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Multifunctional Silicone Elastomers: Advances in Synthesis, Characterization and Dental Applications — A Comprehensive Review

Eyarefe Oghenekowhoro Stephen[1*], Atuegbu Chinwendu Nneka[2], Nwaogwugwu Nicholas Uba[3], Okonkwo Joseph Ifeanyichukwu[4], Otuiheneme Chibunnam Dave[5], Enyeribe Chisom Augustus[6] & Arukalam Okechi Innocent[7]

[1,4,6]*Department of Dental Technology, Federal University of Technology Owerri (FUTO), Imo State, Nigeria*

[2]*University of Port Harcourt Teaching Hospital Rivers State, Nigeria*

[3]*Federal Medical Centre, Abeokuta Ogun State, Nigeria*

[5]*Abia state Hospitals management board, Dental Centre Aba, Abia State*

[7]*Department of Polymer and Textile Engineering, Federal University of Technology Owerri Imo State Nigeria*

[*]**Corresponding Author:** Eyarefe Oghenekowhoro Stephen, Department of Dental Technology, Federal University of Technology Owerri (FUTO), Imo State, Nigeria.

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Abstract

Silicone elastomers occupy a critical position in contemporary dental and maxillofacial prosthetics, serving as the material of choice for dentures, facial prostheses, dental impression systems, occlusal splints, and soft tissue substitutes. Despite their inherent biocompatibility and tissue-mimicking properties, unmodified silicones are limited by susceptibility to microbial colonisation, mechanical fatigue, and aesthetic degradation. Over the past decade, nanotechnology has revolutionised this field by enabling the synthesis of multifunctional silicone elastomeric systems with simultaneous improvements in antibacterial efficacy, mechanical resilience, colour stability, and biocompatibility. This comprehensive review synthesises approximately 70 primary studies and reviews (2014–2025) examining key domains of silicone elastomer research: (i) synthesis strategies including nanoparticle compounding and in situ polymerisation; (ii) antibacterial functionalisation using silver nanoparticles (AgNPs), zinc oxide (ZnO) nanoparticles, quaternary ammonium compounds (QACs), and chlorhexidine nanoparticles; (iii) mechanical reinforcement with silica nanofillers, carbon nanotubes (CNTs), nanocellulose fibres (CNFs), and polyhedral silsesquioxane (POSS); (iv) colour stability enhancement with TiO_2 and ZrO_2 nanoparticles and UV protectants; (v) biocompatibility assessment per ISO 10993 protocols; and (vi) emerging functionalities including diagnostic sensing mouthguards and controlled drug delivery systems. Key findings include up to 74% reduction in Streptococcus mutans biofilm formation, tensile strength improvements from 2.78 to 3.62 MPa with surface-treated SiO_2, and significant colour stability gains using ZrO_2 nanoparticles. Critical gaps identified include the absence of integrated multifactorial testing protocols, the scarcity of long-term in vivo clinical data, methodological heterogeneity, and limited investigation of 3D-printing-compatible formulations. Evidence-based recommendations for future research are proposed, with emphasis on clinical translation, standardisation, and interdisciplinary collaboration.

Keywords: Silicone Elastomers, Nanoparticles, Dental Prosthetics, Antibacterial Functionalisation, Biocompatibility

Abbreviations

AgNPs: Silver nanoparticles
ASTM: American Society for Testing and Materials
CHG: Chlorhexidine gluconate
CHX-NPs: Chlorhexidine nanoparticles
CNFs: Carbon (nanocellulose) fibres
CNTs: Carbon nanotubes
DLS: Dynamic light scattering

EDX: Energy-dispersive X-ray spectroscopy
FTIR: Fourier-transform infrared spectroscopy
ICP-MS: Inductively coupled plasma mass spectrometry
ISO: International Organization for Standardization
MIC: Minimum inhibitory concentration
MRSA: Methicillin-resistant Staphylococcus aureus
NaOCl: Sodium hypochlorite
PDMS: Polydimethylsiloxane
POSS: Polyhedral silsesquioxane
QACs: Quaternary ammonium compounds
QASi: Quaternary ammonium silica
ROS: Reactive oxygen species
RTV: Room-temperature vulcanising
SEM: Scanning electron microscopy
TEM: Transmission electron microscopy
TiO_2: Titanium dioxide
VPS: Vinyl polysiloxane
ZnO: Zinc oxide
ZrO_2: Zirconium dioxide

Introduction

The clinical performance of dental and maxillofacial prostheses is intimately linked to the physicochemical properties of the materials from which they are fabricated. Among the diverse range of materials available, silicone elastomers occupy a uniquely versatile position, combining mechanical flexibility, dimensional stability, and a remarkable capacity to mimic the visual and tactile qualities of living soft tissues. These properties have driven their widespread adoption across applications including removable partial and complete dentures, extraoral maxillofacial prostheses (auricular, nasal, orbital), dental impression materials, obturators, occlusal splints, and soft denture liners [1, 2].

The oral and perioral environments present exceptionally demanding conditions for prosthodontic materials. Thermal cycling between ingested foods and ambient temperatures, cyclic mechanical loading during mastication (generating forces of 200–800 N in the molar region), salivary enzymatic activity, exposure to dietary chromogens and chemical disinfectants, and persistent microbial challenge collectively degrade material performance over time. Unmodified silicones, while biocompatible, exhibit inherent vulnerabilities: relatively low tensile and tear strength, susceptibility to surface discolouration, and a propensity for microbial colonisation particularly by Candida albicans in denture wearers, contributing to denture stomatitis affecting up to 70% of complete denture patients [3, 4].

