INFORMATION BRIEF (RAPID REVIEW)

NANOPARTICLE ANTIMICROBIAL NITRILE EXAMINATION GLOVE

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
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Rapid Review
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TITLE: NANOPARTICLE ANTIMICROBIAL NITRILE EXAMINATION GLOVE

PURPOSE

To provide evidence on the effectiveness and safety of nanoparticle antimicrobial nitrile examination glove in reducing cross contamination and spread of infection amongst healthcare workers compared to latex examination glove. This report has been made on request from th[redacted]

BACKGROUND

Medical gloves are indispensable in modern healthcare settings, serving as a critical barrier against contamination and infection. Their use is fundamental in safeguarding both healthcare professionals and patients from the spread of pathogens during medical procedures. The evolution of medical gloves, from rudimentary coverings to advanced, high-performance materials, reflects ongoing advancements in both medical science and materials engineering.[1]

The primary function of medical gloves is to provide a protective barrier against microbial contamination. Evidence underscores their efficacy in reducing the transmission of infections. For instance, a study by Pittet et al. demonstrated that the use of gloves significantly decreases the risk of healthcare-associated infections (HAIs), which are a major concern in hospital settings. Gloves act as a physical barrier, preventing direct contact with blood, bodily fluids, and contaminated surfaces.[1]

Material science has played a crucial role in the development of medical gloves. The most commonly used materials are latex, nitrile, and vinyl, each with distinct properties and applications. Latex gloves, traditionally favored for their elasticity and tactile sensitivity, have been increasingly associated with allergic reactions in both patients and healthcare workers. In response, nitrile gloves have gained prominence due to their superior chemical resistance and hypoallergenic properties. Vinyl gloves, while less durable, are used in low-risk situations due to their cost-effectiveness.[2]

The choice of glove material is influenced by factors such as the type of procedure, risk of exposure, and individual sensitivities. Research indicates that while nitrile gloves offer robust protection and are preferred in high-risk situations, they are not without limitations, such as higher costs compared to latex or vinyl gloves. Furthermore, the integrity of gloves can be compromised by factors like improper sizing, manufacturing defects, or extended use, highlighting the need for stringent quality control and adherence to usage guidelines.[2]

The development of novel antimicrobial surfaces that can combat microbial contamination and minimize the spread of infection has been gaining increased attention. Contaminated biomedical implants, surgical tools, hospital furniture, personal protective gear, and other clinical surfaces are all potential sources of hospital-acquired infections (HAIs). It is now well recognised that microorganisms have evolved biochemical and mechanical strategies,

including biofilm formation and the emergence of multidrug resistance (MDR) to overcome standard antibacterial approaches. This, in turn, makes HAIs increasingly difficult to treat, often requiring prolonged intravenous systemic antibiotic therapy, sometimes with multiple agents. Therefore, there is a pressing need for novel strategies to be developed to suppress MDR microbial contamination and spread on clinical surfaces.[3]

Technical Features

Nitrile gloves are made from Nitrile Butadiene Rubber (NBR), a synthetic material created in a large vat by combining monomers such as butadiene and acrylonitrile, which polymerize to result in liquid nitrile. The nitrile is then filtered and combined with antioxidant and coagulating agents by glove manufacturers to create a more durable material.[3]

Generally, the antimicrobial agents impregnated in medical gloves act via biochemical mechanisms, which can be further classified as chemically derived or naturally derived. Anti-microbial agents are often selected based on their potency in previous functional characterizations. During the incorporation process, high temperatures and chemical reactions with other elastomer additives can affect the potency of the antimicrobial agents. Thus, the integration method, whether by dispersion or coating, as illustrated in Figure 1, is of utmost importance in maintaining the final antimicrobial efficacy of the gloves while ensuring latex stability.[3]

This nanoparticle regarded as micelles that are embedded in the latex during manufacturing process through method of dispersion, kill microbes by binding the cationic hydro-philic shells to the negatively charged microbial cell wall. This is followed by destroying the local membrane lipid organisation by inserting the hydrophobic proportion.[3]

