



# PROBIOTIC DELIVERY DEVICE

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## Problem Statement

Our client is researching the efficiency of the probiotic Lactobacillus GG in preventing s. aureus infections when the probiotics are applied to the interior nasal passage. A device to deliver the probiotic to the inside of the nose is needed to perform clinical trials with the probiotic. The Lactobacillus GG should live inside the nasal passage for at least one day to allow for daily application of the probiotic.

## Background

### Staphylococcus Aureus (s. aureus)

- Common bacteria native to 30% of people
- Resides in nasal cavity
- Infectious once inside the body
- Methicillin resistant s. aureus (MRSA)
- Economic burden of \$14.5 billion for inpatient hospital stays

### Probiotics

- Bacteria that benefit the host
- Kill harmful bacteria, such as MRSA

### Lactobacillus GG (LGG)

- Normally used to treat digestive problems
- Kills MRSA with secreted peptides
- Lessens possibility for s. aureus to become drug resistant
- LGG is a probiotic NOT an antibiotic

### Clinical Trials Application

- Large scale clinical trials
- Testing the effectiveness of the LGG in killing harmful s. aureus

## Design Criteria



### The delivery device must:

- Accurately deliver  $10^7$  to  $10^9$  LGG organisms
- Keep bacteria viable for up to 2 weeks
- Repeatedly deliver correct dosage
- Prevent far insertion into nose
- Be able to be refrigerated
- Be opaque

### The solution must:

- Be biocompatible
- Allow bacteria to live up to 2 weeks
- Survive in nose for min. of 1 day
- Prevent overgrowing

Lactobacillus GG (LGG), a probiotic with potential to lessen the probability for s. aureus becoming drug resistant.

## Final Design



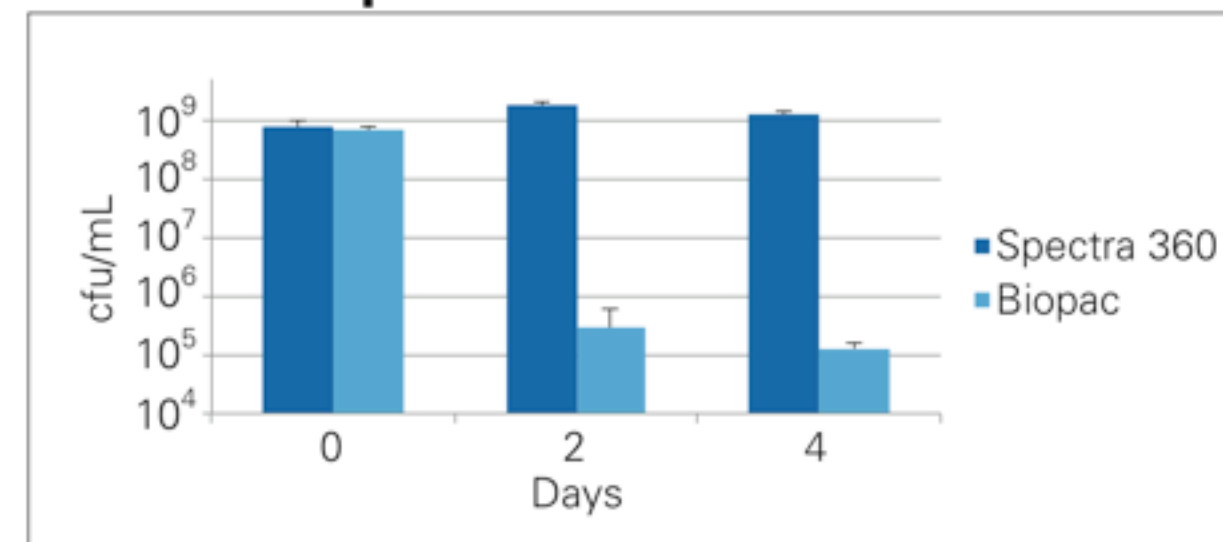
## Testing & Results

Testing includes:

- (1) Survivability in saline
- (2) Gel comparison (Figure A)
- (3) Amount of delivery
- (4) Consistency in different temperature
- (5) Bacteria concentration comparison (Figure B)