These limitations have catalysed an intensive and productive period of materials innovation. Nanotechnology, in particular, has emerged as the most transformative enabling technology, facilitating the creation of composite silicone systems that address multiple performance deficiencies simultaneously. The integration of nanoparticles with dimensions of 1–100 nm confers properties fundamentally different from bulk materials due to dramatically increased surface-area-to-volume ratios, quantum effects, and enhanced interfacial interactions with the polymer matrix. This has enabled researchers to engineer materials with intrinsic antimicrobial activity, superior mechanical durability, improved colour stability, and novel diagnostic or therapeutic functionalities within a single elastomeric system [5, 6].

The literature on this subject has expanded markedly in the period 2014–2025, with studies spanning the continuum from fundamental material characterisation to preclinical in vitro evaluation and, increasingly, clinical application. However, the field remains characterised by methodological heterogeneity, a predominance of single-outcome investigations, and a gap between laboratory innovation and clinical translation. Systematic synthesis of this evidence base is therefore both timely and necessary.

This comprehensive review addresses the following objectives: (1) to critically analyse current strategies for the synthesis and characterisation of multifunctional silicone elastomers; (2) to evaluate evidence for antibacterial functionalisation, mechanical reinforcement, colour stability enhancement, and biocompatibility; (3) to examine emerging novel functionalities; (4) to identify cross-cutting research gaps and methodological limitations; and (5) to propose evidence-based directions for future research and clinical translation.

Methods

Literature Search Strategy

This narrative systematic review was conducted in conformity with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. A comprehensive electronic database search was performed across PubMed/MEDLINE, Scopus, Web of Science Core Collection, Embase, and Google Scholar, covering the period from January 2014 to March 2025. The search strategy employed MeSH terms and free-text keywords in the following Boolean combinations: ("silicone elastomer" OR "silicone rubber" OR "polydimethylsiloxane" OR "PDMS") AND ("dental" OR "maxillofacial" OR "oral" OR "prosthetic") AND ("nanoparticle" OR "nanotechnology" OR "nanofiller" OR "nanocomposite"). Additional search strings included: "antibacterial dental silicone", "mechanical reinforcement silicone dental", "colour stability maxillofacial silicone", "biocompatibility silicone dental", and "silicone impression material". Reference lists of retrieved articles and relevant systematic reviews were hand-searched for additional eligible studies.

Inclusion and Exclusion Criteria

Studies were eligible for inclusion if they: (i) evaluated silicone-based elastomeric materials for dental, oral, or maxillofacial applications; (ii) reported quantitative or qualitative outcomes for at least one of the following domains: antibacterial activity, mechanical properties, colour stability, biocompatibility, or novel functionality; (iii) were published in English in peer-reviewed journals; and (iv) were conducted in vitro, ex vivo, in vivo (animal or human), or were systematic reviews and meta-analyses. Studies were excluded if they: were conference abstracts or grey literature without peer review; reported exclu-

sively on non-silicone elastomeric materials without comparative silicone data; or were retracted.

Data Extraction and Quality Assessment

Data extraction was performed independently by the primary author (E.O.S.) and cross-checked by two co-authors (A.C.N. and N.N.U.), with discrepancies resolved by consensus. Extracted data included: study design, silicone base material, type and concentration of functional additive, synthesis method, outcome measures and units, testing standards applied (e.g., ASTM, ISO), and reported limitations. Due to the substantial heterogeneity of study designs and outcome measures, a quantitative meta-analysis was not feasible; findings are therefore synthesised narratively, with tabular summaries provided for major outcome domains.

Synthesis of Multifunctional Silicone Elastomers

The fabrication of multifunctional silicone elastomeric systems employs three principal synthetic strategies: (a) physical blending or compounding of functional additives into the silicone base prior to crosslinking; (b) surface coating or functionalisation of pre-formed silicone specimens; and (c) in situ polymerisation, in which functional groups are chemically incorporated into the polymer backbone during network formation. Each approach confers distinct advantages and presents specific challenges relevant to clinical application.

Nanoparticle Compounding

Nanoparticle compounding is the most widely reported synthesis strategy, owing to its technical accessibility and compatibility with commercially available silicone systems. incorporated ZnO nanoparticles and chlorhexidine diacetate into commercial maxillofacial silicone (A-2186, Factor II Inc.) via high-speed mechanical mixing, achieving homogeneous dispersion confirmed by scanning electron microscopy (SEM) and energy-dispersive X-ray spectroscopy (EDX). employed a similar approach with silver nanoparticles (AgNPs), reporting stable incorporation at concentrations of 0.5–2 wt% without phase separation. Akay et al. [7] investigated the cytotoxic implications of compounding titanium dioxide (TiO_2), fumed silica, and silanised silica nanoparticles into room-temperature vulcanising (RTV) silicone, employing a two-part compounding protocol with thorough mechanical mixing to minimise agglomeration. The critical importance of dispersion quality was underscored by Zayed et al. [8], who demonstrated that surface treatment of SiO_2 nanoparticles with coupling agents significantly improved filler-matrix interfacial adhesion, with SEM confirming homogeneous distribution and reduced agglomerate formation compared to untreated particles.

Surface Coating and Functionalisation

Surface coating strategies offer the advantage of functionalising pre-fabricated silicone components without altering bulk material properties developed chlorhexidine nanoparticle (CHX-NP) coatings applied to dental silicone surfaces via solvent-based deposition, demonstrating sustained antifungal release over 28 days. employed a surface-binding approach for quaternary ammonium silica (QASi) nanoparticles, achieving covalent attachment to the silicone matrix that prevented leaching while maintaining bactericidal contact activity. fabricated a polydimethylsiloxane (PDMS) coating loaded with chlorhexidine for dental polymer surfaces, with drug release modulated by membrane thickness and cross-linking density.

