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FUNCTIONAL HYDROGEL COATINGS ON MEDICAL-GRADE SILICONE IMPLANTS

This study presents an effective strategy for chemical functionalization of medical-grade silicone implant – polydimethylsiloxane (PDMS) surface by grafting polyvinylpyrrolidone (PVP) hydrogel loaded with an antibiotic (gentamicin). Spectroscopic characterization confirmed the successful formation of a stable PVP hydrogel layer on implant surface. Surface wettability was significantly improved, with the water contact angle decrease from 119° to 77°, indicating enhanced hydrophilicity. Importantly, the functionalized surface containing antibiotic exhibited effective antibacterial activity against *Staphylococcus aureus* (inhibition zone ≥30 mm) and *Escherichia coli* (inhibition zone ≥18 mm) at concentration of 15 mg/mL of gentamicin sulphate. This functionalization approach provides simple and efficient method to enhance silicone implant surface properties and biological performance, and holds strong potential for improving the safety of medical-grade silicone breast implants.

Keywords: Silicone breast implants; Hydrogel coatings; Fenton reaction; Gentamicin; Surface modifications

1. Introduction

PDMS-based silicone elastomers are widely utilized in implantable devices, including catheters, contact lenses, and breast implants [1]. Despite their extensive clinical application, microbial colonization and subsequent biofilm formation on silicone surfaces remain significant challenges, contributing to inflammatory reactions, chronic pain, and implant failure. Surgical site infections represent a serious complication in breast implant procedures, affecting approximately 2-2.5% of patients and frequently leading to capsular contracture, chronic inflammation, or the need for implant removal. The intrinsic hydrophobicity of PDMS surfaces not only limits the effective incorporation of antimicrobial agents but also promotes bacterial adhesion and biofilm formation, thereby compromising long-term implant performance [2]. An additional factor influencing bacterial adhesion is the surface texturization of breast implants. Textured implants were introduced to enhance tissue integration of the implants in the human body [3], and their surface topography can be achieved by different techniques such as imprinting, salt-loss, and gas expansion methods [4]. However, the breast implant surface with added surface roughness can trigger infections, especially in breast reconstruction after mastectomy, ranging from 4.5% to 19.4% [5-7].

Therefore, a variety of strategies have been developed to mitigate microbial colonization and biofilm formation on silicone surfaces, among which, hydrogel-based coatings have shown particular promise. Hydrogels can enhance surface hydrophilicity and biocompatibility, while reducing the risk of implant-associated infections. Surface coatings represent one of the most widely applied approaches for biomaterial surface modification due to their simplicity and versatility. When further functionalized with antimicrobial agents or antibiotics, they provide a flexible platform for controlled infection prevention and localized drug delivery. However, many current hydrogel-based coatings strategies are limited by weak adhesion to the substrate, uncontrolled or burst drug release, or the requirement for harsh chemical conditions that may compromise the intrinsic properties of the underlying material and limit clinical applicability. These challenges underscore the need for more robust and practically applicable surface modification strategies [8,9]. In this context, the Fenton reaction, first reported in 1894, constitute a versatile and effective strategy, enabling the simultaneous initiation of free-radical graft polymerization and crosslinking leading to the formation of a stable and strongly adhered hydrogel layer on polymeric substrates [10]. The Fenton process is based on a redox reaction between ferrous ions (Fe^{2+}) and hydrogen peroxide (H_2O_2), resulting in generation

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of highly reactive hydroxyl radical (•OH), which are among the most potent oxidizing species in aqueous systems. The reaction mechanism proceeds through three principal stages. In the first stage, Fe^{2+} react with H_2O_2 to produce hydroxyl radical (•OH) and ferric ions (Fe^{3+}) Eq. (1). Subsequently, the generated radicals react non-selectively with organic compounds (R), inducing oxidation, bond cleavage, and, in advanced stages, mineralization to CO_2, H_2O, or simple inorganic ions Eq. (2).

$$Fe^{2+} + H_2O_2 \rightarrow Fe^{3+} + OH^- + \bullet OH \quad (1)$$

$$\bullet OH + R \rightarrow \text{oxidation products} \quad (2)$$

In the third and final stage, catalyst regeneration occurs, during which ferric ions (Fe^{3+}) are reduced back to ferrous ions (Fe^{2+}), for example through further reactions with hydrogen peroxide or intermediate radical species. The redox cycling enables iron to function as a homogenous catalyst, thereby sustaining continuous radical generation and allowing the process to proceed in a cyclic manner.