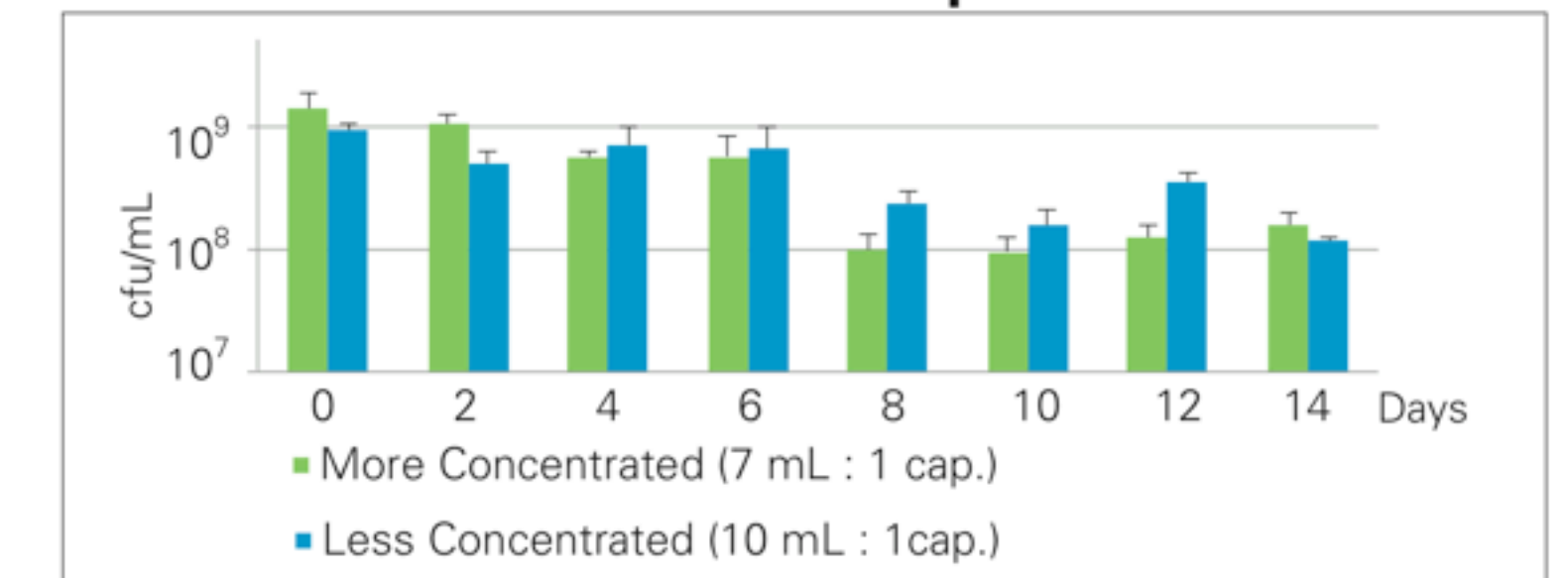


### A. Gel Comparison



The figure compares the survivability of LGG in two types of gel, Spectra 360 and Biopac. The Spectra 360 gel was mixed 2:1 with 0.9% saline and the Biopac gel was mixed 1:1 with saline based on their viscosity. At day 0, the concentrations of LGG in each gel were roughly the same. This indicated that our method to mix the gels with LGG was fairly consistent. After a period of 4 days, the survivability of LGG in Spectra 360 gel remained consistent, while the concentration of LGG significantly dropped.

### B. Bacteria Concentration Comparison



The figure shows how well the LGG survived over 2 weeks when they were packed with different concentrations of LGG in the Spectra 360 gel solution (as shown in legend). The concentration of gel solution in both groups were both at 3:1 ratio (gel:saline). The data indicated that LGG survived better in the less concentrated group. The greater amount of decrease in the more concentrated group may be caused by the limited growth space. However, the concentrations of LGG in both groups were still within the desired range after 2 weeks.

## Future Work

### Delivery Device

- Test the amount of LGG surviving in the nose
- Determine the amount of LGG lost when using finger and Q-tip to apply gel
- Adjust delivered volume accordingly

[1] Farmer, S. (2002). "Probiotic, lactic-acid producing bacteria and uses thereof." Ganeden Biotech Inc. U.S. Patent Number: 6,461,607.

[2] Food and Drug Administration (FDA). (2010). "Code of Federal Regulations." U.S. Department of Health and Human Services. <www.fda.gov/MedicalDevices/default.htm>

[3] Lu, R., P. Nataro, J., & Fasano, A. (2010). Lactobacillus GG (LGG) peptides can inhibit antibiotic-resistant bacteria growth. Anti-Infective Agents in Medicinal Chemistry, 9(2), 48-51.

[4] National Center for Biotechnology Information. (2008). "Mupirocin." PubMed Health. <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000875>