Functional Additives for Impression Materials

For vinyl polysiloxane (VPS) impression materials, synthesis strategies focus on improving wettability and dimensional stability. Khan et al. [9] incorporated the non-ionic surfactant Rhodasurf CET-2 at 0.1–0.5 wt% into experimental VPS formulations, significantly reducing contact angle on hydrophilic surfaces and improving detail reproduction on moist dental substrates. Shahab et al. [10] introduced a tetrafunctional crosslinker (tetrafluorodimethyldisiloxane, TFDMSOS) alongside a novel surfactant, achieving improved water absorption behaviour and enhanced dimensional stability over 24 hours, with compatibility confirmed across plaster and stone die materials. More recently, characterised a new-generation hydrophilic VPS demonstrating improved dimensional accuracy in the presence of blood and saliva contamination, with direct clinical implications for impression techniques.

Antibacterial Functionalisation of Silicone Elastomers

The oral cavity supports a complex polymicrobial ecosystem comprising more than 700 bacterial species, with biofilm formation on prosthetic surfaces representing a primary aetiological factor in denture stomatitis, peri-implant mucositis, and secondary infections. Silicone prostheses—particularly those designed for continuous or long-term wear—are especially susceptible to colonisation by Candida albicans, Streptococcus mutans, Staphylococcus epidermidis, and Pseudomonas aeruginosa. This clinical challenge has stimulated sustained research into silicone systems with intrinsic or incorporated antimicrobial activity [11, 12].

Silver Nanoparticles (AgNPs)

AgNPs represent the most extensively studied antibacterial additive for silicone dental materials, with a well-characterised multimodal mechanism of action: (i) direct interaction of silver ions (Ag^+) with thiol groups of bacterial membrane proteins, disrupting membrane integrity; (ii) inhibition of DNA replication and transcription; (iii) interference with the respiratory electron transport chain; and (iv) generation of reactive oxygen species (ROS) that induce oxidative stress. [13] provided a landmark systematic review confirming that AgNPs and ZnO nanoparticles in composite dental materials reduced bacterial adhesion by up to 74% against demonstrated that AgNP-modified silicone at 1 wt% maintained potent anti-S. mutans activity over 30-day simulated aging without significant reduction in material elasticity, a critical finding given the rheological demands of tissue-contacting prostheses. [14] incorporated AgNPs into silicone facial prosthetic material and reported effective inhibition of C. albicans growth in biofilm models at concentrations that produced no measurable cytotoxicity in human fibroblast cultures (ISO 10993-5 protocol). biosynthesised AgNPs directly on orthodontic elastomeric modules using plant-mediated reduction,

achieving enhanced mechanical integrity alongside antibacterial activity, a synthesis approach that reduces the use of chemical reducing agents and may offer sustainability advantages. [15] employed silica-coated AgNPs (Ag@SiO_2) in experimental dental resins, where the silica shell served dual functions: preventing AgNP agglomeration and limiting silver ion release, thereby reducing cytotoxicity while maintaining efficacy. Confocal laser scanning microscopy confirmed a 74% reduction in S. mutans biofilm biomass at 3 wt% Ag@SiO_2, with dose-dependent effects and no significant cytotoxicity to L929 fibroblast lines.

Zinc Oxide Nanoparticles (ZnO NPs)

ZnO nanoparticles exert antimicrobial effects primarily through ROS generation particularly hydrogen peroxide (H_2O_2) and superoxide anions alongside direct physical disruption of bacterial membranes. Their photocatalytic activity under UV and visible light further enhances antimicrobial potency in surface-exposed prostheses. demonstrated concentration-dependent antibacterial activity of ZnO-modified maxillofacial silicone, though this was accompanied by a reduction in tensile strength, highlighting the need for concentration optimisation. [16] observed enhanced antifungal activity against C. albicans in ZnO-modified silicones compared to controls, with minimum inhibitory concentrations established for clinical reference.

Quaternary Ammonium Compounds (QACs)

QACs represent a structurally distinct class of antibacterial agents characterised by cationic nitrogen centres that disrupt anionic bacterial cell membranes through electrostatic interaction. Their key clinical advantage when chemically tethered to the silicone matrix is a non-leaching, contact-killing mechanism that does not depend on sustained ion release and therefore persists throughout the prosthesis lifespan. [17] incorporated quaternary ammonium silica (QASi) nanoparticles into medical-grade silicone at 0.5–1 wt%, achieving complete bactericidal activity (≥6-log reduction) against S. epidermidis, S. aureus (MRSA), E. faecalis, and P. aeruginosa in ISO direct-contact assays. No inhibition zones were observed in agar diffusion assays, confirming a non-leaching mechanism and supporting safety for implantable device applications. Nogueira, functionalised experimental silicone with covalently bound QAC moieties via silane coupling chemistry, confirming durable contact-killing activity across simulated 12-month aging protocols including salivary immersion and thermal cycling. This durability represents a significant clinical advantage over leachable systems such as CHX-loaded coatings, where antimicrobial efficacy inevitably diminishes as the reservoir depletes. Kula et al. [46] explored innovative quaternary ammonium methacrylate monomers for copolymerisation with dental silicone precursors, achieving covalent integration with preserved bulk mechanical properties—an approach that represents the current frontier in QAC-based dental material functionalisation.

Other Antimicrobial Agents

Beyond the three principal agent classes, chlorhexidine nanoparticles (CHX-NPs) have demonstrated sustained antifungal efficacy in silicone coating systems [18]. reported concentration-dependent antifungal activity in RTV silicone elastomers modified with chitosan nanoparticles, a biopolymeric agent with inherent mucoadhesive and antifungal properties that also offers potential for drug co-delivery. [19] demonstrated that PDMS coatings loaded with chlorhexidine free base achieved sustained release over 21 days, effectively inhibiting S. mutans and Candida species in planktonic and biofilm modes.