In particular, hydrophobic polymeric substrates such as polyurethane have previously been modified using Fenton-initiated grafting approaches, as demonstrated by Butruk-Raszeja et al. [11]. Their study revealed that stable, hydrogel-like PVP coatings can be effectively immobilized on polyurethane surfaces, leading to significant improvements in surface physicochemical properties, especially increased hydrophilicity and enhanced hemocompatibility, while exhibiting no detectable cytotoxicity.

In this study, we demonstrate the functionalization of silicone breast implants via a PVP hydrogel coating incorporating gentamicin, a broad-spectrum antibiotic commonly used in prophylaxis against *Staphylococcus aureus* in breast reconstruction after mastectomy, at varying concentrations (2, 5, 10, 15 mg/mL). Coating efficiency and chemical interactions with the inherently hydrophobic silicone surface were characterized using Attenuated Total Reflection-Fourier Transform Infrared spectroscopy (ATR-FTIR). The morphology, uniformity, and thickness of the hydrogel layer were further assessed using micro-computed tomography (micro-CT) and scanning electron microscopy (SEM). Surface wettability was evaluated by water contact angle measurements. Antibacterial efficacy of the coated implant samples was investigated against *Staphylococcus aureus* and *Escherichia coli* using the agar disc diffusion method. The proposed modification approach represents a promising platform for the design of infection-resistant silicone implants and may contribute to reducing implant-associated infections, especially in breast reconstruction after mastectomy.

2. Materials and methods

2.1. Materials

Medical-grade silicone breast implant from Nagor (IMP-EHR 390:261312) was used as a polymer substrate for surface modification. This type of implant is characterized by soft and textured shell, has an anatomical shape and filled with highly cohesive gel (Fig. 1).

Reagents, namely iron (II) chloride ($FeCl_2$), ascorbic acid (AA), ethylene glycol dimethacrylate (EGDMA) and sodium dodecyl sulphate (SDS) were obtained from Sigma-Aldrich (Poznań, Poland). PVP powder with an average molecular weight of 360 kDa was purchased from Fluka Analytical (Buchs, Switzerland), while gentamicin sulphate (GS) was obtained from Roth. Phosphate-buffered saline (PBS) was prepared by dissolving PBS tablets (Fisher BioReagents) in 200 mL of distilled water, pH was adjusted to 7.4. All chemicals were used as received, without further purification. *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11303) were purchased from American Type Culture Collection (ATCC, Manassas, VA, USA).

2.2. Methods

2.2.1. Hydrogel coating preparation

The hydrogel coatings were fabricated using a two-step dip-coating method. Four specimens (3×1 cm) were cut from the implant and immersed in isopropanol for 10 min to eliminate residual organic contaminants from the surface before subsequent surface modification procedures. The reaction solutions were

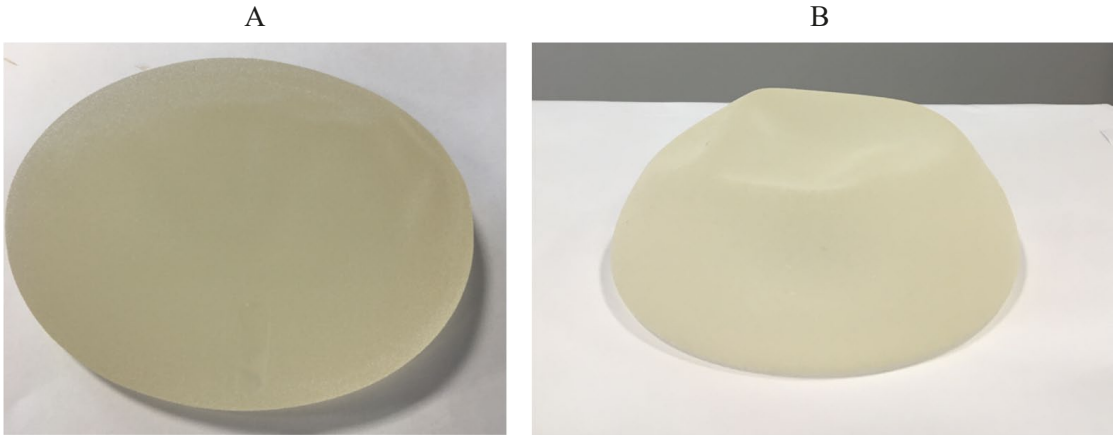


Fig. 1. Breast implant used in the study: top view (A) and side view (B)

prepared to induce the radical species formation and subsequent hydrogel coating. The concentration of the reagents in each solution systems are collected in TABLE 1.

