quad \text{Eq.10}$$

We are utilizing Navier solutions to address the issue, as they are outlined in the following:

$$\overline{x_0}=\sum_{m=1,3,5}^{\infty}x_m\times\cos(\varsigma\times x).....\overline{z_0}=\sum_{m=1,3,5}^{\infty}z_m\times\sin(\varsigma\times x). \quad \text{Eq.11}$$
$$\psi=\sum_{m=1,3,5}^{\infty}\psi_m\times\cos(\varsigma\times x).....\Upsilon(x)=\sum_{m=1,3,5}^{\infty}\frac{4\times\Upsilon_0}{m\times\pi}\times\sin(\varsigma\times x).$$

The Υ_0 is the maximum uniform load, using the relation rigidity displacement equal to the force generated to determine the deflection (z_m) ; With [**Kr**] as the rigidity matrix, {**Ud**} as the displacement vector, and {**Pr**}as the force vector; when (**œ**) the parameter is non-local and cogent the characteristics of materials used in analyses, it's noted that (**n**) written with this formula {$\mathbf{n=(k_0\times œ)^2}$}; noting the next relation matrix to solve the problems and calculate the deflexion $\overline{\overline{Z_{adm}}}$:

$$\{P_r\}=[K_r]\times\{U_d\}. \quad \text{Eq.12}$$

Let's define the last matrix of rigidity [**Kr**], force {**Pr**} and displacement {**Ud**}.

$$[K_r]=\begin{bmatrix}\bar{A}\times\varsigma^2 & -\bar{B}\times\varsigma^3 & \bar{C}\times\varsigma^2\\ -\bar{B}\times\varsigma^3 & D\times\varsigma^4 & -\bar{E}\times\varsigma^3\\ \bar{C}\times\varsigma^2 & -\bar{E}\times\varsigma^3 & \bar{F}\times\varsigma^2+\bar{G}\end{bmatrix}....\{U_d\}=\begin{Bmatrix}x_m\\ z_m\\ \psi_m\end{Bmatrix}. \quad \text{Eq.13}$$
$$\{P_r\}=\frac{4\times\Upsilon_0}{m\times\pi}\begin{Bmatrix}0\\ (1+n\varsigma^2\\ 0\end{Bmatrix}.....\varsigma=\frac{m\times\pi}{L}.$$

The dimensionless deflection is written in following:

$$\overline{\overline{Z_{adm}}}=100\times\frac{E_P}{\Upsilon_0\times L^4}\times\frac{e\times t^3}{12}. \quad \text{Eq.14}$$

3. Results and discussion

3. 1. Model of homogenization Comparison

At first, to validate that the young model is valid by the developed model, we compare the results by the reference of (Marianna Rinaldi) (Rinaldi et al., 2023) with the diameter of CNTs **(dcnt =06 nm)** in **Table 1,** where ($\mathbf{E_{polymere}=3\ GPA;\ n_{polymere}=0.3}$) and the nanotube of carbon reinforced are ($\mathbf{E_{CNTs}=5.6466\ TPa,\ v_{CNTs}=0.34}$). You can see the error between the real modulus of elasticity and the effective modulus of elasticity when the matrix is the polymer and the fibres reinforced are the

CNTs when the units are **[GPa]**. The error will be presented as a percentage [**%**] under the following formula:

$$\Delta_{error(\%)} = \frac{E_{piggot} - E_{real}}{E_{real}} \qquad \text{Eq.15}$$

Table 1. Model of homogenization Comparison by Model created and with other results from other scientific journals.

	$E_{measured}$	(Marianna Rinaldi) (Rinaldi et al., 2023)		(Jamalzadeh N and al ….) (Jamalzadeh et al., 2018)		(Zare Y and al…) (Zare & Rhee, 2020)		**Present**	
V% CNTs	E_{real}	E_{piggot} **Eq 1**	$\Delta_{error(\%)}$ **Eq 16**	E_{piggot} **Eq 1**	$\Delta_{error(\%)}$ **Eq 16**	E_{piggot} **Eq 1**	$\Delta_{error(\%)}$ **Eq 16**	E_{piggot} **Eq 1**	$\Delta_{error(\%)}$ **Eq 16**
0%	3	3	0	3	0	3	0	**3**	**0**
3%	3.1	7.2	132	5.3	70.8	2.97	0.9	**3.195**	**3.064**
5%	3.5	10	186	3.7	5	3.3	7	**3.324**	**-5.028**
10%	3.7	17.2	356	3.4	8	4.1	11	**3.649**	**-1.378**

According to **Table 1**, the uncertainty is between **±5.1%,** which means that our homogenization model is very close to the experimental parts and the theoretical models mentioned in this last table. So, this developed law is valid for homogenizing non-short fibres (de Bilbao et al., 2010). The elastic modulus and Poisson's ratio of the matrix (Plaster) are as follows: (**E =1.75 GPa ;v=0.25**) and (MERZOUD Mouloud and HABITA Mohamed Fouzi) (Merzoud & Habita, 2008),(Lakhemissi Touam and Semcheddine Derfouf) (Touam & Derfouf, 2021), Layth Mohammed and al …) (Mohammed et al., 2015) reinforcement properties of nano short fibre from Algerian DISS are also noted as: (**E =6.7 GPa ;v=0.2**)

$$\text{Where: } \zeta_d = \frac{D^D_{f\max}}{D^P_{p\max}} = \frac{3nm}{5nm}$$

$$\text{And: } \lambda_l = = \frac{L^D_{f\max}}{L^D_{f\min}} = \frac{700nm}{250nm}$$

The results are well illustrated in the following **Table 2**. This last table declares and shows that the mechanical properties increase concerning the increase in nano-short fibres of organic reinforcement (Algerian DISS). We were obliged to stop the increase of **30%** in reinforcement in organic materials in cases where organic materials have the role of reinforcement.

Table 2. The effective results of the model created for the homogenization between plaster and nano fibers of Algerian DISS.

(V%) DISS	$E^{P\&D}_{\hom}$	$\upsilon^{P\&D}_{\hom}$	$G^{P\&D}_{\hom}$	**(V%) DISS**	$E^{P\&D}_{\hom}$	$\upsilon^{P\&D}_{\hom}$	$G^{P\&D}_{\hom}$
0% (Matrix)	1.750	0.25	0.7	**0% (Matrix)**	1.750	0.25	0.7
5%	1.897	0.2475	0.7632	**20%**	2.338	0.24	0.9427
10%	2.044	0.245	0.8129	**25%**	2.485	0.2375	1.0040
15%	2.191	0.2425	0.8817	**30%**	2.632	0.235	1.0656

3. 2. Static bending of the beam (plaster reinforced with nano short fibres from DISS Algeria)

Firstly, we note that the results are compared using our mathematical model by comparing two works of Pr. SAYYAD (Sayyad

& Ghugal, 2021; Sayyad et al., 2023), when the material is considered isotropic, where (**E = 1 GPa ;v=0.2**).

Table 3. Comparison of the results obtained by the model created for an isotropic material with recent scientific work in the same context., where (***E = 1 GPa ;v=0.3***) and the geometric parameters (***t=1;e=1×t;L=ħ ×t***).

$\hbar = \frac{L}{t}.$	**Nonlocal parameter (n) (m=100)**	**The dimensionless deflection** $\overline{\overline{Z_{adm}}}$			
		Sayyad &) (Ghugal, 2021	Sayyad et al., 2023 x=2.634	Sayyad et al., 2023 x=1	**Present**
10	0	1.3394	1.3381	1.3345	**1.3394**
	1	1.4675	1.4660	1.4621	**1.4655**
	2	1.5956	1.5940	1.5897	**1.5983**
	3	1.7237	1.7220	1.7173	**1.7364**
	4	1.8517	1.8498	1.8449	**1.8520**

Table 3 shows that the mathematical model for calculating the bending of isotropic beams is similar to the other researchers' results, which means that the new shear estimation function is valid.

In addition, we also compare the results obtained according to non-local parameters; the results are very close to the article by Professor SAYAD. Table 4 shows the comparison, which means that our beam bending calculation model is very close; therefore, studying the bending of the plaster beam reinforced by DISS is also functional.

The non-linear model varies between 0 to 4. All results are very close, although the non-linear modes will be changed.

Table 4. Comparison of the results obtained by the model created for an isotropic material with recent scientific work in the same context., where (***E = 1 GPa ;v=0.3***) and the geometric parameters (***t=1;e=1×t;L=10t***).

$\hbar = \frac{L}{t}.$	**Nonlocal parameter (n) (m=100)**	**The dimensionless deflection** $\overline{\overline{Z_{adm}}}$	
		(Sayyad & Ghugal, 2021)	**Present**
5	0	1.4347	**1.4433**
	1	1.5716	**1.5647**
	2	1.7045	**1.7123**
	3	1.8415	**1.8479**
	4	1.9804	**1.9861**
10	0	1.3394	**1.3394**
	1	1.4675	**1.4655**
	2	1.5956	**1.5983**
	3	1.7237	**1.7364**
	4	1.8517	**1.8520**
20	0	1.3134	**1.3132**
	1	1.4406	**1.4418**
	2	1.5637	**1.5638**
	3	1.6919	**1.6920**
	4	1.8161	**1.8121**
100	0	1.3036	**1.3035**
	1	1.4301	**1.4308**
	2	1.5567	**1.5547**
	3	1.6802	**1.6806**
	4	1.8047	**1.8055**

We begin the study with our new materials, plaster reinforced with DISS nano-short fibres. The deflection will be calculated for the different volume fractions of the nano-short fibres by the effective properties of the materials (Plaster + DISS Algerian).

From **Tables 3 and 4**, if the ratio between the length and thickness of the beam changes, the deflection decreases; on the other hand, if we fix the recent ratio and the modes of the non-linear parameter (**n**) increase such that (**m=100**), the deflection of the beam decreases.

The results are presented in **Table 5** (The cross-section is a square **t=e**). The deflection decreases when the section is created if the length ratio is along the length of the beam. For this, the results are logical.

In **Tables 6, 7, and 8**, successively and alternately, we vary the cross-section **e = {1;0.75;0.5;0.25}×t**; with a geometric relationship that also varies between the beam length and the thickness.

If the section becomes rectangular on the semi-axis [oy), the transverse section becomes rectangular automatically; the inertia will change, then the arrow increases, and the opposite is correct.

So, it is better to have the thickness reversed so the beam is more resistant to gains in inertia.

Table 5. Comparison of the results obtained by the model created for an isotropic material with recent scientific work in the same context. Where (***E=E(V%) GPa*** ; ***v=v(V%)***) and the geometric parameters (***t=1;e=1×t;L=ℏ ×t***).

$\hbar = \frac{L}{t}$.	Nonlocal parameter (**n**) (**m=100**)	The dimensionless deflection $\overline{\overline{Z_{adm}}}$						
		V(00%)	V(05%)	V(10%)	V(15%)	V(20%)	V(25%)	V(30%)
5	0	1.0164	1.0803	1.1528	1.2357	1.3314	1.4433	0.9596
	1	1.1019	1.1712	1.2497	1.3396	1.4434	1.5647	1.0403
	2	1.2059	1.2817	1.3677	1.4660	1.5796	1.7123	1.1385
	3	1.3014	1.3832	1.4760	1.5821	1.7047	1.8479	1.2287
	4	1.3987	1.4866	1.5863	1.7004	1.8322	1.9861	1.3205
10	0	0.9432	1.0025	1.0698	1.1467	1.2356	1.3394	0.8905
	1	1.0321	1.0970	1.1706	1.2547	1.3520	1.4655	0.9744
	2	1.1256	1.1964	1.2766	1.3684	1.4745	1.5983	1.0627
	3	1.2228	1.2997	1.3869	1.4866	1.6018	1.7364	1.1545
	4	1.3042	1.3862	1.4792	1.5856	1.7085	1.8520	1.2314
20	0	0.9248	0.9829	1.0489	1.1243	1.2115	1.3132	0.8731
	1	1.0154	1.0792	1.1516	1.2344	1.3301	1.4418	0.9587
	2	1.1013	1.1705	1.2491	1.3389	1.4427	1.5638	1.0398
	3	1.1915	1.2664	1.3514	1.4486	1.5609	1.6920	1.1250
	4	1.2762	1.3564	1.4474	1.5515	1.6717	1.8121	1.2049
100	0	0.9179	0.9757	1.0411	1.1160	1.2025	1.3035	0.8667
	1	1.0076	1.0710	1.1428	1.2250	1.3199	1.4308	0.9513
	2	1.0948	1.1637	1.2417	1.3311	1.4342	1.5547	1.0337
	3	1.1835	1.2579	1.3423	1.4388	1.5503	1.6806	1.1174
	4	1.2715	1.3515	1.4421	1.5458	1.6656	1.8055	1.2005

The non-dimensional deflection is presented in **Figure 2**; the tracing of the latter is correct because the beam is supported, and the maximum deflection is in the middle of the beam.

Therefore, if the volume fraction (**V%**) of Algerian DISS increases, the deflection will be less each time with an increase of **5%**. The best results are **30%**. We remind you that stopping at **30%** of nano-short fibres is required because the reinforcement is an organic material, and we can go further with the fractions we limit ourselves to **30%.**

In this part of the diagnosis of the results of **Figure 2**, the stress depends on the bending moment of this reason in the elasticity level. If Young's modulus increases, the resistance will be better, and the deflection will return more minor.

DISS Algerian nano-fibres become more efficient in reducing deflection along the semi-axis [**oz**). Therefore, this reinforcement is perfect for reinforcing plaster.

The improvement between the ordinary dry plaster and the plaster with a fraction of **30%** we have is a reduction of 42% in the deflection, which presents the importance of this reinforcement. The significant reduction in deflection (42%) achieved with a 30% addition of fibres underscores the practical value of the proposed material. The experimental and theoretical results are

consistent and well-illustrated. The mathematical model based on recognized theories (HSDT, Piggot) is a significant strength. The validations with comparative data demonstrate consistency with both theoretical and experimental results.

Table 6. Comparison of the results obtained by the model created for an isotropic material with recent scientific work in the same context., where (***E=E(V%) GPa***; ***ν= ν(V%)***) and the geometric parameters (***t=1;e=0.75×t;L=ħ ×t***).

$\hbar = \frac{L}{t}$.	Nonlocal parameter (**n**) (**m=100**)	The dimensionless deflection $\overline{\overline{Z_{adm}}}$						
		V(00%)	V(05%)	V(10%)	V(15%)	V(20%)	V(25%)	V(30%)
5	0	1.4433	1.3314	1.2357	1.1528	1.0803	1.0164	0.9596
	1	1.5647	1.4434	1.3396	1.2497	1.1712	1.1019	1.0403
	2	1.7123	1.5796	1.4660	1.3677	1.2817	1.2059	1.1385
	3	1.8479	1.7047	1.5821	1.4760	1.3832	1.3014	1.2287
	4	1.9861	1.8322	1.7004	1.5863	1.4866	1.3987	1.3205
10	0	1.3394	1.2356	1.2357	1.0698	1.0025	0.9432	0.8905
	1	1.4655	1.3520	1.3396	1.1706	1.0970	1.0321	0.9744
	2	1.5983	1.4745	1.4660	1.2766	1.1964	1.1256	1.0627
	3	1.7364	1.6018	1.5821	1.3869	1.2997	1.2228	1.1545
	4	1.8520	1.7085	1.7004	1.4792	1.3862	1.3042	1.2314
20	0	1.3132	1.2115	1.1243	1.0489	0.9829	0.9248	0.8731
	1	1.4418	1.3301	1.2344	1.1516	1.0792	1.0154	0.9587
	2	1.5638	1.4427	1.3389	1.2491	1.1705	1.1013	1.0398
	3	1.6920	1.5609	1.4486	1.3514	1.2664	1.1915	1.1250
	4	1.8121	1.6717	1.5515	1.4474	1.3564	1.2762	1.2049
100	0	1.3035	1.2025	1.1243	1.0411	0.9757	0.9179	0.8667
	1	1.4308	1.3199	1.2344	1.1428	1.0710	1.0076	0.9513
	2	1.5547	1.4342	1.3389	1.2417	1.1637	1.0948	1.0337
	3	1.6806	1.5503	1.4486	1.3423	1.2579	1.1835	1.1174
	4	1.8055	1.6656	1.5515	1.4421	1.3515	1.2715	1.2005

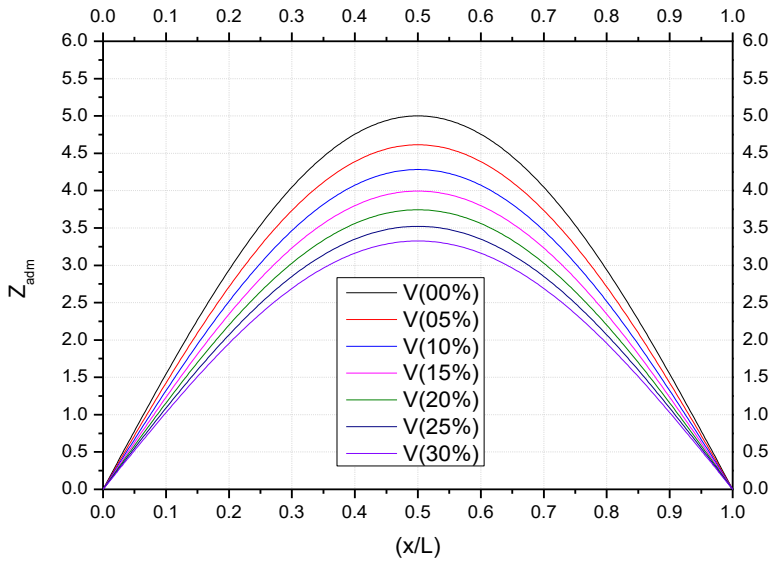


Figure 2. The deflection $\overline{\overline{Z_{adm}}}$ for the different volume fractions is **V(%)** or the following geometrics parameters **(t=1;e=1×t;L= 5×t)**

Table 7. Comparison of the results obtained by the model created for an isotropic material with recent scientific work in the same context. where (***E=E(V%) GPa*** ; ***v=v(V%)***) and the geometric parameters (***t=1;e=0.5×t;L=ħ ×t***).

$\hbar = \frac{L}{t}$.	Nonlocal parameter (**n**) (**m=100**)	The dimensionless deflection $\overline{\overline{Z_{adm}}}$						
		V(00%)	V(05%)	V(10%)	V(15%)	V(20%)	V(25%)	V(30%)
5	0	1.4433	1.3314	1.2357	1.1528	1.0803	1.0164	0.9596
	1	1.5647	1.4434	1.3396	1.2497	1.1712	1.1019	1.0403
	2	1.7123	1.5796	1.4660	1.3677	1.2817	1.2059	1.1385
	3	1.8479	1.7047	1.5821	1.4760	1.3832	1.3014	1.2287
	4	1.9861	1.8322	1.7004	1.5863	1.4866	1.3987	1.3205
10	0	1.3394	1.2356	1.1467	1.0698	1.0025	0.9432	0.8905
	1	1.4655	1.3520	1.2547	1.1706	1.0970	1.0321	0.9744
	2	1.5983	1.4745	1.3684	1.2766	1.1964	1.1256	1.0627
	3	1.7364	1.6018	1.4866	1.3869	1.2997	1.2228	1.1545
	4	1.8520	1.7085	1.5856	1.4792	1.3862	1.3042	1.2314
20	0	1.3132	1.2115	1.1243	1.0489	0.9829	0.9248	0.8731
	1	1.4418	1.3301	1.2344	1.1516	1.0792	1.0154	0.9587
	2	1.5638	1.4427	1.3389	1.2491	1.1705	1.1013	1.0398
	3	1.6920	1.5609	1.4486	1.3514	1.2664	1.1915	1.1250
	4	1.8121	1.6717	1.5515	1.4474	1.3564	1.2762	1.2049
100	0	1.3035	1.2025	1.1160	1.0411	0.9757	0.9179	0.8667
	1	1.4308	1.3199	1.2250	1.1428	1.0710	1.0076	0.9513
	2	1.5547	1.4342	1.3311	1.2417	1.1637	1.0948	1.0337
	3	1.6806	1.5503	1.4388	1.3423	1.2579	1.1835	1.1174
	4	1.8055	1.6656	1.5458	1.4421	1.3515	1.2715	1.2005

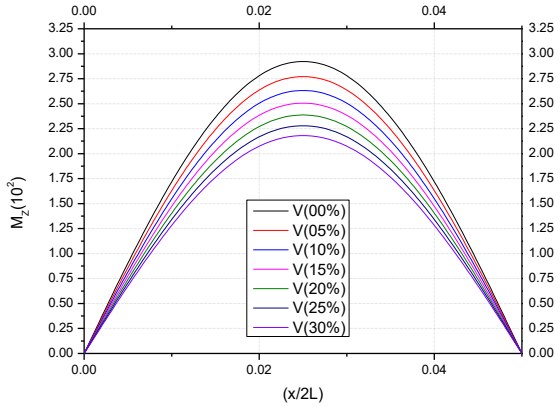


Figure 3. The pure bending **Mz** for the different volume fractions is **V (%)** or the following geometrics parameters **(t=1; e=1×t; L= 10×t)**

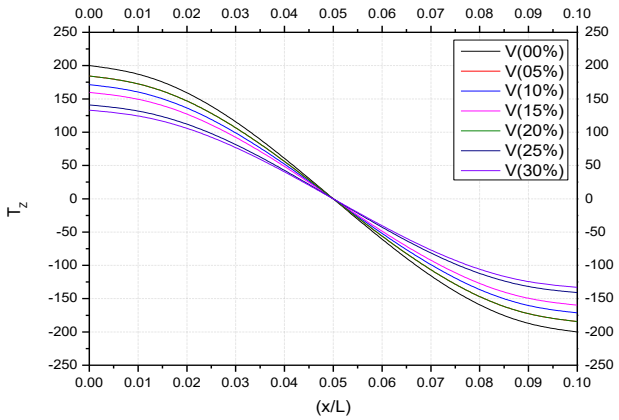
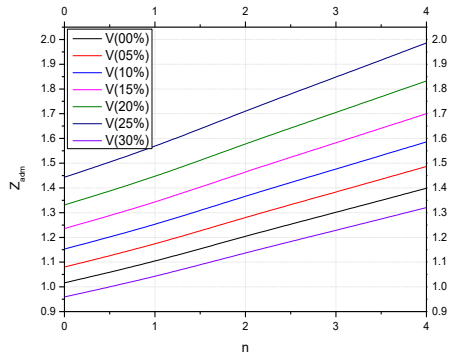


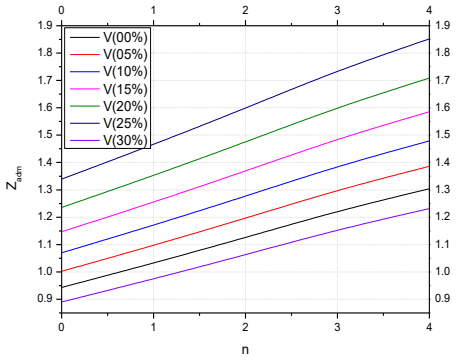
Figure 4. The pure shear force **Tz** for the different volume fractions is **V (%)** or the following geometrics parameters **(t=1; e=1×t; L= 10×t)**

Table 8. Comparison of the results obtained by the model created for an isotropic material with recent scientific work in the same context., where (***E=E(V%) GPa***; v= ***v(V%)***) and the geometric parameters (***t=1; e=0.25×t;L=ħ ×t***).