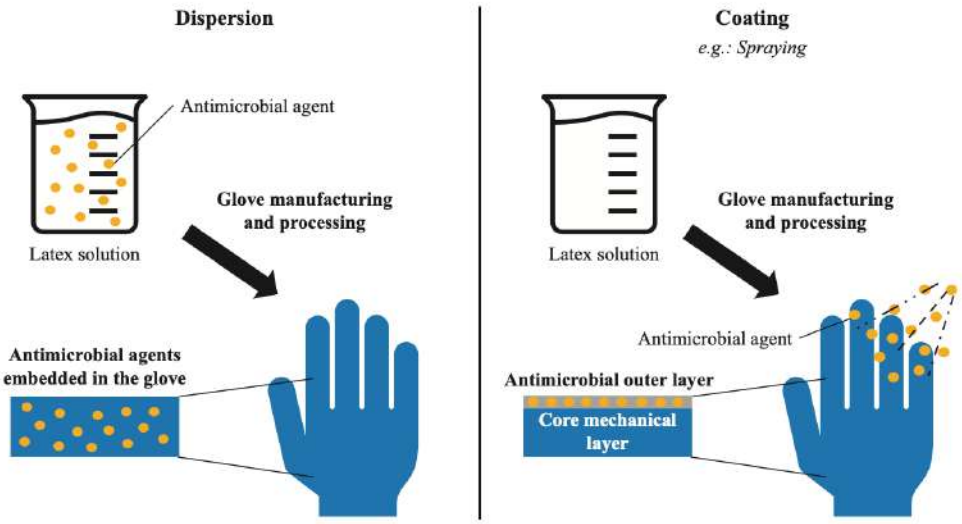
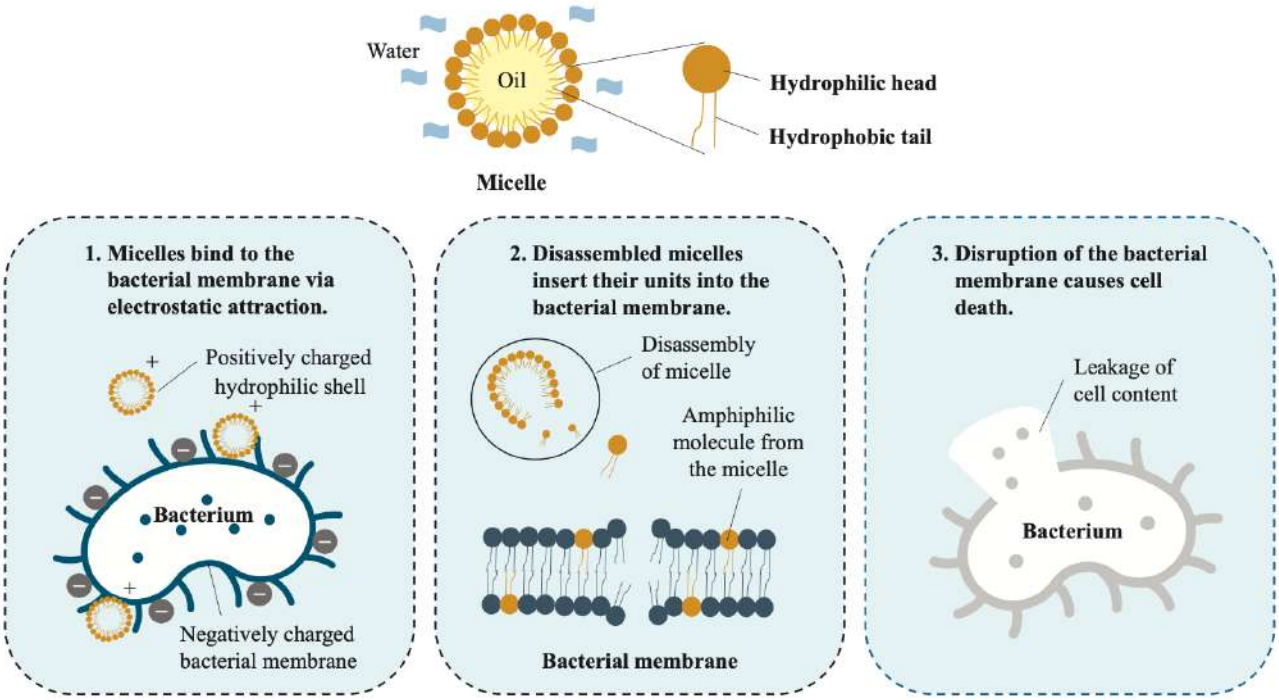


Figure 1. Methods of integration include dispersion and coating. In contrast to the dispersion method, coating occurs after an initial glove product is produced, and the antimicrobial agents are not present in the core mechanical layer.



