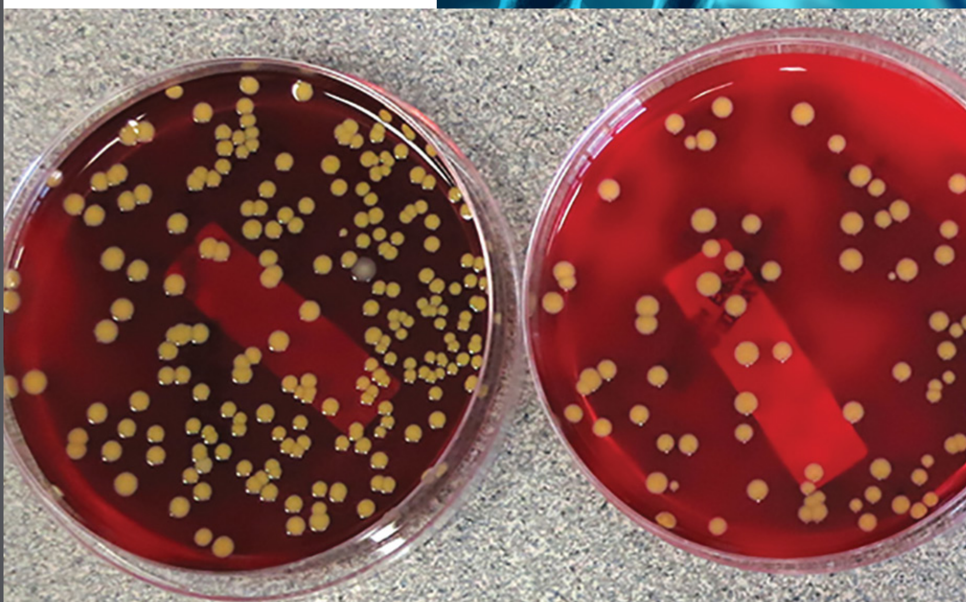
Water-Based Antimicrobial Coating For 3D Printed Medical Devices



White Paper

Water-Based Antimicrobial Coating For 3D Printed Medical Devices

There is a growing demand for surgically viable medical devices produced via 3D printing. As reported in this study, excellent antimicrobial properties can be achieved by applying a commercially available, water-based, antimicrobial coating to 3D printed devices.

Introduction

3D printing, or additive manufacturing, is an emerging technology used to implement new concepts and explore new possibilities. One example is the creation of 3D printed medical devices that have been specially designed to meet the needs of different patients[1].

The concept of an on-demand 3D printed surgical kit was studiedby the Defense Advanced Research Projects Agency (DARPA)[2] (2013). In their study, DARPA used tools that were printed on a 3D printer with a specially made ABS modeling material compounded with a small amount of silver additive. The study demonstrated that functioning surgical devices can be successfully produced on a 3D printer using commercially available equipment and software. However, the sterility of these devices was determined to be limited. Specifically, the antimicrobial efficacy of these 3D printed devices was demonstrated to be a 60% reduction in bacterial growth as compared to those printed with standard ABS model materials. The research concluded that further study was needed in order to reach 4 log or higher log reduction in bacterial growth.

The process of sterilizing 3D printed devices was also studied by Espalin, et. al. (2012) in a joint project between Stratasys® and the University of Texas at El Paso[3]. This study demonstrated that the process of sterilizing 3D printed medical devices is actually quite complicated — especially when the devices have been produced with ABS modeling materials — because the high temperatures involved in the autoclave sterilization process can cause deformation.

It is with this goal in mind that Stratasys initiated a follow-up study to evaluate the antimicrobial efficacy of a commercially available water-based antimicrobial coating that contains 10% by weight silver sulfadiazine from Surface Solutions Laboratories (Carlisle, MA)[4]. It is well-known that silver sulfadiazine is effective in killing a variety of bacteria and has been widely used to prevent and treat infections. It was hypothesized that the application of this antimicrobial coating to 3D printed medical devices would create an effective way to reduce or eliminate bacteria without the need for autoclaving. Plus, since a water-based coating system contains little or no organic solvents, the solution would not deform nor breakdown the 3D ABS parts. Finally, this study sought to determine if a water-based coating could be applied to 3D printed parts with uniform, consistent coverage[5].

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Sample Prepations And Evaluations

The testing of antimicrobial efficacy on 3D printed parts was conducted by ATS Labs, an external antimicrobial lab, by following a standard test protocol6 based on ASTM E2180 “Standard Testing Method for Determining Antimicrobial Activity in Polymeric or Hydrophobic Materials”.

Sample Preparation

As specified in ASTM E2180, test samples (3.0 cm x 3.0 cm x 0.3 cm). The samples were printed with two different materials: (i) Stratasys standard ABS modeling material; and (ii) modified Stratasys ABS modeling material that was compounded with a small amount of silver additive.

The antimicrobial coating solution was prepared following the instructions provided by the supplier, and applied to the 3D printed parts using a dipcoater at a constant speed of 10 mm/s. All coated parts were then dried in an oven at 70 °C for one hour. Finally, the parts were stored for seven days at room temperature in covered boxes, with each sample kept in its own individual compartment.