TABLE 1

Concentrations of reagents in two-step dip coating method using Fenton reaction

Step	Reagents	Process
1	EGDMA (5%) H_2O_2 (0.1%)	Silicone samples were immersed for 10 minutes in aqueous solution containing EGDMA and H_2O_2 to activate the surface
2	PVP 360 kDa (10%) $FeCl_2$ (0.1%) AA (1%)	Immersion for another 15 minutes in an aqueous PVP solution containing Fenton's reagent in the presence of ascorbic acid in order to initiate the grafting process.

These reagents were used for a Fenton reaction, where peroxide decomposition (e.g., hydrogen peroxide (H_2O_2) or cumene hydroperoxide (CHP)) generates hydroxyl radicals in the presence of Fe^{2+} that oxidize the polymer surface and introduce reactive end groups [10].

The procedure followed the protocol described in [8], where the substrate samples were immersed in a solution of EGDMA (10 ml, 5%) and H_2O_2 (2 ml, 0.1%) for 15 minutes, allowing monomer adsorption and cross-linked microstructure formation. Subsequently, the materials were transferred to an aqueous solution containing PVP (360 kDa) and $FeCl_2$ again for 15 minutes, where radicals induced PVP grafting and cross-linking. Ascorbic acid was used to adjust pH to 2-4 and maintain Fe^{2+} ions, ensuring covalent bonding between hydrogel and substrate for coating integrity.

Following completion of the two modification stages, the samples were washed with 0.1% sodium dodecyl sulphate (SDS) solution to remove non-covalently bound PVP from the implant surface. The samples were then rinsed with phosphate-buffered saline (PBS; one tablet dissolved in 200 mL of deionized water). Finally, the samples were dried in a vacuum dryer overnight.

For antibiotic loading, aqueous gentamicin sulphate solutions were prepared at concentrations of 2, 5, 10, and 15 mg/mL by dissolving the appropriate amount of gentamicin sulphate in deionized water. The modified samples were immersed in these solutions for 48 h, allowing adsorption of the antibiotic into the hydrogel coating.

2.2.2. Materials surface characterization

The chemical composition of the PDMS surface was confirmed using ATR-FTIR spectroscopy (BRUKER ALPHA Platinum Spectrophotometer, Germany) at room temperature (4000-600 cm^{-1}, 2 cm^{-1}, 32 scans). The analysis of the silicone breast implant surface was performed using micro-CT scanner (Bruker Skyscan 1272, Germany). The acquisition parameters were set as follows: current 150 μA; voltage 50 kV; frame averaging 4; Cu filter 0.10 mm; pixel size 2.25 μm; rotation 360° with a step of 0.1°. After acquisition, reconstruction was performed using NRecon (version 1.7.0.4) with the InstaRecon engine (version 2.0.2.6). The surface area of the coated and uncoated samples was quantified using CTAn v.1.20 software. The scanning electron microscope micrographs were obtained using a TESCAN Vega 3 microscope (2013) using 15 kV accelerating voltage. The samples were dried in a vacuum oven at 50°C for 2 days and subsequently sputter-coated with a 10 nm layer of gold. The thickness of the hydrogel coating layer was determined from SEM micrographs using ImageJ software. Measurements were taken at eight distinct locations, and the results are reported as the mean value with the corresponding standard deviation. Surface wettability of all samples was evaluated using Krüss DSA 100 Drop Shape Analyzer (Germany). The droplet volume was 2 μL and the value given is the average of 6 measurements.

2.2.3. Antimicrobial test

A bacterial suspension in PBS was prepared at a concentration of 1.5×10^8 CFU/mL (0.5 McFarland standard). The suspension was evenly spread onto Mueller-Hinton agar plates (Mueller Hinton 2 LAB-Agar, Biomaxima). Discs of modified implant samples with a diameter of 0.6 mm were placed onto the agar surface. An unmodified implant was used as a negative control. As a positive control, 100 μL of a gentamicin solution (Sartorius) at a concentration of 100 μg/mL was applied into an agar well. The plates were stored at 4°C for 2 h and subsequently incubated at 37°C for 24 h. After incubation, the zones of bacterial growth inhibition around the samples were measured using a calliper.

3. Results and discussion

3.1. Spectral analysis of PDMS surfaces by ATR-FTIR spectroscopy

Fenton-type reaction was used for medical-grade silicone implant surface modification in this study for the first time. Infrared spectroscopy was used in order to confirm the presence of characteristic bands confirming formation of PVP layer on the substrate and successful incorporation of gentamycin.

