Elastomer Impregnated with silver ions using a unique mixture of solvents imparts unique silver ion elution characteristics

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Statement of Purpose

There are a number of ways in which medical devices, through their use, may increase risk of infection. These device-related infections are most commonly associated with devices that are implanted in and/or are in direct contact with wounds, or are connected to catheters that lead to openings in the body. Microbial contamination of such medical devices is not uncommon.

Prior and emerging biomaterial technologies are frequently focused on producing materials with surfaces that prevent microbial colonization and/or biofilm formation. Typically, this is done by using a traditional medical device material and combining it with one or more antimicrobial agents. Such modification of a device is typically accomplished by incorporating antimicrobial(s) within the substrate material (polymeric device) or incorporating said antimicrobials into a coating on the device surface. In the case of the polymeric material, antimicrobials can be incorporated within the polymer during the extrusion or molding process, or by swelling an elastomeric polymer in the presence of an antimicrobial agent.

Impregnating a polymeric material with a soluble form of ionic silver while simultaneously obtaining an extended elution profile has proven difficult. In contrast to polymers used previously, polyisoprene (PI) has been discovered to have superior properties with respect to impregnation and release of silver compounds. PI impregnated with silver nitrate using a mixture of solvents imparts silver ion elution characteristics not demonstrated previously.

Methods

Cylindrical (with a height of 5 mm and a 5 mm diameter) polyisoprene samples with an average mass of 60 mg and impregnated with silver nitrate (in under 2 hours) using a unique mixture of solvents. The resulting samples where tested for efficacy using zone of inhibition measurements for the following organisms: *E. faecalis, S. aureus,* , *K pneumoniae*, *C. albicans*, *E. coli*, and *P. aeruginosa*. Every 24 hours the zones were measured and the PI samples were transferred into fresh plate of agar. This process was repeated mostly everyday for 43 days (see Figure 1).

An Elution profile, for a silver treated PI sample, was performed in water, at room temperature for 77 days (see Figure 2). The silver was measured using atomic absorption.

Results and Discussion

Prior silver salt impregnation techniques incorporated silver salts into polymers slowly (1 – 6 weeks) and with fairly low loads of silver salt[1]. In contrast, results of a transfer ZOI (mm) study using silver impregnated PI shows significantly large ZOIs. The PI where transferred from agar plate to agar plate for 43 days. An elution profile was also evaluated (Figure 2). The resulting elution profile demonstrates significant quantities of silver ions released from the PI over an extended period.

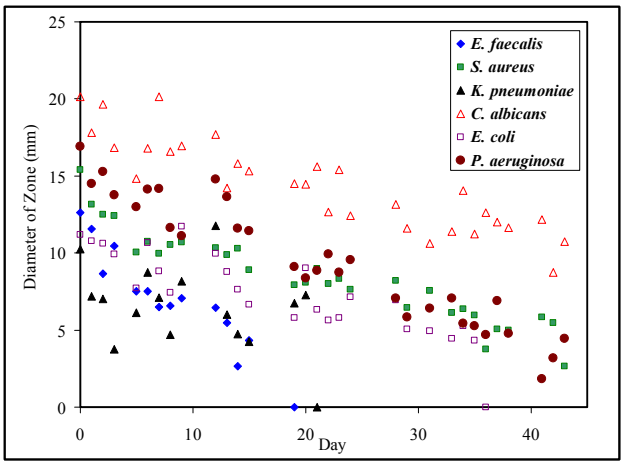

Figure 1. Daily zone of inhibition results for 60 mg PI samples transferred to fresh agar plates.

The resulting elution rate is extended as well, by the quantity of silver loaded in the article and by the release characteristics afforded by the polyisoprene.

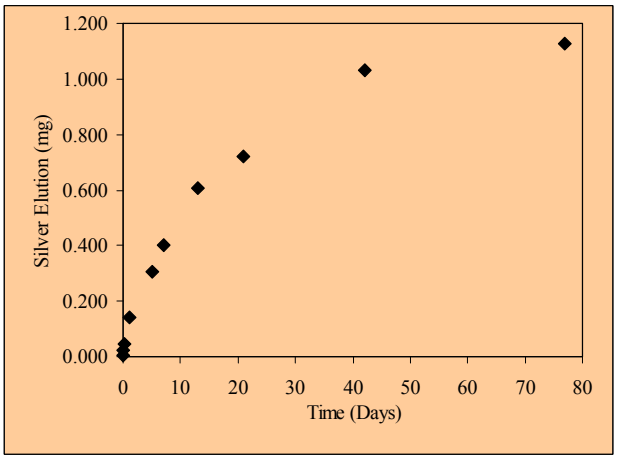

Figure 2. Cumulative silver elution results for a 60 mg PI sample in 35 mL transferred to fresh agar plates.

Conclusions

A unique combination of solvents has, unexpectedly, resulted in a significantly faster rate of incorporation, and considerably higher impregnation quantities of silver nitrate into PI. In addition to the increased rate of incorporation, the resulting silver (I) ion elution profile is extended, due to the increased quantity of silver loaded in the material.

References

1. Illner, H. *et al.* (1989) Use of topical antiseptic in prophylaxis of catheter-related septic complications. *Surg Gynecol Obstet* 168, 481-490)