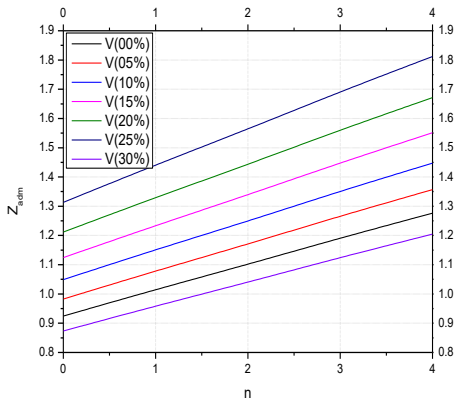
$\hbar = \frac{L}{t}.$	Nonlocal parameter (n) (m=100)	The dimensionless deflection $\overline{\overline{Z_{adm}}}$						
		V (00%)	V (05%)	V (10%)	V (15%)	V (20%)	V (25%)	V (30%)
5	0	1.4433	1.3314	1.2357	1.1528	1.0803	1.0164	0.9596
	1	1.5647	1.4434	1.3396	1.2497	1.1712	1.1019	1.0403
	2	1.7123	1.5796	1.4660	1.3677	1.2817	1.2059	1.1385
	3	1.8479	1.7047	1.5821	1.4760	1.3832	1.3014	1.2287
	4	1.9861	1.8322	1.7004	1.5863	1.4866	1.3987	1.3205
10	0	1.3394	1.2356	1.1467	1.0698	1.0025	0.9432	0.8905
	1	1.4655	1.3520	1.2547	1.1706	1.0970	1.0321	0.9744
	2	1.5983	1.4745	1.3684	1.2766	1.1964	1.1256	1.0627
	3	1.7364	1.6018	1.4866	1.3869	1.2997	1.2228	1.1545
	4	1.8520	1.7085	1.5856	1.4792	1.3862	1.3042	1.2314
20	0	1.3132	1.2115	1.1243	1.0489	0.9829	0.9248	0.8731
	1	1.4418	1.3301	1.2344	1.1516	1.0792	1.0154	0.9587
	2	1.5638	1.4427	1.3389	1.2491	1.1705	1.1013	1.0398
	3	1.6920	1.5609	1.4486	1.3514	1.2664	1.1915	1.1250
	4	1.8121	1.6717	1.5515	1.4474	1.3564	1.2762	1.2049
100	0	1.3035	1.2025	1.1160	1.0411	0.9757	0.9179	0.8667
	1	1.4308	1.3199	1.2250	1.1428	1.0710	1.0076	0.9513
	2	1.5547	1.4342	1.3311	1.2417	1.1637	1.0948	1.0337
	3	1.6806	1.5503	1.4388	1.3423	1.2579	1.1835	1.1174
	4	1.8055	1.6656	1.5458	1.4421	1.3515	1.2715	1.2005



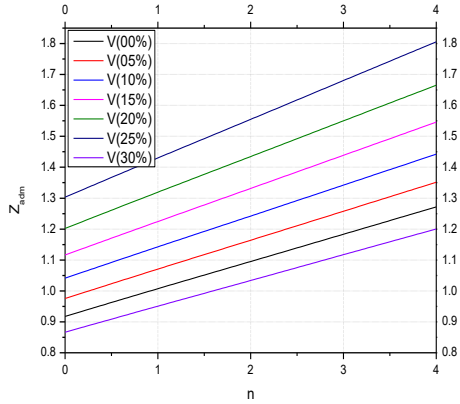
(A) : (t=1 ; e=1×t ; L= 5×t)



(B) : (t=1 ; e=1×t ; L= 10×t)

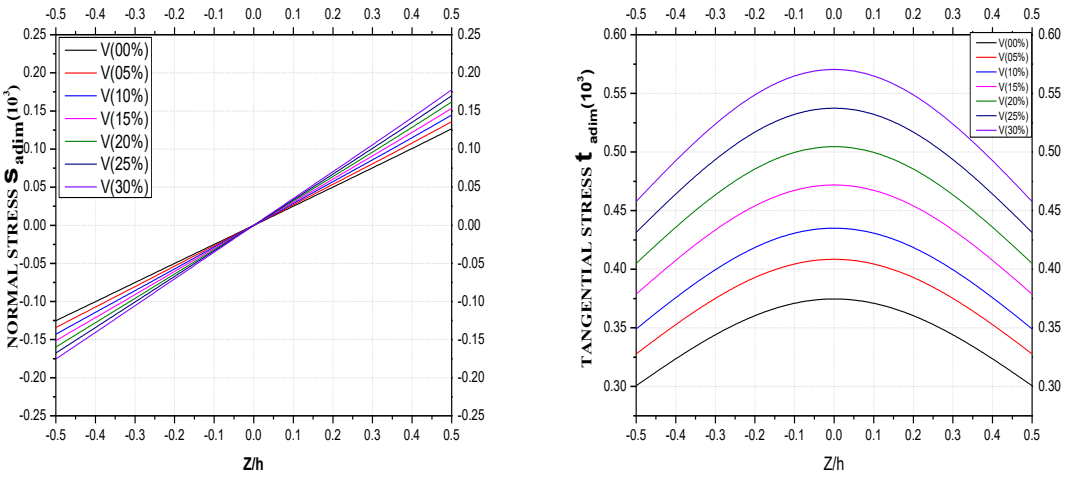


(C) : (t=1 ; e=1×t ; L= 20×t)



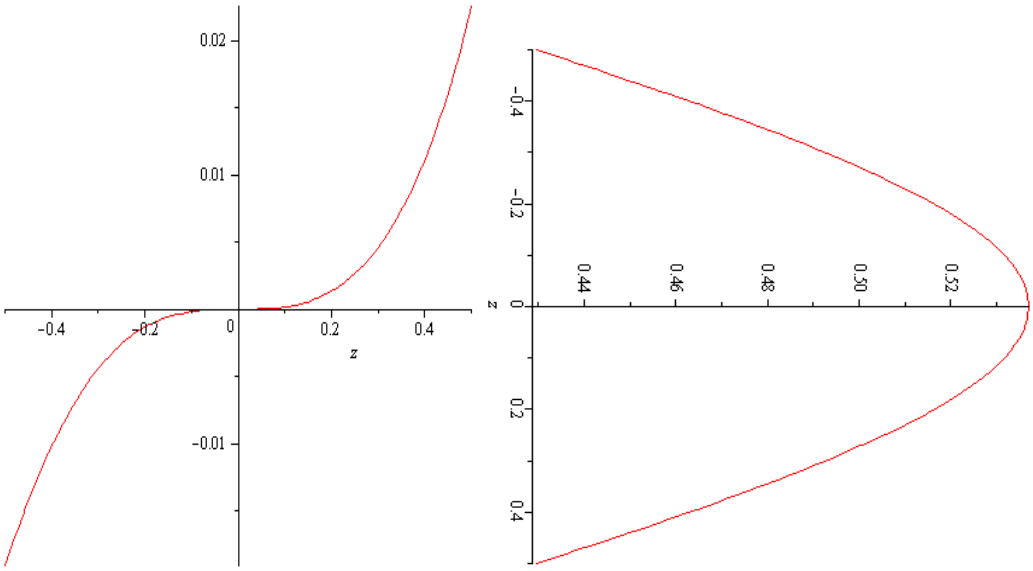
(D) : (t=1 ; e=1×t ; L= 100×t)

Figure 5. The deflection for all four non-local parameters **(n=0;1;2;3;4)** for the different volume fractions is **V (%). {A, B, C, D}**



(A) Normal stress **(B): Tangential stress**

Figure 6. The deflection for all four non-local parameters **(n=0;1;2;3;4)** for the different volume fractions is **V (%). {A, B, C, D}**



(A) Function of Normal stress **(B) Function of Tangential stress** $\left[-\frac{h}{2}..\frac{h}{2}\right]$

Figure 7. The Plotting of the function of the normal stress and the tangential stress in the interval $\left[-\frac{h}{2}..\frac{h}{2}\right]$ are presented in the two graphs **{A, B}**

We base ourselves on basic mathematical books to determine the new functions and estimate the shear under a hyperbolic function, and also for the development of calculation models, among its references (TAHA SOSHY) (Sochi, 2022); (Wihlem Flugges) (Flügge, 1972). In **Figure 3**, it is always noted that the weighting relationship between the bending and the stress in the elasticity of the bending moment is the greatest in the case where (**V%=0%**), the greatest is considered in the middle of the arrow. The lowest is (**V%=30%**), so these reinforcements work perfectly to reduce the bending moment of this type of beam. In this part of the diagnosis of the results of **Figure 2**, the stress depends on the bending moment of this reason in the elasticity level. If Young's modulus increases, the resistance will be better, and the deflection will return more minor. Since the maximum value of the stress is at the middle of the beam, we notice that the cutting force is zero in the middle of the beam and maximum at the limited once by a negative value and the second time by a positive value, and increasing the reinforcement reduces the value of the shear force. The difference in the shear force of an ordinary plaster beam and a plaster reinforced in 30% by DISS nano-fibres is of a value of 38%. In all graphs {**A, B, C,** and **D**}, the **30%** gives the least tracing in all cases in variation of the

geometry of the beams. The deflection increases as a function of change in nonlinearity (the parameter non-local) (**n**), and the deflection increases as a function of the non-locality of the beam. What shows up in **Figure 4**. Graph A of **Figure 5** shows that the everyday stress increases on the variation in the thickness (z) and will become (**zero**) in the middle of the beam in the transverse section because of the central core and, in turn, the neutral axis. While either the extremity or **z=-h/2** or **z=h/2** the shear force is low, the best results or **z=0** are displayed in graph (**B**) of **Figure 5**. Concerning the volume of the fraction, as always, the reinforcement chosen works perfectly in the case of bending. The plots of the two functions, A for the usual stresses and **B** for the shear stresses, as shown in **Figure 6**, clearly illustrate tensile and compressive stresses. Consequently, a parabolic shear force is depicted, which reaches its optimal value at **z=0.** These two graphs represent the standards of material strength and plane elasticity. $(\tau = 0 \rightarrow \sigma^{\max})$; $(\sigma = 0 \rightarrow \tau^{\max})$. The work method is purely theoretical; the effective method involves randomly mixing gypsum with Algerian fibre courses. This study was conducted under static conditions, and future studies will incorporate the effects of hygrothermal conditions and climate change. The maximum allowable volume fraction for organic materials is limited to 30% for safety reasons. It is noted that several constructions have been carried out using this technique. This method can be used in concrete structures for acoustic and thermal applications.

4. Conclusion

At the end of this work, we conclude the following:

1- The non-local parameter (n) increases the deflection of the beam in all cases.

2-The geometrical relationships influence the beams' deflection; the best choice is the rectangular beam based on its base or a square section.

3-Increasing the volume fraction of nano-short fibres reduces deflection and improves the resistance of plaster against bending.

4-The nano-short fibres of DDIIS designed as plant material (biomaterials) have positive results in improving the properties of plasters.

5-The laws developed to function as improved HSDT, which can be used for verification and homogenization by biological materials.

6-This paper is important because it combines two heterogeneous materials and two different mineral and biological sources, opening a broad vision in research into innovative materials. After all, we can go up to 30% by biological reinforcements.

7-Biomaterials are renewable resources that have never been replenished, which can reinforce construction materials in civil engineering.

8- This new plaster can be used in architectural aesthetics, reinforcing old buildings and rehabilitating old mosques and churches built using plaster.

9-It is also demonstrated that this new mathematical model can calculate the bending of beams using HSDT.

10-The improved homogenization model can be used as a reference for combined hydraulic binders and short organic nano-fibres.

11- The impact of using these fibres in construction is to improve the socioeconomic sector by promoting and enhancing the value of this type of material in building applications for declared objectives.

12- The role of fibres in construction materials is primarily to reduce thermal conductivity and enhance acoustic insulation.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Data Availability

No data was used for the research described in the article.

List of Abbreviations

ζ_d : The ratio between the maximum fibre diameter and the particles diameters of the ultimate plaster grains;

$\hat{\lambda}_l$: The ratio between the maximum fibre length and the minimum length fibre of the reinforcing fibers;

$E_{\text{hom}}^{P\&D}$: Young's Modulus homogeneous;

$E_P; E_D$: The Young's Modulus of Plaster and the DISS respectively;

$\upsilon_{\text{hom}}^{P\&D}; \nu_P; \nu_D$: The Poisson ratio homogeneous, Plaster and the DISS respectively ;

V_D : Volume fraction ;

$G_{\text{hom}}^{P\&D}$: shear modulus;

$\overline{X}$ and $\overline{Z}$: The Poisson ratio homogeneous, Plaster and the DISS respectively axial and transverse displacement respectively in x and z directions ;

ψ : The shear slope;

$\overline{x_0}$ and $\overline{z_0}$: The displacement in any position;

$\overline{\overline{Z_{adm}}}$: The dimensionless deflection;

Ω_x : The normal deformation (in x-axis);

$\wp_{xz}$: The transverse deformation (in two axis x,y);

$\chi(z)$: Function representative of shear deformation;

$\delta(z)$: One minus first derivation of function representative shear deformation;

ψ : Rotation;

$\wp_{xz}^0$: first deformation produces buy rotation;

Ω_x^0 : first displacement;

$\wp_{xz}^0$: first distortion;

P_x^b : normal deformation in beam;

P_x^s : Distortion produce buy the shear deformation;

σ_x : The bending of a beam;

τ_{xz} : The normal and the tangential stress are as follows;

$E_{\text{hom}}^{P\&D}$ and $\upsilon_{\text{hom}}^{P\&D}$: The elastic modulus and Poisson's ratio of a homogeneous plaster beam reinforced by short DISSS fibers are determined after homogenization as an isotropic beam;

(**$\mathbf{d_i}$**) : The initial during;

(**$\mathbf{d_f}$**): The final during ;

P: Potential energy;

H: Kinetic energy;

$\Upsilon(x)$: The loading applied to the beam studied;

$(F_r^x; M_r^b; M_r^s; \Re')$: The resulting forces and moments ;

(z= $\{-\frac{t}{2}$ to $\frac{t}{2}\}$) : The thickness ;

$(\bar{A}_{st}; \bar{B}_{st}; \bar{C}_{st}; \bar{D}_{st}; \bar{E}_{st}; \bar{F}_{st}; \bar{G}_{st})$: The stiffness coefficients;

e: Nonlinear parametrium;

δ : Variation ;

[**$\mathbf{K_r}$**] : The rigidity matrix ;

{**$\mathbf{U_d}$**}: The displacement vector ;

{**$\mathbf{P_r}$**} : The force vector ;

(**œ**): The parameter non-local cogent the characteristics of materials used in analyses ;

$\Delta_{error(\%)}$: Variation error;

V(%) : Volume fraction ;

$\hbar$: Parameter length devise by thicknessm;

m, n : buckling Mods.

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Prevalence of Cholelithiasis Among Nigerians: A Prospective Sonographic Study In A Tertiary Center In Sokoto, Northwest Nigeria

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ABSTRACT

Gallstone is a common and major biliary disease of modern society and is thought to be rare among Asians and the Black population. However, this narrative may also be changing with the increasing westernization of the African diet and changing lifestyle. We aimed to evaluate the sonographic prevalence of gallstones in Sokoto, North-west Nigeria. This was a descriptive, prospective study. Socio-demographic, clinical and sonographic data of all consenting patients presenting to the radiology department of Usmanu Danfodiyo University Teaching Hospital (UDUTH) Sokoto for an abdominal ultrasound between April 2024 and September 2024 were prospectively collected using a structured proforma. Statistical significance was set at a p-value of <0.05. There were 1456 who met the inclusion criteria and thus participated in the study. The majority (sixty-nine per cent) were females, the mean age was 38.3±15.0 years, and forty-nine per cent were above 40 years. The majority had a normal body mass index (BMI). The number of patients with cholelithiasis was 52, giving a prevalence of 3.57%. Prevalence among females, 4.5%, was significantly higher than that among males, 1.6% (p=0.001). Likewise, prevalence was significantly higher among overweight (6.5%) and obese (8.2%) patients than in standard (1.6%) and underweight patients (0.9%). The prevalence was observed to rise with increasing age, higher in diabetic patients and those with a family history of gallstones; however, these observed differences were not statistically significant. Cholelithiasis remains a relatively uncommon condition in our setting. Female gender and obesity significantly increased the odds of developing cholelithiasis.

Keywords: Cholelithiasis, Gallstones, Nigerians, Native black population.

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1. Introduction

Gallstones are precipitations of the bile constituents in the biliary tree, usually in the gallbladder, occurring in a background of imbalance of its chemical composition. The disease is old and has been known to humans for over a thousand years BC when it was demonstrated in Egyptian mummies (Berci, 2004). Gallstones are seen worldwide with a highly variable geographic prevalence (Cao & Eslick, 2018). It's a significant health problem in modern society, with a prevalence of 10-15% among the adult white population in high-income countries (Marschall & Einarsson, 2007). The prevalence reaches an epidemic proportion of 73% among the adult female American Pima Indians, while 30% and 64% are seen in males and females, respectively, of other American Indian populations (Everhart et al., 2002; Marschall & Einarsson, 2007). The burden is substantial, with about 750,000 cholecystectomies performed yearly in the US, costing the economy about $6.5 billion annually and a yearly mortality of 1090 patients (Stinton & Shaffer, 2012). The disease is comparatively rare among Africans and Asians, with a prevalence of 3-5% (Kratzer et al., 1999). The reported associated risk factors with lithogenesis in the gallbladder include increasing age, female gender (especially during their fertile years), use of oral contraceptives, genetic predisposition, obesity, rapid weight loss, exposure to a western-type diet (high in fat, refined sugar and low in fibre), sedentary lifestyle and low physical activity level, drugs (fibric acid derivatives), and diabetes (Njeze, 2013). Among these several risk factors implicated in the formation of stones within the gallbladder, diet and lifestyle have often been postulated to partly explain the relative rarity of gallstones among Africans (Rahman, 2005). With increasing urbanization and the resultant westernization of African diet and lifestyle, the epidemiology of many non-communicable diseases hitherto rare among the African population is changing. We postulate that there may be a corresponding increase in the prevalence of gallstones among Africans. Ultrasonography, a non-invasive and safe imaging modality, is the most common in diagnosing gallstones. It is a dynamic procedure with a sensitivity of 95% and specificity of 93% for stones of 2mm with a high diagnostic accuracy. It is ideal for determining the point prevalence of gallstones in a population (Everhart et al., 2002). This study highlights the ultrasonographic prevalence and risk factors for gallstone disease among patients presenting for transabdominal ultrasound in a referral center in Northwestern Nigeria.

- **Research questions**

This study aims to answer the following questions:

1. What is the hospital prevalence of gallstones in our center?
2. What are the socio-demographic distributions of gallstones in Sokoto?

- **Aims and Objectives**

Aim: To describe the sonographic prevalence of gallstones in Sokoto, Nigeria.
Specific objectives: To determine

1. The hospital sonographic prevalence of gallstones in our hospital.
2. The socio-demographic distribution of gallstones amongst patients in Sokoto.

2. Patients and Methods

2. 1. Study design

This was a prospective descriptive single-center study. The study was conducted over a six-month duration.

2. 2. Study setting

This study was conducted at the radiology department of Usmanu Danfodiyo University Teaching Hospital (UDUTH), Sokoto, and Sokoto state. UDUTH is an 850-bed tertiary hospital located in Sokoto metropolis rendering specialist care to patients from Sokoto, Kebbi, Zamfara, Katsina, and parts of Niger state. The population is not immune to increasing consumption of foods rich in fats and oil, saturated fats of animal origin, calorie-based sweeteners and reduced physical activity across the West African subregion (Mbogori & Mucherah, 2019).