The spectroscopic analysis of the uncoated and coated implant samples is presented in Fig. 2. The spectrum of uncoated PDMS exhibited characteristic vibrational bands corresponding to Si-C-H stretching and CH_3 rocking modes at 783 and 1256 cm^{-1}, symmetric Si-O stretching at 1008 cm^{-1}, and CH_3 stretching at 2963 cm^{-1} [12]. A broad absorption band around 3500 cm^{-1} was attributed to hydroxyl groups (–OH) originating from both PVP and gentamicin, confirming the successful formation of the hydrogel layer and the incorporation of the antibiotic. The carbonyl (C=O) stretching band of PVP appeared in the region of 1650-1750 cm^{-1}. In addition, the C-N stretching band observed at 1250-1350 cm^{-1} increased the intensity with increasing

gentamicin concentration, suggesting enhanced intermolecular interactions involving amine functional groups. Furthermore, the band detected between 1050-1200 cm^{-1}, was assigned to HSO_4^- originating from gentamicin sulphate, indicating interactions between the hydrogel network and ionic species introduced during the drug incorporation process [13].

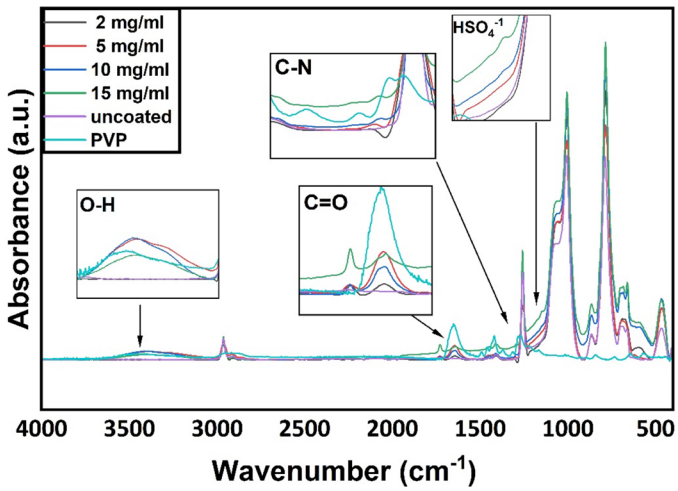


Fig. 2. FTIR spectra of the uncoated silicone implant sample and after surface modification with PVP hydrogel containing variable concentration of antibiotic

The possible mechanism of hydrogel formation on silicone breast implant is starting from hydroxyl radicals generation which can induce oxidation of the silicone surface, leading to the formation of reactive oxygen-containing functional groups and surface-bound radical sites. These activated sites may contribute to improved interfacial interactions with the subsequently formed polymer layer. Simultaneously, radical processes occurring in the PVP solution containing EGDMA lead to the formation of a crosslinked three-dimensional hydrogel network. EGDMA acts as a crosslinking agent due to the presence of two methacrylic groups capable of participating in radical-mediated reactions, resulting in the formation of bridges between polymer chains and stabilization of the hydrogel structure. Schematic of this mechanism is visualized in Fig. 3.

3.2. Surface structure assessment by micro-computed tomography

Micro-CT analysis was used as a non-destructive 3D imaging technique to evaluate the presence and spatial distribution of the hydrogel coating on the silicone substrate. Differences in X-ray attenuation between the silicone matrix and the hydrogel phase enabled visualization of coating morphology and assessment of surface coverage. Micro-CT images of uncoated implant (Fig. 4A) revealed a rough and heterogeneous surface characterized by non-uniform texturing, including a square-like pattern with visible interstitial gaps. Following surface modification, a pronounced colour shift towards red was observed (Fig. 4B), indicating increased X-ray attenuation consistent with the presence of a surface-bound hydrogel layer that is distinguishable from the underlying silicone substrate. Localized blue regions suggest the presence of minor surface discontinuities or areas of reduced coating thickness: however, the overall surface mor-

