



## Production of Medical Grade Silicone for Facial Prosthesis with Bactericidal Properties from the Inclusion of Poly (Diallyldimethylammonium Chloride): An in Vitro Study


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### Abstract

**Objective:** To evaluate the inclusion capacity and bactericidal efficiency of diallyl dimethyl ammonium chloride (PDADMAC) diluted in tetrahydrofuran (THF) upon inclusion in the medical grade silicone polymer structure. **Material and Methods:** It was diluted the PDADMAC in THF at the concentration of 4wt%. It was included in the silicon paste during its vulcanization process. The contact angle measurements were performed to evaluate whether the biocide inclusion into the silicon paste was successful. All samples were sterilized with gamma radiation at 25kGy-dosage prior to the microbiological tests. Microbiological testing strictly followed the Antibacterial products - Test for antibacterial activity and efficacy JIS Z 2801: 201010 and the used of specific bacteria, as Staphylococcus aureus ATCC 6538P and Escherichia coli ATCC 8739. **Results:** The results showed that PDADMAC, when dissolved in THF at 4wt%, displayed good incorporation in medical silicone and a broad-spectrum antibacterial response. The results of the tests using Escherichia coli ATCC 8739 and Staphylococcus aureus ATCC 6538P showed that the silicone with no biocide addition did not present antibacterial activity. In contrast, the experimental group plus 2 mL of PDADMAC would have an ideal antibacterial response. **Conclusion:** Medical grade silicone can be used as a material with antibacterial properties, since it has been able to keep PDADMAC compound attached to its structure, thus acquiring antimicrobial property.

**Keywords:** Dental Materials; Silicone Elastomers; Maxillofacial Prosthesis.

## Introduction

Medical grade silicones are high molecular weight polymers, biocompatible, resistant to friction, easy to hygienize, flexible, durable and non-heat conductive [1]. Due to these properties, silicones have been widely used for biomedical devices such as catheters [2], stents [3], bucomaxillofacial prostheses [1,2] and voice prostheses [4].

However, biomedical devices made of silicone are associated with the likelihood of infections, since the silicone surface is prone to bacterial adhesion [5,6]. A possible solution for bacterial adhesion is the modification of silicone surface by attaching biocides to silicon surface, which inactivate or kill certain microorganisms [7].

Having in mind that silicone may be a possible anchoring structure for the biocide, in the present work the biocide poly (diallyldimethylammonium chloride) (PDADMAC) diluted in tetrahydrofuran (THF) was added to the silicone to produce a material with antibacterial properties.

## Material and Methods

The biocidal PDADMAC is widely used in water purification, easy to use and to access [8]. It was diluted in tetrahydrofuran (THF) at the concentration of 4wt%. It was included in the silicon paste during its vulcanization process. The specimens were prepared using pre-established molds with dimensions of 45 x 45 cm<sup>2</sup>.

In order to evaluate if the biocide inclusion into the silicon paste was successful, contact angle measurements were performed in a SEO Phoenix equipment (South Korea) at the Institute of Chemistry, University of São Paulo, São Paulo, Brazil. The test specimens were divided into a control group consisting of silicone without the biocide and an experimental group consisting of silicone with two milliliters (mL) of the PDADMAC solution. All samples were sterilized with gamma radiation at 25K Gy-dosage prior to the microbiological tests.

Microbiological testing strictly followed the Antibacterial products - Test for antibacterial activity and efficacy [9]. This protocol is based on the use of specific bacteria, as *Staphylococcus aureus* ATCC 6538P (106 mL<sup>-1</sup> cells) and *Escherichia coli* ATCC 8739 (106 mL<sup>-1</sup> cells). All tests were performed at the Bacterial Resistance and Alternative Therapies Laboratory, Biological Sciences Institute, University of São Paulo, São Paulo, Brazil.

*S. aureus* and *E. coli* were maintained in close contact with the surface of the specimens in each of the two test replicates and stored for 24 hours at 37° C under humid conditions. The size of surviving bacterial population was determined using the JIS protocol [9]. Bacterial colonies were then enumerated in the suspension by counting viable cells in Mueller Hinton Agar® broth after incubation at 37°C for 24 and 48 hours using a 100 µL sample drawn from the tests' surface.

Thus, according to the above mentioned protocol, any material that has the ability of bacterial inactivation or death in about 80% rate will be classified as an antibacterial material. By the time of this test, the specimens were divided into three groups: a control group, in which there was no biocide in its polymer structure, the experimental group one, in which there was one mL of the

PDADMAC dissolved in THF added to the polymer structure, and the experimental group two, in which there were two mL of PDADMAC dissolved in THF in the polymer structure.

It is worth noting that the objective of the control group in this experiment would be only to confirm that medical grade silicone, when used without any support, has no antibacterial properties.

## Results

### Contact Angle Measurements

Figures 1A and 1B show the contact angle measurements determined for the control group and experimental group, respectively. The control group amounted to  $86.63^\circ \pm 0.04^\circ$  and the experimental group amounted  $78.3^\circ \pm 0.1^\circ$ . The decrease in the contact angle values of approximately  $8^\circ$  clearly indicates the presence of PDADMAC on the surface of medical grade silicone because it is a hydrophilic polymer.

