

Halal Critical Material Analysis of Dental Bone Graft in the Indonesian Market: Implications for Clinical Decision-Making

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Abstract: *The integration of halal principles in the selection of bone graft materials, remains insufficiently studied. In Indonesia, is essential for meeting technological and ethical standards. In Indonesia, no structured framework currently exists to assess the halal criticality of commercially available bone graft products. This study aimed to analyze the potential presence of halal-critical materials in dental bone grafts available in the Indonesian market. An observational descriptive study was conducted on 16 commercial dental bone graft products classified into five categories: allografts, xenografts, alloplasts, growth factors, and composite grafts. Product compositions were identified using Material Safety Data Sheets (MSDS), Chemical Abstracts Service (CAS) numbers, and manufacturer disclosures, and evaluated against the Halal Positive List issued by LPPOM MUI. The results showed that alloplasts exhibited the lowest halal criticality, as they consist solely of synthetic, non-animal, and non-human materials. Conversely, xenografts and allografts demonstrated higher halal risk due to animal and human-derived components, while growth factors and composite grafts showed variable risk profiles. This study provides a material-based halal criticality analysis to support clinical decision-making and underscores the need for clearer halal regulatory guidance for dental biomaterials in Indonesia.*

Keywords: biomaterial, dental bone grafts, halal risk assesmet, Indonesian halal regulation

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Received: October 26, 2024

Accepted: February 27, 2026

Published: February 28, 2026

How to cite this article (APA 7th Edition Reference Style): Hatta, R., Pratama, M. A. B. P., Nurfiанти, N., Azzahrah, F., Suriyah, W. H., Arsista, D., & Ichwan, S. J. A. (2026). Halal Critical Material Analysis of Dental Bone Graft in the Indonesian Market: Implications for Clinical Decision-Making. *Indonesian Journal of Halal Research*, 8(1), 1–16. <https://doi.org/10.15575/ijhar.v8i1.40117>

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1. Introduction

Alveolar bone resorption may occur as a consequence of tooth extraction, periodontal disease, trauma, pathological conditions such as malignancies, or congenital malformations. This resorptive process is generally irreversible and often results in insufficient bone volume, thereby limiting the feasibility of various dental treatments (Zhao et al., 2021). Among the available therapeutic strategies, bone grafting is widely employed as a primary approach to manage dental bone loss (Zhao et al., 2021). Bone grafts are defined as biological or synthetic materials capable of supporting and promoting bone healing when transplanted into osseous defects, either alone or in combination with other grafting substances. In recent years, the use of bone grafts and bone substitute materials in dentistry has increased markedly (Thalakiriyawa & Dissanayaka, 2024).

Bone graft materials play a crucial role in regenerative dentistry, particularly in managing alveolar bone defects, periodontal regeneration, and implant-related procedures (Ferraz, 2023; Zhao et al., 2021). The increasing demand for effective and biocompatible bone substitutes has led to the widespread use of various graft types, including allografts, xenografts, alloplasts, growth factors, and composite grafts (Ferraz, 2023).

The main function of the bone graft is to provide mechanical support and stimulate osteoregeneration with the ultimate goal of bone replacement. An ideal bone graft material must include four fundamental biological properties: osteogenesis, osteoconduction, and osteoinduction (Ferraz, 2023; Govoni et al., 2021). Osteoinduction is a mechanism to stimulate osteoprogenitor cells to differentiate into osteoblasts and form new bone. Osteoconduction occurs when bone graft material serves as a scaffold for new bone growth, spread, and the generation of new bone with osteoblasts. Osteogenesis occurs when osteoblasts from bone graft material contribute to the growth of new bone formation (Patel & Tatum, 2023).

While advances in biomaterial technology have improved clinical outcomes, material selection remains a critical clinical decision that must balance biological effectiveness, patient safety, and ethical considerations (Govoni et al., 2021; Jumiono, 2022). An ethical perspective should be considered carefully when recommending the use of a bone graft because the patient's cultural, spiritual, or religious beliefs will influence their treatment preferences (Patel & Tatum, 2023). One of the major conflicts reported is the use of animal-derived products or tissue from another human in bone graft materials.

In providing dental care, clinicians must adhere to the fundamental principles of biomedical ethics, including beneficence, nonmaleficence, justice, autonomy, and veracity. These principles guide dentists in delivering treatments that are not only clinically effective but also ethically and culturally acceptable (Herdiana & Rusdiana, 2022). When the use of dental bone graft materials conflicts with a patient's religious beliefs, it may negatively affect treatment acceptance and overall therapeutic outcomes (Alzeer et al., 2020). Studies report that conflicts between medical treatments and patients' religious beliefs can lead to treatment discontinuation and nonadherence, potentially compromising clinical success. Similar findings have been observed in dental practice, where religious considerations influence patient acceptance of graft materials (Assari et al., 2022).

Dentists are ethically and legally obligated to clearly explain the source and nature of bone graft materials to patients as part of the informed consent process. Transparent communication regarding the biological origin of graft materials is important when religious beliefs and personal values may influence treatment acceptance (Iftikhar et al., 2021). Dentists should actively engage in discussions about religious beliefs and values when considering the use of bone grafts to better understand patient priorities and prevent potential conflicts. Failure to address these concerns may result in patient discomfort, loss of trust, deterioration of the dentist-patient relationship, and legal implications (Gill et al., 2022). Educating patients about the risks, benefits, and material composition of bone grafts supports a shared decision-making process, enabling patients to make informed choices aligned with their ethical and religious considerations. In this context, the availability of halal certification for dental biomaterials is an important supporting factor in ensuring patient confidence and treatment acceptance (Kasri et al., 2023; Windasari et al., 2024).

In Muslim-majority populations, such as Indonesia, halal compliance has emerged as an essential ethical dimension in healthcare, extending beyond pharmaceuticals and food products to medical and dental biomaterials (Islam et al., 2023). Bone grafts derived from animal or human sources raise halal concerns related to the origin of raw materials, slaughtering methods, donor consent, and traceability throughout the production process (Charitos et al., 2021). These concerns are relevant to xenografts, allografts, and biologically derived growth factors that may contain porcine components, non-halal-slaughtered animals, or human donor tissues. Despite their clinical utility, the halal status of these materials is often unclear to clinicians and patients (Akbar et al., 2023; Lutfika et al., 2022).