2. 3. Study population

2. 3. 1. Inclusion Criteria

i. All patients presenting to the radiology department for an abdominopelvic ultrasound, irrespective of the indication.

2. 3. 2. Exclusion Criteria

i. Patients who have had previous cholecystectomy.
ii. Patients who withheld consent.

2. 4. Data collection

Data was collected using a uniform predesigned proforma and entered into a spreadsheet. Information to be obtained will include socio-demographic variables, clinicopathologic data indicating abdominopelvic ultrasound and major ultrasound findings. The Body Mass Index (BMI) was also documented. The BMI was calculated as the ratio of the patient's weight to squared height (in Kg/m^2). The patient's BMI was further classified according to World Health Organization (WHO) stratification into the following groups: obese (≥30.0), overweight (25.0- 29.9), normal weight (18.5- 24.9) and underweight (< 18.5). A transabdominal ultrasound scan was performed by the radiologists at the radiology department using both low (3-5MHz) and high (7.5MHz) resolutions ultrasound transducers of the MINDRAY DIAGNOSTIC ULTRASOUND SYSTEM, MODEL DC-3, and VERSION TW.FS.9 B. DN (Made in China, 03/2012) set to the 2D mode. The patient was asked to lie on the examination couch and expose the abdomen from the xiphisternum to the symphysis pubis. Ultrasound gel was generously applied over the abdomen as a complaint. The patient's abdomen was then scanned in sagittal, coronal and oblique planes, emphasising the right hypochondriac region. Gallstones on ultrasound were defined as echogenic structures casting posterior acoustic shadowing, demonstrated within the anechoic gallbladder luminal content. The number and sizes of the gallstones were measured. The presence or absence of cholecystitis (thickened gallbladder wall >3mm) will also be noted. The applied gel was cleaned with tissue paper, and the patient was asked to dress properly and sit up. The sonographic findings were explained to the patient before discharge to the appropriate clinic.
Data collected was collated and imputed into the Statistical Package for Social Sciences Software for analysis.

2. 5. Sample size determination

The minimum size of the sample was calculated using the Kish Leslie equation suitable for a cross-sectional study (Wiegand, 1968).

$$n = Z^2 x\ p\ (\ 1 - p\ )/d^2 \qquad (1)$$

Where:

n = Minimum sample size.

z = standard error of the mean which corresponds to 95% confidence level (standard value of 1.96).

p = The prevalence is unknown for the target population; we assumed a 50% prevalence to obtain the maximum sample size.
d = margin of error at 5% (standard value of 0.05).
n= 1.96^2 x 0.5 (1-0.5) / $(0.05)^2$= 385 participants.

2. 6. Data analysis

Continuous variables were presented using mean and standard deviation (median and interquartile range). Categorical data will be analyzed using proportions. Charts and tables will be used to demonstrate the frequency distribution of the variables. Comparative analysis of numerical and categorical variables was done using the independent t-test and Chi-Square (or Fisher's test), respectively. Reporting of data obtained from this study will follow the STROBE guideline. Statistical significance will be set at a p-value of <0.05. IBM SPSS Version 25.0 will be used to analyze all data obtained from the study.

2. 7. Ethical approval

The UDUTH hospital research and ethics committee issued and applied ethical clearance. All patients were granted informed consent. Confidentiality of patient information was ensured.

3. Results

3. 1. Patient Demographics

There were 1465 who had abdominal ultrasounds in the period under review; however, 1456 were selected based on the inclusion criteria and thus participated in the study. The majority were females (sixty-nine per cent). The average age was 38.3±15 years, and forty-nine per cent were above 40 years. The majority had a body mass index (BMI) within standard reference. Table 1 summarizes the patient's demographics.

Table 1. Patients' demographics

Variable	Number	Percentage
Age Groups		
<20	266	18.26923
20-40	480	32.96703
>40	710	48.76374
Sex		
Male	447	30.70055
Female	1009	69.29945
BMI		
<18.5	230	15.7967
18.5-24.9	630	43.26923
25-29-9	511	35.09615
≥30	85	5.837912
Family History		
Yes	25	1.717033
No	1431	98.28297
Diabetes		
Yes	148	10.16484
No	1308	89.83516
Parity (Females Alone)		
0	280	27.75025
1--5	520	51.53617
>5	209	20.71358

3. 2. Prevalence of Gallstones

The number of patients with cholelithiasis was 52, giving a prevalence of 3.57%. Among these patients, 32 had gallstones without evidence of gallbladder inflammation, and 10 had sludge. Table 2 summarizes the prevalence of cholelithiasis in the cohort of patients.

Table 2. Prevalence of Cholelithiasis

Finding	Frequency (N)	Prevalence %
Normal	1404	96.42857
Gall Stone	32	2.197802
Gall Bladder Sludge	10	0.686813
Calculous Cholecystitis	10	0.686813

3. 3. Analysis of Prevalence among different Demographic Cohorts

Prevalence among females (4.5%) was significantly higher than that among males, 1.6% (p=0.001). Similarly, the prevalence among overweight (6.5%) and obese (8.2%) patients was statistically significantly higher than in standard (1.6%) and underweight patients (0.9%). The prevalence was observed to rise with increasing age, higher in diabetic patients and those with a family history of gallstones; however, these observations were not significant. Table 3 summarizes the univariate analysis of prevalence and the demographic variables.

Table 3. Univariate analysis of prevalence and the demographic variables

Variable	Frequency (N)	Number With Cholelithiasis	Prevalence Of Cholelithiasis	Or	P Value
Sex					
Female	447	45	4.459861	14.51103	**0.001**
Male	1009	7	1.565996		
Bmi					
<18.5	230	2	0.869565		
18.5-24.9	630	10	1.587302	4.809843	**0.04**
25-29-9	511	33	6.457926		
≥30	85	7	8.235294		
Family History					
Yes	25	2	8	2.2896	0.61
No	1431	50	3.49406		
Diabetes					
Yes	148	8	5.405405	1.60688	0.82
No	1308	44	3.363914		
Parity (Females Alone)					
0	280	11	3.928571		
1--5	520	24	4.615385	1.18718	0.78
>5	209	10	4.784689		
Age Groups					
<20	266	3	1.12782		
20-40	480	14	2.916667		
>40	710	35	4.929577		
Age Groups					
≤40	746	17	2.27882	2.163215	0.58
>40	710	35	4.929577		

4. Discussion

The literature is replete with reports of marked geographic variation in the prevalence of gallstones. Gallstone is one of the non-communicable diseases with a high prevalence in high-income countries. It is thought to be uncommon in low and middle-income countries where the population traditionally consumes a cereal-based diet (Schwesinger et al., 1999). Epidemiologic ultrasound studies demonstrate a difference in prevalence based on racial background, with 10-15% seen in adult Europeans while 3-5% reported among African and Asian populations (Kratzer et al., 1999). Similarly, in the US, the racial and gender differences in prevalence were reported, with 5% seen among non-Hispanic Black men, while prevalence was as high as 27% among Mexican-American women (Everhart et al., 1999). Gallstone disease has been described in epidemic proportions among the American Indians, more so among the American Pima Indians, where the prevalence among adult females was reported to be 73% (Sampliner et al., 1970). The reported prevalence in the Male Pima Indians was 30%, while other Female American Indians were 64% (Everhart et al., 2002). In the index cohort study of native black patients in Sokoto, 1456 patients (n = 1009 women, 69.3%; 447 men, 30.7%) were prospectively evaluated, and the study showed that cholelithiasis may still be a relatively rare occurrence, with only 3.6% of the population having the disease. These findings are consistent with reported figures from most studies done among native African populations. The prevalence of cholelithiasis was reported to be 2.1% in Ibadan (Nigeria) (Sampliner et al., 1970), 4% in Tunisia (Safer et al., 2000), 5.2% in Sudan (Bagi Abdel et al., 1991), 5.9% in Ghana and 6.0% in South Africa (Walker et al., 1989). The observed low prevalence rate of cholelithiasis in this study and reported from previous studies in African populations is likely a combination of nature and nurture, i.e., genetic, dietary and other environmental factors thought to discourage the formation of stones in the biliary tree. There is a consensus in the literature that advancing age is a significant risk factor for gallstones, increasing 4-10 times with age (Stinton & Shaffer, 2012). Older individuals have a longer duration of exposure to the adverse effects of the causative environmental factors and thus may account for the increased relative risk (Njeze, 2013). Our study revealed an increasing prevalence of ageing; however, a univariate analysis of patients under 40 years and those above 40 did not show a statistically significant association between age and the prevalence of gallstones (p=0.58). This finding is consistent with previous studies worldwide where the prevalence of gallstones increases with ageing (Stinton & Shaffer, 2012). Population dynamics could explain our cohort's lack of statistical significance, where life expectancy is short. Different workers have proposed theories to explain the etiopathogenesis of the increasing prevalence of gallstones with age. Bertolotti propounded that the increasing prevalence resulted from increased biliary saturation with age, resulting from a decline in the activity of cholesterol 7α hydroxylase, a known rate-limiting enzyme in bile acid synthesis (Bertolotti et al., 1993). The activity of intestinal bacteria-derived 7α dihydroxylation increases with age with resultant increased production of deoxycholic acid in bile and thus increased lithogenesis with age (Einarsson et al., 1985). Gender was an important risk factor for gallstones in our study population, with females having a higher odds of developing cholelithiasis (p=0.001). This is consistent with reports in the majority of studies found in the literature (Kratzer et al., 1999). It is noteworthy that worldwide, irrespective of the stone prevalence rate, women are reported to have at least twice the prevalence of gallstones in men. This is true to a lesser extent in the postmenopausal years; however, the observed gender preponderance narrows with advancing age, but the sex difference narrows with increasing age (Njeze, 2013). The effect of female hormones, endogenous or exogenous, on bile acid synthesis, and gallbladder wall motility are thought to be responsible for the preponderance in the female gender (Njeze, 2013). A notable deviation from this general consensus in literature is a Taiwan study where no statistical significance was found between the prevalence of cholelithiasis and gender (Chen et al., 2006). The more commonly found pigment stones in that population have been offered as a possible explanation for this exception. As stated above, cholesterol stones preponderance in the female gender is driven by the effects of the female hormones which is not true for pigment stones, thus the positive effect of these hormones was obviously blurred by the preponderance of pigment stones in the Taiwan study (Chen et al., 2006; Kratzer et al., 1999). The index study demonstrated increased odds of

cholelithiasis with increasing parity; however, on univariate analysis, this was not statistically significant. Most of the previous authors have demonstrated a positive association between the prevalence of gallstones and parity consistent with the findings in our study (Eze et al., 2017; Gyedu et al., 2015). In contrast, there are some studies from Europe that could not verify these findings (Caroli-Bosc et al., 1999; Walcher et al., 2005). A plausible explanation for these observed differences could be thought to be due to differences in fertility status among women in the African and European population. In the later studies, most women have 2-3 children with higher interpregnancy intervals. However, in a recent meta-analysis and systematic review by Salari et al., they concluded that there is a positive relationship between pregnancy and gallstones (Salari et al., 2023), stating the effect of estrogen on cholesterol saturation and the effect of progesterone on gallbladder contractility as possible causes. Obesity is a key risk factor for developing gallstones, irrespective of gender (Eze et al., 2017; Gyedu et al., 2015; Stinton & Shaffer, 2012). Our findings were consistent with this observation, with a significant odd among patients with a BMI less than 25 compared to those with a BMI of at least 25 (p=0.04). On the contrary, few studies have found no association between BMI and gallstones (Gyedu et al., 2015) or even reduced odds of cholelithiasis among individuals with higher BMI (Salinas et al., 2004). Diabetes mellitus is thought to be positively associated with increased lithogenesis, resulting in increased cholesterol saturation in bile (Ratheesh et al., 2023). In our study, diabetes mellitus was associated with non-significant decreased odds of cholelithiasis on univariate analysis. Patients who admitted to being diabetic had 1.6 odds of having gallstones; however, this was not statistically significant. Not conducting a blood glucose test on our population could have missed patients with undiagnosed diabetes mellitus. This could have affected our results and may be responsible for the non-significance of the finding. Our study findings suggest that those with a family history had increased odds of developing gallstones; however, this was not statistically significant (p=0.61). The literature is dotted with reports from similar studies that support our findings (Attili et al., 2005; Gyedu et al., 2015). Attili et al., in their study on this subject, found that the strongest association was found in first-degree relatives, more so with mothers. There was no association between the prevalence of gallstones in the index case and his/her brother or spouse. The findings of a relationship between family histories noted in this study must be interpreted cautiously. Further studies with a more elaborate screening of relatives of gallstone patients are required to elucidate this relationship.

5. Conclusion

Cholelithiasis still remains a relatively uncommon condition in our setting; however, it is higher than reports from old literature. Female gender and obesity significantly increased the odds of developing cholelithiasis. Other risk factors for developing cholelithiasis in Sokoto included ageing, diabetes mellitus, family history and multiparity. Eating healthy and exercising physically to prevent obesity is key to preventing it.

Data Availability

The data for the research is stored in completed proformas and on the personal computer of the corresponding author. The data is available on request.

Author Contributions

"**Conceptualization**, Umar Muktar.; **Methodology,** Umar Muktar and Farouk Kabir Umar.; **software**, Umar Muktar.; validation, Umar Muktar and Farouk Kabir Umar.; **formal analysis**, Umar Muktar.; investigation, Umar Muktar and Farouk Kabir Umar.; **resources**, Umar Muktar and Farouk Kabir Umar.; **data curation**, Umar Muktar.; **writing—original draft preparation**, Umar Muktar.; **writing—review and editing**, Umar Muktar.; **visualization**, Umar Muktar.; **supervision**, Umar

Muktar.; **project administration**, Umar Muktar and Farouk Kabir Umar.; **funding acquisition**, Umar Muktar and Farouk Kabir Umar. All authors have read and agreed to the published version of the manuscript.

Conflicts of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Review of Cooperation between Visible Light Communication Networks and 5th Generation Cellular Networks

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ABSTRACT

Ultra-fast wireless networks, such as Visible Light Communication (VLC) and Cellular 5th Generation (5G), are gaining more attention because of increased demand for higher speeds. These technologies promise to provide a higher transmission rate at a reasonable cost. This paper investigates the collaboration of both technologies by reviewing three papers in the field. Reviewing is done by contrasting several aspects of the technologies, such as their architecture, technology, and even used bandwidth. Findings showed that it is difficult to precisely decide whether both technologies will collaborate or not due to their structural differences and the target applications of each technology.

Keywords: VLC, 5G, Cellular, wireless, Wi-Fi

1. Introduction

The primary objective of the research is to determine if these technologies will compete in the wireless industry or collaborate to enhance service for wireless users (Ahson & Ilyas, 2018). Although the answer to this issue may be intricate and contingent upon multiple aspects, we will concentrate on pinpointing the primary elements that influence the compatibility or disparities between the two technologies. This will yield two advantages: executing the investigation and conserving time. Since the introduction of VLC as a viable wireless technology in 2011, capable of transmitting high-speed data streams primarily via Line Of Sight (LOS), attempts have been made to adapt this technology to meet contemporary network requirements. Standard variants were adopted in 2015, 2017, and 2019. This enhanced scalability permitted more channels, significantly augmenting reliability (Andrews et al., 2007). The advancements of VLC in facilitating extremely high speeds across short distances have rendered it a prospective future technology, garnering interest from numerous investors in the communications sector for specific applications. Examples include hospitals and aircraft. Furthermore, the technology guarantees enhanced user service efficiency as a last-mile solution. This is attributable not only to its incredible speed but also to its cost-effective installation. Moreover, numerous contemporary wireless applications might leverage this technology to enhance their services and augment efficiency. Specific applications have efficient, high-speed infrastructures that link WiFi hotspots and provide rapid internet access to urban regions. Furthermore, VLC has incorporated other potential uses, including rapid data transmission (such as audio and video) and providing high-speed internet access to computer users (Asif, 2018). The latter may include conventional laptop users and numerous applications, such as delivering Audio/Video over the Internet and Voice over IP.

Table 1. Visible Light Communication technology standards (Asif, 2018)

	802.15.7	**802.15.13**	**802.11bb**
Published	April 2019	August 2023	June 2023
Technology	Specifies PHY and MAC for impulse radio ultra-wideband (UWB) ad hoc connectivity	Introduces a novel MAC and two PHY layers that provide excellent dependability, minimal latency, and reduced power consumption.	Specifies the methodology for reapplying the 802.11 MAC and OFDM-based PHYs in optical optically
Wavelength	10 nm to10,000 nm	10 nm to 10,000 nm	800 to 1,000 nm
Data rate	12 kbps to 96 Mbps	12 kbps to 10Gbps	10 Mbps to 9.6 Gbps
Transmission scheme	Single carrier only	Single carrier, 256 OFDM or 2048 OFDM	Single carrier, 256 scalable or OFDM with 128, 512, 1024 or 2048 sub-carriers
Uses	Indoor localization and vehicular networking	Industrial and medical applications	Residential applications such as WI-FI

On the other hand, 5G technology has been present in the market in recent years. The aim of 5G wireless technology is to provide a more consistent user experience, increased multi-Gbps peak data rates, ultra-low latency, higher reliability, significant network capacity, and improved accessibility for a larger user base (Forge & Bohlin, 2008). Emerging sectors are interconnected, and enhanced performance and efficiency empower novel user experiences. This research will assess several pertinent resources,

focusing primarily on two categories of these networks. Numerous methods exist to compare, contrast, or assess various technologies. For instance, one technology may exhibit a significant advantage over another in a specific domain, whereas in a different domain, both technologies may have equivalent prevalence. Initially, the research aimed to select certain subject areas that could successfully evaluate both technologies and facilitate predictions on their shared future. Additionally, to enhance the readability and comprehension of the research, each technology will be examined individually and thoroughly. Subsequently, an examination of the capacity of either to assume control or collaborate with the other. The final phase will summarize the data and incorporate realistic forecasts derived from the preceding processes.

2. Employed Methodology

Research design is governed by the principle of 'fitness for purpose.' The objective of the research is to ascertain the approach and design employed. Research is fundamentally an activity or process, and despite the multitude of research methodologies, specific generic qualities delineate its essence. (*3GPP News*, 17 decembre 2018). Various research methodologies were employed to gather information for the study. This document outlines the methods used for data collection and analysis. Two research methodologies exist: deductive and inductive. The inductive approach involves data collection, analysis, and theory generation. Conversely, the deductive approach involves a theory and a defined research topic or hypothesis. Data is subsequently gathered and employed to evaluate the theory.

2. 1. Deductive Approach

It is a technique of theory testing that commences with a recognized theory or generalization and aims to determine its applicability to particular circumstances (*3G W-CDMA and CDMA2000 Infrastructure Markets Up.*, 2017). The deductive technique often begins with a review of the theory, followed by data collection, from which conclusions are subsequently drawn.

2. 2. Inductive Approach

This method can be regarded as a manifestation of the deductive approach. This methodology transitions from empirical evidence to theoretical frameworks. Observations serve as the foundation for this methodology, aiming to build theory rather than evaluate it. An inductive methodology is employed in this research, progressing from broad principles to specific details. The wireless networks possess more theoretical and identifiable variables, making their analysis more specific. Research planning assists the researcher in identifying necessary activities, organizing sub-tasks sequentially, and calculating the time required to complete the research (*CDG : Technology : 5g – VLC* 2019). The research plan, illustrated in Fig. 1, is a reference for determining the timing and methodology of subsequent research steps. This streamlines the study duties and facilitates the seamless execution of subsequent phases. The data is collected by choosing a set of papers in the scope and then by applying critical thinking to develop results.

Three papers were selected in this study and discussed in more detail in the following sections.

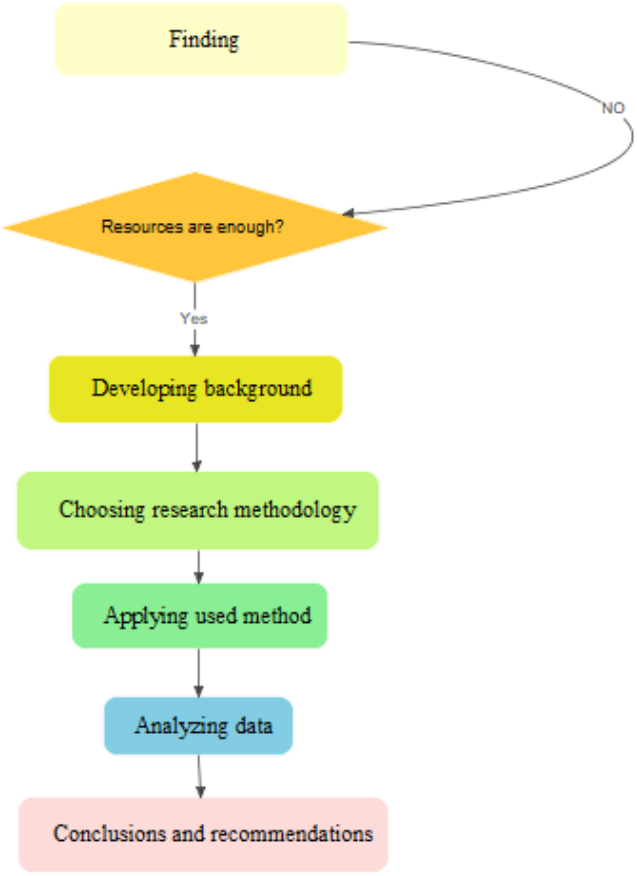

Figure 1. Research Plan

3. Results and Discussion

The mentioned papers are utilized as case studies. These case studies were carefully selected to provide the best evaluation of both technologies. These papers are:

- Facilitating 5G indoor services for home settings with VLC technology.
- Implementation of VLC in 5G Networks: Frameworks and Essential Technologies.
- Visible Light Communications in 5G Wireless Networking Systems: Transitioning from Fixed to Mobile Communications.