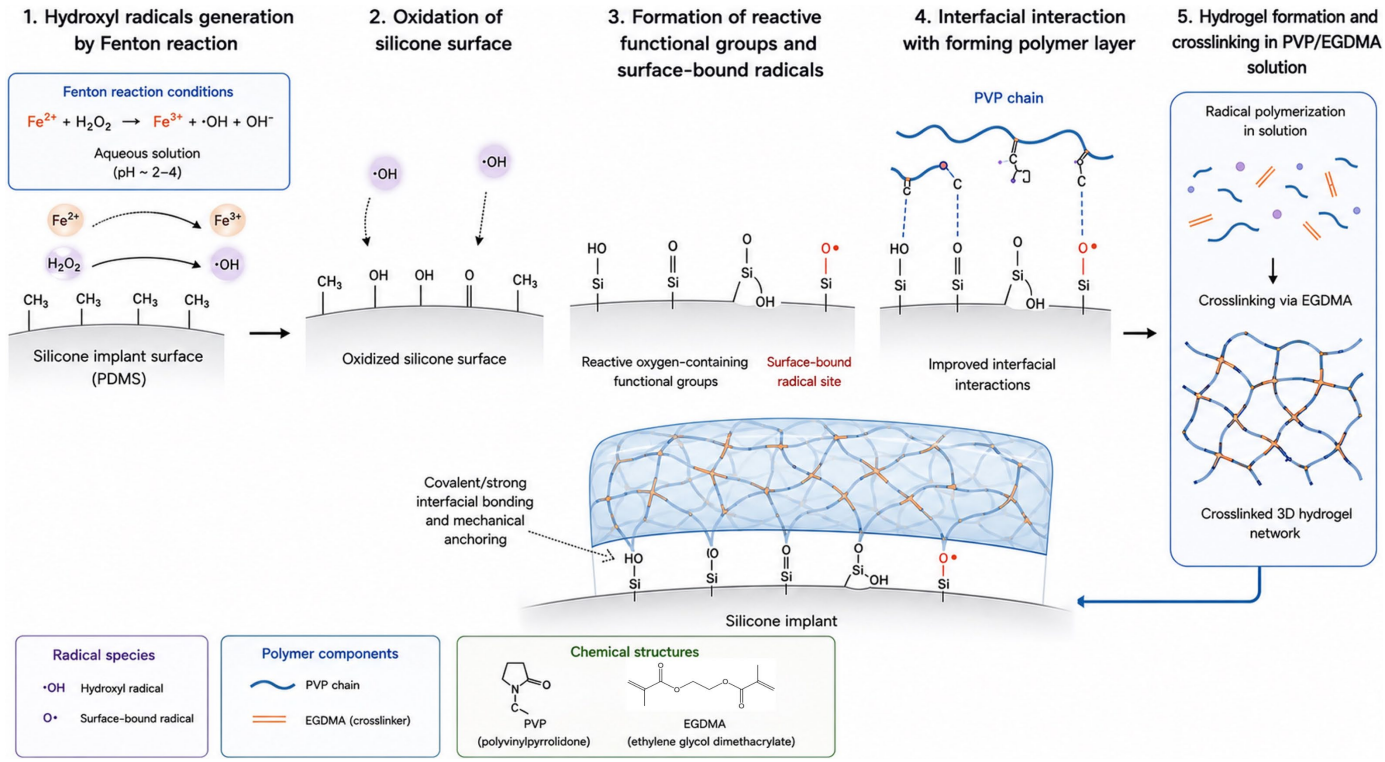


Fig. 3. Proposed mechanism of PVP hydrogel formation on silicone breast implant using Fenton chemistry

phology appeared quite uniform according to colour mapping of the surface thickness. These findings demonstrate the successful formation of a PVP-based hydrogel coating predominantly confined to the implant surface, with no evidence of penetration into the bulk PDMS matrix. The preservation of the internal structure further confirms that the modification process primarily affected the surface layer while maintaining the integrity of the underlying material. The surface area of the uncoated sample was determined to be 2.141 mm^2, whereas the hydrogel-coated sample exhibited a surface area of 1.507 mm^2. These results indicate that approximately 70% of the original surface area was covered by the hydrogel coating.

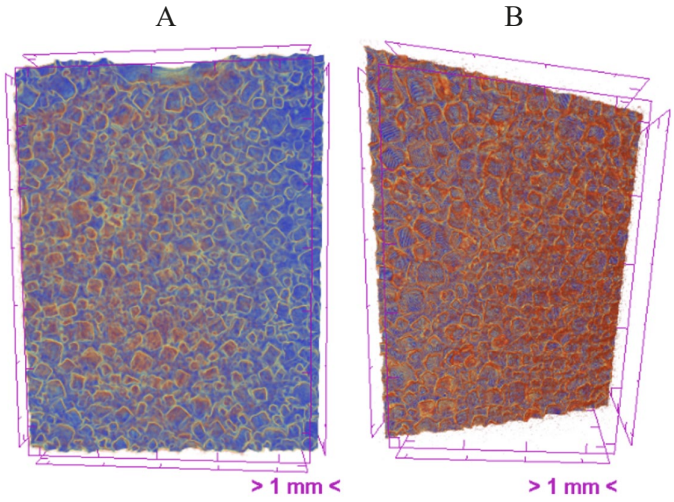


Fig. 4. Micro-CT images of uncoated (A) and coated (B) silicone implant surface

3.3. Scanning electron microscopy (SEM)

A detailed analysis of surface topography of silicone implants before and after modification has been performed with SEM. As can be seen from Fig. 5, the textured implant surface exhibited squared pores with variable dimensions ranging from approximately 10 to over 200 µm. Implant surface before modification (Fig. 5. A1, A2) shows numerous pores of irregular size