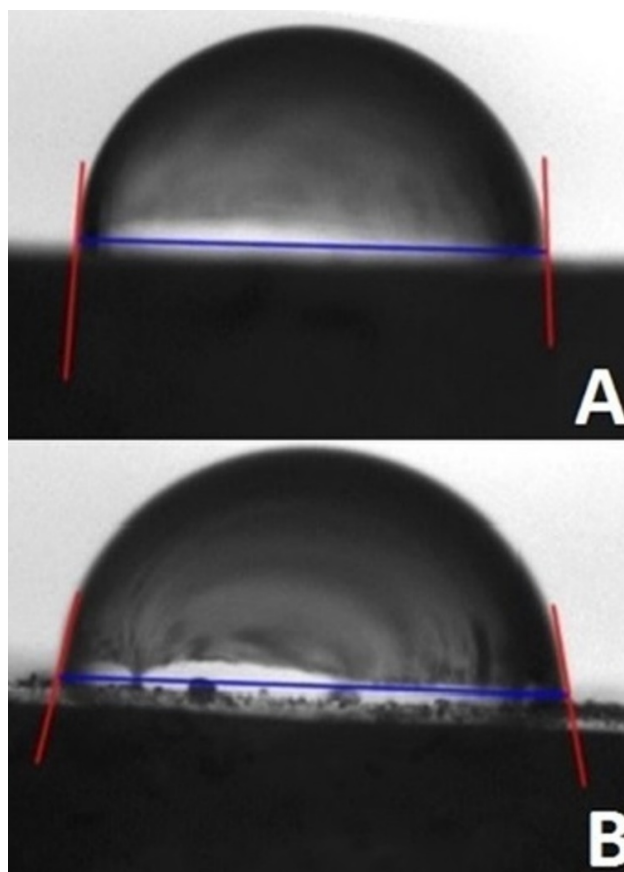


Figure 1. Contact angles measured (A) for the control group and (B) experimental group.

### Microbiological Test

The results of the tests using *Escherichia coli* ATCC 8739 and *Staphylococcus aureus* ATCC 6538P (Table 1) showed that the silicone with no biocide addition did not present antibacterial activity. In contrast, the experimental group plus 2 mL of PDADMAC would have an ideal antibacterial response.

**Table 1. Efficacy of test specimens made of medical silicone with biocide against *Escherichia coli* and *Staphylococcus aureus* bacteria.**

Bacteria	Groups	Efficacy
<i>Escherichia coli</i>	Control	0.0%
	Experimental with 1 mL	41.0%
	Experimental with 2 mL	96.0%
<i>Staphylococcus aureus</i>	Control	0.0%
	Experimental with 1 mL	99.2%
	Experimental with 2 mL	99.5%

## Discussion

Currently, in the health area, devices made with medical grade silicone have been essential for increasing life expectation and improvement. However, these devices tend to increase microbial adhesion due to a variety of factors. Knowing this, many authors have conducted tests in silicones verifying their adhesion to microorganisms. In recent research, *Candida albicans* was tested and it was observed that some silicones are more propitious to the adhesion of this microorganism than others [10].

Aiming to minimize this adhesion, several studies have already been carried out seeking the effectiveness against microorganisms and the interaction of the most diverse surfaces with antimicrobial compounds [11-15].

Among these compounds, biocides containing quaternary ammonium salts and iodine, N-haloamines, phenol derivatives, benzoic acid [16] and sulfoderivatives [17] are highlighted in research. In addition, it is common to introduce inorganic antimicrobial compounds to the polymers, especially silver nanoparticles [18]. However, noted that these surface-prepared antibacterial silicones with biocidal compounds are more efficient at immediate and long-term response when compared to similar silver materials [19].

Many materials already have antibacterial profile with the aid of other types of biocides. As an example, a polydopamine-coated catheter with bactericidal action and an antimicrobial coating for resistant bacteria [20,21]. Other research, had already demonstrated that simple manipulation of the nonionic silicone polyether structure leads to significant changes in antibacterial activity [22]. This shows a worldwide tendency to search for devices that reduce microbial adhesion with the help of antimicrobial substances, always observing its specific use.

In the present study, medical grade silicone was tested with the PDADMAC biocide dissolved in THF. The inclusion of the material was tested according to the contact angle, same methodology used for other research [23]. The protocol of Japanese Industrial Standard was used [9]. At the end of the tests it was evident the success regarding this polymer's antibacterial profile. In 2015, it was synthesized PDADMAC with poly (methyl methacrylate) particles, which reduced cell viability by eight-logs (*E. coli*), seven-logs (*S. aureus*) or two-logs (*C. albicans*) [24]. Recent research investigated the brushing of this same biocide on the surface of test specimens of medical grade silicones [25]. The results were satisfactory regarding the antibacterial activity against the bacteria

used in the research, but there was aesthetic loss of the material, an important feature in the prosthetic preparation.

In the present study, the silicone of medical grade, when added to PDADMAC in its polymer, besides presenting antibacterial activity, did not present loss of material aesthetics, which allows its use in bucomaxillofacial prostheses manufacturing as its need to be durable and have good aesthetics. However, the present study cannot evaluate the mechanical and physical properties of the material in time, being a limiting factor. These properties should be evaluated in the future for better employability and functionality of the material proposed in this article.

## Conclusion

Medical grade silicone can acquire antibacterial properties by a simple method of including PDADMAC diluted in THF to the silicone. This property, together with the simplicity of the applied methodology, is able to avoid bacterial development in devices made by silicone of medical grade without putting the aesthetics at risk, and making it possible to be indicated to the use in bucomaxillofacial prostheses.

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**Conflict of Interest:** The authors declare no conflicts of interest.

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