



Chemical Resistance Evaluation of Various Medical-Grade Materials Exposed to a Stabilized and Isotonic 0.057% Sodium Hypochlorite Antimicrobial Solution (Anasept®)

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Abstract

Device-associated healthcare-associated infections (DA-HAIs) are a major health problem that requires development of new treatments options. A chemical resistance evaluation was conducted on a set of medical-grade materials (316L stainless steel, polyglycolic acid, polyetheretherketone, polyethylene, polylactide, polypropylene, polyurethane, and silicone), following ASTM D543-14 standards. A set of 8 medical-grade materials were exposed to various immersion times (30 seconds, 1 minute, 5 minutes, and 24 hours) in a stabilized and isotonic 0.057% sodium hypochlorite antimicrobial solution (Anasept®). All the set of evaluated medical-grade materials demonstrated chemical resistance across all immersion times in Anasept®. The above results demonstrate that stabilized and isotonic 0.057% sodium hypochlorite antimicrobial solution (Anasept®) could be used together with all the set of medical-grade materials tested in all the immersion times without affecting its chemical resistance.

Keywords: Sodium hypochlorite, Antimicrobial, Stabilized & Isotonic

Introduction

Antimicrobial agents are substances that are used to reduce the risk of sepsis and infection; those are classified into two main groups: 1.- Antibiotics: Natural or synthetic, absorbable agents with bactericidal or bacteriostatic activity [1] The antibiotics prophylactic use prior

to surgery is increasingly supported by evidence and is considered standard of care in procedures involving implants. [2] Nevertheless, the overuse of antibiotics has led to an increased prevalence of bacterial resistance, a recognized global health issue. [3] 2.- Antiseptics: Substances applied topically with minimal systemic absorption, which effectively reduce infection risk. [1] Compared to antibiotics, antiseptics exhibit broader antimicrobial spectra and a lower potential for bacterial resistance. [4] In surgery, antiseptics reduce infection sources [5] but are associated with cytotoxic effects and impaired wound healing. [6] Additionally, some antiseptics adversely affect common medical-grade materials (e.g., iodine deteriorates silicone; alcohol and polyethylene glycol degrade polyurethane and silicone) [7]. Recent efforts aim to enhance conventional antiseptic therapies by developing formulations with minimized drawbacks and improved efficacy [8]. Dakin's solution, first introduced during World War I, significantly reduced wound-related disabilities [9]. Its full-strength form contains 0.5% NaOCl, and the medium-strength form contains 0.25% NaOCl; both demonstrate antimicrobial efficacy but are limited by cytotoxic effects and delayed wound healing [10]. A "modified Dakin's solution" containing only 0.025% NaOCl was published in 1991, that new version retained bactericidal properties without development cytotoxic effects [11]. Recent research comparing antiseptic effects on human fibroblast and keratinocyte cultures found that NaOCl in low concentration had the lowest detrimental effects, making it the least aggressive from different antiseptics studied options [12]. Saline solution (NaCl-based) is widely used in clinical practice due to its isotonicity, which helps avoid disrupting the wound healing process [13]. The World Health Organization recently recommended the use of 0.015% HOCl for wound management, citing its minimal impact on the structural integrity of healing tissue [14].

Anasept®, an isotonic modified solution containing only 0.057% NaOCl (being below cytotoxic concentrations) [15, 16], demonstrated superior effectiveness in reducing bacterial load and promoting healing compared to saline solution in a controlled, randomized, double-blind pilot study in hard-to-heal wounds in adult patients [16], a recent comparative study associates intra-abdominal lavage with Anasept® with more favourable outcomes (less 1 month follow up complications) a shorter hospital stay and a reduction in hospital cost in adult patients with complicated appendicitis [17], finally also a cross sectional study associated the use of Anasept® with a reduction in the infection rates associated to haemodialysis catheters in adult patients under the current international recommendations. [18]. Due to its benefits in controlling bioburden [16-19] without cytotoxicity [15] Its potential use is proposed as a new treatment option in device-associated healthcare-associated infections (DA-HAIs).