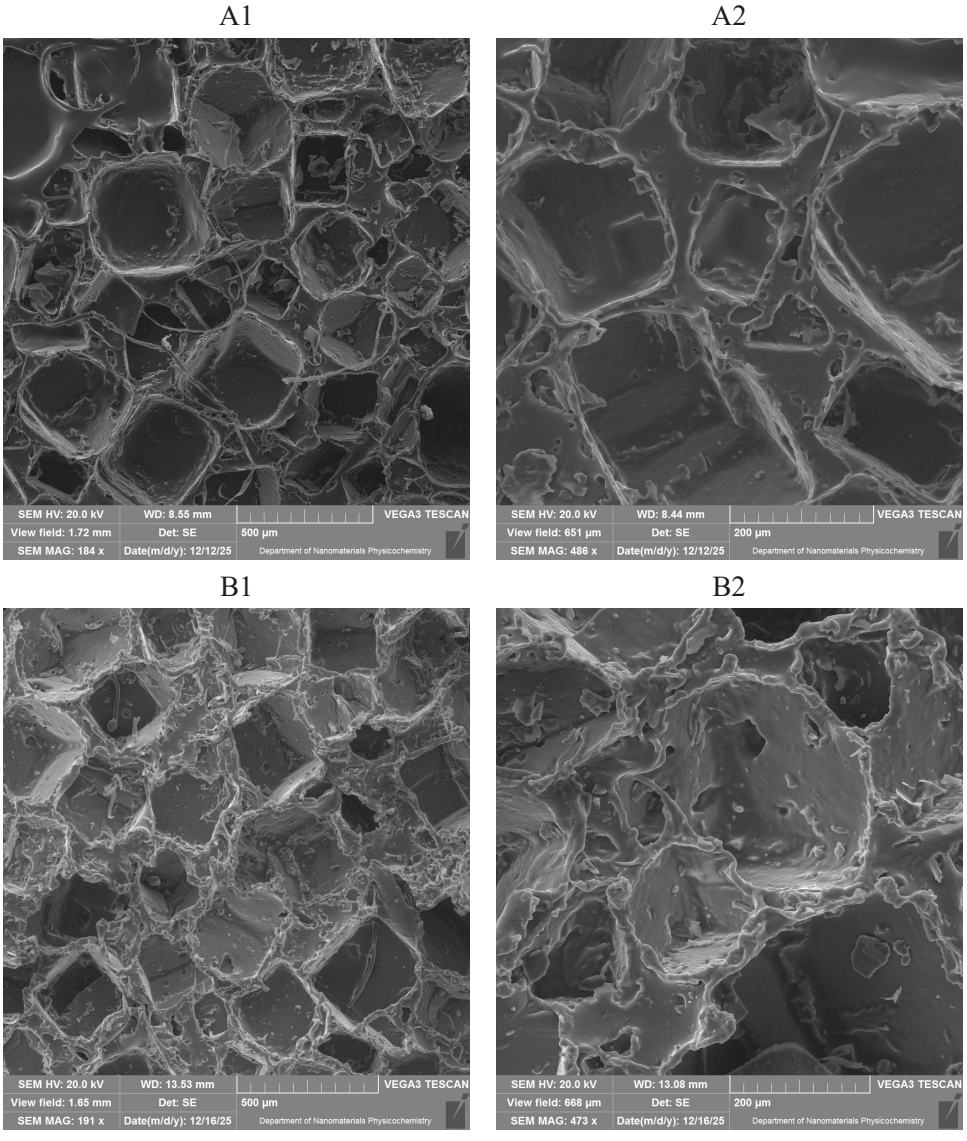


Fig. 5. SEM images of uncoated (A1) 184×, (A2) 486× magnification; and coated (B1) 191×, (B2) 473× silicone implant surface

and morphology, characterized by rough pore walls, localized surface deposits, and structural irregularities. The heterogenous morphology and absence of a continuous surface layer, can provide multiple favourable sites for bacterial attachment and subsequent biofilm formation, which is consistent with literature reports describing the susceptibility of porous and rough PDMS substrates to microbial colonization [14].

SEM micrograph after modification (Fig. 5B1, B2) revealed the formation of a thin (submicron), continuous polymer layer on textured polymer surface. The modified surface appeared smoother, with less pronounced pore edges and a more uniform overall morphology, indicating successful deposition of the hydrogel coating. Importantly, the coating partially filled the inter-pores spaces without completely occluding the pore openings, thereby preserving the original microstructural features and surface roughness. Retention of the textured architecture is advantageous in clinical applications, as it supports implant-issue integration while simultaneously providing a functional coating layer. Submicron-sized particulate features observed on the surface are attributed to crystalline deposits of gentamicin sulphate, indicating successful incorporation of the antibiotic within the hydrogel matrix. Analysis of the SEM images indicated that the hydrogel coating has an average thickness of 0.32 μm ± 0.06 μm.