The globalization of dental products has raised the issue of halal compliance, with 20% of Muslims concerned about the halal status of their daily products (Lestari & Pertiwi, 2021). A survey by the Center for Halal Lifestyle and Consumer Studies (CHCS) reported that 72.5% of Muslim consumers in Indonesia consider halal certification a religious obligation when purchasing consumer goods (Aliyah, 2019). Similarly, research in the United States indicates that 83% of Muslim consumers prefer or exclusively purchase products with halal certification (Mogahed, 2023).

Indonesia has established a national halal assurance system through regulatory bodies such as the Halal Product Assurance Organizing Agency (BPJPH) and the Indonesian Council of Ulama (MUI), supported by the Halal Positive List of Materials issued by Indonesian Ulema Council's Food, Drug and Cosmetics Research Institute (LPPOM MUI). However, current halal regulations primarily focus on food, pharmaceuticals, and cosmetics, with limited guidance for dental biomaterials and implantable medical devices. As a result, clinicians lack a structured reference to assess the halal criticality of bone graft materials used in daily practice, leading to uncertainty in clinical decision-making and informed consent, particularly in elective dental procedures.

Although previous studies discuss halal issues in healthcare and biomaterials, most remain conceptual or normative and do not provide a material-based analytical framework for evaluating commercially available dental products. To date, there is no systematic assessment of halal-critical components in dental bone grafts available in the Indonesian market, nor a practical classification that supports risk-based decision-making in clinical settings. This gap highlights the need for an analytical approach that integrates material science data with halal regulatory references.

This study analyzes the potential presence of halal-critical materials in commercially available dental bone graft products in Indonesia by examining their compositions using Material Safety Data Sheets (MSDS), Chemical Abstracts Service (CAS) numbers, and manufacturer disclosures, then evaluating them against the Halal Positive List issued by LPPOM MUI. The novelty of this study lies in its material-based halal criticality analysis, which categorizes bone graft products according to their halal risk profiles and provides an initial decision-support framework for clinicians. By bridging clinical needs, halal considerations, and regulatory perspectives, this study contributes to the development of clearer halal guidance for dentistry in Indonesia.

2. Materials and Methods

2.1. Study Design and Setting

This study employed a descriptive observational design conducted in 2024 at a laboratory of the Dental Materials Science and Technology, Faculty of Dentistry, Universitas YARSI, Jakarta, Indonesia. The study evaluated the halal criticality of dental bone graft materials by systematically analyzing their composition and material origin based on secondary data sources, including product documentation and manufacturer disclosures.

2.2. Product Selection and Sample Size

Products were included if they met all of the following criteria: commercially available and distributed in Indonesia, intended for dental or oral and maxillofacial applications, and providing accessible and verifiable composition information through Material Safety Data Sheets (MSDS), CAS numbers, and/or official manufacturer disclosures. Conversely, products were excluded if they were not commercially available in Indonesia, if their composition data were incomplete, proprietary, or not publicly accessible, or if an MSDS or equivalent documentation was unavailable or not written in English.

2.3. Product Identification and Verification

The availability of bone graft products in Indonesia was verified through multiple sources, including official distributors and dental suppliers, dental e-commerce platforms operating in Indonesia, the Indonesian National Agency of Drug and Food Control (BPOM), and manufacturer websites and authorized catalogs.

2.4. Analytical Framework for Halal Criticality Assessment

This study applied a material-based halal criticality analysis framework to evaluate each product. The assessment focused on identifying halal-critical components based on material origin and production source. The second stage focused on Islamic principles, particularly *fiqh* and *maqāsid al-Sharī'ah*, and the concept of necessity (*darūrah*). This was followed by a risk categorization phase based on a halal critical matrix. Finally, the clinical and regulatory implications were considered, including adherence to the regulatory guidelines of the Halal Positive List of Materials issued by Indonesian Ulema Council's Food, Drug and Cosmetics Research Institute (LPPOM MUI).

2.5. Halal Criticality Scoring System

Each product was classified into a halal criticality level using a three-tier risk matrix (Table 1)

Table 1. Halal Critical Level Matrix

Halal Criticality Level	Criteria
Low Risk	Products composed exclusively of synthetic or chemical materials with no animal- or human-derived components.
Medium Risk	Products containing animal-derived hard tissue materials, where the slaughtering or processing status is unclear.
High Risk	Products containing human-derived materials, porcine-derived materials, or animal-derived soft tissue components from non-halal slaughtered sources.

This classification was guided by Islamic legal principles, including *al-ashlu fil asy-yaa' al-ibahah* (permissibility by default) and *ad-darurat tubihul mahdhurat* (necessity permits prohibition).

2.6. Regulatory and Religious References

The halal assessment framework was supported by current Indonesian halal regulations and fatwas, including: 1) List of ingredients that are exempt from the obligation to be halal certified as regulated in Regulation of the Minister of Religion of the Republic of Indonesia No. 1360 of 2021; 2) National halal assurance regulations under the Halal Product Assurance Organizing Body (BPJPH), Ministry of Religious Affairs of the Republic of Indonesia; and 3) Islamic legal maxims and fatwas concerning the use of human- and animal-derived materials in medical treatments.

2.7. Data Analysis

The collected data were systematically analyzed using a structured halal criticality assessment framework. Initially, all identified material components were extracted from product documentation and classified based on their origin (synthetic, animal-derived, or human-derived). Subsequently, each product was evaluated using a predefined halal risk matrix to determine its level of criticality (low, medium, or high risk). The categorized data were then organized according to bone graft type and compiled into a comparative product analysis table. Patterns of halal criticality across different graft categories were identified and interpreted using a halal-oriented clinical decision-making perspective, with emphasis on material traceability and regulatory implications.

3. Results and Discussion

This study provides a comprehensive understanding of the classification and composition of commercially available bone graft materials in Indonesia, and the potential presence of critical components that may affect the halal status of these materials.