Table 1: Summary of Antibacterial Modifications to Silicone Elastomers for Dental Applications.

Agent	Matrix	Key Findings	Limitations	References
AgNPs (1–20 nm)	Silicone maxillofacial prosthesis	Inhibition of C. albicans; no cytotoxicity to fibroblasts	Concentration-dependent; leaching possible at high loads	[3, 14, 19]
ZnO NPs	Maxillofacial silicone / composite resin	74% reduction of S. mutans adhesion; antifungal activity	Reduces tensile strength at high concentrations	[5, 12]
QASi nanoparticles (0.5–1%)	Medical-grade silicone	Complete kill of MRSA, E. faecalis, P. aeruginosa	Non-leaching; safe for implantable devices	[16]
Chitosan NPs	RTV maxillofacial silicone	Concentration-dependent antifungal vs. C. albicans	Biocompatible; in vitro only	[37]
CHX-NPs coating	Dental silicone surfaces	Sustained antifungal efficacy	No long-term in vivo data	[18]
Ag@SiO_2 NPs (3 wt%)	Experimental dental resin	74% S. mutans biofilm reduction; minimal cytotoxicity	Silica shell limits ion release; dose-dependent	[20]

AgNPs: silver nanoparticles; ZnO: zinc oxide; QASi: quaternary ammonium silica; CHX: chlorhexidine; MRSA: methicillin-resistant Staphylococcus aureus; ND: not determined.

Mechanical Properties and Reinforcement

Mechanical integrity is a fundamental prerequisite for clinical silicone prostheses, which must withstand cyclic loading during mastication, facial movement, and donning and doffing. The principal mechanical parameters of clinical relevance are tensile strength, tear resistance, elongation at break, Shore A hardness, and peel bond strength to underlying frameworks. Unfilled addition-cure and condensation-cure silicones typically exhibit tensile strengths of 2.5–4.0 MPa and tear strengths of 10–20 N/mm properties that may be insufficient for long-term maxillofacial prosthetic use [20- 22].

Silica Nanofillers

Nano-silica reinforcement is the most mechanically effective and well-characterised modification strategy. conducted a landmark study demonstrating that surface-treated SiO_2 nanoparticles at 3 wt% increased the tensile strength of A-2186 maxillofacial silicone from 2.78 to 3.62 MPa (+30%), tear strength from 19.32 to 45.90 N/mm (+138%), and elongation at break to 754.8% at 1.5% concentration. SEM analysis attributed these gains to homogeneous filler dispersion and strong covalent filler-matrix interfaces mediated by silane coupling. [23] independently reported a 35% overall improvement in tensile and tear properties using nano-silica in experimental silicone composites, with transmission electron microscopy (TEM) confirming nanoparticle distribution at the 10–30 nm scale. The mechanism of silica reinforcement involves multiple concurrent phenomena: (i) physical cross-linking points that restrict polymer chain mobility and increase elastic modulus; (ii) stress redistribution across a large interfacial area, delaying crack initiation; and (iii) crack deflection and bifurcation at the filler-matrix interface, absorbing fracture energy. The critical requirement is uniform dispersion: silica agglomerates act as stress concentrators and can paradoxically reduce tensile properties. Surface treatment with silane coupling agents (e.g., 3-methacryloxypropyltrimethoxysilane) is therefore essential for clinical-grade composites [24, 25].

Nanocellulose Fibres (CNFs)

Nanocellulose fibres represent an emerging class of bio-sourced reinforcing agents with high aspect ratio (>100), inherent hydroxyl surface functionality facilitating matrix bonding, and a renewable origin. [26] incorporated CNFs into RTV maxillofacial silicone at 0.1–1 wt%, reporting peak mechanical performance at 0.5 wt%: tensile strength increased from 5.52 to 6.07 MPa (+10%), tear strength improved to 28.73 N/mm, and elongation reached 676.3%. FTIR spectroscopy confirmed hydrogen bonding between CNF hydroxyl groups and the silicone oxygen atoms, while Shore A hardness (38.2) remained within the clinically acceptable 25–35 range for maxillofacial applications. Notably, agglomeration was observed at 1 wt% loading, emphasising the existence of a performance-optimising concentration window.

Carbon Nanotubes (CNTs)

Carbon nanotubes offer exceptional intrinsic mechanical properties (tensile strength up to 100 GPa, Young's modulus ~1 TPa) that translate into substantial reinforcement when adequately dispersed within the polymer matrix. reviewed CNT-reinforced silicone rubber composites, reporting tensile strength improvements of 56% and elastic modulus gains of 63% at 2–3 parts per hundred resin (phr) versus unfilled controls. Patel, Desai, and Rao [26] demonstrated additional gains in toughness and thermal stability, attributing these to efficient stress transfer across the CNT-matrix interface and CNT-mediated suppression of thermal degradation pathways. The potential application of CNT-reinforced silicones in strain-sensing prosthetics capitalising on the piezoresistive properties of CNT networks represents a convergence of mechanical reinforcement and diagnostic functionality [27].

However, CNT incorporation presents significant practical challenges. The tendency of CNTs to form van der Waals-stabilised bundles necessitates high-energy dispersion techniques (probe ultrasonication, high-shear mixing) and surface functionalisation (acid treatment, covalent grafting) to achieve adequate matrix distribution. Unresolved cytotoxicity concerns particularly for oxidatively damaged or short CNTs present a regulatory barrier to clinical application, with ISO 10993 testing for CNT-modified devices remaining incomplete in the published literature.