3. 1. Enabling 5G indoor services for residential environment using VLC technology

With the rise of 5G-based applications that require higher levels of connectivity and (QoS). The IEEE established the 802.11bb "Light Communications (LC) for Wireless Local Area Networking" standardization group as part of current efforts to improve VLC standards (Dawson, 2005). This study uses VLC to examine the network needs of 5G indoor services, including high-definition (HD) video and virtual reality (VR), for home settings. Using Reproducing Kernel Hilbert Space (RKHS) techniques, a parameter-free hyper-mitigation strategy is presented for such common VLC cases. This includes additional impairments like light-emitting diode (LED) nonlinearity and faulty channel feedback.

Utilizing an adaptive VLC transmission method founded on direct current-biased optical orthogonal frequency division multiplexing (DCO-OFDM) to attain the intended outcomes. This employs adaptive BER-based modulation-order switching and precomputed bit error rate (BER) expressions as RKHS-based detection methodologies. The adaptive transmission method demonstrates significantly improved error rates and enhanced performance, as Channel Impulse Response (CIR) simulations

indicate. It is a promising choice for high data rate VLC-based 5G indoor applications. A site-specific channel simulator (Murawwat & Ahmed, 2008) is introduced to develop channel models for high data rate 5G indoor communication systems employing an advanced ray-tracing technique. Moreover, the study addresses the advancement of 5G-based applications necessitating high quality of service and extensive connection demands. There are three primary steps in the channel modelling approach. Initially, a 3D platform is developed that accurately specifies the indoor environment's dimensions, shape, and reflection characteristics. Subsequently, the physical layer (PHY) strategies that can be considered for IEEE 802.11bb (3G W-CDMA and CDMA2000 Infrastructure Markets Up., 2017) are thoroughly discussed, taking into account the channel models described in the previous section. To reduce ISI for the frequency-selective VLC channels, OFDM was suggested in (NGUYEN-VUONG Quoc-Thinh et al., 2016) since the standards cover the desired peak data speeds of up to 10 Gbps. Nonetheless, it should be stated that specific adjustments are needed to establish optical OFDM to guarantee that the signal is genuine and non-negative. To fulfil the high data rate needs of 5G indoor applications like VR and HD films, an adaptive data transmission technique for VLC systems was developed in this study. To fully integrate the user model and artificial objects into the channel model and meet the illumination requirements.

3. 2. Applying VLC in 5G Networks: Architectures and Key Technologies

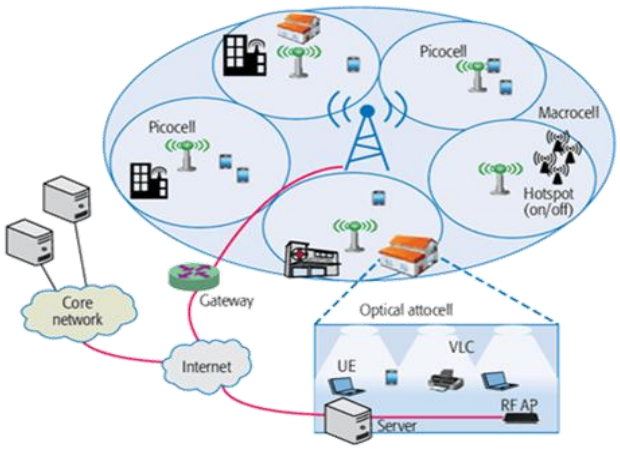

Figure 2. A multi-layer 5G cellular architecture (Feng et al., 2016).

In short-range communication scenarios for forthcoming 5G networks, visible light communication has lately garnered significant interest as an adjunct technology to millimeter-wave communication. To satisfy the stringent 5G system requirements for substantial capacity, elevated data rates, enhanced spectrum efficiency, superior energy efficiency, minimal battery consumption, and reduced latency, VLC offers several significant advantages. Numerous gigabit-per-second data rates, reduced energy usage, little installation expenses, and ample license-free spectrum. This research introduces a heterogeneous multi-layer 5G cellular architecture that delineates the control plane from the user plane. This architecture comprises three layers, each addressing specific coverage and communication requirements: the Macro-cell layer, functioning below 3 GHz; the Pico-cell layer, operating within the millimeter wave spectrum; and the optical Atto-cell layer, utilizing the visible spectrum. We also examine potential techniques for downlink communications in an optical Atto-cell, backhaul connectivity, and uplink communications. The text also addresses several critical technologies utilized in VLC downlink communications, including modulation, multiple access, and error control systems.

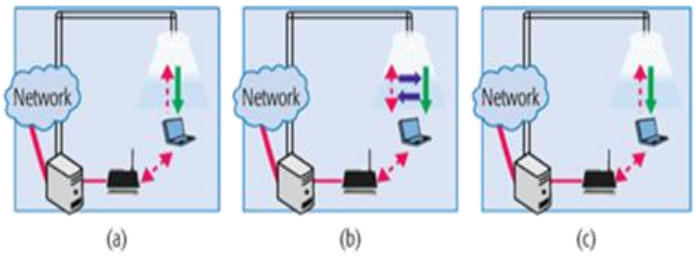

Figure 3. Downlink methodologies for an optical Attocell: a) VLC-downlink; b) mm-Wave backup downlink; and c) mm-Wave parallel downlink (Feng et al., 2016).

3. 3. Visible Light Communications for 5G Wireless Networking Systems: From Fixed to Mobile Communications

Visible light communication has garnered interest as a potential access method for 5G wireless communications. Both VLC's extensive bandwidth and energy efficiency contribute to this methodology. This study aims to provide a comprehensive review of the latest advancements in VLC research applicable to 5G wireless communication systems (Feng et al., 2016). This paper elucidates the advantages and disadvantages of VLC in comparison to RF-based communications, specifically concerning spectrum, spatial reuse, security, and energy efficiency. The various illumination sources proposed for VLC systems are also analyzed. The literature on VLC networking is divided into two categories: mobile and fixed VLC communications. The balance between spectrum and energy efficiency is considered. Consequently, bidirectional, fully networked wireless communication technology of VLC can satisfy the high-speed requirements of the future. VLC has the potential to utilize almost 300 THz of the visible light spectrum, which is nearly 139,000 times greater than the 2.16 GHz wireless gigabit channel of the IEEE 802.11ad standard. It has been shown that using orthogonal frequency division multiplexing, a single light-emitting diode (LED) may achieve a data rate of 10 Gbit/s. The optical OFDMA method is employed for multiple access in each VLC cell. The Wi-Fi Access Point is expected to comply with the IEEE 802.11ad standard for the Wi-Fi system. Each station STA is capable of communicating with the AP (uplink and downlink) or with other STAs (direct link) in compliance with this standard.

4. Conclusion

This research examined VLC and 5G to see whether these competing technologies will interact. The factors influencing the competency and collaboration of both technologies are significantly more complex. For example, a comparison of the technical architectures of both technologies is unfeasible for two reasons: VLC is constructed on the IP protocol and adheres to the OSI model, while 5G systems do not. Furthermore, even if a universal OSI model were to delineate the 5G systems, it would pertain solely to that specific system utilizing VLC, rather than encompassing all systems. The first case study examined a collaborative network architecture for VLC integrated with 5G technology. It was presumed that 5G performance would not be equivalent to VLC. This notion is partially valid, even though 5G remains in its nascent stage. The findings of this case study provide greater insights into the current state of 5G technology. The second topic pertains to the utilization of VLC in high-velocity web applications. This case primarily investigated the performance difficulties of VLC using many simulations. The results of the simulations were satisfactory, albeit several restrictions. Nevertheless, the example did not evaluate the performance of VLC; so, the simulations were regarded as general VLC simulations. The final study assesses the market of Information and Communications Technologies (ICTs). These technologies, particularly wireless networks, significantly contributed to economic progress. Furthermore, the model exemplifies one of the most prosperous sectors in wireless technology. Numerous wireless technologies now exist, with additional innovations forthcoming. The future is likely to depend significantly on wireless networks, potentially leading to the obsolescence of current wired systems. The multitude of existing and emerging wireless

technologies complicates the prediction of which will endure. The reasons influencing the proliferation or cessation of these technologies are numerous, and the duration and extent of the research were insufficient to assess all of them.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Data Availability

No data was used for the research described in the article.

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Experimental and computational analysis of the corrosion inhibition performance of 2-[2-(hydroxy benzylidene)amino]benzoic acid Schiff base on mild steel in 1M hydrochloric acid

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ABSTRACT

The corrosion inhibition efficiency of 2-[2-(hydroxybenzylidene)amino] benzoic acid Schiff base on mild steel in an acidic medium was evaluated using gravimetric analysis and potentiodynamic polarisation (PDP) techniques. Characterization via FTIR and SEM confirmed the formation of a protective inhibitor layer on the metal surface. The inhibitor's efficiency increased with concentration, reaching 89.98% at 0.4 mM, but decreased with temperature, dropping to 51.54% at 333 K. PDP analysis classified the Schiff base as a mixed-type inhibitor, and the adsorption followed the Langmuir isotherm. A negative value of ΔG_{ads} (-34.04 kJ/mol) indicates strong and spontaneous adsorption. DFT calculations highlighted strong electron density around the C=N and hydroxyl groups, reinforcing the physisorption mechanism. Overall, experimental and computational results validated the Schiff base as an effective corrosion inhibitor for mild steel in 1 M HCl, demonstrating strong adsorption and excellent protective properties.

Keywords: Corrosion, Schiff base, PDP, SEM, DFT, and MDS.

1. Introduction

Corrosion poses a significant challenge for various industries, particularly for the common use of corrosion-sensitive mild steel under acid environments. Mild steel corrosion under hydrochloric acid solution is a significant challenge for petrochemical, building, and manufacturing industries where acid cleaning, pickling, and descaling operations are common. The corrosion inhibitors were studied extensively to address this challenge, and Schiff bases were identified as one promising organic inhibitor type (Chahul et al., 2015; Muhammad et al., 2024). Schiff bases, characterised by the azomethine (–C=N–), often exhibit limited solubility in aqueous acidic environments due to their molecular structure. However, the presence of functional groups such as hydroxyl (–OH) and carboxyl (–COOH) in 2-[2-(hydroxybenzylidene)amino]benzoic acid may enhance its solubility in acidic media through hydrogen bonding and protonation mechanisms. The solubility trend for structurally similar benzoic acid derivatives has also been extensively studied using various solvents, providing the basis for the understanding of the trend for this Schiff base (Kaabi et al., 2021; Ma et al., 2021). They are synthesized through the carbonyl compounds' condensation reaction with primary amines. They work by adsorbing onto the surface of the metal and forming protective layers over the surface, shielding against corrosive interactions. Having heteroatoms such as nitrogen, oxygen, and sulfur in their structure increases their electron-donating capacity, thus forming strong interactions against the surface of the metal (Ma'rufah et al., 2021). While the corrosion inhibition efficiency can be assessed by experimentations—i.e., chemical, electrochemical, and surface morphology analysis of the metals—a greater understanding about the mode of interaction between inhibitor molecules and the surface of the metal can be attained through the use of the computational calculations (Bouhraoua et al., 2023; Khamaysa et al., 2021; Khamaysa et al., 2020). DFT (density functional theory) modelling of inhibitor–metal interactions has emerged from recent studies as being very useful for the corrosion inhibition processes prediction. Considering the above points, this work investigates the corrosion inhibition efficiency and adsorptivity characteristics of the Schiff base 2-[2-(hydroxybenzylidene)amino] benzoic acid for the corrosion of mild steel under the impact of 1M HCl solution. Inhibition efficiency against corrosion was evaluated by weight loss measurements and potentiodynamic polarization analysis. Besides this, the surface morphology of the steel surface after corrosion exposure has also been studied by scanning electron microscopy (SEM). To complement the experiment data, detailed computer calculations were performed for the investigation of electronic and chemical reactivity features of the investigated inhibitors and their adsorptivity towards the steel surface. Results will yield valuable insights into its mode of inhibition, absorptivity features, and suitability towards industrial corrosion inhibition.

2. Methods and material

2. 1. Schiff base synthesis

Drop by drop, while stirring, 2-hydroxybenzaldehyde (6.08ml, 7.29mmol) was added to 50ml of hot absolute ethanol after 2-aminobenzoic acid (10.00g, 7.29 mmol) had been dissolved in 50 ml of hot ethanol. After refluxing for two hours, an orange precipitate formed overnight. The resulting solution was filtered, cleaned with cold ethanol, and allowed to air dry. The product was dried in a desiccator after being recrystallised from heated ethanol (I.A et al., 2020).

2. 2. Specimen preparation

Mild steel was the specimen (coupons) used in this study. C 0.21%, Si 0.38%, P 0.1%, S 0.04%, Mn 0.05%, and Al 0.01% make up the mild steel's chemical composition, with Fe making up the remaining portion. The mild steel was cut into dimensions of 4 cm by 2.5 cm by 0.1 cm. It underwent chemical treatments, including acetone drying and absolute ethanol degreasing (Selatnia et al., 2018). Before the experiment, the coupons were placed in desiccators. All the chemicals used here are analytical grades .

2. 3. Weight loss measurement

The experiment involved weighing coupons, submerging them in a 1M HCl solution with or without inhibitor concentrations, covering them with aluminum foil, and placing them in a water bath at 30°C for various time periods. The weight loss, corrosion rate, inhibition efficiency, and surface coverage were determined using equations (Benahmed et al., 2020):

$$\text{Weight loss } (\Delta W) = W_2 - W_1 \quad (1)$$

$$C_R \text{ (mg/cm}^2\text{h)} = \frac{\Delta W(mg)}{A(sq.cm) \times T(h)} \quad (2)$$

$$\text{I.E \%} = \left(1 - \frac{W1}{W2}\right) \times 100 \quad (3)$$

$$\Theta = 1 - \frac{W1}{W2} \quad (4)$$

Where C_R is the corrosion rate, A is the mild steel coupon's area (cm^2), I.E. is the inhibition efficiency, t is the immersion duration (in hours), Θ is the surface coverage, and W1 and W2 are the weight losses for the mild steel coupon with and without inhibitor, respectively (Jimoh & Musa, 2024).

2. 4. Analyses of Potentiodynamic Polarisation (PDP)

The study investigates the corrosion rate of mild steel coupons by immersing them in a 1M HCl solution containing inhibitors at different concentrations. The coupons were analyzed using Autolab potentiostat and NOVA software, with the results depicted in a graph of potential versus current density. The inhibitory efficiency was computed using Equation 5, which includes the corrosion potential and current density. The experiment aimed to understand the effects of different inhibitors on corrosion.

$$\%I = \frac{I\,corr\,(0) - Icorr(inh)}{Icorr(0)} \times 100 \quad (5)$$

Where $I_{corr}(inh)$ and $I_{corr}(0)$ are the corrosion current densities with and without the inhibitor (Khan et al., 2017).

2. 5. Fourier Transform Infra-Red Spectrophotometry (FT-IR)

FT-IR spectra were used to analyse the corrosion products and Schiff base. For four days, coupons were submerged in HCl to form an adsorbed layer. They were scanned for analysis after drying. The surface morphologies of mild steel were investigated using SEM. Prior to examination, the samples were dried after being immersed in HCl for a whole day (Shkoor et al., 2023).

2. 6. Research on computations

Quantum chemistry simulations were conducted using Density Functional Theory (DFT) Gaussian 09 software, optimizing the inhibitor structure in the gas phase. The ionisation potential and electron affinity were calculated using Koopman's theorem.

$$I = -E_{HOMO} \quad (6)$$

$$A = -E_{LUMO} \quad (7)$$

The electronegativity (ƛ), softness (σ) and hardness (η) were determined using **equations (8 – 10)** respectively.

$$ƛ = \frac{I+A}{2} \quad (8)$$

$$\eta = \frac{I-A}{2} \quad (9)$$

$$\sigma = \eta^{-} \quad (10)$$

The fractional number of transferred electrons (ΔN) was determined using equation 11.

$$\Delta N = \frac{\lambda Fe - \lambda inh}{2(\eta Fe + \eta inh)} \quad (11)$$

For iron (λFe), the electronegativity value was 7ev, and as per equation 12, the hardness of iron (ηFe) was 0eV.

$$\Delta N = \frac{7 - \lambda inh}{2(\eta inh)} \quad (12)$$

The difference between the electrophilic and nucleophilic Fukui functions is what is defined as the second Fukui function, or dual description, in equation (13- 15). Where f^2 (r) is less than zero, site K promotes an electrophilic attack. This implies that f^2 (r) serves as a selectivity index for attacks that are either nucleophilic or electrophilic .

$$F(k)^+(\text{nucleophilic attack}) = qk(N+1) - qk(N) \quad (13)$$

$$F(k)^-(\text{electrophilic attack}) = qk(N - qk(N-1) \quad (14)$$

$$F(r) = f^+ - f^- = f^2 \text{ (Fukui function)} \quad (15)$$

2. 7. Molecular dynamics simulation

The study used COMPASS FORCEFIELD and smart ALGORITH to simulate the surface of iron. The fractional depth of 3.0 was used to separate Fe crystals along the Fe (111) plane. The iron surface was developed into a 10 x 10 supercell to minimize edge effects. The temperature was set at 350K to quench molecules on the surface. Different interactions were produced, and binding energy between inhibitors and the Fe (111) surface was calculated (Awe et al., 2015)

$$\text{Binding energy} = E_{total} - (E_{inhibitor} + E_{Fe\ surface}) \quad (16)$$

3. Result and discussion

3. 1. Effect of Time on Corrosion

Experimental analysis was used to study the effect of time on the corrosion control of mild steel using the Schiff base. The study was carried out at a constant temperature (303K) at varying concentrations of the Schiff base (0.1 to 0.4mM), and time (1 h to 4 h).

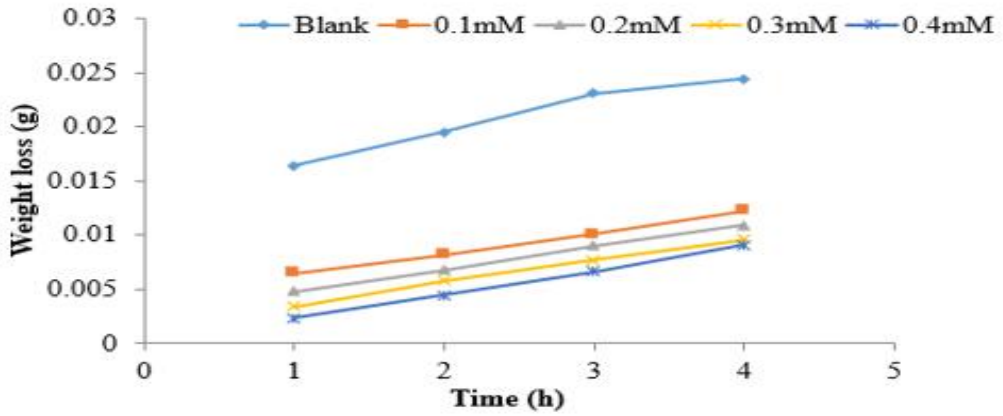


Figure 1. Variation of Weight loss (g) with time (h) for the corrosion of mild steel in 1.0M HCl in the absence and presence of different concentration of Schiff base at 303K

Weight loss rose as immersion duration increased, as seen in the **Figures 1**. According to the result, mild steel loses less weight when an inhibitor is present than when it is not. The reduction in weight loss was caused by the Schiff base adsorption on the metal surface. Different researchers came up with similar conclusions (Ameh & Eddy, 2018; Husaini et al., 2018)

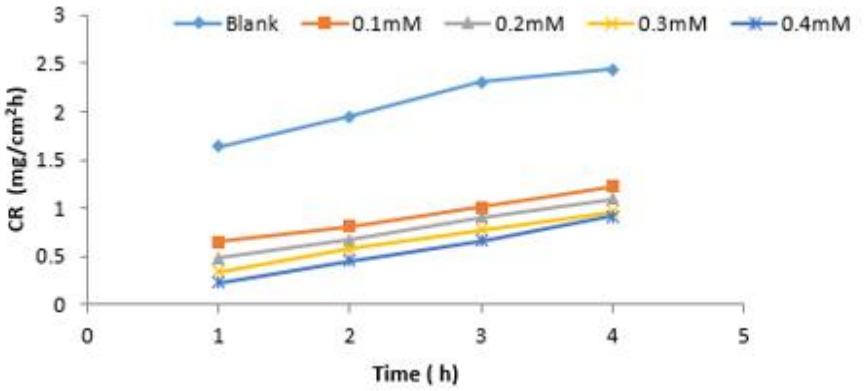


Figure 2. Effect of immersion time on the corrosion rates of mild steel in 1.0 M HCl in the absence and presence of Schiff base

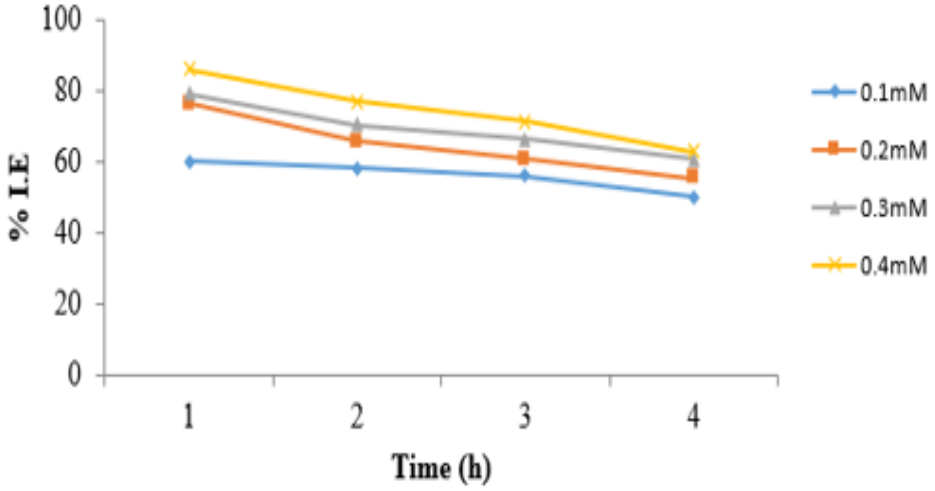


Figure 3. Effect of Immersion Time (h) on Corrosion Inhibition Efficiency (%IE) of mild steel in 1.0 M HCl in the presence of various concentrations of Schiff base

Figures 2 and **3** illustrate the corrosion rate and inhibition efficiency of mild steel in 1.0 M HCl 303K as a function of time in the presence of Schiff bases, respectively, using the weight loss technique. **Figure 2** makes it clear that as the inhibitor concentration increased, the mild steel coupons' corrosion rates in the presence of Schiff base reduced. In the meanwhile, **Figure 3** makes it evident that as immersion duration grew, inhibition efficiency declined. This outcome is consistent with what Musa et al. (2018), Chahul et al.,(2019), Sefiyyah & Magaji, (2023) reported (Chahul et al., 2019; Husaini et al., 2018; Minjibir & Ladan, 2023).