Table 2. The Properties of Bone Grafts in the Process of Tissue Formation and Regeneration

No.	Bonegraft Properties	Details	Example
1	Osteoconductive	The ability of a material to act as a scaffold supporting new bone growth is central to its application in bone regeneration. Osteoconductive materials do not directly induce bone formation; instead, they provide a physical structure that facilitates the attachment and migration of bone cells (osteoblasts), thereby enabling the formation of new bone around or within it.	<ul style="list-style-type: none"> Hydroxyapatite Beta-tricalcium phosphate (b-TCP)
2	Osteogenic	The ability of a material or tissue to generate new bone cells is essential in regenerative medicine. Osteogenic materials contain living cells capable of directly forming new bone, a property typically exclusive to living tissues.	Autograft: contains osteoblasts or osteoblast precursor cells.
3	Osteoinductive	The ability of a material to stimulate the differentiation of mesenchymal or other precursor cells into osteoblasts (bone-forming cells) is critical for bone engineering. This indicates the material can induce or trigger bone formation in areas that may have previously lacked significant osteogenic potential.	Bone morphogenetic proteins (BMPs)

Table 2 depicts the properties of bone grafts within the context of bone tissue formation and regeneration. This study identified three principal properties: osteoconductive, osteogenic, and osteoinductive. This research underscores the importance of selecting appropriate bone graft materials based on these properties to achieve optimal regenerative outcomes in clinical applications.

Bone grafts play a crucial role in dental regenerative procedures, with a range of materials available to meet different clinical needs. Autologous bone remains the gold standard due to its osteogenic properties, but its use is limited by availability and donor site morbidity (Ferraz, 2023). Alternatives include allografts, xenografts, and synthetic materials, each with distinct advantages and limitations (Zhao et al., 2021). Among the synthetic options, β -tricalcium phosphate (β -TCP) has gained attention for its osteoconductive and osteoinductive properties, though its effects on bone healing require further investigation (Lu et al., 2021). Hydroxyapatite and biphasic calcium phosphate are also widely used alloplastic bone substitutes, with varying formulations approved across different countries (Fukuba et al., 2021). The development of new alloplastic materials combines improved osteoconductivity and osteoinductivity with easier handling and appropriate resorption rates, potentially incorporating growth factors or cell-based approaches to enhance bone regeneration (Fukuba et al., 2021).

This study also discusses the vital role of BMPs, particularly BMP-2, in osteogenesis by inducing mesenchymal stem cell differentiation into osteoblasts (Sanjaya & Maliawan, 2022). This enables bone formation in areas previously lacking significant osteogenic potential. Combining these properties in bone graft materials allows physicians to select the appropriate graft type based on the patient's needs and clinical situation, such as sinus augmentation, socket preservation, or craniofacial reconstruction (Cicciù et al., 2021; Patel & Tatum, 2023). The findings are presented in Table 3, which classifies the types of bone grafts used in dentistry. Table 3 summarizes the sources, biological characteristics, and properties of available bone grafts, providing a clear guide for the appropriate selection of materials in clinical applications.

Table 3. Types of Bone Grafts Used in Dentistry

No.	Bone Graft Type	Details	Properties
1	Autograft	Bone grafts are harvested from the patient's body, typically from areas such as the iliac crest, mandible, or tibia	<ul style="list-style-type: none"> • Excellent biocompatibility • High osteogenic potential
2	Allograft	Bone grafts sourced from another human donor, typically provided by tissue banks	<ul style="list-style-type: none"> • Osteoconductive • No surgical procedure required for tissue harvesting from the patient's body
3	Xenograft	Bone grafts derived from other species, usually bovine	<ul style="list-style-type: none"> • Osteoconductive • Lacks osteogenic and osteoinductive capabilities
4	Alloplast	Synthetic bone grafts are made from artificial materials such as calcium phosphate, hydroxyapatite, or bioactive glass	<ul style="list-style-type: none"> • Excellent biocompatibility • Lacks osteogenic and osteoinductive capabilities
5	Growth factors	Proteins or other molecules that promote bone formation by stimulating cells in the graft area	<ul style="list-style-type: none"> • Enhance the efficacy of bone regeneration
6	Composite graft	A combination of several types of graft materials, such as autografts, allografts, xenografts, and/or alloplasts, combined with growth factors	<p>Enhances the efficacy of bone regeneration by combining the benefits of each material to improve bone regeneration outcomes, including:</p> <ul style="list-style-type: none"> • Osteoconductive, • Osteogenicity, and • Osteoinductivity
7	Other specialty products	Covers a wide range of innovative materials and technologies that do not fall into standard categories, such as bioengineering-based products or advanced biomaterials	<ul style="list-style-type: none"> • Designed for bone regeneration • Enhances osteointegration in bone implantation

Autografts, often considered the gold standard for bone grafting, offer the highest biocompatibility and osteogenic potential, as they use the patient's bone, which contains live cells capable of forming new bone. This is critical for optimal bone regeneration in areas requiring substantial tissue restoration. However, the primary disadvantage of autografts lies in the surgical complexity and risk of donor site morbidity, as a second surgical site is required to harvest the bone (Ferraz, 2023). Additionally, autografts are limited by availability and the patient's anatomical suitability for bone harvesting, which may hinder their use in some clinical settings (Archunan & Petronis, 2021).

In contrast, allografts, which are sourced from human cadavers, are an attractive alternative to autografts, as they eliminate the need for a second surgical site. Allografts are typically osteoconductive, meaning they are a scaffold for new bone growth. However, allografts carry a risk of disease transmission despite extensive screening, and some patients may be opposed to their use due to religious or ethical concerns about the use of human-derived materials (Steijvers et al., 2022).

Xenografts, derived from animal bones, such as bovine bone, also provide an osteoconductive scaffold for bone regeneration. However, xenografts have a significant disadvantage in terms of ethical and halal concerns, particularly for Muslim patients, as they are derived from animals that may not be slaughtered according to Islamic law. This makes the use of xenografts controversial in some cultural and religious contexts (Jumiono, 2022). The use of products derived from these animals is prohibited in Islam due to the principle that pork and its derivatives are haram (forbidden) under the Qur'anic verse Surah Al-Baqarah (2:173). While these grafts can be useful in situations where autografts and allografts are unavailable, they lack osteoinductive capabilities, making them less effective at stimulating bone regeneration than other graft types (Ferraz, 2023).

On the other hand, alloplasts represent a synthetic alternative to biological grafts. Made from materials such as calcium phosphate or hydroxyapatite, alloplasts are biocompatible and do not pose the same ethical dilemmas as xenografts or allografts (Cheah et al., 2021). They are classified as non-critical materials from a halal perspective, making them a favourable option for Muslim patients (Cheah et al., 2021). However, they lack osteogenic or osteoinductive properties, meaning they less actively promote bone growth, relying instead on the body's natural healing processes. Despite this limitation, alloplasts are often preferred in clinical applications where ethical concerns or cost factors play a significant role (Thirukonda et al., 2023).