Polyhedral Silsesquioxane (POSS) and Other Agents

Rao, Gupta, and Padmini demonstrated that 1 wt% POSS addition to RTV maxillofacial silicone produced statistically significant increases in both tensile strength and tear resistance, while maintaining acceptable hardness and colour stability over accelerated aging. The cage-like silsesquioxane structure is hypothesised to form interfacial links that enhance crosslink density without compromising the flexibility essential for tissue simulation. evaluated both organic and inorganic nanoparticles (including polytetrafluoroethylene, PTFE, particles) in heat-vulcanised silicone, reporting improved mechanical properties alongside maintained colour stability, suggesting dual-function potential for some inorganic fillers. [28]

Table 2: Mechanical Property Improvements with Nanofiller Reinforcement of Silicone Elastomers.

Filler/Agent	Matrix	Tensile Strength	Tear Strength	Elongation at Break	Ref.
Surface-treated SiO_2 (3 wt%)	A-2186 silicone	3.62 MPa (vs 2.78 control)	45.90 N/mm (vs 19.32)	754.8% at 1.5%	[22]
Nanocellulose fibres (0.5 wt%)	RTV silicone	6.07 MPa (vs 5.52 control)	28.73 N/mm	676.30%	[24]
CNTs (2–3 phr)	Silicone rubber	+56% vs unfilled	+63% modulus	ND	[25]

POSS (1%)	RTV maxillofacial silicone	Significantly increased	Significantly increased	ND	[27]
Nano-silica (ND)	Silicone elastomer	35%	+35% tear resistance	ND	[23]
ZnO NPs	Maxillofacial silicone	Decreased tensile	ND	ND	[5]

CNTs: carbon nanotubes; POSS: polyhedral silsesquioxane; RTV: room-temperature vulcanising; ND: not determined. Values represent peak reported performance from cited studies.

Biocompatibility and Cytotoxicity Considerations

The introduction of functional additives however beneficial for material performance carries an inherent obligation to demonstrate biological safety. ISO 10993 ("Biological Evaluation of Medical Devices") provides the internationally recognised framework for this assessment, comprising a tiered battery of cytotoxicity, sensitisation, irritation, systemic toxicity, genotoxicity, and implantation tests. For dental silicone elastomers, ISO 10993-5 (cytotoxicity) and ISO 10993-12 (sample preparation and reference materials) are most commonly applied [29 - 31].

Nanoparticle-Associated Cytotoxicity

A central mechanism of nanoparticle-associated cytotoxicity is the generation of reactive oxygen species (ROS), including superoxide ($O_2^{\bullet-}$), hydroxyl radicals (•OH), and hydrogen peroxide (H_2O_2), which exceed cellular antioxidant capacity and produce oxidative damage to lipids, proteins, and nucleic acids. [32] systematically evaluated MDX4-4210 silicone modified with AgNPs and TiO_2 NPs, finding that AgNPs at 1 wt% yielded 42.10% cell viability on MG63 osteosarcoma lines compared to controls, decreasing to less than 20% at higher concentrations. TiO_2 at 3 wt% produced only 18.06% viability, indicating significantly greater cytotoxic potential than AgNPs at equivalent concentrations. Lim, Park, and Kim [33] identified a critical trade-off in AgNP-embedded silicones: while bacterial adhesion was significantly reduced, measurable increases in ROS were detected in primary human oral fibroblast cultures exposed for 72 hours. These findings underscore that the concentration, size distribution, and surface chemistry of AgNPs are primary determinants of the antibacterial-cytotoxic balance, a relationship that necessitates precise formulation control.

Non-Leaching Systems and Safety Profiles

Non-leaching systems in which the active antimicrobial agent is covalently tethered to the silicone matrix offer a fundamentally safer biocompatibility profile than leachable nanoparticle systems. [34] confirmed this principle for QASi-integrated silicone, demonstrating that the absence of ion leaching (confirmed by inductively coupled plasma mass spectrometry) prevented systemic silver or quaternary ammonium exposure, and no cytotoxicity was observed in ISO 10993-5 testing. This non-leaching property also confers practical clinical advantages: maintained antimicrobial efficacy throughout the prosthesis lifespan without concerns about cumulative patient exposure. [35] demonstrated that the $Ag@SiO_2$ (silica-coated silver) strategy represents a viable approach to cytotoxicity mitigation: the silica shell restricts silver ion release kinetics, maintaining antibacterial efficacy while reducing fibroblast toxicity to negligible levels. Santos, Oliveira, and Costa [36] conducted a comprehensive biocompatibility assessment per ISO 10993 of experimental multifunctional silicone formulations, reporting acceptable cytotoxicity, sensitisation, and genotoxicity profiles, while noting that chronic in vivo implantation data remained absent, a gap that persists across the field.

Methodological Considerations

Inter-study comparability in biocompatibility assessment is significantly hampered by heterogeneity in: (i) cell line selection (oral fibroblasts, MG63 osteosarcoma, L929 murine fibroblasts, keratinocytes, and human umbilical vein endothelial cells have all been employed); (ii) exposure duration (24 h to 7 days); (iii) extract preparation protocol (ISO 10993-12 compliance is inconsistent); and (iv) endpoint measures (MTT assay, resazurin reduction, Alamar Blue, live/dead staining). These variations make definitive cross-formulation comparisons impossible without standardised head-to-head testing. Long-term in vivo models assessing chronic inflammation, immunotoxicity, and genotoxicity under simulated clinical use conditions represent the most critical unmet need in this domain [37].

Table 3: Biocompatibility Outcomes for Functionalised Silicone Elastomers.

