Cleanability of Reusable Medical Devices

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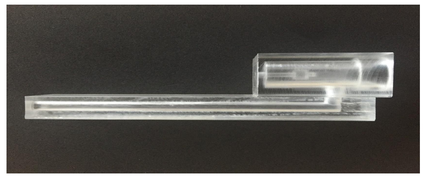
Introduction

This research looks at the 'cleanability' of surgical equipment, specifically arthroscopic shaver handles. Shavers are tools used to remove cartilage, bone, and tissue. After an outbreak of surgical site infections, it was discovered that the **shavers were still contaminated after reprocessing**. In response, the FDA created plastic prototypes of the shavers and ran synthetic bone cement through them to discover the location of the buildup[1]. To make this process more efficient, doctoral student, Casey O'Brien, created a simulation of flow through the shaver handles.



Picture of a plastic model

Objectives

The goal is to validate the accuracy of the simulation by:

- Characterizing the data from plastic models
- Finding a scaling factor for the plastic model data, so the plastic and simulation correspond
- Determining the run time for the simulation model

Conceptual Model

What is a conceptual model?

- An alternate way to think about a problem that is familiar and easier to understand

For our research we used traffic flow & congestion models

- Vehicles= particles of bone cement
- Roads= inside of the shaver
- Collisions= buildup

Follow-the-Leader Models[2]

- Vehicles will adjust to their environments when there are collisions and back-ups, which changes traffic flow
- Shows us how the flow inside the shaver may change when buildup is present
- Lets us see the effect that buildup has on the flow of particles that are not stuck

Plastic Model Data

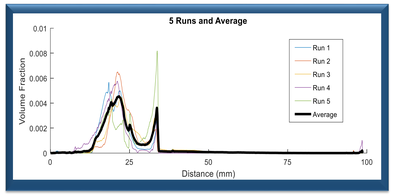


Figure 1

- 5 runs and their average of synthetic bone cement through the shaver
- µCT scan is used to find buildup
- Data presented as a PDF

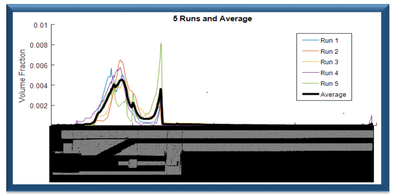


Figure 2

- Same data as Figure 1, but a cross section of the shaver handle is overlaid on the x-axis
- Gives an idea of where buildup occurs inside the shaver

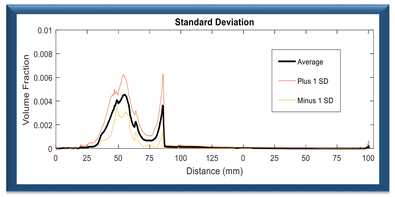


Figure 3

- Average bounded by bounded by + and – 1 standard deviation
- Shows the variability between the 5 runs

Simulation Model Data

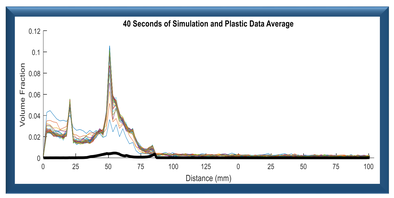


Figure 4

- Ran simulation for 40 seconds and took a measurement of particles every second (the different colored lines)
- The thick black line is the average from the plastic model data

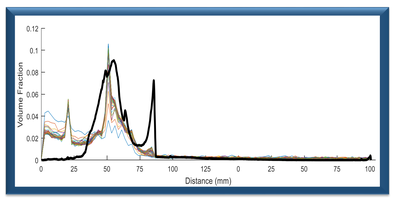


Figure 5

- Same simulation data as Figure 4
- Found the average area under the simulation curves to be 20.07 mm
- Multiplied the average from the plastic data by a scaling factor of 20, so the area under the plastic average curve matches the area under the simulation curves

Results

- To validate the simulation, sum of squared differences (SSD) between the simulation and plastic data are used
- Looking for a U-shaped curve

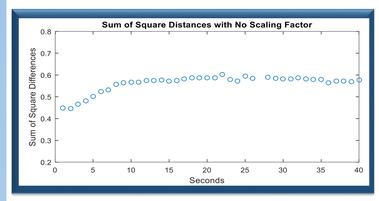


Figure 6

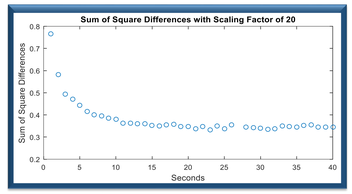


Figure 7

- Figure 6 has no calibration constant and lacks a minimum
- In Figure 7 the SSD has a scaling factor of 20 and a broad minimum (U-shape) appears

Conclusion

- Plastic model characterization can be seen in Figures 1-3
- By comparing area under the curve we determined 20 to be a reasonable scaling factor
- Looking at the scaled SSD in Figure 7, an appropriate run time for the simulation would be 20 seconds, as it clearly falls in the minimum

Looking at the data from the simulation and plastic models, specifically Figures 5 and 7, we have sufficient reason to believe that the simulation corresponds to the plastic model.

Thus, the simulation can be used in place of the plastic models

Acknowledgements and References

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1. Lucus, Anne D., Srinidhi Nagaraja, Edward A. Gordon, and Victoria M. Hitchins. "Evaluating Device Design and Cleanability of Orthopedic Device Models Contaminated with a Clinically Relevant Bone Test Soil." *Biomedical Instrumentation & Technology* (2015): 354-362.
2. Mathew, Tom V., and K V Krishna Rao. "Microscopic Traffic Flow Modeling." *Introduction to Transportation Engineering*. 2007. Print.