Growth factors play a crucial role in enhancing bone regeneration by stimulating mesenchymal stem cell differentiation into osteoblasts, thereby promoting bone formation in areas where bone healing is needed. BMPs are the most well-known growth factors, particularly BMP-2, which is commonly used in bone grafting procedures to accelerate healing and enhance bone formation (Sanjaya & Maliawan, 2022). However, ethical concerns arise when growth factors are derived from porcine or bovine sources, as these materials may not comply with halal principles due to religious restrictions on animal sources and slaughter methods (Ramli & Zain, 2023). As a result, the use of growth factors derived from such sources must be carefully considered, and alternative synthetic or plant-based growth factors are recommended.

Composite grafts, which combine different types of graft materials, enhance the efficacy of bone regeneration by combining the osteoconductive properties of materials such as allografts, xenografts, or alloplasts with the osteoinductive properties of growth factors or other biological agents. These grafts have the advantage of potentially offering improved bone regeneration outcomes compared to single-material grafts, as they combine the strengths of each material. However, the halal status of composite grafts can be complicated, as they may contain materials derived from non-halal animal sources or human-derived allografts (Assari et al., 2022). It is therefore essential to ensure that composite grafts used in clinical settings adhere to strict halal guidelines, especially in Muslim-majority regions where religious concerns about material sourcing are paramount.

Finally, other specialty bone grafting products often rely on innovative biomaterials and advanced technologies designed for specific applications in bone regeneration. These include bioengineered grafts or nanomaterials that mimic the natural properties of bone and promote faster healing and osteointegration. While these specialty products show promise in improving clinical outcomes, their use is limited by regulatory approval and high costs (Patel & Tatum, 2023). Additionally, as with composite grafts, the halal status of these specialty products needs careful review, especially if they contain materials derived from non-halal sources, such as animal tissues or recombinant proteins of porcine or bovine origin (Ismail & Maifiah, 2023). Therefore, the selection of these advanced bone graft materials must balance clinical effectiveness with ethical considerations, particularly in Muslim patients who prioritize halal compliance in medical treatments.

The analysis conducted in Table 4 encompasses seven primary categories of bone grafts: autografts, allografts, xenografts, alloplasts, growth factors, composite grafts, and other specialized products. Only five of these categories are available in the Indonesian market; autografts and other specialized products are not found. Bone grafts are essential in various medical fields, including dentistry and orthopedics, for repairing bone defects (Archunan & Petronis, 2021). The four main types of available bone grafts are: autografts, allografts, xenografts, and alloplasts (Moussa & Dym, 2020).

Table 4. Commercially Available Bone Grafts Worldwide

No.	Graft Type	Brands	Manufacturers	Country	Available in Indonesia
1.	Autograft	Autogenous Bone Graft	-	-	-
2.	Allograft	Puros®	Zimmer Biomet	USA	Yes
		AlloOss®	ACE Surgical	USA	Yes
		DFDBA (Demineralized Freeze-Dried Bone Allograft)	Various providers	Various countries	-
		Oragraft®	LifeNet Health	USA	Yes
		Cortical and Cancellous Chips	Various providers	Various countries	-
		Regenaform®	Exactech	USA	-
		Grafton® DBM	Osteotech	USA	-
		Osteofil®	Regeneration Technologies	USA	-
		Maxgraft®	Botiss Biomaterials	Germany	-
		3.	Xenografts	Bio-Oss®	Geistlich Pharma
Cerabone®	Botiss Biomaterials			Germany	Yes
OsteoBiol®	Tecnoss			Italy	Yes
NuOss™	Ace Surgical			USA	Yes
Endobon®	Biomet 3i			USA	-
Osseograft®	Advanced Biotech Products			India	-
Orthogen™	Curasan			Germany	-
CopiOs®	Zimmer Biomet			USA	-
PerioGlas®	NovaBone			USA	-
PepGen P-15™	DENTSPLY			USA	-
XenoGraft™	Exactech			USA	-
4.	Alloplast	SynthoGraft™	Bicon	USA	-
		BoneCeramic®	Straumann	Switzerland	Yes
		Norian® CRS	DePuy Synthes	USA	-
		MBCP® (Micro Macroporous Biphasic Calcium Phosphate)	Biomatlante	France	Yes
		Bioglass®	NovaBone	USA	Yes
		OsteoGraf® LD300	DENTSPLY Implants	USA	-
		Biosorb®	Stryker	USA	-
		Vitoss®	Orthovita	USA	-
		Conduit™ TCP	DENTSPLY Implants	USA	-
		Ossix® Plus	Datum Dental	Israel	-
		Easy-graft™	Degradable Solutions AG	Switzerland	-
		Cerasorb®	Curasan	Germany	Yes
		OsteoMimix®	Collagen Matrix	USA	-
		Osteon™	Dentium	South Korea	Yes
		Tigran™ Perio	Tigran Technologies	Sweden	-
		IngeniOs® HA	Zimmer Biomet	USA	-
5.	Growth Factor	INFUSE® Bone Graft (rhBMP-2)	Medtronic	USA	-
		Gem 21S®	Lynch Biologics	USA	Yes
		PDGF (Platelet-Derived Growth Factor)	Various formulas	Various countries	-
		Emdogain®	Straumann	Switzerland	Yes
		OsteoAMP®	Bioventus	USA	-
		Recombinant Human Platelet-Derived Growth Factor (rhPDGF-BB)	BioMimetic Therapeutics	USA	-

Table 4. Commercially Available Bone Grafts Worldwide (continued)

No. Graft Type	Brands	Manufacturers	Country	Available in Indonesia
6. Composite Graft	MinerOss®	BioHorizons	USA	-
	OsteoGraf® N	DENTSPLY Implant	USA	-
	OsteoMimix®	Collagen Matrix	USA	-
	Allomatrix®	Wright Medical	USA	-
	DynaGraft®	Integra LifeSciences	USA	-
	Regenaform®	Exactech	USA	-
	Fortoss® VITAL	Biocomposites	UK	-
	OsteoGen®	Implant Direct	USA	-
7. Other Specialty Product	BoneSource®	Stryker	USA	-
	OSTEOMESH®	Osteopore	Singapore	-
	Tisseel®	Baxter	USA	-
	Progenix®	NuVasive	USA	-
	Opteform®	Exactech	USA	-
	Actifuse®	Apatech	UK	-
	Fortilink®	RTI Surgical	USA	-
	OsteoAMP® Select	Bioventus	USA	-

Overall, the discussion highlights that proper selection of bone graft materials relies heavily on their combination of properties and the intended clinical application. The optimization of osteoconductive, osteogenic, and osteoinductive properties, along with advancements in composite materials and growth factors, will continue to drive the success of bone regeneration therapies in the future.