Agent	Matrix	Cell Line	Cell Viability	Protocol	Ref.
AgNPs (1 wt%)	MDX4-4210 silicone	MG63 osteosarcoma	42.10%	ISO 10993	[34]
TiO_2 NPs (3 wt%)	MDX4-4210 silicone	MG63 osteosarcoma	18.06%	ISO 10993	[34]
AgNPs (low conc.)	Silicone prosthesis	Human fibroblasts	Acceptable; no cytotox.	Direct contact	[14]
AgNPs (mod. conc.)	Silicone elastomer	Oral fibroblasts	Elevated ROS detected	MTT assay	[35]
QASi (0.5–1%)	Medical-grade silicone	In vitro cell lines	Non-cytotoxic (non-leaching)	ISO 10993	[16]

Ag@SiO_2 NPs (3 wt%)	Experimental resin	Fibroblasts	No cytotoxicity	MTT + ion release	[20]

ROS: reactive oxygen species; QASi: quaternary ammonium silica; MTT: 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide assay.

Colour Stability and Aesthetic Properties

Colour stability is a paramount aesthetic requirement for maxillofacial prostheses and visible dental devices, where discolouration directly undermines prosthesis credibility and patient quality of life. Colour change is quantified by the CIELAB colour difference (ΔE*ab) metric, with values ≤3.3 generally considered clinically imperceptible, 3.3–6.8 marginally acceptable, and >6.8 clinically unacceptable. Silicone elastomers are susceptible to colour degradation through multiple pathways: photochemical oxidation by UV radiation, staining by dietary chromogens (coffee, tea, red wine), surface sorption of disinfectant chemicals, and pigment fading [38, 39].

UV Protectants and Titanium Dioxide

Turhan Bal, Tuncer, conducted systematic investigations of UV-protective agents in addition-type maxillofacial silicone, finding that benzophenone-3 at 1 wt% and titanium dioxide at 0.5–1 wt% significantly reduced ΔE*ab values following accelerated UV aging (1000 h xenon arc lamp). TiO_2 functioned through combined UV absorption and photocatalytic degradation of chromogenic species at the material surface. However, [40] demonstrated that TiO_2 addition substantially increased material whiteness (L* value) and reduced translucency, optical effects that must be carefully managed through pigment formulation to maintain lifelike aesthetics.

Zirconium Dioxide (ZrO_2) Nanoparticles

Tuncer, Turhan Bal, and Akca [41] demonstrated that ZrO_2 nanoparticles at 0.5–2 wt% improved colour stability of heat-polymerised maxillofacial silicone across multiple pigment formulations, with ΔE*ab values reduced below the clinical perceptibility threshold (≤3.3) for several chromatic groups after 1000 h artificial aging. ZrO_2 is notable for its combination of UV-scattering properties, chemical inertness in salivary conditions, and minimal effect on translucency compared to TiO_2 making it a more aesthetically nuanced opacifier/stabiliser candidate. [42] independently confirmed these findings in an evaluation of ZrO_2 effects on artificially aged heat-polymerised silicone, reporting consistent colour stability improvements across thermal cycling and UV exposure protocols.

Disinfectant-Induced Discolouration

Prosthesis hygiene regimens introduce an additional chemical discolouration pathway distinct from UV and dietary staining. [42] systematically examined the effects of common disinfectants, chlorhexidine gluconate (CHG, 0.12%), sodium hypochlorite (NaOCl, 0.5%), and effervescent tablet solutions on pure and nano-TiO_2-modified silicone (A-2000 and A-2006), finding that CHG was the least discolouring disinfectant and that TiO_2 provided significant protective effects in A-2006 formulations against CHG- and NaOCl-induced colour change. These findings have direct clinical implications for prosthesis maintenance protocols. [43] conducted the most comprehensive systematic review and meta-analysis of maxillofacial silicone colour stability, incorporating 24 studies and finding that human/environmental aging (UV radiation, perspiration, and sebum exposure) produced significantly greater colour change than laboratory accelerated aging alone, with TiO_2 NPs consistently associated with improved stability across subgroup analyses. The meta-analysis highlighted the near-total absence of patient-based longitudinal colour measurements, a critical gap, as accelerated laboratory protocols cannot faithfully replicate the complexity of in vivo degradation.

Table 4: Colour Stability Modifications in Silicone Elastomers for Dental and Maxillofacial Applications

Agent	Matrix	Key Findings	Limitations	Ref.
TiO_2 NPs	Addition-type silicone	Reduced colour change post UV aging	Alters translucency / whiteness; opacification risk	[8,31]
ZrO_2 NPs	Heat-polymerised silicone	ΔE below perceptibility threshold for several pigments	Pigment-specific efficacy; limited clinical data	[29]
Ethylhexyl salicylate	Addition-type silicone	Significant reduction in ΔE vs artificial aging	UV-protectant only; no mechanical benefit	[8]
Barium sulphate (0.2%)	Pigmented silicone	UV-induced changes attenuated	Limited to specific pigment formulations	[30]
CHG disinfection	Nano-TiO_2 silicone (A-2006)	TiO_2 protective against CHG/NaOCl-induced change	NaOCl remains problematic at high concentrations	[32]

ΔE: colour difference; CHG: chlorhexidine gluconate; NaOCl: sodium hypochlorite; UV: ultraviolet radiation.

Novel Functionalities

Wearable Diagnostic Sensing Devices

The integration of sensing capabilities into silicone-based intraoral devices represents a significant frontier with transformative potential for point-of-care dental diagnostics. Hu et al. [39] fabricated a PDMS mouthguard incorporating gold-silver

(Au@Ag) nanorods functionalised with 4-aminothiophenol as a surface-enhanced Raman scattering (SERS) reporter. The device achieved colorimetric detection of hydrogen sulphide (H_2S), a biomarker for periodontal disease and caries activity at concentrations as low as 10 nM in artificial saliva, with visible colour change detectable without instrumentation. This approach enables non-invasive, patient-administered screening for early periodontal deterioration. Zhang et al. [40] engineered a ZnO-PDMS nanocomposite flexible mouthguard that exploits the fluorescent properties of ZnO quantum dots to visualise hidden dental lesion sites. When illuminated with UV light, the device produced spatially resolved fluorescence maps corresponding to enamel demineralisation zones, enabling accurate lesion localisation in locations inaccessible to standard clinical examination. The combination of PDMS flexibility, biocompatibility, and optical transparency makes it an ideal platform for wearable diagnostic integration.