Materials and Methods

Following the ASTM D543-14 guidelines for polymer material resistance, [19] the evaluation assessed visible physical changes, dimensional changes, and weight variations through a series of measurements performed before and after immersion in Anasept® (Bravida Medical; Genova, Illinois, USA) for various immersion times (30 seconds, 1 minute, 5 minutes, and 24 hours). Immersion times were selected based on the standard intervals used to assess the antimicrobial efficacy and residual effects of Anasept® (Bravida

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Citation: Jiménez-Palomar I, González-Lemus R, Barajas-Cervantes A (2026) Chemical Resistance Evaluation of Various Medical-Grade Materials Exposed to a Stabilized and Isotonic 0.057% Sodium Hypochlorite Antimicrobial Solution (Anasept®). Biomater Med Appl 16: 508

Received: 22-July-2026, Manuscript No: BMA-26-192850, **Editor Assigned:** 24-Jul-2026, Pre-QC No: BMA-26-192850 (PQ), **Reviewed:** 07-Aug-2026, QC No: BMA-26-192850, **Revised:** 12-Aug-2026, Manuscript No: BMA-26-192850 (R), **Published:** 19-Aug-2026, DOI: 10.4172/2577-0268.1000508

Medical; Genova, Illinois, USA). [15] The following medical-grade materials were tested: 316L stainless steel, polyglycolic acid, polyetheretherketone, polyethylene, polylactide, polypropylene, polyurethane, and silicone.

Results

After subjecting all medical-grade materials to all immersion times in Anasept® as is specified in the Materials and Methods section and after making all the corresponding subsequent reviews, it was determined that: All materials demonstrated good resistance at all evaluated immersion times. Based on the findings, implant irrigation may be safely performed with Anasept® for the evaluated materials in the immersion times tested, as the materials demonstrate good chemical resistance (Table 1).

Discussion

Further studies are required to evaluate additional materials, material combinations and different clinical scenarios. The use of medical implants is critical in the treatment of patients with functional deficits or tissue loss across a range of anatomical sites. However, implantable devices are associated with an elevated risk of biofilm-associated infections. One current strategy to reduce this risk involves intraoperative irrigation of implants with antimicrobial solutions. [20] Evaluation of degradation through analysis of physical, mechanical, and chemical properties is a key factor in the selection of clinically appropriate materials. [21] This work establishes a first precedent that Anasept® does not interfere with the proved medical-degree materials at the tested immersion times; future research could consider the above (Figure 1).

Significance of Research

Infections associated with medical devices, or device-associated healthcare-associated infections (DA-HAIs) are a serious public health problem commonly associated with a complex treatment which frequently requires device removal increasing dramatically health cost by hospital stays, readmissions and utilization of specialized treatments. This study demonstrates a good resistance between the interaction of the antimicrobial agent (Anasept®) and the most used medical materials; this could favor a future possible integration of this agent in therapeutic schemes for management of (DA-HAIs).

Alignment with Journal Scope

This study reports new information about the physical properties (chemical resistance) of an antimicrobial solution (Anasept®) to the most common medical materials. This result creates an opportunity of a treatment for device-associated healthcare-associated infections (DA-HAIs) offering a novel emerging Biomaterial applications to Medical Sciences.

Publication Agreement

All the authors approved the manuscript and agree with the content and its submission to the Biomaterials and Medical Applications journal. This manuscript is original, has not been published previously, and has not currently been submitted to any other journal.

Acknowledgement

This work is dedicated to the memory of the master’s in science Alfonso Barajas-Cervantes who very unfortunately left this world shortly after completing the experiments mentioned in this article. Those of us who have the privilege of knowing Alfonso are grateful for the good fortune of having been able to share the laboratory, experiences, and a part of life with him. The authors also wish to thank Moises Carvente-Ochoa and his company BIVIUM International for having fully funded this study.

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Table 1: Medical-degree grade material resistance at different times.

Material	30 seconds	1 minute	5 minutes	24 hours
316L Stainless Steel	A	A	A	A
Polyglycolic Acid	A	A	A	A
Polyetheretherketone	A	A	A	A
Polyethylene	A	A	A	A
Polylactide	A	A	A	A
Polypropylene	A	A	A	A
Polyurethane	A	A	A	A
Silicone	A	A	A	A

A = Good resistance

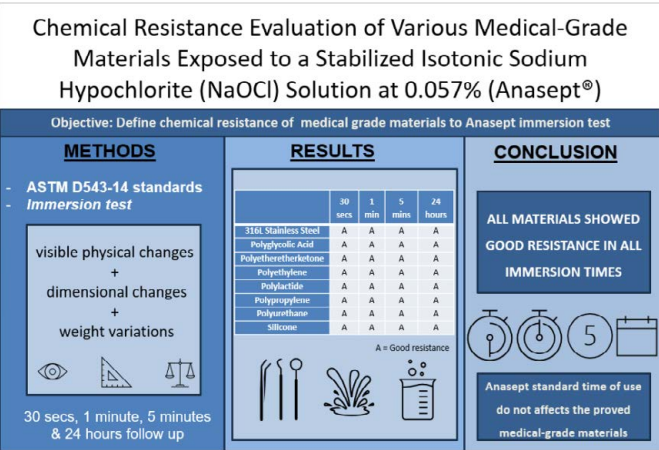


Figure 1: Graphical abstract.

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