Figure 1 illustrates the distribution of bone graft products by country of manufacture, as detailed in Table 4. It provides a visual representation of the availability of various types of bone grafts, including Allografts, Xenografts, Alloplasts, Growth Factors, Composite Grafts, and Other Specialty Products, across different countries. This graph not only offers insight into the global distribution of bone grafts but also emphasizes the diversity of regional variations in product availability. It is beneficial for understanding the international supply chain and the global reach of bone graft materials, as well as their implications for clinical use in dental procedures.

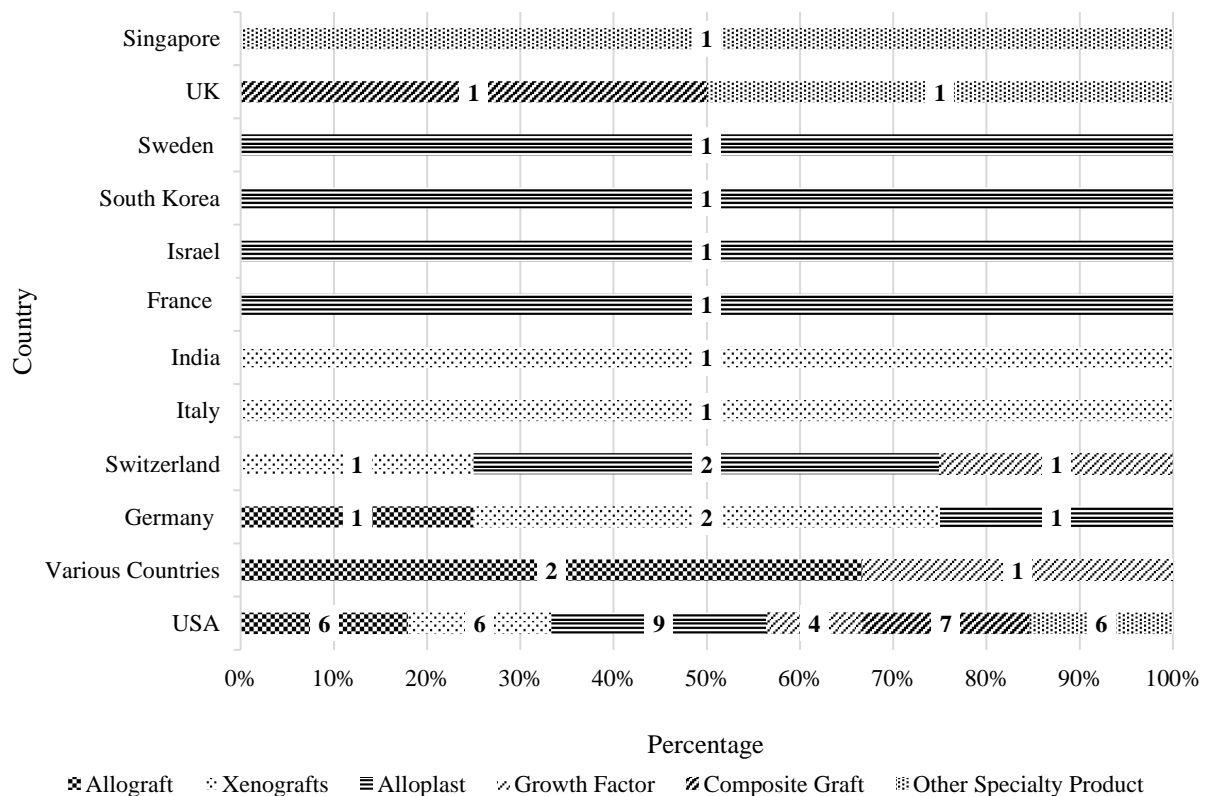


Figure 1. Distribution of bone graft products based on their country of manufacture.

The graph shows that the USA is the dominant supplier of dental bone grafts, followed by significant contributions from Germany and Switzerland. Other countries contribute only one or two items across the various categories of bone grafts.

3.1. Availability of Dental Bone Graft Products in Indonesia

From the initial global list of commercially available dental bone grafts, only 16 products (n= 16) were confirmed to be available and distributed in the Indonesian market at the time of data collection. These products were classified into five bone graft categories: allografts (n= 3), xenografts (n= 5), alloplasts (n= 5), growth factors (n= 2), and composite grafts (n= 1). Autografts and other specialty products were excluded from further analysis due to their unavailability as commercial products in Indonesia.

This finding indicates that Indonesian clinicians operate within a restricted product ecosystem, making halal-oriented material selection highly dependent on the limited range of imported biomaterials rather than local manufacturing alternatives. Our analysis suggests that alloplasts are the only bone graft category without identifiable halal-critical materials among products available in Indonesia. In contrast, allografts and xenografts may contain materials not compliant with halal principles, such as those derived from animals not slaughtered according to Islamic law or from human donor bone (Table 5).