Controlled Drug Delivery

Silicone matrices offer well-established diffusion-controlled drug release characteristics, with release kinetics modifiable through polymer crosslink density, filler incorporation, and membrane thickness. [44] advanced this paradigm by fabricating PDMS-based triblock copolymer vesicles (PDMS-b-PEG-b-PDMS) that encapsulated cariogenic biofilm inhibitors (specifically, the quorum-sensing inhibitor farnesol and the antibiofilm agent trans-cinnamaldehyde) within hydrophilic vesicle cores. These nanocarrier-PDMS composites demonstrated pH-responsive release under acidic conditions (pH 5.5–6.0) characteristic of active caries lesions, delivering therapeutic concentrations that reduced S. mutans biofilm volume by >60% in a rodent caries model providing the first in vivo demonstration of PDMS-based caries chemoprevention [45]. demonstrated that PDMS coatings loaded with chlorhexidine free base at 2–5 wt% achieved sustained release profiles conforming to pseudo-first-order kinetics over 21 days, with bacteriostatic concentrations maintained throughout. The coating was applied to 3D-printed dental polymer frameworks, demonstrating compatibility with digital fabrication workflows an important feature given the growing adoption of digital denture technology.

Self-Healing Silicone Systems

Reported on the development of 3D-printable elastomers with autonomous self-repair capabilities, incorporating dynamic covalent bonds (e.g., disulphide linkages, Diels-Alder adducts) into the silicone polymer backbone. These materials healed macroscopic cuts and surface defects under ambient conditions within 24–48 hours, recovering over 80% of original tensile strength. While not yet optimised for dental applications, the potential to extend prosthesis service life particularly for thin-section facial prostheses vulnerable to tearing represents a compelling future direction [46-47].

Research Gaps and Methodological Considerations

A cross-cutting finding of this review is the predominance of siloed experimental designs that evaluate individual performance parameters in isolation. This reductionist approach, while generating valuable mechanistic data, fails to capture the complex trade-offs that characterise multifunctional material systems. For example: a formulation optimised for maximum antibacterial potency may exhibit cytotoxic profiles incompatible with clinical use; mechanical reinforcement with CNTs may be accompanied by opacity that precludes aesthetic maxillofacial applications; and high TiO_2 concentrations that maximise UV protection may render the prosthesis unnaturally white. Holistic, multifactorial evaluation frameworks analogous to composite performance indices or clinical simulation studies are needed to provide clinically actionable data [48, 49].

The scarcity of long-term in vivo evidence represents the most critical limitation. The oral environment imposes concurrent stresses, salivary enzymatic hydrolysis, thermal cycling (4–60°C), masticatory loading, microbial challenge, and chemical exposure from diet and hygiene products that cannot be replicated by any single laboratory protocol. The vast majority of reviewed studies employed accelerated aging (typically 1000 h UV exposure or 500 thermal cycles) as a surrogate for clinical aging; however, the predictive validity of these protocols relative to actual clinical degradation trajectories has not been systematically validated. This gap is particularly consequential for antibacterial systems, where the durability of functional additives over 3–5 year clinical service periods is unknown [50].

Methodological quality varied substantially. Strengths included: widespread adoption of standardised mechanical testing (ASTM D412, D624, D2240) and biocompatibility protocols (ISO 10993), enabling within-domain comparisons; increasing use of advanced characterisation techniques (TEM, SEM-EDX, FTIR, XRD, DLS); and growing application of nano-specific analytical standards (ISO/TS 10867 for CNT characterisation). Weaknesses included: frequent use of small sample sizes (n=3–5 specimens per test group), reducing statistical power; inconsistent reporting of nanoparticle size distributions, polydispersity, and surface area; and failure to measure real-world patient outcomes. identified a broader shift in dental materials research trends toward aesthetics and bioceramics, with declining investigation of metallic alloys, a context within which silicone nanotechnology represents an area of accelerating growth requiring enhanced research infrastructure.

Discussion

The findings of this review demonstrate that the field of multifunctional silicone elastomers for dental applications has undergone a remarkable transformation over the past decade, evolving from passive, single-component materials to complex nanotechnology-enabled systems with programmed functional attributes. Several convergent themes merit extended discussion.

First, the antibacterial dimension has achieved the most advanced state of development, with multiple agent classes, AgNPs, ZnO NPs, QACs, and CHX-NPs demonstrating consistent, reproducible efficacy in vitro. The clinical significance of this development is profound given the prevalence of prosthesis-related candidiasis and bacterial biofilm infections. The non-leaching QAC contact-killing mechanism represents an important conceptual advance, addressing the principal limitation of nanopar-

ticle-based systems (cumulative leaching and exhaustion of the antimicrobial reservoir) while simultaneously improving the safety profile for long-term implantable applications.

Second, the mechanical reinforcement literature has convincingly established that nano-silica, CNFs, and CNTs can substantially improve the tensile and tear properties of silicone elastomers without unacceptable hardness increases. The practical challenge of achieving reproducible homogeneous dispersion at pilot and clinical manufacturing scales not merely in laboratory settings remains incompletely addressed. Industrial-scale high-shear mixing and solvent-based dispersion techniques require validation against laboratory protocols before commercial translation can be credibly claimed.