EVIDENCE SUMMARY

A total of 128 titles were retrieved from the scientific databases such as Medline, using the search term; *Gloves, Surgical, Gloves, Protective, Anti-Infective Agents, Anti-Bacterial Agents, Nitriles, Nanoparticles.* No limits were applied to the search. The last search was run on 30 May 2024. After reading full articles, there were no studies found assessing efficacy and safety of nanoparticle antimicrobial nitrile examination glove.

EFFECTIVENESS

There was no evidence retrieve on effectiveness of the nanoparticles and dispersion method in reducing cross contamination and spread of infection amongst healthcare workers. Other studies were focused on nitrile and coating method. However, based on document submitted by [redacted], according to ASTM D7907-14 (2019) conducted by ISO 17025 Accredited Antimicrobial Testing Laboratory in determining the bactericidal/virucidal efficacy on the surface are more than 99%. It has been proven to have a killing effect against microorganisms.[6]

SAFETY

There was no evidence retrieve on the safety of the PENTANANO gloves from electronic databases. However, based on the document received from the company, it has been tested by [redacted] were within Acceptable Quality Level)[7], chemically tested in accordance with EN ISO 21420:2020 were found to meet with the requirements[8], and been

tested on acute systemic toxicity in Swiss Albino Mice, were found not inducing any systemic toxicity.[9] However, it has been considered as moderate irritant when tested for skin irritation in New Zealand White Rabbit[10], weak sensitizer when tested on Skin Sensitization Test in guinea pigs[11].

It has been approved by U.S Food & Drug Administration (FDA), certified by Medical Device Regulation (EU MDR/2017/745)[12], certified by [redacted][3], Medical Device Authority (MDA) Malaysia[14], Zenith Quality Assessors Pvt Ltd[15], and Global Management Certification Services Pvt Ltd[16].

COST-EFFECTIVENESS (If any)

There was no evidence retrieved on cost-effectiveness of PENTANANO Gloves compared with currently used nitrile gloves.

CONCLUSION

There was no evidence retrieved that was specifically mentioned on effectiveness and safety of nanoparticle antimicrobial nitrile examination glove in reducing cross contamination and spread of infection amongst healthcare workers compared to latex examination glove.

Although based on submitted document showed positive results regarding safety & effectiveness, infection control measures in hospitals must always be adhered to by healthcare professionals.

A further research and clinical test need to be done regarding dispersion method of glove manufacturing as the evidences available at the moment are only on coating method.

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5. Patil D, Golia V, Overland M, et al. (2023). Mechanobactericidal nanotopography on nitrile surfaces toward antimicrobial protective gear. ACS macro letters. 2023 Jan 27;12(2):227-33.

6. [redacted]
7. [redacted]
8. Chemical innocuousness testing in accordance with EN ISO 21420:2020 and EN 16523-1:2015+A1:2018 resistance to permeation by chemicals, EN ISO 374-4:2019 determination of resistance to degradation by dangerous chemicals, testing in accordance with ISO 16604:2004 to meet the requirement of EN ISO 374-5:2016 for resistance to penetration by blood borne pathogens, powder free in accordance with EN ISO 21420:2020 clauses 5.1 sizing and 5.2 dexterity and EN ISO 374-2:2019 by SATRA Technology – (Document submitted by the company)
9. Study on Acute Systemic Toxicity in Swiss Albino Mice, Skin Irritation by GLR Laboratories Pvt Ltd – (Document submitted by the company)
10. Study on Skin Irritation Test in New Zealand White Rabbit by GLR Laboratories Pvt Ltd – (Document submitted by the company)
11. Study on Skin Sensitization Test in guinea pigs by GLR Laboratories Pvt Ltd – (Document submitted by the company)
12. Certificate of Compliance Medical Device Regulation (EU MDR/2017/745) – (Document submitted by the company)
13. Certification and authorization to use of [redacted] Complying with ISO 13322-1:2014 – (Document submitted by the company)
14. Medical Device Registration Certificate by Medical Device authority Malaysia – (Document submitted by the company)
15. Certificate by Zenith Quality Assessors; had been found to conform to the requirements of Medical Devices – Quality Management System Standard ISO 13485:2016 – (Document submitted by the company)
16. Certified by Global Management Certification Services Pvt Ltd in accordance with ISO 9001:2015, ISO 14001:2015, and ISO 45001:2018 – (Document submitted by the company)

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