Table 5. Composition of Commercially Available Dental Bone Grafts in Indonesia

No.	Graft Type	Brands and Manufacturer	Compositions	Forms	Clinical Applications
1	Allograft	Puros® (Zimmer Biomet)	Mineral and collagen matrix of human cortical bone and/or cancellous bone	Particles of various sizes (250-1000 µm, 1000-2000 µm)	<ul style="list-style-type: none"> • Periodontal bone regeneration • Sinus augmentation • Alveolar crest augmentation
2		AlloOss® (ACE Surgical)	Mineral component (hydroxyapatite) of donor human cortical bone	Freeze-dried chip or cortical block	<ul style="list-style-type: none"> • Alveolar ridge augmentation • Periodontal defect repair
3		Oragraft® (LifeNet Health)	The mineral matrix of human cortical and/or cancellous bone is made in the form of: Freeze-Dried Bone Allograft (FDBA) Demineralized Freeze-Dried Bone Allograft (DFDBA)	Cortical (mineralized) particles, cancellous particles, and cortical/cancellous mixtures	<ul style="list-style-type: none"> • Sinus augmentation • Craniofacial reconstruction • Socket preservation
4	Xenograft	Bio-Oss® (Geistlich Pharma)	Natural bone mineral from bovine, structure similar to hydroxyapatite, namely calcium phosphate (Ca ₁₀ (PO ₄) ₆ (OH) ₂)	<ul style="list-style-type: none"> • Granules of various sizes • Blocks for bone grafting 	<ul style="list-style-type: none"> • Sinus augmentation • Socket preservation • Periodontal bone regeneration
5		Cerabone® (Botiss Biomaterials)	Hydroxyapatite (Ca ₁₀ (PO ₄) ₆ (OH) ₂) of bovine bone	Granules of various sizes	<ul style="list-style-type: none"> • Sinus augmentation • Socket preservation • Alveolar crest augmentation
6		OsteoBiol® (Tecoss)	Natural collagen and hydroxyapatite matrix (Ca ₁₀ (PO ₄) ₆ (OH) ₂) of heterologous bone (bovine or pig)	<ul style="list-style-type: none"> • Granules • Paste • Membrane sheet 	<ul style="list-style-type: none"> • Sinus augmentation • Socket preservation • Peri-implant bone regeneration

Table 5. Composition of Commercially Available Dental Bone Grafts in Indonesia (continued)

No.	Graft Type	Brands and Manufacturer	Compositions	Forms	Clinical Applications
7		NuOss™ (Ace Surgical)	Pure hydroxyapatite (Ca ₁₀ (PO ₄) ₆ (OH) ₂) of bovine bone	<ul style="list-style-type: none"> • Granules • Particles 	<ul style="list-style-type: none"> • Sinus augmentation • Socket preservation • Alveolar ridge grafting
8	Alloplast	BoneCeramic® (Straumann)	60% hydroxyapatite (Ca ₁₀ (PO ₄) ₆ (OH) ₂) 40% β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂)	Granules of various sizes	<ul style="list-style-type: none"> • Sinus augmentation • Socket preservation • Alveolar bone regeneration
9		MBCP® (Biomatlante)	A mixture of hydroxyapatite (Ca ₁₀ (PO ₄) ₆ (OH) ₂) dan β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂) in proportions of 20:80 to 60:40	<ul style="list-style-type: none"> • Granules • Blocks 	<ul style="list-style-type: none"> • Sinus and ridge augmentation • Socket preservation • Periodontal bone regeneration
10		Bioglass® (NovaBone)	Sodium silicate (Na ₂ SiO ₃) Calcium phosphate (Ca ₃ (PO ₄) ₂) Calcium silicate (CaSiO ₃)	<ul style="list-style-type: none"> • Granules • Paste • Putty 	<ul style="list-style-type: none"> • Fracture healing • Bone defects filler • Maxillofacial bone augmentation
11		Osteon™ (Dentium)	Hydroxyapatite (Ca ₁₀ (PO ₄) ₆ (OH) ₂) β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂)	Granules of various sizes	<ul style="list-style-type: none"> • Sinus augmentation • Socket preservation • Alveolar bone regeneration
12		Cerasorb® (Curasan)	100% β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂)	<ul style="list-style-type: none"> • Granules • Paste 	<ul style="list-style-type: none"> • Periodontal bone regeneration • Socket preservation • Bone defects filler
13	Growth Factors	Gem 21S® (Lynch Biologics)	Active compound: rhPDGF-BB (recombinant human Platelet-Derived Growth Factor-BB) Scaffold: β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂)	<ul style="list-style-type: none"> • Liquid: rhPDGF-BB • Granules: β-TCP 	<ul style="list-style-type: none"> • Periodontal bone regeneration • Ridge augmentation • Socket preservation • Bone defects filler
14		Emdogain® (Straumann)	Active compound: amelogenin (protein from pig embryos) Carrier: propylene glycol alginate (PGA)	Gel injected into the regenerated area	<ul style="list-style-type: none"> • Periodontal regeneration • Post-surgery recovery
15	Composite Graft	MinerOss® (BioHorizons)	Active compound: a mixture of allograft and xenograft Addition: β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂)	Granules of various sizes, often supplied in ready-to-use kits	<ul style="list-style-type: none"> • Alveolar ridge augmentation • Socket preservation • Periodontal bone regeneration

Table 5. Composition of Commercially Available Dental Bone Grafts in Indonesia (continued)

No.	Graft Type	Brands and Manufacturer	Compositions	Forms	Clinical Applications
16		OsteoGraf® (DENTSPLY Implants)	Active compound: alloplast consisting of sodium fluoride and calcium phosphate Addition: hydroxyapatite (Ca ₁₀ (PO ₄) ₆ (OH) ₂) or β-tricalcium phosphate (β-TCP, Ca ₃ (PO ₄) ₂)	Granules or powder mixed with saline solution before application	<ul style="list-style-type: none"> • Bone defect repair • Alveolar bone regeneration • Sinus augmentation

Bone grafts derived from xenografts and allografts can contain critical components that may not comply with halal requirements. For example, xenografts often use porcine bone, which is explicitly forbidden in Islamic law as stated in Quran Surah Al-Baqarah (2:173), which prohibits the consumption of pig flesh. The use of such materials in dental bone grafts can cause religious concerns among Muslim patients, making it critical to consider the source of the bone used. Similarly, allografts sourced from human donors may be contentious if not properly consented or if the source does not meet the ethical and religious requirements under Islamic law, as described by the Hadith Muslim, which emphasizes the sanctity of the human body.

On the other hand, alloplasts, which are synthetic bone grafts made from materials such as hydroxyapatite or β-tricalcium phosphate, are classified as non-critical from a halal perspective because they do not contain animal- or human-derived components. These materials are generally accepted in the Muslim community because they do not raise ethical or religious issues, as evidenced by their widespread use in halal-conscious countries (Cheah et al., 2021; Thirukonda et al., 2023). Therefore, alloplasts are considered the safest option when ensuring halal compliance in bone graft materials.