3. 2. Effect of Temperature

The effect of temperature on the weight loss of mild steel in the absence and presence of Schiff base in a 1M HCl solution is shown in **Figures 4.**

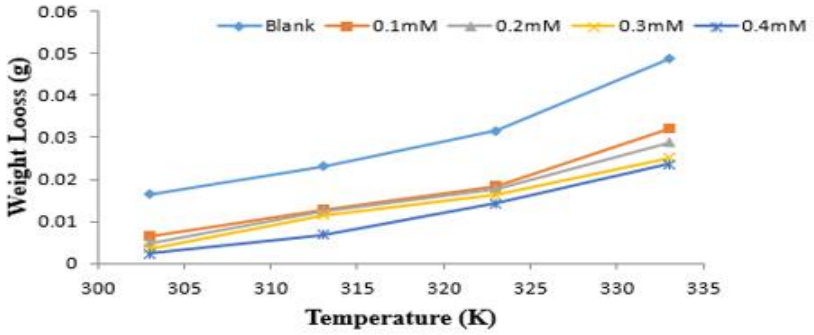


Figure 4. Variation of weight loss with temperature for the corrosion of mild steel in absence and presence of Schiff base in 1M HCL

Table 1. Weight loss, corrosion rate, surface coverage inhibition efficiency of various concentration of Schiff base in 1M HCl at varying temperature.

Temperature (K)	Concentration (mM)	ΔW (g)	CR (mg/cm²h)	Θ	% I.E
303	Blank	0.0164	1.64	-	-
	0.1	0.0065	0.65	0.6036	60.36
	0.2	0.0048	0.48	0.7073	70.73
	0.3	0.0034	0.34	0.7927	79.27
	0.4	0.0023	0.23	0.8998	89.98
313	Blank	0.0231	2.31	-	-
	0.1	0.0128	1.28	0.4459	44.59
	0.2	0.0125	1.25	0.4589	45.89
	0.3	0.0115	1.15	0.5022	50.22
	0.4	0.0068	0.68	0.7056	70.56
323	Blank	0.0315	3.15	-	-
	0.1	0.0184	1.84	0.4159	41.59
	0.2	0.0178	1.78	0.4349	43.49
	0.3	0.0162	1.62	0.4857	48.57
	0.4	0.0142	1.42	0.5492	54.92
333	Blank	0.0487	4.87	-	-
	0.1	0.0320	3.20	0.3429	34.29
	0.2	0.0288	2.88	0.4086	40.86
	0.3	0.0251	2.51	0.4846	48.46
	0.4	0.0236	2.36	0.5154	51.54

The kinetic energy of the reaction increased as temperature rose, accelerating corrosion. However, as the Schiff base concentration increased, the weight loss decreased. **Table 1** and **Figure 4** show that the corrosion rate increases as temperature rises, but inhibition effectiveness decreases. This suggests that the Schiff base slows mild steel dissolution, but the rate of

chemical reaction also increases, causing the surface to etch and desorb more quickly (Abbas et al., 2018; Ameh & Eddy, 2018; Eddy et al., 2015; Godwin-Nwakwasi et al., 2017).

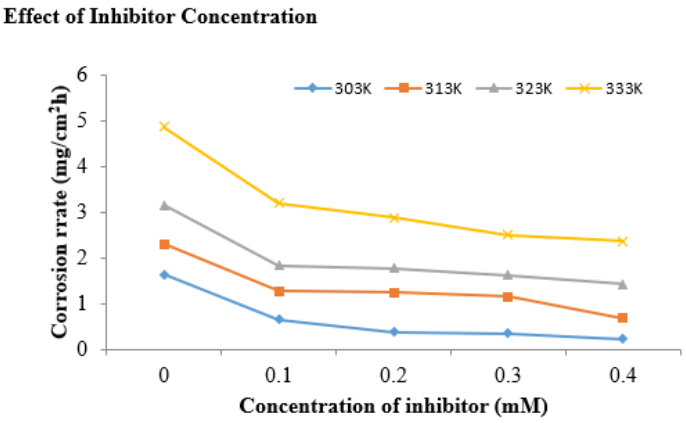


Figure 5. Variation of Corrosion Rate with Inhibitor Concentration of Schiff base for mild steel corrosion in HCl

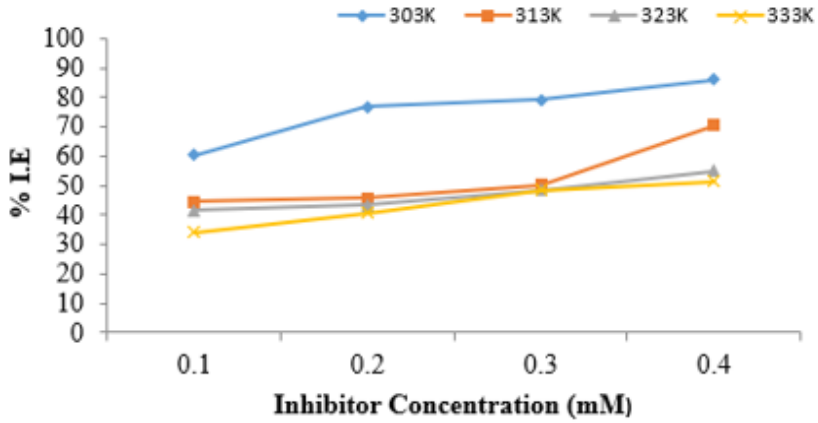


Figure 6. Variation of Inhibition Efficiency with Inhibitor Concentration of Schiff base for Mild steel Corrosion in HCl

The study demonstrates that inhibited systems have a lower corrosion rate than uninhibited ones in 1M HCl. The corrosion rate decreases with increasing inhibitor concentration as inhibitor molecules are adsorbed on the surface, creating a barrier that slows down the corrosion process. The inhibitor's effectiveness increases with concentration, as mild steel absorbs more of the inhibitor's molecules at higher concentrations. The adsorption isotherm, based on surface coverage, was used to understand the interaction between the inhibitor and the mild steel surface. The Langmuir adsorption isotherm was found to be the best fit for the data (Asmara et al., 2018; Chahul et al., 2015; Yaro et al., 2013).

$$\frac{Cinh}{\theta} = \frac{1}{Kads} + C_{inh} \qquad (17)$$

Where K_{ads} is the adsorption equilibrium constant, surface coverage (Θ) and Cinh is the concentration of inhibitor. A graph of $\frac{Cinh}{\theta}$ against Cinh was plotted as shown in **Figure 7.**

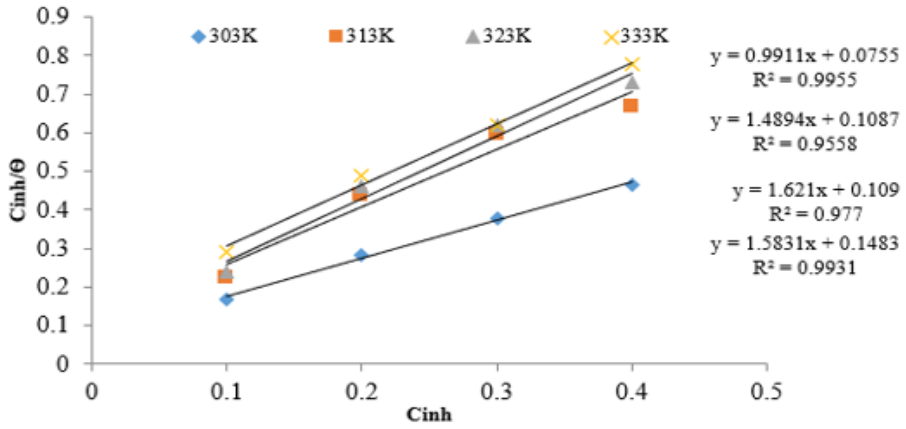


Figure 7. Langmuir adsorption plots for the corrosion of mild steel in IM HCl solution in the presence of the SB1 at different temperature

Table 2. Adsorption parameters for the adsorption of Schiff base on mild steel surface

Isotherm	Temperature (K)	Slope	K_{ads} x10^3	ΔG_{ads} (kJ/mol)	R^2 values
Langmuir	303	0.991	13.333	-34.045	0.995
	313	1.489	9.259	-34.222	0.955
	323	1.489	9.174	-35.291	0.977
	333	1.583	6.757	-35.537	0.993
Freundlich	303	0.254	1.086	-27.731	0.952
	313	0.281	0.794	-27.830	0.641
	323	0.191	0.625	-28.078	0.855
	333	0.303	0.684	-29.195	0.987
Temkin	303	0.183	1.017	-27.565	0.988
	313	0.156	0.763	-27.727	0.606
	323	0.090	0.608	-28.003	0.833
	333	0.127	0.630	-28.968	0.979

The Langmuir adsorption isotherm plots show that Schiff bases adsorb at temperatures between 30 and 60 degrees Celsius, with frequent sites at the metal/solution interface. The adsorption equilibrium constant (K_{ads}) decreases as temperature rises, suggesting stronger engagement between inhibitor molecules and mild steel. At 303 K, the adsorption equilibrium constant (K_{ads}) value is greater, suggesting Schiff base is more effective as an inhibitor (Aljibori et al., 2024; Koraee et al., 2019; Siaka et al., 2013).

3. 3. Free energy of Adsorption

Equations 18(a, b) relate the adsorption equilibrium constant (K_{ads}) to the adsorption free energy (ΔG_{ads}).

$$K_{ads} = \frac{1}{55}\exp\left(\frac{-\Delta Gads}{RT}\right) \quad (18a)$$

This can be written as:

$$\Delta G_{ads} = -RT \ln (55.5K_{ads}) \quad (18b)$$

The study investigates the adsorption of Schiff base on mild steel using a combination of chemisorption and physisorption modes. The adsorption rates at different temperatures were used to calculate the activation energy of mild steel coupon corrosion in 1.0 M HCl with and without Schiff base. The results show that inhibitor molecules adsorb spontaneously on the mild steel surface, while the Langmuir isotherm shows a combination of chemisorption and physisorption modes (Ameh et al., 2012; Olasehinde et al., 2012; Omotosho, 2016).

$$ln(CR) = A - \frac{Ea}{RT} \quad (19)$$

Where A is the Arrhenius pre-exponential factor, C_R is the rate of corrosion, T is the absolute temperature in Kelvin and R is the universal gas constant.

Table 3. Energy parameters for the dissolution of Mild Steel in IMCI in the absence and presence of difference concentration of Schiff base

Concentration (mM)	E_a (kJ/mol)	ΔH (kJ/mol)	ΔS (kJ/mol)
Blank	29.723	27.11	-0.152
0.1	42.768	40.14	-0.116
0.2	47.607	45.03	-0.101
0.3	52.712	50.05	-0.087
0.4	64.193	61.58	-0.053

The activation energy (E_a) of a Schiff base in mild steel was found to slow corrosion in 1.0M HCl, possibly due to its uniform adsorption on the metal's surface. The study found that chemisorption requires an activation energy of 80 kJ/mol or higher, while physisorption requires less than 80 kJ/mol (Jeyaprabha & Bhuvaneswari, 2020). The study also used the transition state equation to calculate the enthalpy and entropy of activation.

$$\ln \frac{CR}{T} = [\ln (\frac{R}{hN}) + (\frac{\Delta S*}{R})] - \frac{\Delta H*}{RT} \quad (20)$$

The study reveals that the mild steel dissolution process is endothermic, with adsorption heat increasing with increasing inhibitor concentration. The activation values' entropy changes decrease as the inhibitor concentration rises, suggesting a reduction in disorder as it moves from the reactant to the activated complex. The study also introduces potentiodynamic polarization for inhibited and uninhibited corrosion for the corrosion system of the mild steel, and the electrochemical characteristics for corrosion for the corrosion of the mild steel metal under various Schiff base concentrations in the 1M HCl solution (Gaya et al., 2019; Jeyaprabha & Bhuvaneswari, 2020).

3. 4. Potentiodynamic polarization

Figure 8. Is the potentiodynamic polarization curve for the inhibited and uninhibited corrosion system for the mild steel and the table for the electrochemical parameters for the corrosion of the mild steel metal in the solution containing 1M HCl and various Schiff base concentrations from the Tafel curve is provided in Table 4.

Table 4: Electrochemical characteristics for mild steel metal corrosion in 1M HCl solution with varying concentrations of Schiff base

Inhibitor Conc (mM)	I_{Corr} ($mAcm^{-2}$)	E_{Corr} (mV)	B_a ($mVdec^{-1}$)	B_C ($mVdec^{-1}$)	C. R D ($mmpy^{-1}$)	% I.E
0.0	8.63	-565.97	185.70	460.47	4.77	-
0.1	6.16	-569.62	168.10	371.10	3.41	28.58
0.2	2.85	-558.53	112.80	209.60	1.58	66.92
0.3	2.21	-566.92	98.90	130.40	1.22	74.38
0.4	1.82	-563.31	65.60	105.90	1.01	78.86

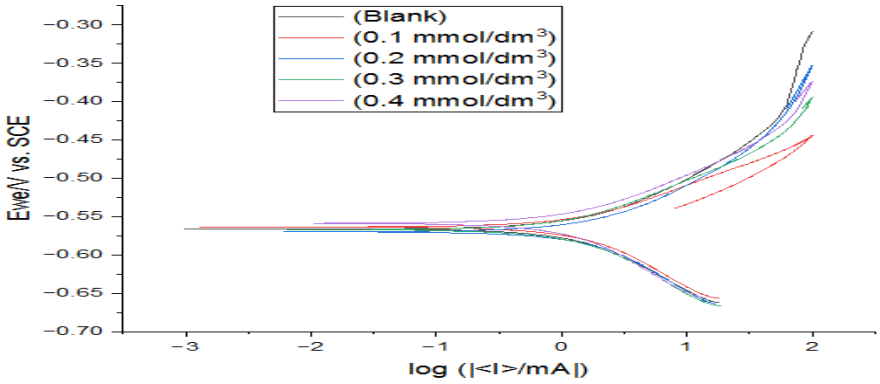


Figure 8. Tafel plot of the mild steel in the absence and presence of Schiff base

The study examined the effects of Schiff bases on anodic and cathodic plots on a mild steel electrode in a 1M HCl. The results showed that the addition of Schiff bases affected the anodic and cathodic parts of the Tafel slopes. The addition of an inhibitor molecule to an acidic medium reduced the formation of hydrogen gas and anodic metal dissolution, suggesting that inhibitor concentrations affected both reactions (Oshomogho et al., 2020; Pankaj & Gargi, 2014; Ravari & Dadgarinezhad, 2012).

3. 5. Surface morphology

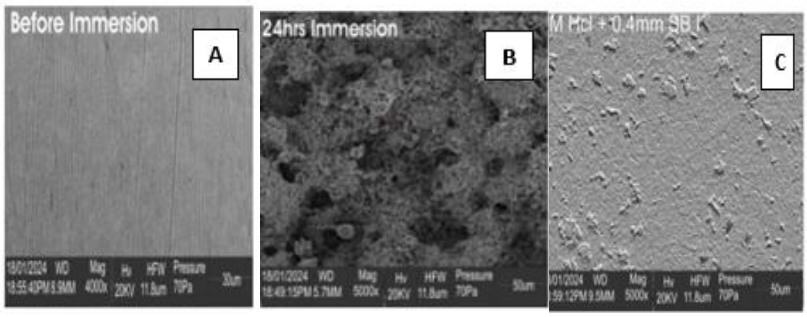


Figure 9. SEM micrographs of mild steel surface after immersion in IM HCl for 24 hours at room temperature: (a) Polished Mild Steel surface; (b) Mild steel immersed in 1M HCl (c) immersion in 1M HCl containing 0.4mM SB inhibitor

SEM imaging was used to analyze the shape of a mild steel surface. Results showed pitting and cracking in the absence of inhibitors, while a smooth surface was observed when inhibitors were present. This suggests that mild steel cannot dissolve when a Schiff base inhibitor is present, as it creates a protective coating (Ijuo et al., 2016; Musa et al., 2020).

3. 6. Fourier Transform Infra-Red Spectroscopy

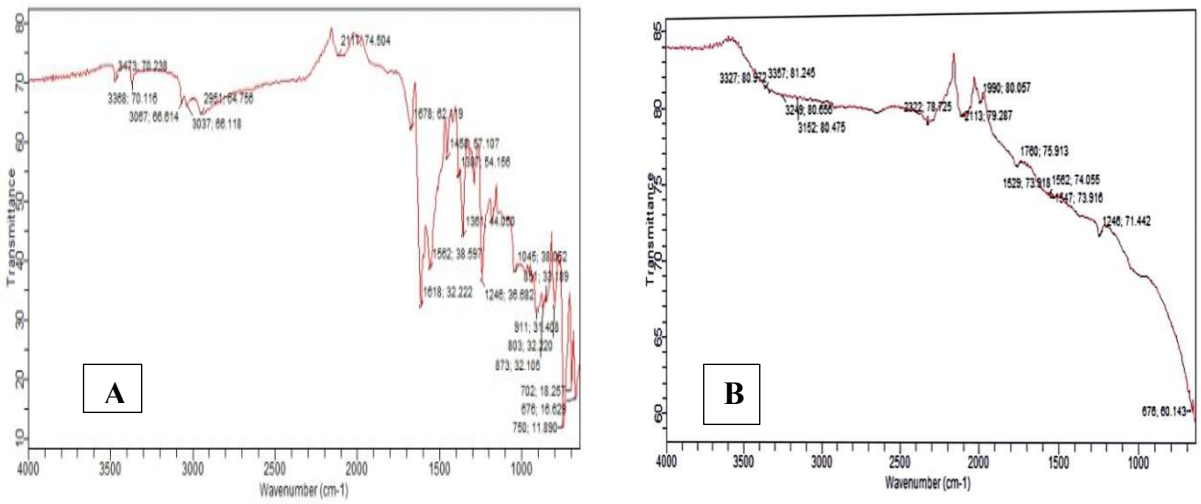
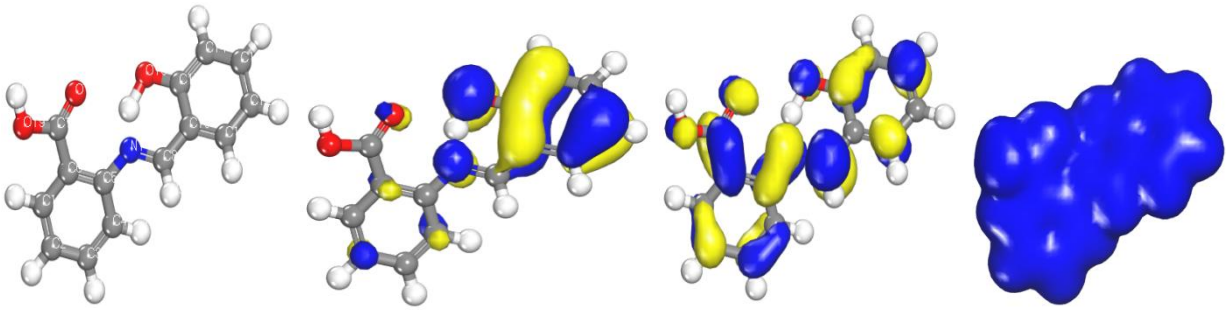


Figure 10. FTIR spectrum of (A) Schiff base (b) Corrosion product of mild steel in 1M HCl medium with 0.3mM SB

FTIR spectroscopy confirmed the inhibitor's adsorption behavior on mild steel surfaces. The inhibitor's FTIR spectrum showed frequency shifts, suggesting interaction with SB and SB2. The mild steel surface interacts with SB and SB2, resulting in SB adsorbed using a pi-electron and a functional group (Alian & Andresman, 2017; Eddy et al., 2011; Verma & Khan, 2016).

3. 7. Quantum Chemical Parameters

With the density, highest occupied molecular orbital (HOMO), lowest unoccupied molecular orbital (LUMO), and optimal structure, the structure in **Figures 11.** Depicts the optimal molecules of Schiff base.



Optimized molecules HOMO LUMO Density

Figure 11. Showing the optimized structure, HOMO orbital, LUMO orbital and Density of the molecule.