3.4. Water contact angle (WCA) measurements

WCA measurements were performed using the sessile drop method and the results are summarized in TABLE 2. Static water contact angle measurements were performed using a 2 μL droplet on both unmodified implant samples and hydrogel-modified samples. Measurements were conducted for each of the tested samples prior to modification and after hydrogel coating with different gentamicin concentrations (n = 6 per sample). The uncoated PDMS surface exhibited a high degree of hydrophobicity, with a water contact angle of approximately 119°. Following surface modification with PVP hydrogel loaded with GS, a reduction in contact angle was observed, indicating increased surface wettability. The most pronounced decrease was detected for the lowest antibiotic concentration (2 mg/mL), where the contact angle decreased from 119° to 77°±12°. In contrast higher GS concentrations (5, 10, and 15 mg/mL) resulted in more moderate changes in wettability, with contact angles decreasing to 92°±6, to 110°±3, and to 103°±5, respectively. The observed decrease in contact angle confirms the successful modification of the silicone implant surface with a hydrophilic PVP-based hydrogel. The less pronounced wettability enhancement at higher gentamycin sulphate concentrations may be associated with increased sulphate ion content and intermolecular interactions within the hydrogel network, leading to structural rearrangements that particularly expose more hydrophobic domains at the surface. Such effects may influence the balance between hydrophilic and hydrophobic functional groups available at the interface, thereby affecting the overall surface energy and wettability characteristics [15].

3.5. Antibacterial activity

Antibacterial activity against *Staphylococcus aureus* and *Escherichia coli* demonstrated a concentration-dependent effect of gentamicin incorporated within the PVP hydrogel layer, with increased drug loading corresponding to enhanced bactericidal efficacy (TABLE 3).

All coated samples exhibited measurable inhibition of bacterial growth, with the greatest zones of inhibition observed at a GS concentration of 15 mg/mL, with inhibition zone ≥30 mm for *Staphylococcus aureus* and inhibition zone ≥18 mm for *Escherichia coli* (Fig. 4), which is consistent with previously reported effective concentrations in the literature [1]. In contrast, uncoated implants showed no detectable antibacterial activity. The negative control consisted of an uncoated reference implant, while the positive control comprised a gentamicin solution at a concentration of 100 μg/mL. All results were collected in TABLE 3 and visually represented in Fig. 6.

TABLE 2

WCA measurements of the gentamicin loaded samples

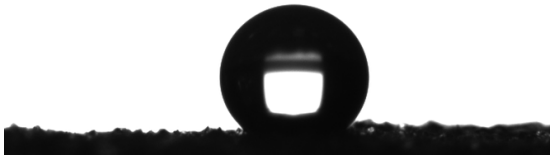
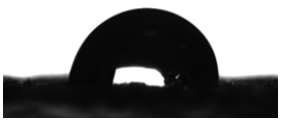
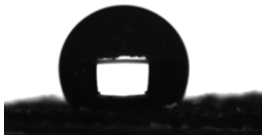
Average contact angle of silicone breast implant:  **119°±3 (n = 24)**			
Hydrogel coated silicone containing variable gentamicin concentration (C) (mg/mL) (n = 6)			
 **C=2**	 **C=5**	 **C=10**	 **C=15**
77°±12	**92°±6**	**110°±3**	**103°±5**

TABLE 3

Quantitative antibacterial activity (size of inhibition zone in mm) of the gentamicin-loaded samples

	2 mg/ml	5 mg/ml	10 mg/ml	15 mg/ml	Positive control
E. coli	7.08	9.53	14.48	18.37	38.08
S. aureus	7.20	20.04	23.05	31.46	30.8

4. Conclusions

The present study demonstrates an efficient and straightforward approach for the surface functionalization of silicone breast implants through the formation of a PVP-based hydrogel coating using a Fenton-type reaction. The applied method enabled simultaneous grafting and crosslinking, resulting in the formation of hydrogel layer on the silicone implant surface.

Comprehensive characterization confirmed the successful surface modification. ATR-FTIR analysis verified the incorporation of characteristic functional groups associated with both PVP and gentamicin, while micro-CT and SEM observations revealed the formation of a thin coating that preserved the native microstructural features of the implant surface. The introduction of the hydrogel layer improved surface wettability, indicating enhanced hydrophilicity that may contribute to reduced bacterial adhesion.