3.2. Halal Risk Matrix of Dental Bone Grafts Available in Indonesia

The ingredient-based halal risk matrix (Table 6) was applied to 16 products available in Indonesia to classify their halal criticality levels into low, medium, and high risk categories, based on the origin and composition of the ingredients.

Table 6. Halal Criticality Level and Rationale of Dental Bone Graft

Halal Risk Level	Bone Graft Category	Number of Products	Halal Criticality Rationale
Low Risk	Alloplasts	5	Fully synthetic materials; no animal- or human-derived components
Medium Risk	Xenografts	4	Animal-derived materials with uncertain slaughtering and processing status
High Risk	Composite Grafts	2	Combination of xenograft/allograft components
High Risk	Growth Factors	2	Risk dependent on biological source and carrier materials
High Risk	Allografts	3	Human-derived donor bone; halal permissibility conditional on necessity

Alloplast bone grafts constituted the only category consistently classified as low halal risk, as their compositions were limited to synthetic calcium phosphate-based materials listed as non-critical substances in the Halal Positive List of Materials.

3.3. Traceability and Supply Chain Halal Risks

The categorization of potentially critical material content in bone grafts is based on principles outlined by authoritative sources, particularly within the context of Islamic law. Table 7 provides these fundamental guidelines for researchers, medical practitioners, and other stakeholders.

Analysis of product documentation revealed that traceability remains a major halal risk factor for dental bone grafts available in Indonesia. Most xenograft and allograft products are imported, and MSDS documentation generally does not disclose halal-specific information, such as slaughtering methods, donor consent protocols, or segregation during manufacturing and transportation.

For xenografts, particularly bovine-derived products, the absence of verified halal slaughter certification introduces uncertainty in halal status. For growth factor-based products, halal risk is compounded by the use of biologically derived active compounds, where the source species and processing methods are often insufficiently detailed. Composite grafts present additional complexity due to multi-source material integration, increasing the likelihood of cross-contamination and halal

status ambiguity throughout the supply chain. These findings demonstrate that halal compliance for dental biomaterials cannot rely solely on final product composition, but must also consider upstream supply chain transparency and traceability.

3.4. Clinical and Regulatory Implications

Bone grafts may include materials that are potentially non-halal or controversial in Islam, such as human-derived materials (allografts), animal-derived materials from non-Islamically slaughtered animals (xenografts), or active substances or growth factors of animal origin. Several important considerations include the fiqh rules regarding the use of human or animal body parts, the conditions for their use in emergencies, and the absence of halal alternatives. The availability of these guidelines is intended to aid in the selection of bone grafts, particularly for users who prioritize halal compliance in medical products.

Table 7. Guidelines for Categorizing Potentially Critical Material Content in Bone Grafts

No.	Bone Graft Types	Critical Material Potential	Guidelines
1	Allograft	<ul style="list-style-type: none"> Human bone donor Cadaver bone 	<ol style="list-style-type: none"> The fundamental principle in Islam regarding the sanctity of the human body: “Breaking a dead man’s bone is like breaking it when he is alive” (Hadith Muslim). Fiqh rules: “Ad-darurat tubihul mahdhurat” (A state of emergency permits actions that are otherwise prohibited). Conditions for use include obtaining consent from the donor or their family, the absence of a halal alternative, and the procedure must be based on urgent necessity rather than cosmetic purposes.
2	Xenograft	<ul style="list-style-type: none"> Pig/porcine bone Non-halal slaughtered bovine bone 	<ol style="list-style-type: none"> The fundamental principle is found in Surah Al-Baqarah (2:173): “He has only forbidden to you dead animals, blood, the flesh of swine, and that which has been dedicated to other than Allāh.” Fiqh rules: the use of bones or body parts from animals that were not slaughtered under halal principles is considered impure (<i>najis</i>) by the majority of scholars. Conditions for use: the absence of halal alternatives and the presence of an emergency.
3	Alloplast	-	According to the fatwa of Indonesian Ulema Council's Food, Drug and Cosmetics Research Institute (LPPOM MUI), consent for use of this material falls under the category of chemical compounds classified as non-critical substances.
4	Growth Factors	Active ingredient derived from porcine protein	It is classified as a critical substance if any component contains materials derived from pigs or other animals not slaughtered in the name of Allah.
5	Composite Graft	Active ingredient derived from allograft or xenograft	It is classified as a critical substance if any component contains materials derived from humans or other living beings (such as pigs or other animals not slaughtered in the name of Allah).

The study findings demonstrate that the halal status of dental bone graft materials cannot be assessed solely on clinical performance or graft category, but must be evaluated through an integrated framework encompassing material composition, ethical considerations, and Islamic legal principles. From a halal perspective, the use of biomaterials derived from human or animal sources raises concerns related to *hifz al-dīn* (protection of faith) and *hifz al-nafs* (protection of life), two central objectives of *Maqāṣid al-Sharī'ah*.

For allografts, which are bone grafts derived from human donors or cadaver bones, a basic principle in Islam emphasizes the honor of the human body, as stated in a Hadith Muslim: “Breaking a dead man’s bone is like breaking it when he is alive.” Allografts are permitted in emergencies, provided

that permission has been obtained from the donor or their family and no other halal material alternatives exist. This underscores the importance of ensuring procedures comply with ethical and religious values towards the human body while allowing its use when medically necessary (Dayan et al., 2021).

Meanwhile, xenografts, which are derived from animal bones such as pigs or cows, become critical materials if the animals used are not slaughtered according to Sharia rules. In the Qur'an, Surah Al-Baqarah (2:173) states: "He has only forbidden to you dead animals, blood, the flesh of swine, and that which has been dedicated to other than Allāh". The use of pig bones is explicitly prohibited in Sharia, while cow bones are only permitted if the cow was halal slaughtered. Xenografts may be used in emergencies or severe cases if there are no halal alternatives and there is a critical need.

Research highlights that the use of xenografts derived from animals, especially pigs, is debated in the Muslim community (Qotadah & Syarifah, 2022). This study emphasizes that, according to Sharia law, using materials derived from pigs is prohibited except in emergencies and if no alternatives are available (Ismail & Maifiah, 2023). Studies also note that Muslim patients more widely accept xenograft materials from cows slaughtered according to Islamic rules (Mohd Zailani et al., 2023). However, attention must still be given to the source and production process to ensure compliance with Sharia law.