Samples & Preparation Methods	
Control T0	3D printed part using Stratasys standard ABS, no antimicrobial coating.
Sample T1	3D printed part using Stratasys modified ABS with silver additive, no antimicrobial coating.
Sample T2	3D printed part using Stratasys modified ABS with silver additive, applied with antimicrobial coating.
Sample T3	3D printed part using Stratasys standard ABS, applied with antimicrobial coating.

Table 1

Testing Of Antimicrobial Efficacy

Antimicrobial efficacy was tested by following a standard testing protocol SRT01102513.E2180[6] with two test organisms: a grampositive bacterial Staphylococcus aureus (ATCC 11229) and a gramnegative bacterial E. coli (ATCC 11229).

Both test organisms were obtained from the American Type Culture Collection (Manassas, VA). A five percent organic soil load with fetal bovine serum was added to the test organism. Letheen broth was used as the neutralizer and tryptic soy agar with five percent sheep’s blood was used as the agar plate medium.

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For each sample, three replicas were tested. They were exposed to the test organisms for 24 hours at 36.0 °C with 78% – 80% of relative humidity, then transferred to a neutralizer and assayed for survivors. Tests included appropriate culture purity, initial suspension, organic soil load sterility, neutralizer sterility, neutralization confirmation and stainless steel controls. Percent and $\log_{10}$ reductions of bacterial growth for the test samples were determined by comparing the test samples to the T0 control sample[6].

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Results And Discussions

Test results against the two baterials of Staphylococcus aureus and E. coli, including the geometric mean for the colony forming units in each sample (CFU/Carrier), log10 reduction, and the percent reduction as compared to the control sample of T0, are shown in Tables 2 and 3. Test results for Control (T0) showed a tremendous amount of bacterial growth in both Staphylococcus aureus and E. coli – i.e., 2.51 x 106 CFU/Carrier and 3.02 x 107 CFU/Carrier in Staphylococcus aureus and E. coli, respectively. Results for Sample T1 showed slight reductions in bacterial growth— 0.37 and less than 0.05 of log10 reductions —in Staphylococcus aureus and E. coli respectively. These are equivalent to reductions of 57% and 11% as compared to those printed with standard ABS modeling material. Results for Samples T2 and T3 showed nearly 100% reduction in bacterial growth, with log10 reductions for both T2 and T3 achieved more than 5.40 and 6.48 in Staphylococcus aureus and E. coli respectively.

Test plates for the four samples after 48 hours of incubation are shown in Figures 1 and 2. Large numbers of Staphylococcus aureus and E. coli were observed in T0 and T1 while none were observed in T2 and T3.

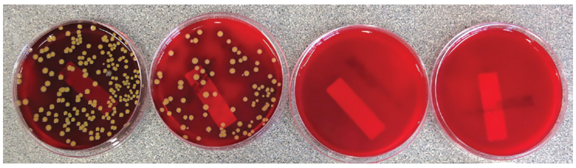

Figure 1: Test plates after 48 hours of incubation in Staphylococcus aureus. Note that T0 and T1 were diluted by 10-3 while T2 and T3 were not diluted.

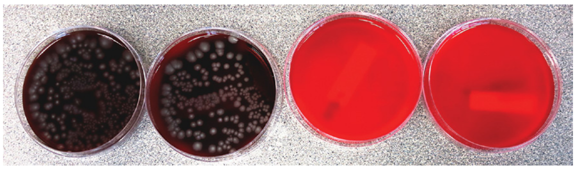

Figure 2: Test plates after 48 hours of incubations in E. coli. Note that T0 and T1 were diluted by 10-3 while T2 and T3 were not diluted.

Tested Results Against Staphylococcus Aureus				
Sample-ID	**Control T0**	**Sample T1**	**Sample T2**	**Sample T3**
Geometric Mean, FU/Carrier	2.51×10^6	1.07×10^6	$< 1 \times 10^1$	$< 1 \times 10^1$
Log_{10} Reduction	N/A	0.37	> 5.40	> 5.40
Percent Reduction	N/A	57.40%	> 9.9999%	> 9.9999%

Table 2

Tested Results Against E. coli.				
Sample-ID	**Control T0**	**Sample T1**	**Sample T2**	**Sample T3**
Geometric Mean, FU/Carrier	3.02×10^7	2.69×10^7	$< 1 \times 10^1$	$< 1 \times 10^1$
Log_{10} Reduction	N/A	< 0.05	> 6.48	> 6.48
Percent Reduction	N/A	<10.9%	> 9.9999%	> 9.9999%

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Conclusions

As indicated by the test results, 3D printed ABS samples treated with a water-based antimicrobial coating achieved more than 5 log10 reductions in bacterial growth which is equivalent to a 99.9999% reduction in bacterial growth as compared to those non-treated 3D printed standard ABS samples. The addition of a small amount of silver into ABS modeling material was shown to provide limited sterility, however, further research and development work is needed in order to determine its potential viability.

References

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(6) ATS Labs (Eagan, Minnesota), project number: A15919, completed on January 2, 2014.

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