Furthermore, antibacterial assays demonstrated that the modified surfaces exhibited bactericidal activity for all tested samples, with antibacterial efficacy increasing in a concentration-dependent manner with respect to gentamicin loading. This effect was observed against both *Escherichia coli* (Gram-negative) and *Staphylococcus aureus* (Gram-positive), with the highest tested concentration (15 mg/mL) yielding the most pronounced antibacterial performance.

Overall, these results confirm that the proposed surface modification strategy may enhance the antibacterial properties of silicone implants. This approach holds a potential for reducing implant-associated infections and improving patient outcomes.

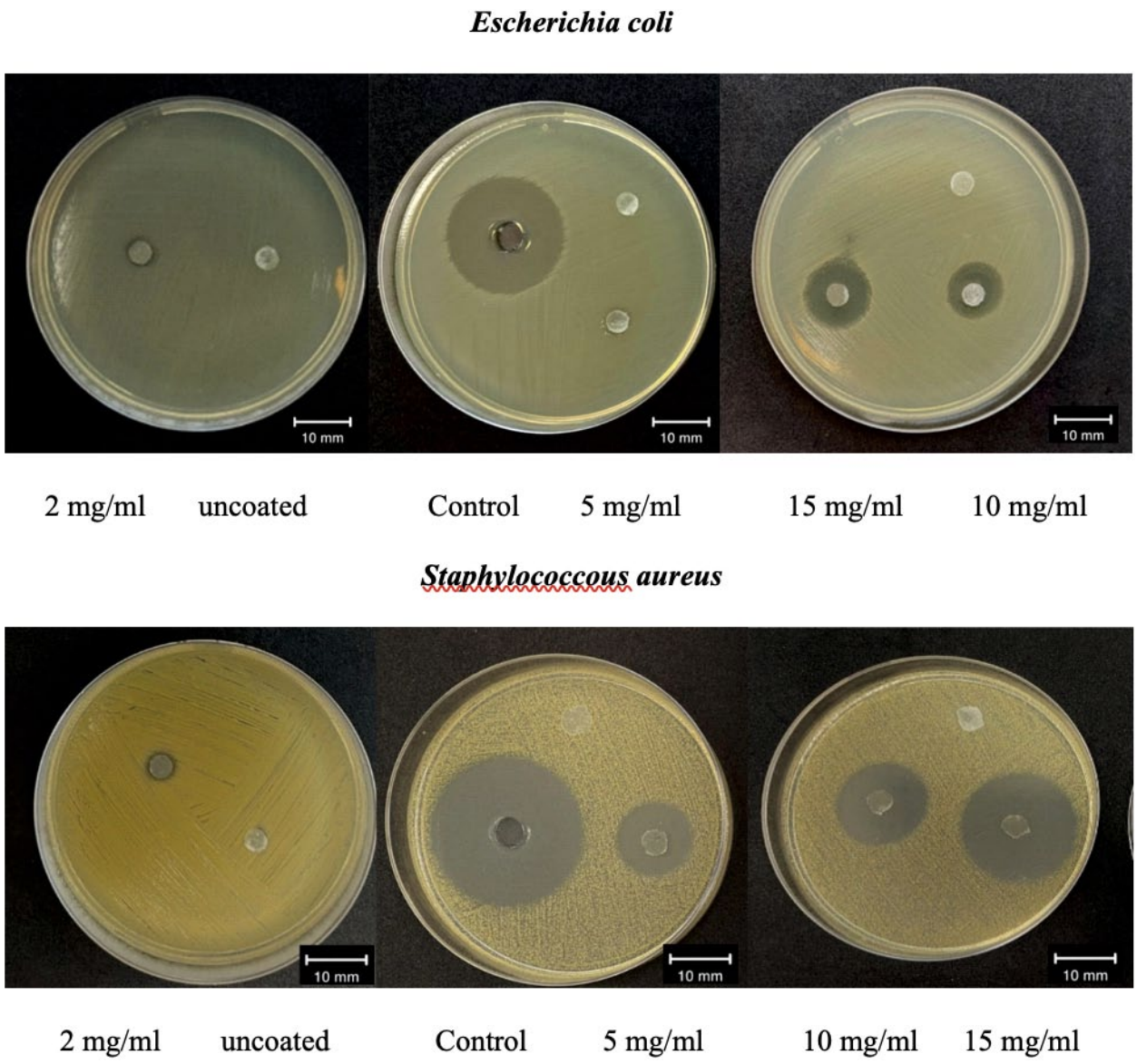


Fig. 6. Representative images of the antibacterial activity of uncoated and coated samples containing variable concentration of gentamycin

Future work will be focussed on long-term stability, drug release kinetics, and *in vitro* and *in vivo* biocompatibility to further assess its clinical applicability.

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