Table 5. The chemical parameters of Schiff bases at the DFT/B3LYPB/6-3IG (d) theory level

Properties	SB
E_{HOMO}	-5.331

E_{LUMO}	-3.050
Energy gap (eV)ΔE	2.281
Ionization energy (eV)I	5.331
electron affinity (eV) A	3.050
Absolute electronegativity (eV)χ	4.191
Global hardness (eV)η	1.141
Global softness (eV) $^{-1}$σ	0.876
ΔN (Fraction of electron transferred)	1.231
Global electrophilicity index (eV)ω	7.695
Nucleophility (eV) Ɛ	0.130
Back donation(eV)ΔE_{b-d}	-0.285

Researchers used the frontier molecular orbital (FMO) concept to study the reactivity and interaction between an inhibitor molecule and a mild steel surface (Ishaq & Ladan, 2023). The Schiff base molecules showed a strong ability to donate and receive electrons from the metal and mild steel, with lower E_{LUMO} values indicating a greater electron donation tendency. The Schiff base molecule's value for E_{HOMO} being 5.331 eV suggests that the corrosion impact can be reduced by the Schiff base molecule (Nyijime et al., 2023). ΔE ($E_{LUMO} - E_{HOMO}$) also played its part towards the efficiency of the barrier being one that is active towards corrosion (Shehu & Usman, 2023). The Schiff base molecule's lower value for the ionisation energy suggests its flexibility. Acid-base hypothesis suggests the softer the molecule is, the greater will the level of the inhibitor effectiveness will be. Inhibitory effectiveness for the Schiff base containing greater global softness has also been said to be greater. Interaction for the inhibitory molecule towards the surface of the metal has also been proved using the reverse donation ΔE_{b-d} energy (Esan et al., 2022; Siaka et al., 2014).

\

Table 6. Fukui functions of the molecule used for the inhibition

Atom of SB1	Fukui(+) Nucleophilic attack	Fukui (-) Electrophilic attack	f^2
C (1)	0.03	0.016	0.014
C (2)	0.043	0.025	0.018
C (3)	0.038	0.017	0.021
C (4)	0.028	0.022	0.006
C (5)	0.032	0.014	0.018
C (6)	0.036	0.017	0.019
N (7)	0.033	0.062	-0.029
C (8)	**0.094**	0.041	0.053
H (9)	0.033	0.025	0.008
C (10)	0.027	0.057	-0.03
C (11)	0.044	0.057	-0.013
C (12)	0.034	0.104	-0.07
C (13)	0.054	0.046	0.008
C (14)	0.034	0.078	-0.044
C (15)	0.041	0.059	-0.018
O (16)	0.073	**0.121**	-0.048
C (17)	0.048	0.011	0.037
O (18)	0.053	0.02	0.033
O (19)	0.04	0.009	0.031
H (20)	0.018	0.007	0.011

H (21)	0.019	0.011	0.008
H (22)	0.018	0.009	0.009
H (23)	0.016	0.012	0.004
H (24)	0.021	0.03	-0.009
H (25)	0.018	0.039	-0.021
H (26)	0.022	0.027	-0.005
H (27)	0.019	0.035	-0.016
H (28)	0.013	0.023	-0.01
H (29)	0.02	0.003	0.017

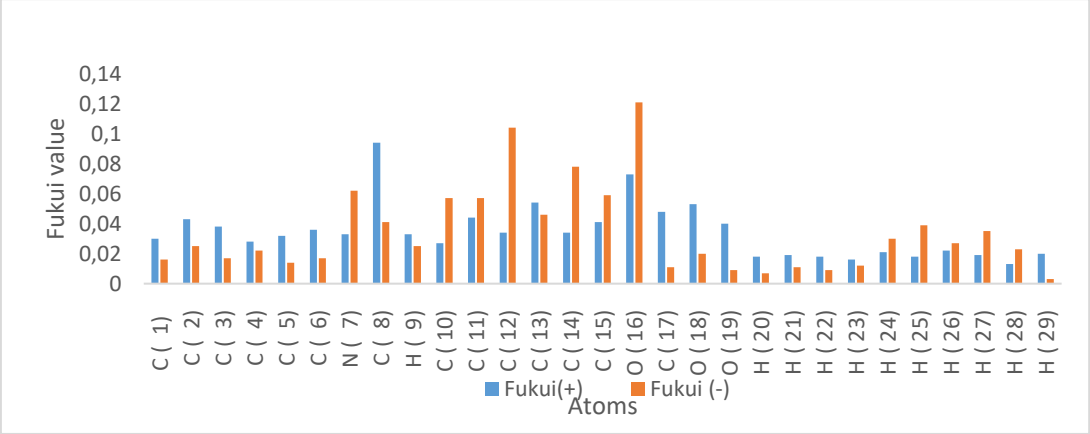


Figure 12. Fukui in graphical representation

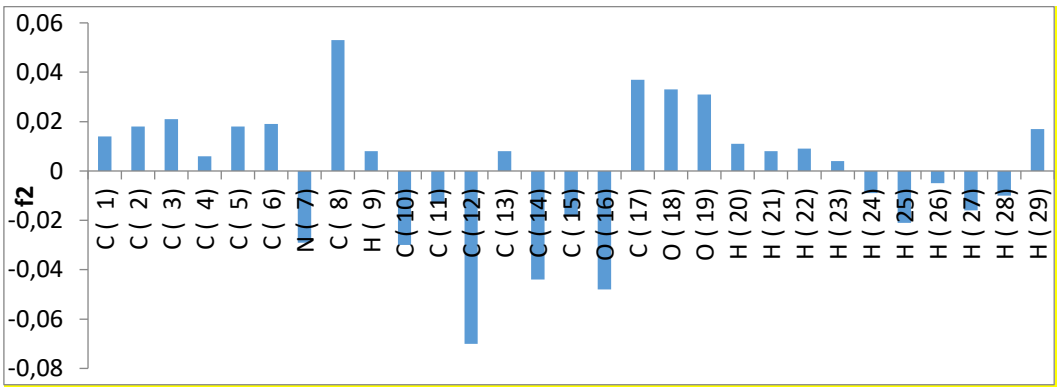


Figure 13. Second function

Table 7. Percentage of second order Fukui function

Inhibitor	Nucleophile	Electrophile
SB1	58.62%	41.38%

The study investigates the inhibitor molecules' reactivity over the surface of the metal using the Fukui indices, which define the molecules' parts responsible for nucleophilic and electrophilic attacks. Limited acceptor-donor interaction is responsible for the inhibitor molecules' reactivity over the surface of the metal. In the study, the highest f+ value atoms were the best sites for nucleophilic and electrophilic attacks when the highest value for the Fukui function is attained. Schiff base, being nucleophilic, is the best inhibitor for corrosion prevention over the surface of the metal for the case of iron. Molecular dynamic simulation data indicate the compounds under investigation adsorbed over the surface, where adsorption and the type of the energy for the

binding were calculated using the Forcite quench dynamic simulation technique. According to the molecular dynamic simulation data, the compounds under investigation adsorbed over the surface .

3. 8. Molecular dynamic simulation

The Forcite quench dynamic simulation method has been applied for the estimation of adsorption and the energy of binding.

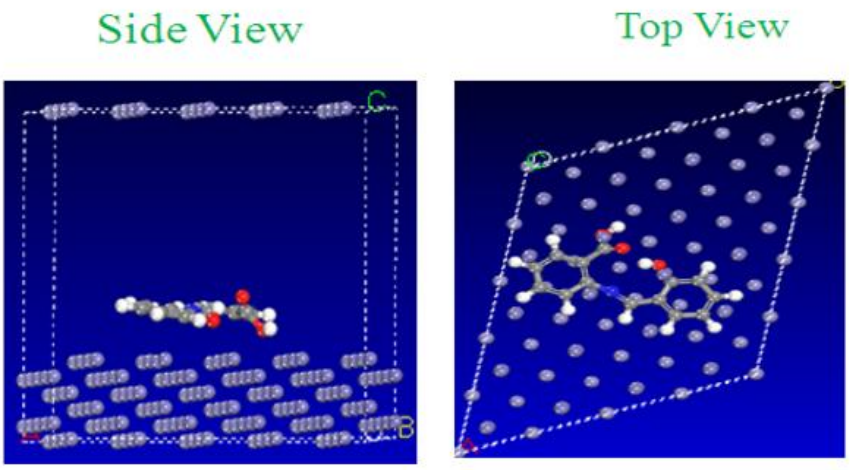


Figure 14. The snapshots (side view and top view) of the simulation as the optimized molecules interact with the Fe (111) surface

Table 8. Interaction energies of the Schiff bases molecules on Fe (111) simulation

Properties	Properties
Energy of the Fe (111) (kcalmol^{-1})	0.0000±0.0
Adsorption Energy (kcalmol^{-1})	-98.180±0.3
Binding Energy (kcalmol^{-1})	98.180±0.3

Molecular dynamic simulations were carried out for the evaluation of the adsorption of the inhibitor onto the surface of the metal at the molecular level. Forcite quench was used for the sampling of different low-energy structures and the discovery of the low-energy minima (Siaka et al., 2014) Mild steel adsorption by the inhibitor molecules reported were simulated by the modelling of the interactions of the inhibitor molecules and the surface of the Fe (111) crystal.

Equations 21 and 22 were used to determine the adsorption energy and binding energy for the interaction between the Schiff bases and the surface of Fe (111).

$$E_{ads} = E_{total} - (E_{mol} + E_{Fe}) \quad (21)$$

$$E_{binding} = - E_{ads} \quad (22)$$

Where $E_{mol,}$ E_{Fe} and E_{total} are the total energies of the molecules, Fe (111) and the adsorbed Mol/Fe (111) coupled in the gas phase respectively.

The study focuses on the adsorption and inhibition potential of inhibitor molecules on the metallic surface of Fe (111) using simulated systems. The binding and adsorption energies on the metal surface are crucial for evaluating inhibitory effects. The results align with experimental values, with adsorption energies less than 100 kcal/mol, which are within the range of physisorption interactions. The adsorption energy of the inhibitor-metal interface is inversely related to the inhibitor's degree of adsorption onto the metal surface.

4. Conclusion

The research leads to the following conclusion:

- The synthesis of the Schiff base was accomplished effectively.
- In a 1M HCl solution, the Schiff base effectively inhibits mild steel corrosion, exhibiting an inhibition effectiveness of 89.98% at a concentration of 0.4mM. The corrosion efficiency rose as the concentration of the inhibitor increased and fell as the temperature rose.
- The inhibitor functions as a mixed-type inhibitor, according to polarisation studies.
- The Langmuir adsorption isotherm is followed by the adsorption of Schiff bases on the surface of mild steel in a 1M HCl solution, which is categorised as chemical adsorption. The endothermic character of the process was shown by the positive enthalpy change of activation (ΔHad) in both blank and inhibited acid solutions. The process was entropically favorable, as shown by the negative activation entropy (ΔSad). Additionally, the spontaneity of the adsorption process was demonstrated by the negative values of ΔGads.
- The FTIR showed that the inhibition is caused by the adsorption of certain functional groups and aromatic rings in the Schiff bases, while the SEM result showed that the mild steel surface is shielded by adsorption coatings.
- The Schiff bases were adsorbed on the mild steel surface by a physisorption process, with inhibitory efficacy based on molecule size, according to the quantum chemical calculation.
- The information gathered using a range of techniques (both experimental and theoretical) shows a strong correlation, indicating the reliability and quality of the data. The metal surface is in closer contact with the Schiff base due to electron donation and acceptance, which results in lower energy levels. The quantum computation verified the Schiff base's high inhibitory efficiency.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Data Availability

No data was used for the research described in the article

Reference

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A Scoping Review of Factors Contributing to Relapse in Substance Use Disorders

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ABSTRACT

Substance use disorder is a significant global public health concern that affects individuals, families, and communities. Recovery from substance use disorder is typically characterized by relapses, which are backsliding moments in the recovery process. This scoping review will present the significant determinants of relapse for individuals with substance use disorder consisting of biopsychosocial determinants, Post-traumatic stress disorder, childhood trauma, neurodevelopmental determinants, and environmental cues. The literature has also identified determinants of relapse that consist of family-expressed emotion, peer pressure, cravings, negative affect, and psychological vulnerabilities. Besides this, the review also emphasizes the role of healthcare interventions in preventing relapse by employing a multidisciplinary strategy that integrates pharmacological interventions with psychosocial care. This scoping review employed the framework provided by Arksey and O'Malley (2005) to explore the determinants of substance use disorder relapse. The review thematically and systematically selected studies to identify gaps and inconsistencies within studies. The evidence suggests a multifaceted interrelationship between the biological, psychological, and social determinants sheds valuable light on mechanisms of relapse and informs future research and clinical interventions. Lastly, substance use disorder relapse is the result of complex interplay between determinants that are psychological, social, and environmental. Successful measures to prevent relapse require an integrative treatment strategy that combines medical, psychological, and social interventions to bring about enduring recovery. The research underscores measures such as comprehensive education programs that focus on the adverse consequences of addiction on the individual, family, and society. Modifying prevention programs to safeguard against substance abuse.

Keywords: Scoping Review, Factors, Relapse, Substance Use, Disorders.

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1. Introduction

Substance use disorders (SUDs) are a global public health issue that affects millions of individuals, families, and communities around the world. Characterized by harmful substance use patterns, SUDs include a large array of substances like alcohol, opioids, stimulants, and hallucinogens, among other drugs. Despite improvements in recovery programs and treatment, relapse is a common and often unavoidable part of the recovery process for many. Relapse is the resumption of substance use following a period of abstinence or successful treatment. Relapse is the culmination of an intricate interrelationship between biological, psychological, and social determinants. Knowledge about these determinants is important to the creation of the right kind of prevention and intervention strategies that can help bring about sustainable recovery and alleviate the burden of SUDs from individuals and the community (Latimore et al., 2023).

The process of recovery from substance dependence is not often linear, and recurrence is commonly considered a setback instead of a failure. Relapse can be a learning opportunity to improve, with the added benefit of information regarding individuals' triggers and challenges with recovery maintenance. This review will discuss the complex nature of recurrence of substance use disorder through the examination of theoretical models, contributing factors, and evidence-informed interventions applicable to preventing recurrence. This study synthesizes the evidence to explain the causes of recurrence and the necessity for multidisciplinary treatment (Guenzel & McChargue, 2019).

2. Purpose and Scope of the Review

The major goal of this review is to describe and consolidate the existing body of literature on the factors contributing to relapse in substance use disorders. Specifically, the review attempts to:

1. **Explore Theoretical Frameworks**: Analyse main theories elucidating relapse, including the Disease Model Theory, the Cue-Reactivity Theory, and the Integrated Treatment Model, to establish a foundational comprehension of the mechanisms that govern relapse.

2. **Identify Contributing Factors**: Examine the biological, psychological, and social determinants that elevate the likelihood of relapse, including childhood trauma, post-traumatic stress disorder (PTSD), stress, neurodevelopment, and environmental factors.

3. **Classify Substance Use Disorders**: Summarise the many categories of Substance Use Disorders (SUDs), such as alcohol, opioids, stimulants, hallucinogens, and polysubstance use, and examine the impact of each category on relapse tendencies.

4. **Describe Relapse Correlates:** Describe factors associated with relapse, including family-expressed emotion, peer influence, psychological stressors, cravings, and exposure to triggers.

5. **Evaluate Treatment and Prevention Strategies**: Examine evidence-based approaches, encompassing medical treatments (e.g., pharmacotherapy), psychosocial therapies (e.g., cognitive-behavioral therapy, motivational interviewing), and relapse prevention methods, to ascertain optimal practices for diminishing relapse rates.

6. **Highlight the Role of Healthcare Professionals**: Examine the essential functions of psychiatric mental health nurses and community mental health nurses in assisting persons with substance use disorders, especially with relapse prevention and sustained recovery.

This review encompasses a comprehensive array of substances and variables that contribute to relapse. It utilises both historical and present research to offer a comprehensive perspective on the challenges and opportunities associated with relapse in substance use disorders. This study seeks to merge theoretical insights with practical treatments to enhance clinical practice, direct future research, and foster the creation of more effective, patient-centered relapse prevention strategies.

This study aims to connect theory and practice by providing a thorough analysis of the factors contributing to relapse in substance use disorders and the ways to limit these risks. This study seeks to assist healthcare practitioners, researchers, and policymakers in enhancing outcomes for individuals with substance use disorders.

3. Literature Review

Despite tremendous attempts to overcome substance misuse, relapse remains a challenge for those who have experienced it. The excessive use of psychoactive substances, such as alcohol, illegal drugs, or prescription medications that negatively impact a person's physical, mental, and emotional health is known as substance abuse (Stringer, 2024). Substance misuse, on the other hand, refers to the improper or erroneous use of substances, such as taking prescribed medication over what is recommended, which eventually results in substance abuse. Relapse is the term used to describe the recurrence of drug or alcohol use following a time of abstinence or recovery, and it is commonly associated with the recovery process from substance misuse. That being said, a relapse does not guarantee failure. For many people, it is a typical and expected aspect of the healing process, and it can be viewed as a chance for development and education (Runyan, 2024).

The history of all substance abuse types, such as cannabis, coca, alcohol, and opium poppy, is discovered and extracted from natural plants (Crome & Nutt, 1960). Ancient societies, including the Egyptians, Greeks, and Chinese, understood the therapeutic benefits of these natural plants to treat their ailments, ease the suffering of warriors during battle, change consciousness, and be used for recreational and spiritual purposes (Jones & Vigo, 2023). Additionally, because there was a lack of knowledge about illnesses and the benefits of the plants, such as increased energy, alertness, stamina, relaxation, happiness, drowsiness, and peace, the use of medicinal plants in ancient times was based on experience (Fitzgerald et al., 2020). A more methodical approach to . scientific researchers' shift in focus until the sixteenth century to identify active compounds in plants and their mechanisms of action (Saxon, 2024).

3. 1. Theoretical Framework

3. 1. 1. Disease Model Theory

According to the disease model theory, relapses are caused by modifications to the brain's reward system and compromised decision-making abilities. Disease model theory, according to (Paul, 2022), stresses the need to view abuse as a medical problem rather than a moral failing and the necessity of all-encompassing treatment strategies that address the psychological and physical components of abuse (Smith, 2021)

3. 1. 2. The Cue-Reactivity Theory

According to the cue-reactivity theory, certain signals, such as the smell of alcohol or drug paraphernalia, can set off addictive behaviors by triggering the brain's reward system, which in turn causes cravings and ultimately relapse (Reinhard, 2021). According to Evans (Guy-Evans, 2020), this theory emphasises the importance of identifying and managing these triggers in addiction treatment and relapse prevention strategies.

3. 1. 3. Integrated Treatment Model

The integrated therapy strategy reduces relapse rates and improves care quality by amalgamating several therapies for co-occurring illnesses. It differs from traditional methods like simultaneous or parallel treatment, which addresses both conditions by several providers, and sequential or serial treatment, which focuses on one ailment at a time. Additionally, this model is favored for treating patients with substance abuse because it addresses all diagnoses and symptoms within a single agency or service system, combining the psychological and physical components of addiction, such as the use of medications and support groups, which makes it more effective at treating the full person (Panoo, 2023).

3. 2. Factors that Contribute to Substance Use Disorders

3. 2. 1. Biopsychosocial Approach

Substance abuse and use problems are more likely to occur when biological variables, such as genetic susceptibility and family history of addiction, are present. Addiction and craving are the result of adaptations brought on by neurochemical imbalances and dopamine release in the brain. Substance use disorders may manifest at particular ages in individuals with distinct physiologies, such as teenagers and young adults, because of phases of brain development (Nestler, 2025). Psychological aspects that were taken into A common coping strategy for stress, anxiety, depression, or emotional pain, substance misuse frequently co-occurs with mental health conditions. Previous experiences can make a person more vulnerable to drug use disorders (Greener & Storr, 2023). Social elements include peer pressure, the familial environment, socioeconomic considerations, cultural acceptance, and trauma as a coping technique all have an impact on substance use. Substance abuse risk is raised by financial difficulty, illiteracy, and a lack of work options (Halsey & Boodhai, 2018).

3. 2. 2. Childhood Trauma

Childhood trauma is one of the most frequent causes of drug use disorders in people. A history of traumatic childhood experiences, such as physical and sexual abuse, is often present in those with substance use problems (Mackey, 2020). Furthermore, scientists asserted that physical and sexual abuse throughout infancy causes psychological and mental health issues in maturity, which in turn encourages substance dependence. Interpersonal violence incidents like physical assault, mugging, sexual assault, and kidnapping are associated with the highest lifetime consumption risk of all drug kinds, and they also increase the possibility that children will use drugs (Greener & Storr, 2023).

3. 2. 3. Post-Traumatic Stress Disorder (PTSD)

Post-traumatic stress disorder (PTSD) is another factor that contributes to substance abuse. One of the most prevalent co-occurring mental diseases that contribute to substance addiction is post-traumatic stress disorder. People with this disorder use substances as a coping method to manage their feelings and symptoms. Three clusters of symptoms are indicative of post-traumatic stress disorder (PTSD): intrusive reexperiencing (unwanted trauma memories, reminders, and flashbacks); emotional numbness, or avoiding reminders of prior trauma; and hyperarousal and hypervigilance. People with PTSD frequently turn to substance addiction as a coping mechanism to manage their anxiety and avoid dealing with the impacts of trauma.