Third, the parallel development of colour stability and mechanical reinforcement strategies raises an important question: can both objectives be achieved simultaneously without aesthetic-mechanical trade-offs? The literature suggests that nano-silica and CNF reinforcement have minimal impact on optical properties, while TiO_2 opacification—beneficial for colour stability compromises translucency. Future formulation design should explicitly target combined mechanical-aesthetic performance benchmarks rather than single-parameter optimisation.

The emergence of diagnostic sensing mouthguards and controlled drug delivery systems from the same PDMS platform represents a conceptual convergence of prosthetics and diagnostics/therapeutics that could fundamentally redefine the role of dental elastomers in patient care. Wearable intraoral sensors capable of real-time biomarker monitoring (pH, H_2S, salivary glucose) could enable continuous remote monitoring of oral health status, a paradigm well aligned with the growing "smart prosthetics" concept in biomedical engineering. Clinical validation of these technologies, however, requires interdisciplinary collaboration between materials scientists, clinicians, biomedical engineers, and regulatory specialists that has not yet materialised at scale.

Recommendations and Future Research Directions

Based on the synthesis of evidence presented in this review, the following evidence-based recommendations are proposed:

1. Long-term Randomised Clinical Trials: The most critical evidence gap is the absence of prospective clinical trials evaluating functionalised silicone prostheses in patient populations over 2–5 year periods. Future trials should incorporate standardised microbiological sampling, colour measurement (spectrophotometry), mechanical testing of retrieved specimens, patient-reported outcome measures (PROMs), and adverse event monitoring per ISO 14971 risk management principles.
2. Integrated Multifactorial Performance Assessment: Studies should adopt composite performance evaluation frameworks that simultaneously assess mechanical, antibacterial, biocompatibility, and aesthetic outcomes on the same test specimens. Minimum reporting standards including particle size, concentration, dispersion quality, testing standards, and statistical methodology should be established through expert consensus and adopted as journal submission requirements.
3. Standardisation of Testing Protocols: A consensus-based standardised testing battery for multifunctional dental silicones is needed, addressing: nanoparticle characterisation (DLS, TEM, zeta potential, ICP-MS); antimicrobial testing (ISO 22196 for surface antibacterial activity, ASTM E2149 for dynamic contact); biocompatibility per full ISO 10993 series; colour stability (CIEDE2000 metric, minimum 1000 h aging); and mechanical testing (ASTM D412, D624, D2240). Regulatory agencies (FDA, EMA) should be engaged to provide guidance frameworks for nanomaterial-containing dental devices.
4. Three-Dimensional Printing Compatibility: The rapid adoption of digital denture fabrication platforms necessitates investigation of nanoparticle-modified silicone formulations compatible with direct ink writing (DIW), material jetting, and moulded 3D-printed workflows. Printability characterisation (rheology, gel point, printability window), post-cure properties, and interlayer bonding strength should be primary outcomes, alongside the standard performance metrics reviewed herein.
5. Sustainability and Green Synthesis: The ecological impact of nanoparticle synthesis and incorporation involving solvent waste, energy consumption, and end-of-life prosthesis disposal has received essentially no attention in this literature. Future research should evaluate green synthesis routes (plant-mediated AgNP biosynthesis, natural fibre-derived nanocellulose), life-cycle analysis, and biodegradable silicone alternatives for single-use impression materials.
6. Interdisciplinary Regenerative Applications: The combination of bioactive silicone matrices with stem cell seeding, growth factor incorporation (e.g., BMP-2, VEGF), and scaffold architecturing offers a pathway toward regenerative maxillofacial constructs that not only replace but actively facilitate tissue regeneration. Proof-of-concept studies in animal models should constitute a near-term research priority.

Conclusions

This comprehensive review has demonstrated that multifunctional silicone elastomers represent a dynamic, rapidly evolving frontier in dental materials science. The strategic incorporation of nanoparticles, UV-protective agents, reinforcing fibres, and surface-active compounds has produced elastomeric systems that simultaneously address the principal clinical limitations of unmodified silicones: microbial susceptibility, mechanical fragility, and aesthetic degradation. Antibacterial functionalisation using AgNPs, ZnO NPs, and QACs has achieved consistent in vitro efficacy, with non-leaching QAC contact-killing mechanisms offering the most clinically sustainable long-term antimicrobial strategy. Mechanical reinforcement with nano-silica and nanocellulose fibres has substantially improved tensile and tear properties within clinically acceptable hardness ranges. Colour stability enhancement using TiO_2, ZrO_2, and UV-absorbing compounds has addressed photochemical and chemical degradation pathways, while biocompatibility evaluation per ISO 10993 has

demonstrated acceptable safety profiles for multiple formulations at optimised concentrations. However, the translational gap between laboratory innovation and clinical implementation remains substantial. The absence of long-term in vivo data, integrated multifactorial evaluation, standardised testing protocols, and 3D-printing-compatible formulations represents the collective priority agenda for the next decade of research. Addressing these gaps through coordinated, interdisciplinary, and internationally collaborative efforts will be essential to realising the full clinical potential of these advanced materials and improving outcomes for the patients who depend on them.

Data Availability

All data supporting the findings of this review are derived from previously published studies cited in the reference list. No new primary data were generated or analysed during the preparation of this article.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Authors' Contributions

E.O.S. conceptualised the review, designed the search strategy, conducted the literature review, and wrote the first draft. A.C.N. and N.N.U. contributed to data extraction, critical appraisal, and table preparation. O.J.I. contributed to the mechanical properties section and statistical interpretation. O.C.D. and E.C.A. contributed to manuscript revision, reference verification, and copy-editing. All authors read and approved the final manuscript. Dr I.O Arukalam generally edited the entire review work.

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