Allografts and xenografts are alternatives, but their acceptance varies among patients due to religious beliefs (Assari et al., 2022). A study in Saudi Arabia found that porcine xenografts had the highest rejection rate (63.1%), primarily due to religious concerns (Assari et al., 2022). Xenografts and allografts involve animal- and human-derived materials, placing them in the medium and high halal risk categories. Their permissibility is therefore conditional and must be evaluated in light of *ḍarūrah* (necessity), as articulated in the legal maxim *al-ḍarūrāt tubīḥ al-maḥzūrāt* (necessity permits what is otherwise prohibited).

Other types of bone grafts, such as alloplasts, were considered non-critical materials and classified as low halal risk due to their fully synthetic composition, which aligns with the Islamic legal maxim *al-aṣlu fī al-ashyā' al-ibāḥah* (permissibility is the default ruling for things). Alloplasts are often used as a safer alternative in religious contexts, especially for patients requiring bone grafts who object to using biological materials from animals or humans (Cheah et al., 2021). Alloplasts or synthetic bone grafts were identified as a safer alternative from a religious and ethical standpoint. Alloplasts based on calcium phosphate or hydroxyapatite are highly biocompatible and widely accepted without ethical concerns, as they do not originate from humans or animals (Cheah et al., 2021; Thirukonda et al., 2023). This study supports the use of alloplasts, particularly among patients who object to biological materials.

The use of active materials derived from pig or human proteins for growth factors and composite grafts requires careful consideration due to their critical nature. Products containing pig protein, for instance, are typically non-compliant with Sharia law, unless used in emergencies where no halal alternatives exist (Ramli & Zain, 2023). Consequently, it is crucial to thoroughly understand the composition of these products and evaluate the availability of suitable halal alternatives that meet clinical requirements. The use of growth factors, such as BMPs, in bone regeneration is effective in enhancing osteoinduction. However, this study highlights ethical challenges associated with the use of pig protein-based products, as found in some BMP formulas. In line with Islamic principles, this study recommends developing products based on human or synthetic proteins to provide a more suitable alternative for the Muslim patient population (Wong & Faris, 2023).

The study by Khalaf et al. (2021) provides a fiqh perspective on using bone grafts in medical procedures. They state that Islam allows the use of materials derived from humans or animals in emergencies, provided there are no better or halal alternatives. Additionally, the use of human materials (allografts) is permitted provided it meets the principle of *ad-darurat tubihul mahdhurat* (emergencies permit the prohibited), and consent has been obtained from the donor or their family (Binti Mod Ali & Gunardi, 2021; Bokek-Cohen et al., 2023). This study supports careful case-by-case evaluation, informed consent, and justification based on clinical necessity for a bone graft.

The primary limitations of this study stem from its dependence on secondary data sources, such as product composition details from MSDSs and CAS numbers, which may lack comprehensive information on critical material components, especially for products with proprietary formulations. Additionally, the study is limited to commercially available bone grafts in Indonesia, restricting its applicability to other regions with different products or regulatory frameworks. The ethical and religious considerations discussed are specific to the Islamic context, potentially reducing the relevance of the findings to non-Muslim populations. Furthermore, the study does not address patient-specific preferences or practical clinical challenges, such as material availability and cost, which could affect the use of halal-compliant products.

In general, the results of this study provide beneficial guidance for dentists and healthcare professionals in selecting bone graft materials that comply with ethical and legal principles to ensure that medical procedures are clinically effective and meet the applicable religious requirements. This becomes an essential foundation for doctors when making clinical treatment decisions, especially in countries where the majority of the population is Muslim.

Beyond material origin, this study highlights traceability and supply chain transparency as major determinants of halal risk. Most bone graft products available in Indonesia are imported, and current manufacturer documentation rarely includes halal-specific information such as slaughtering method, donor consent protocols, or segregation during processing and transportation. This lack of transparency complicates halal verification and places clinicians in a challenging position when addressing patient concerns.

From a regulatory perspective, these findings underscore the need for clearer halal governance of dental biomaterials in Indonesia. While national halal assurance frameworks administered by BPJPH and MUI provide guidance for consumable products, implantable dental materials remain insufficiently regulated. The development of halal certification pathways or standardized disclosure requirements for dental biomaterials would enhance clinician decision-making, protect patient autonomy, and strengthen public trust in halal-compliant healthcare services.

4. Conclusion

This study demonstrates that the halal status of dental bone graft materials varies according to graft category and material origin among products available in Indonesia. Based on a material-based halal criticality analysis, alloplastic bone grafts were consistently identified as the lowest risk category, as they are composed entirely of synthetic, non-animal, and non-human materials. In contrast, xenografts and allografts exhibited higher halal risk profiles due to their reliance on animal- or human-derived components, while growth factor-based and composite grafts showed variable risk levels depending on the biological origin of their active ingredients and carriers. From clinical and ethical perspectives, these findings indicate that bone graft selection should integrate technical efficacy with patient values and religious considerations.

From a regulatory and industrial perspective, this study highlights a significant gap in halal governance for dental biomaterials in Indonesia. Existing halal assurance frameworks do not fully address implantable dental materials, underscoring the need for clearer guidelines, standardized labeling, and halal certification pathways for bone graft products. The dental biomaterials industry is encouraged to prioritize the development of halal-compliant alternatives and to improve supply chain transparency for biologically derived products. Future research should expand this framework by incorporating laboratory-based verification of halal-critical components, assessing patient perceptions and acceptance of halal-certified dental materials, and evaluating the clinical performance of halal-compliant grafts. Such efforts are essential to support ethical, patient-centered, and halal-oriented dental care in Indonesia.

CRedit Authorship Contribution Statement

Ridhayani Hatta: Conceptualization, Methodology, Data curation, Formal analysis, Writing – original draft, Review, Editing. **Mohamad Arif Budiman Putra Pratama:** Writing – review & Editing. **Nurfianti:** Validation, Review. **Fathimah Azzahrah:** Project administration, Formal analysis, Writing – review. **Wastuti Hidayati Suriyah:** Formal analysis, Writing – review & Editing. **Dede Arsista:** Investigation, Resources. **Solachuddin J. A. Ichwan:** Formal analysis, Supervision, Writing – review.

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Declaration of Competing Interest: The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.



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