3. 2. 4. Stress

Because stress increases cortisol levels in the body, which can worsen symptoms of anxiety and depression, stress is a major contributing factor to substance misuse. As a coping strategy to overcome these unpleasant feelings, some people may turn to drugs. Homeostasis is upset by stress, which also triggers physiological reactions and anticipatory behavior. An increase in

impulsivity and a decrease in behavioral control are the outcomes of high stress, which causes the striatum to become more sensitive and the prefrontal cortex to become less active. Chronic stress response activation also raises the risk of psychopathology, including alcohol and drug addiction. The HPA axis is impacted by chronic stress, which may intensify the effects of drugs. Substance abuse disrupts this axis, making it difficult for people to cope with stress (Runyan, 2024).

3. 2. 5. Brain Development

Stressors in life and early childhood trauma can have an impact on brain development. These factors have a significant impact on a person's brain development and can result in long-term issues like mental health issues, which raise the likelihood of substance use disorders. Early neural network development is influenced by both genetic information and environmental factors, and either of these factors can reduce the brain's ability to operate in later life stages. Furthermore, when a child's brain is still developing, exposure to trauma or outside stimuli triggers the amygdala, which is responsible for emotional regulation and flight response. This can have long-term effects on emotional regulation and harmful behaviors like substance abuse (Mousali et al., 2021).

3. 2. 6. Environmental

Environmental factors include family conflict, social networks, poverty, peer pressure, trauma, stress, and wealthy people because of their accessibility, cost, and social acceptance can all have an impact on substance use disorders. Additionally, the neighborhood's characteristics include economic inferiority and violent crime. These elements might help create an environment where people are more likely to turn to drugs as a coping strategy to get away from their environment (Walker et al., 2024).

3. 3. Types of Substance Use Disorder

3. 3. 1. Alcohol

Fermentation procedures employing sugar sources such as malted barley, grapes, or berries are utilised to abuse a psychoactive drug (Barerah, 2018). Ethanol, the primary active component of alcoholic beverages, is produced by this process from sugars (Karlsson, 2024). Slurred speech, hangovers, and problems with focus, memory, and judgment are all signs of intoxication (Mosel, 2024b). Tremors, sweating, nausea, vomiting, anxiety, irritability, hallucinations, seizures, and delirium are typical withdrawal symptoms. Young adults, especially those in their late teens and early twenties, are most likely to abuse alcohol because of stress, coping strategies, and peer pressure. Latvia and other Eastern European Union nations have the highest rates of alcohol consumption, at about 19% (Rehm et al., 2021).

3. 3. 2. Sedatives, Hypnotics, and Anxiolytics

Classified as CNS depressants, sedatives, hypnotics, and anxiolytics, these are medications used to treat anxiety and sleep disorders; they are frequently referred to as "downers." Also known as sedatives, sleeping medicines, or tranquilizers. Because of their soothing properties, these drugs are frequently recommended to treat anxiety disorders, sleeplessness, and specific medical diseases, including muscular spasms or seizures. Slurred speech, poor coordination, fatigue, disorientation, memory loss, and mood swings are all signs of intoxication, which happens when someone takes more medicines than is recommended (LaGrotta & Thomas, 2020). On the other hand, sudden drug withdrawal can result in a number of negative symptoms, including anxiety, sleeplessness, perspiration, tremors, nausea, vomiting, elevated blood pressure, heart rate, hallucinations, seizures, autonomic hyperactivity, and psychomotor agitation (Simone & Bobrin, 2020).

3. 3. 3. Stimulants (Euphoriants)

Euphoriants, often known as stimulants, are medications that are categorized as central nervous system stimulants. They work by interacting with many neurotransmitter systems, such as the dopamine and norepinephrine systems, to stimulate central nervous system activity. Amphetamines, methylphenidate, cocaine, and illegal substances like methamphetamine can all contribute to alertness, energy, focus, and attention in the end. They are sometimes called "uppers" because they boost vitality and mood (Spinks, 2023). Additionally, stimulant intoxication causes mood changes, increased energy, and alertness. However, within hours to days of stopping stimulants suddenly, people may develop withdrawal symptoms, commonly referred to as crash symptoms. Fatigue, depression, heightened appetite, agitation, insomnia, anxiety, restlessness, trouble focusing, and drug cravings are some of these symptoms (Buffo, 2024).

3. 3. 4. Hallucinogens

Often referred to as psychedelics, hallucinogens are a class of psychoactive compounds that affect perception and emotion. They are also the most widely used as illegal narcotics. Treatments for mental health conditions like anxiety, depression, and post-traumatic stress disorder (PTSD) may involve the use of hallucinogens. Misuse, however, can result in euphoria, relaxation, well-being, changed perception, increased hunger, nausea alleviation, and problems with sociability (Miller, 2024). Symptoms of intoxication brought on by hallucinogens include distorted reality perception, euphoria, changed perception of time and space, and visual and aural hallucinations. Although they don't usually result in withdrawal or physical dependence, some people may have psychological "flashbacks" to hallucinogenic effects. Furthermore, among men and young adults aged 20 to 29, the United States had a higher rate of hallucinogen usage, ranging from 0.62% to 9.32%.

3. 3. 5. Inhalants

Inhaling a psychoactive drug that alters one's thoughts is called inhalant abuse, sometimes referred to as solvent abuse, volatile substance misuse, sniffing, huffing, and bagging. Aliphatic and aromatic hydrocarbons, which are present in gasoline, glue, paint thinner, and spray paint, are common inhalants. It is also utilised in cleaning and housekeeping items. Addicts experience respiratory side effects ranging from coughing and wheezing to dyspnea, emphysema, and pneumonia since the inhalants are absorbed through the lungs (Radparvar, 2023). Higher doses of inhalants can cause stupor or coma. Inhalant intoxication causes euphoria, altered consciousness, decreased coordination, dizziness, hallucinations, delusions, nausea, vomiting, headaches, impaired judgment, fast heart rate, and psychomotor slowness. Withdrawal symptoms such as irritability, mood fluctuations, sleeplessness, anxiety, elevated heart rate, and perspiration can occur when inhalant use is reduced or stopped. Additionally, the highest prevalence of inhalant use in Ireland is among teenagers and adolescents, who make up about 18% of the population (Koposov et al., 2018).

3. 3. 6. Cannabis

Tetrahydrocannabinol (THC) and Cannabidiol (CBD) are two of the more than 60 cannabinoids found in cannabis, commonly referred to as marijuana or weed. The plant's upper leaves, flowering tops, and stems are used to make marijuana. The female plant's leaves are used to make hashish, a dried sticky exudate. Cannabis is a hemp plant that is grown for its fiber, which is used to manufacture oil, paper, rope, and clothing. It is used recreationally for pleasure and relaxation as well as in medicine to reduce pain, inflammation, and regulate seizures and spasms (Florimbio, 2024). Euphoria, a changed sense of time, relaxation, hunger, memory loss, bloodshot eyes, and dry mouth are some of the signs of intoxication. Irritability, sleeplessness, anxiety, decreased appetite, restlessness, mood swings, headaches, chills, and sweating are some of the milder withdrawal symptoms. However,

compared to alcohol or narcotics, cannabis withdrawal is usually less severe. Approximately 35.4% of young people in the US use it, making it one of the most popular drugs in the country (NIDA, 2019).

3. 3. 7. Opioids

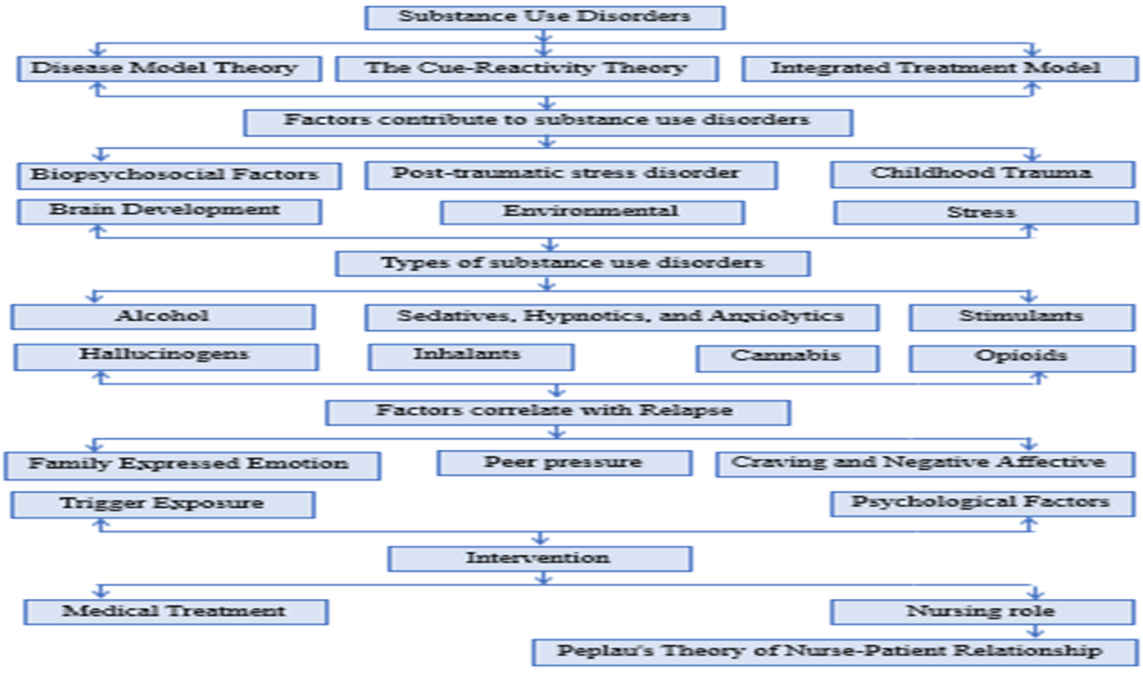
Because they can desensitize users to both physical and psychological pain, opioids are a common substance of abuse that produces feelings of euphoria and wellbeing. Strong prescription analgesics, including heroin, codeine, meperidine, and morphine, are among these substances. However, abusing opioids causes reliance, which affects a person's mental and physical health (Azadfard et al., 2023). Euphoria, altered consciousness, slurred speech, reduced coordination, constricted pupils, drowsiness, and a lowered breathing rate are all signs of opioid intoxication, which appears shortly after the initial euphoric experience. Anxiety, sleeplessness, muscle aches, nausea, vomiting, diarrhea, sweating, chills, yawning, pupil dilatation (the reverse of constricted pupils when drunk), and cravings for opioids are some of the symptoms associated with withdrawal. Additionally, opioids are used by around 5.8% (296 million) of the world's population.

3. 3. 8. Polysubstance Use

According to (Linda, 2022), polysubstance use is the use of two or more drugs that are misused concurrently. Drug combinations can result in harmful intoxication effects that affect the person in multiple ways, including immune system degeneration, bodily issues like kidney and liver damage, and cognitive function impairment. For instance, combining stimulants with opioids can increase heart rate and blood pressure, which can lead to brain damage, heart attacks, and strokes. Accordingly, the polysubstance disorder may cause further difficulties that could eventually result in unexpected mortality (Boileau-Falardeau et al., 2022).

4. Conceptual Framework

The conceptual framework illustrates the factors influencing substance use disorders and relapse based on theoretical models such as the Disease Model Theory and Cue-Reactivity Theory. It categorizes types of substance use disorders, identifies relapse-related factors, and highlights treatment interventions, including medical and nursing roles, as shown in the diagram.



5. Negative Consequences of Substance Abuse

Substance misuse frequently affects people through a variety of symptoms, such as tolerance, which is the gradual decrease in a substance's effectiveness and the need for the user to take larger doses to have the desired effect (Ragab & Hassabo, 2021). Additionally, intoxication is a transient and reversible condition that affects the central nervous system (CNS) and causes behavioral or psychological changes, including decreased mood, judgment, social functioning, motor skill performance, and cognition. Furthermore, the person has psychological symptoms like anxiety, despair, and strong cravings as well as physical withdrawal symptoms like nausea, sweating, and tremors when they attempt to cut back on or quit using the substances (Jahan & Burgess, 2021).

An individual's mental and emotional health is greatly impacted by substance misuse, which can result in mental health conditions like anxiety, sadness, and psychosis. Physical issues include respiratory and neurological disorders, liver damage, heart disease, and a compromised immune system. Additionally, it has detrimental effects on a person's life in severalareas. It may have a detrimental effect on relationships, job performance, or academic achievement. Also, there are legal and financial challenges. Additionally, substance use can result in a number of problems, such as neglecting obligations, abandoning social activities, participating in risky behaviors like illegal activity or unprotected sex, and continuing to use even when the substance could have exacerbated physical or psychological issues (Saquib, 2019).

6. Relapse After Successful Recovery

In substance use disorders, relapse refers to the resumption of drug or alcohol use after a period of abstinence or a successful course of treatment. Relapses are prevalent during the rehabilitation process, with the first episode typically occurring within the first year of treatment. Additionally, there is no appreciable distinction between the relapse rates of addictive behaviors and those of other chronic conditions such as diabetes, hypertension, and asthma. Additionally, between three weeks and six months after therapy, relapse rates might range from 40 to 75 percent. Nonetheless, a relapse does not imply weakness or failure. For many people, it is a normal and expected aspect of the recovery process. It can be viewed as a chance for learning and development since it gives insight into the obstacles and triggers that must be overcome to stay sober (Webber, 2023)

6. 1. Difference between the Relapse and Lapse

The term "substance use disorder relapse" describes the return to drug or alcohol use following a period of successful rehabilitation or abstinence. Resuming addictive behaviors and the inability to sustain sobriety for an extended period of time at the same or higher level are further characteristics of this condition (Saquib, 2019). It is a brief setback in a person's recovery journey and describes a brief period of time when someone who has been working towards sobriety relapses and engages in substance abuse again, in contrast to lapses or slips, which are one-time (slip) or brief occurrences (lapses) during the recovery process. Furthermore, the relapse should be viewed as a setback on the road to recovery rather than a failure. Relapse is a regular component of the path to long-term sobriety, and it is crucial to recognize that substance misuse is a complicated disease (Guenzel & McChargue, 2019).

6. 2. Factors Correlated with Relapse

6. 2. 1. Family Expressed Emotion

Relapse in substance abuse patients is significantly influenced by family members' emotional expression. Three to five factors—criticism, aggression, emotional over-involvement, and positivity and warmth—are evaluated in order to gauge the home environment. In many illnesses, high EE levels are strong indicators of relapse and can impair the prognosis. While hostility

is a negative attitude toward a patient, frequently blaming them for their issues, criticism is a complaint about a patient's behavior. The feelings and actions of a family member toward the patient that show excessive praise or blame, self-sacrifice, and overprotectiveness are known as emotional over-involvement.

Patients who experience high levels of emotional engagement may come to believe that they are powerless to solve their own issues and that they are caused by outside forces. Though it shows a different side from hostile and critical attitudes, emotional over-involvement is comparable to the negative effect that triggers a relapse, which causes the patient to revert to their sickness as a coping technique. Warmth and positive reinforcement are crucial in creating a supportive environment for addicts. Warmth increases motivation, self-esteem, and the therapeutic partnership while decreasing shame and stigma, whereas positive evaluations recognize progress and accomplishments (Shanmugam et al., 2021).

6. 2. 2. Exposure to Triggers

Exposure to triggers, which are experiences or circumstances—such as specific locations, people, or items associated with substance misuse—can rekindle urges and entice people to abuse substances. First, the medications' accessibility and availability. Second, negative emotions like despair, rage, and frustration are caused by interpersonal issues and conflicts between family and friends. Uncontrolled confrontations can result in relapses; in fact, over 50% of all relapses were found to be caused by conflicts. Peer pressure is another element because friends and acquaintances can have a significant impact on a person's conduct. People may feel strongly compelled to use substances or other addictive behaviors again if they are around peers who do so. Additionally, people may experience pressure to engage and comply in order to fit in or keep their social relationships. Accordingly, relapse is strongly predicted by each of these characteristics (Hardey et al., 2023).

6. 2. 3. Psychological Factors

Psychological elements, such as emotional issues like loneliness, sadness, disappointment, rage, despair, coping mechanisms, boredom, stress from work and marriage, and stigma, can cause relapses in substance misuse (Parisi, 2019). High levels of stress and inadequate coping mechanisms also contribute to the actions of addicts, who use them to escape or numb their feelings and deal with the overwhelming challenges in their lives. They could find it difficult to control their stress and run the risk of relapsing if they don't have good coping strategies in place (Ackermann, 2024). Furthermore, maintaining rehabilitation requires a solid support network since it gives people the motivation and direction they need when things get tough (Azmi et al., 2018).

6. 2. 4. Craving and Negative Affect

The relapse phase of substance addiction is significantly influenced by cravings and negative affect states. For main drugs of abuse, craving—the subjective desire to use substances—is a powerful predictor of resuming substance use. According to the negative reinforcement model, the need to alleviate negative emotions like pain, depression, and anxiety is what motivates drug-seeking and relapse. Decision-making in rehabilitation is hampered by unpleasant emotions such as mental strain, boredom, depression, tension, and despair. To stay sober, people with substance use disorders need to manage these feelings (Panoo, 2023).

6. 2. 5. Peer Pressure

One of the things that causes substance addiction patients to relapse is peer pressure. Alcohol and drug addicts often hang out with others who have similar drinking and drug-using habits. When an addict is around people who are still using drugs, they may relapse while in recovery. Social scientists use the "Social Learning Theory" as a framework to study peer pressure. This idea discusses how people learn from one another, including how social contact and praise can directly reinforce a person's conduct. Additionally, social learning theory includes cognitive processes and learning from others, which can undermine

recovery goals and result in emotional vulnerability, temptation, social acceptance, and lack of support. People may find it difficult to resist the temptation to use drugs when they are enticed, particularly when they are in vulnerable situations (Hardey et al., 2023)

7. Treatment

7. 1. Detoxification

Often called a detox, this medical procedure is the first step in treating substance use problems and safely eliminates substances like alcohol or psychiatric medicines from the body. Its functions are to control withdrawal symptoms, maintain mental and physical health, and avoid complications. Also used during physical symptom detoxification are substance-type specific drugs like methadone to manage opioid withdrawal symptoms and benzodiazepines to manage alcohol withdrawal symptoms. Increased fluid intake, a balanced diet plan, non-addictive analgesics to relieve headaches and body pain, and a relaxed atmosphere that supports resting and minimizes stress are some ways to control the physical symptoms (Kemp, 2019). Emotional support, stress-reduction strategies, counseling, and therapies such as cognitive behavioral therapy and motivational interviewing manage psychological complications. These interventions induce relaxation, minimize stress, and alleviate the load of psychological disorders (Das, 2020).

7. 2. Cognitive Behavioral Therapy (CBT)

Changing unhealthy behaviors and encouraging positive changes to one's life are the major goals of cognitive behavioral therapy (CBT). To guarantee lasting rehabilitation, the therapy assists patients to develop coping strategies, enhance the capacity to make decisions, and create a support system (Parisi, 2019). In addition to this, CBT also encompasses skills training such as self-talk therapy that supports substance abuse patients to shift the thought from a negative one to a positive one. After the patient has identified the opposite thought and worked on it, the therapist will assist the patient to replace it with a positive one such as stress management, problem-solving skills, or a rational thought. CBT reduces the chance of relapse by assisting to create an efficient coping mechanism to a given situation (see Appendix 1). It also encompasses strategies to guarantee lasting recovery such as relapse prevention, mindfulness, and cognitive restructuring (Miller, 2024).

7. 3. Support Group (12-step program)

Support groups like Alcoholics Anonymous and Narcotics Anonymous, which are part of the 12-step program (see Appendix 2), can give people a secure and accepting environment in which to talk about their problems and experiences. According to (Spinks, 2023), these programs frequently use an organized methodology that consists of accountability, sponsorship or mentorship, and the chance to network with people who have experienced comparable difficulties.

7. 4. Family Therapy

Teaching the family to build supportive relationships, emotional reassurance, and low criticism promotes high self-esteem, a better self-image, and stronger family ties, increasing the likelihood of recovery and lowering the danger of relapse. Additionally, including family members in education and treatment programs helps them better understand the difficulties that addicts confront, which can enhance empathy and communication within the family (Morgen, 2024).

7. 5. Regular Motivational Interviewing (MI)

Motivational interviewing (MI), a person-centered counselling technique that supports clients in initiating and maintaining good behavioral changes, is crucial for substance misuse treatment on a regular basis (Frankenburg, 2019). It empowers clients to take charge of their journey toward positive transformation by fostering a supportive environment through reflective statements, open-ended inquiries, and sympathetic listening (Mosel, 2024a).

7. 6. Relapse Prevention Strategies

In order to prevent relapsing into addictive behaviors, relapse prevention techniques are essential for those in recovery from substance abuse disorders or addiction. It's critical to recognize triggers like peer pressure and substance exposure. People can avoid reverting to old patterns by learning coping mechanisms, such as talking to a therapist or joining a support group, practicing mindfulness and relaxation techniques, taking up healthy hobbies, and creating a strong support system. Relapse risk can be decreased by changing one's lifestyle to include a healthy diet and regular exercise. Establishing a support network, which includes talking to friends and family and going to support groups, can also help people remain on course by offering accountability, motivation, and a feeling of belonging.

Maintaining sobriety and recognizing relapse warning signals require regular therapy sessions, self-evaluations, and medical check-ins. Long-term recovery requires ongoing treatment and monitoring even after official rehabilitation. Evidence-based treatments for the emotional components of addiction should be made available, and behavioral therapy and counselling should be promoted. Lastly, encouraging self-care entails looking after oneself when one is lacking something or is upset. It entails doing constructive things like journaling, working out, spending time with loved ones, and conversing with encouraging people (Menon & Kandasamy, 2018).

8. Psychiatric Mental Health Nurse Role

When it comes to patients who abuse drugs, the psychiatric mental health nurse plays a vital role. To determine the best course of action for each patient, the psychiatric mental health nurse first assesses the kind, quantity, and duration of usage. In order to assist patients in creating plans to prevent relapses, nurses teach them coping mechanisms. And to guarantee a comprehensive approach to addiction recovery, the nurses also work in conjunction with other medical specialists. Additionally, the nurses offer counselling and education regarding healthy lifestyle choices and coping strategies (Zhao & Li, 2018). Throughout the healing process, nurses offer patients emotional support, inspiration, and empowerment. By building trusting relationships with patients and advocating for their needs, nurses lower the likelihood of relapse. As a result, patients remain inspired and engaged in their care. Further, nurses ensure that patients follow the treatment plan, monitor side effects, and give the medication as directed (Kaswa, 2021).

By teaching patients how to deal with peer pressure situations that lead to relapses, creating a support system, and encouraging healthy coping mechanisms like assertiveness training and self-confidence building, nurses can help patients navigate peer pressure. This can assist patients in circumventing the adverse effects of peer pressure and facilitate informed decisions regarding their rehabilitation. Furthermore, by fostering conflict resolution skills, implementing family therapy interventions, enhancing constructive communication techniques, and cultivating a more supportive environment that encourages the patient's recovery while mitigating the risk of relapse, nurses can shape the influence of family-expressed emotions on relapse (Shanmugam et al., 2021).

9. Role of Community Mental Health Nurse

The role of the community mental health nurse is crucial to primary, secondary, and tertiary prevention of substance use. The primary preventive measure is promoting holistic well-being through evidence-based interventions such as awareness programs and education. Community nurses are able to inform individuals about the risks of addiction and the adverse impacts on physical, social, and emotional well-being. Besides this, community nurses are also able to collaborate with other medical professionals and local organizations to develop holistic preventive interventions that address the causative determinants for addiction and relapse such as peer pressure and family emotional expression (Latimore et al., 2023).

Secondary prevention nurses treat patients with substance use disorders to implement early interventions that prevent the progression of addiction. This can be through different approaches such as medication-assisted therapy, support groups, and counseling to enable individuals to manage addiction and reduce the likelihood of relapse. Secondary prevention also focuses on ongoing monitoring and follow-up care to ensure sobriety and good health (Kaswa, 2021).

The type, quantity, and duration of usage are integral components of the tertiary preventive conduction assessment. During the withdrawal process, nurses must consistently monitor patients' vital signs, administer medications to alleviate discomfort, and provide emotional support. To ensure a holistic approach to addiction recovery, nurses collaborate with other medical professionals, educate patients on coping strategies, and aid them in formulating relapse prevention plans. Furthermore, the nurse must evaluate and document the patient's health and treatment response, as well as monitor the patient's physical and psychological well-being throughout the treatment process and any complications that may arise (Kaswa, 2021).

10. Peplau's Theory of Nurse-Patient Relationship

Nurses can address drug use problems utilising the framework established by Peplau's theory of interpersonal relationships. The nurse-patient interaction fosters a collaborative therapeutic process, enabling patients to articulate their thoughts, feelings, and emotions, so enhancing understanding and aiding nurses in addressing each patient's distinct needs. Besides cultivating coping strategies and instructing patients on managing addiction triggers and relapse, the nurse can also discern the factors that contribute to substance use and recurrence (Olufunke & Oluwakorede, 2016).

11. Methodology:

The selection and analysis process was informed by Arksey and O'Malley's (2005) framework for conducting scoping reviews to ensure a thorough and transparent process. The five steps to the framework—developing the research question, identifying relevant studies, selecting studies, charting the data, and compiling, summarizing, and reporting findings—were undertaken carefully to ensure thoroughness and adherence to criteria. Systematic and thematical selection and analysis of the literature was conducted to ensure comprehensive synthesis of the determinants of substance use disorder (SUD) relapse. By adhering to scoping review guidelines and frameworks, the present review presents an unambiguous and comprehensive view of the current knowledge, highlights gaps within the literature, and informs clinical practice and future research. To ensure the validity and transferability of the findings, a consultation phase was undertaken using experts within the addiction treatment sector and individuals with lived experience of SUD.

12. Discussion

The evidence from this scoping review indicates a complex interplay between biological, psychological, and social mechanisms that underpin substance use disorder (SUD) relapse. Comparison between studies reveals certain trends, gaps, and

discrepancies that are informative about the mechanisms underlying relapse and that will be valuable to future research and clinical care.

12. 1. Patterns in the Literature

1. **Biological Factors**:

   - **Brain Development and Neurobiology**: Numerous studies emphasise the influence of early childhood trauma and chronic stress on brain development, especially in areas related to reward processing and impulse regulation, such as the prefrontal cortex and amygdala. These alterations heighten susceptibility to substance use and relapse (Mousali et al., 2021; Nestler, 2025).

   - **Genetic Predisposition**: A consistent topic in research is the influence of genetic predisposition on substance use disorders, with a familial history of addiction serving as a notable predictor of relapse (Greener & Storr, 2023).

2. **Psychological Factors**:

   - **Craving and Negative Affect**: Craving, frequently elicited by environmental stimuli and adverse emotional conditions (e.g., stress, depression), is universally recognised as a significant predictor of relapse (Panoo, 2023; Reinhard, 2021).

   - **Co-occurring Mental Health Disorders**: PTSD, anxiety, and depression are frequently associated with higher relapse rates, as individuals often use substances to self-medicate.

3. **Social Factors**:

   - **Family Expressed Emotion**: High levels of criticism, hostility, and emotional over-involvement within families are strongly correlated with relapse (Githae, 2015; Shanmugam et al., 2021)

   - **Peer Pressure and Social Networks**: Exposure to peers who use substances significantly increases relapse risk, particularly among adolescents and young adults (Hardey et al., 2023).

4. **Environmental Factors**:

   - **Accessibility of Substances**: Proximity to substances and exposure to triggers (e.g., drug paraphernalia, locations associated with substance use) are consistently linked to relapse (Guy-Evans, 2020).

   - **Socioeconomic Stressors**: Poverty, unemployment, and lack of social support create environments that exacerbate relapse risk (Walker et al., 2024).

12. 2. Gaps in the Literature

1. **Limited Research on Polysubstance Use**:

2. While studies on individual substances (e.g., alcohol, opioids) are abundant, there is a notable lack of research on polysubstance use and its unique relapse patterns. This gap limits our understanding of how interactions between multiple substances influence relapse risk (Boileau-Falardeau et al., 2022).

3. **Cultural and Gender Differences**:

4. Few studies explore how cultural and gender-specific factors influence relapse. For example, the role of stigma, gender-based trauma, and cultural norms in relapse remains underexplored, particularly in non-Western contexts.

5. **Long-Term Outcomes of Integrated Models**:

6. Although integrated treatment models are widely recommended, there is limited longitudinal research on their long-term effectiveness in preventing relapse (Panoo, 2023).

7. **Technology-Based Interventions**:

8. While digital tools (e.g., apps, telemedicine) show promise in relapse prevention, there is insufficient evidence of their efficacy and accessibility across diverse populations.

12. 3. Inconsistencies in the Literature

1. **Role of Pharmacotherapy**:

   While some studies emphasize the effectiveness of pharmacotherapy (e.g., methadone, naltrexone) in reducing cravings and withdrawal symptoms, others highlight its limitations, particularly in addressing psychological and social factors (Jahan & Burgess, 2021; Kemp, 2019).

2. **Definition of Relapse**:

   There is variability in how relapse is defined across studies. Some define it as a single episode of substance use, while others view it as a return to chronic use. This inconsistency complicates comparisons and generalisations (Guenzel & McChargue, 2019).

3. **Effectiveness of Peer Support Groups**:

   While many studies advocate for the benefits of peer support groups (e.g., Alcoholics Anonymous), others question their accessibility and effectiveness for individuals with co-occurring mental health disorders (Spinks, 2023).

12. 4. Interaction of Factors and Influence on Relapse Risk

The interplay of biological, psychological, and social factors creates a dynamic and multifaceted risk profile for relapse. For example:

- **Biological and Psychological Interactions**: Chronic stress and trauma can lead to neurobiological changes that increase susceptibility to cravings and impair decision-making, creating a cycle of substance use and relapse (Runyan, 2024)

- **Psychological and Social Interactions**: Adverse emotional conditions (e.g., depression) might intensify familial discord and social seclusion, hence heightening the chance of recurrence (Hardey et al., 2023).

- **Environmental and Social Interactions**: Interaction with substance-abusing peers in high-risk settings (e.g., disadvantaged neighbourhoods) increases the probability of recurrence, especially in those with inadequate coping mechanisms (Walker et al., 2024)

- These connections underscore the necessity for comprehensive treatment strategies that encompass the entirety of causes leading to relapse. For example, integrating medication with psychosocial therapies (e.g., cognitive-behavioral therapy, family therapy) can address both the biological and social aspects of relapse risk (Panoo, 2023).

12. 5. Implications for Practice and Research

1. **Integrated Treatment Models**:

   The results highlight the significance of comprehensive therapy models that concurrently address biological, psychological, and social aspects. Subsequent research ought to concentrate on assessing the enduring efficacy of these models among varied populations.

2. **Personalised Interventions**:

   Due to the heterogeneity in relapse risk factors, personalised interventions customised to individual requirements (e.g., trauma-informed care, gender-specific programs) are crucial for enhancing outcomes.

3. **Technology-Based Solutions**:

   Augmenting research on digital tools and telemedicine can improve access to relapse prevention options, especially for marginalised communities.

4. **Addressing Polysubstance Use**:

   Further research is required to comprehend the distinct issues of polysubstance use and formulate focused solutions.

5. **Standardizing Definitions and Metrics**:

   Standardising criteria of relapse and implementing uniform outcome measures will enhance the comparability and generalisability of the next investigations.

This scoping study underscores the intricate and interrelated processes that lead to relapse in substance use disorders (SUDs). The review establishes a basis for future research and clinical innovation by finding patterns, gaps, and inconsistencies in the literature. It is crucial to address these issues using integrated, personalised, and evidence-based strategies to decrease relapse rates and enhance long-term recovery results.

13. Conclusion

In summary, substance use disorders (SUDs) are a complex group of mental illnesses with harmful alcohol and opioid consumption habits. Relapse, commonly referred to as the resumption of substance use following a period of sobriety or successful treatment, depicts the chronic and cyclical nature of addiction fueled by psychological vulnerabilities, exposure to traumatic events and adverse affective states, social pressures, environmental cues, cravings, and negative affect. Relapse is a predictable and normative component of the recovery process that is shaped by biological, psychological, and social

determinants. Effective relapse prevention calls for an integrative multidisciplinary treatment plan that addresses the entire spectrum of addiction. Pharmacotherapy is essential to control withdrawal symptoms and alleviate cravings. Psychosocial therapies, including cognitive behavioural therapy (CBT), motivational interviewing (MI), and contingency management, enable individuals to cultivate coping mechanisms for addressing stress, triggers, and emotional difficulties. Establishing robust therapeutic relationships and delivering ongoing support via counselling, peer group initiatives, and family therapy are crucial for maintaining long-term recovery. Healthcare providers, particularly psychiatric nurses and community mental health nurses, play a crucial role in helping individuals recover through the rehabilitation process. Relapse in substance use disorders requires a shift in paradigm, where the understanding of relapse is changed from one of failure to one where it is seen as a learning opportunity for growth. Future research should focus on individualized care and the use of new technology in therapeutic interventions.

14. Recommendations

This scoping review's findings offer a number of recommendations to inform future research, clinical practice, and policy regarding substance use disorders (SUDs) and recurrence. There is an urgent need for models that address the biological, psychological, and social aspects of recurrence simultaneously. The existing evidence is consistent with the interrelatedness of the components such that interventions that address one component are unlikely to be sustainable. The integration of medication to manage cravings and withdrawal with psychosocial interventions like cognitive-behavioral therapy (CBT) and family therapy can offer a more comprehensive strategy to preventing recurrence. Furthermore, trauma-informed care must be integrated into models of care because childhood trauma and post-traumatic stress disorder (PTSD) are key determinants of recurrence. Secondly, forthcoming research should emphasise customised interventions designed to address the specific requirements of persons with substance use disorders (SUDs). Due to the heterogeneity in relapse risk factors, including genetic predisposition, concurrent mental health conditions, and social contexts, personalised interventions can enhance treatment success. Gender-specific programs and culturally tailored treatments can tackle the distinct issues encountered by various populations. Additionally, further investigation is required on polysubstance use, as existing literature primarily emphasises single-substance disorders. Comprehending the distinct relapse patterns and treatment requirements of individuals who engage in polysubstance use is crucial for formulating successful therapies.

Christian and Muslim clergy are highlighted for their counsel on promoting moral principles and avoiding addiction. Sports participation at a young age can shield kids from addiction in adolescence. Addiction is a cause and result of unemployment, hence it is also included. Education programs are created to teach students to be resistant to addiction and to appreciate the dreadful burden that addiction puts on individuals, families, and communities. Policymakers are also encouraged through the media to be aware of substance abuse problems and to create programs for preventing them.

The role of technology-enabled interventions in preventing relapse also warrants further research. Digital interventions like mobile apps and telemedicine can help improve the accessibility of therapy and offer real-time support to recovering individuals. More evidence is required to ascertain the effectiveness of these interventions and ensure availability to various groups, particularly those from resource-limited settings. Standardised measures and criteria for relapse must also be formulated to improve the comparability and generalisability of the evidence. The lack of uniformity in the operationalisation of relapse across studies currently makes evidence synthesis and the development of evidence-based recommendations problematic.

Ultimately, programs for public health and policy must address the social and environmental determinants that cause relapse. This means decreasing stigma, making therapy more available, and encouraging recovery-conducive environments. Community programs that address the socioeconomic determinants that cause poverty and unemployment can help to lower the rate of

relapse. Together with a multidisciplinary and holistic strategy, researchers, clinicians, and policymakers can collaborate to enhance the outcomes for substance use disorder patients and lower the burden that relapse causes to individuals, families, and society.

List of Abbreviations

SUD: Substance Use Disorder.

CBT: Cognitive Behavioral Therapy.

CBD: Cannabidiol.

CNS: Central Nervous System.

U.S: United States. X_{82}^{206}

AA: Alcoholics Anonymous.

NA: Narcotics Anonymous.

Conflict of Interest

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Data Availability

No data was used for the research described in the article.

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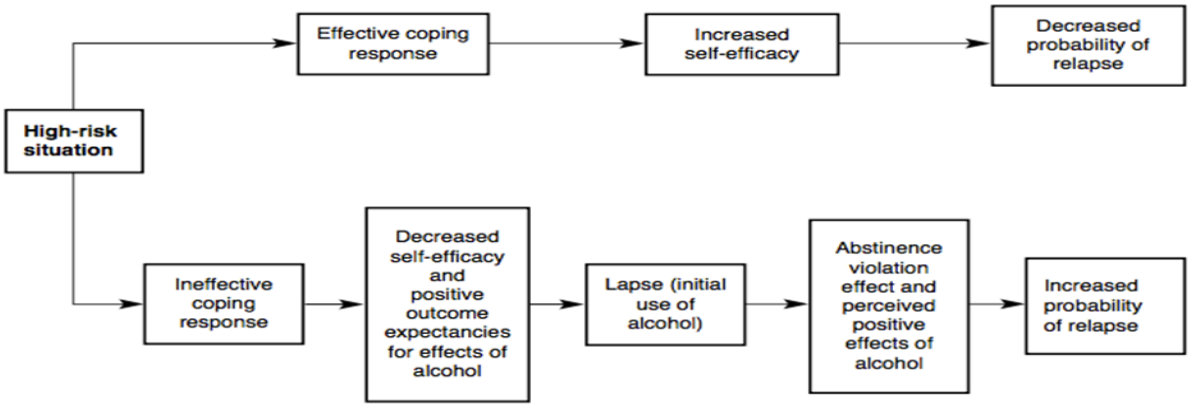
Appendices

- Appendix 1. clarifies the cognitive-behavioral model of the relapse process and posits a central role in high-risk situations and in the drinker's response to those situations. People with effective coping responses have confidence that they can cope with the situations like increased self-efficacy, thereby reducing the probability of a relapse.



- Appendix 2. clarifies the 12-step program for substance abuse to provide a structured framework for individuals struggling with addiction to overcome their dependencies and achieve long-term recovery.

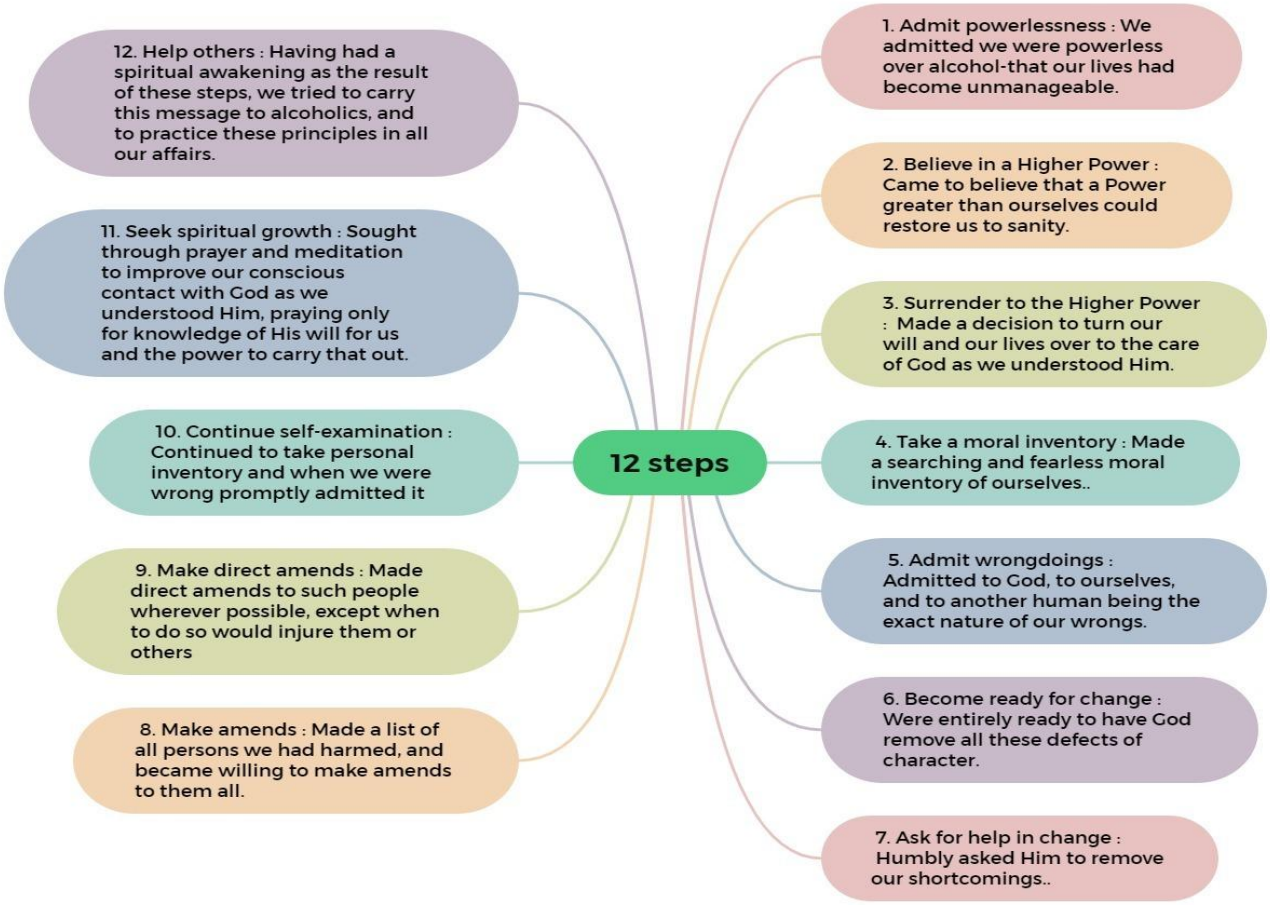


Table 1: Distribution of Studies Addressing Key Factors Contributing to Relapse in SUDs

Factor Category	Subcategory	Number of Studies	Key Findings
Biological Factors	Brain Development	8	Early trauma and stress impact brain regions involved in reward processing.
	Genetic Predisposition	6	Family history of addiction increases relapse risk.
	Neurochemical Imbalances	5	Dopamine dysregulation and reward system changes drive cravings.
Psychological Factors	Craving and Negative Affect	12	Cravings and negative emotions (e.g., stress, depression) are strong predictors.
	Co-occurring Mental Health Disorders	10	PTSD, anxiety, and depression increase relapse risk.
	Coping Mechanisms	7	Poor coping skills exacerbate relapse risk.
Social Factors	Family Expressed Emotion	9	High criticism and emotional over-involvement in families correlate with relapse.
	Peer Pressure	8	Exposure to substance-using peers increases relapse likelihood.

	Socioeconomic Stressors	6	Poverty, unemployment, and lack of support create high-risk environments.
Environmental Factors	Accessibility of Substances	7	Proximity to substances and triggers increases relapse risk.
	Neighborhood Characteristics	5	High-crime and economically disadvantaged areas exacerbate relapse risk.
Interventions	Pharmacotherapy	10	Medications like methadone and naltrexone reduce cravings and withdrawal.
	Psychosocial Therapies (e.g., CBT)	12	CBT and motivational interviewing improve coping skills and reduce relapse.
	Support Groups (e.g., AA, NA)	8	Peer support groups provide accountability and social reinforcement.
	Family Therapy	6	Family therapy improves communication and reduces conflict.

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