Testing and Validation

Team 314: Abbott Reusable RF Probes

Testing Experiments

Two experiments are to be done on the RF probe prototypes. The sterilization test is performed on the prototypes to test how the material withstands pressurized steam sterilization at 132°C. The force test is done on the prototypes to gather information regarding the material strength.

Test	Measurement	Equipment	Model
Sterilization	# of uses until material breakdown	Autoclave	Tuttnauer EZ11+
Force	Elastic modulus/ stress-strain curve	Tensile Test Machine	MARK-10 ESM301

Table 1. Verification Test breakdown

Batch #	Material Type	Temperature	# of cycles	Enzyme?	# of hubs
000	PET	Low (132°C)	5	Y	4
001	PET	Low (132°C)	5	N	4
002	PET	Low (132°C)	15	Y	4
003	PET	Low (132°C)	15	N	4
008	PPSU	Low (132°C)	5	Y	4
009	PPSU	Low (132°C)	5	N	4
010	PPSU	Low (132°C)	15	Y	4
011	PPSU	Low (132°C)	15	N	4

Table 2. Independent and Dependent Test groups.

Sterilization Test

A portion of the hubs were first rinsed and soaked in an enzyme cleaner before being placed in sterilization pouches. The other portion was not exposed to the enzymatic cleaner to maintain a control group of hubs. The hubs were then placed in an autoclave and steam sterilized using the preset for wrapped instruments in pouches, which heats up to 132°C. We used this combination of cleaner and steam sterilization on our devices because this is how the devices are typically cleaned and sterilized in the medical field.

Sterilization Test Procedure:

1. Enzyme solution cleaning
    a. Prepare a 30mL of enzyme solution and 3800mL of warm (30 to 40°C) tap water.
    b. Soak hubs for 30 minutes in prepared solution.
    c. Rinse hubs with distilled water.
    d. Dry with clean non-linting wipes.
2. Place cleaned hubs in labeled sterilization pouches.
3. Place sterilization pouches into autoclave.
4. Set autoclave to standard preset “Wrapped Instruments, Pouches.”
5. Begin sterilization cycle.

Force Test

Hubs were subjected to tensile strength tests to obtain a stress versus strain graphical comparison between the two polymers. The hubs were tested at zero, five, and fifteen sterilization cycles to model how the strength of the hubs altered overtime after going through multiple sterilization cycles and enzymatic cleanings. The hubs were placed in the tensile strength machine and grabbed from end to end. Then they were pulled apart to measure how much force was required to cause the hubs to break down.

Force Test Procedure

1. Load hub into Force Test Stand.
2. Start data gathering software (MESUR® Lite by MARK-10).
3. Perform load test until hub reaches breaking point.
    a. Strain rate: 2mm/min
    b. 5 readings per second
4. Export and save data to excel sheet.
5. Unload hub and make sure all broken pieces are disposed of properly.

Expected Results and Discussion

From the sterilization testing procedure, we expect that the PPSU hubs will last longer (i.e. not break) than the original hubs made out of PET. We expect it will take more force to break the hubs made out of PPSU than it will break PET. Therefore, showing that our PPSU prototypes are stronger and more durable than the original PET hubs.

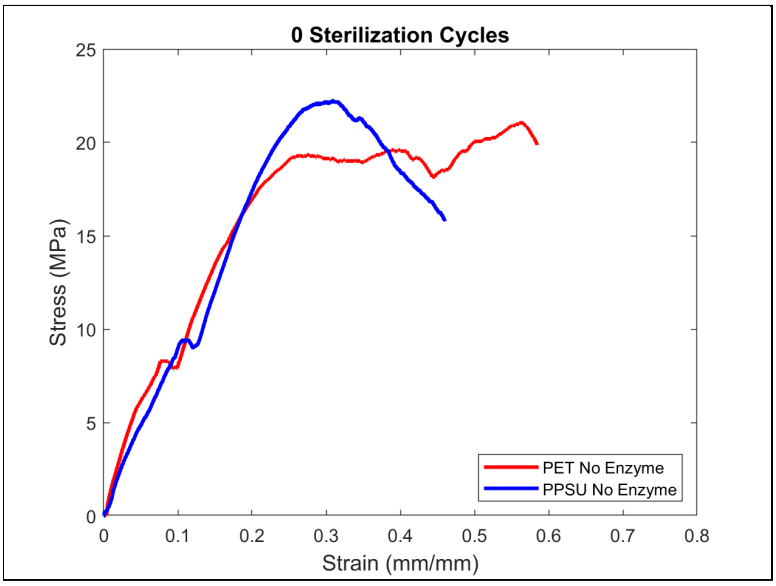

Figure 1. Stress vs Strain curve for hubs with zero sterilization cycles.

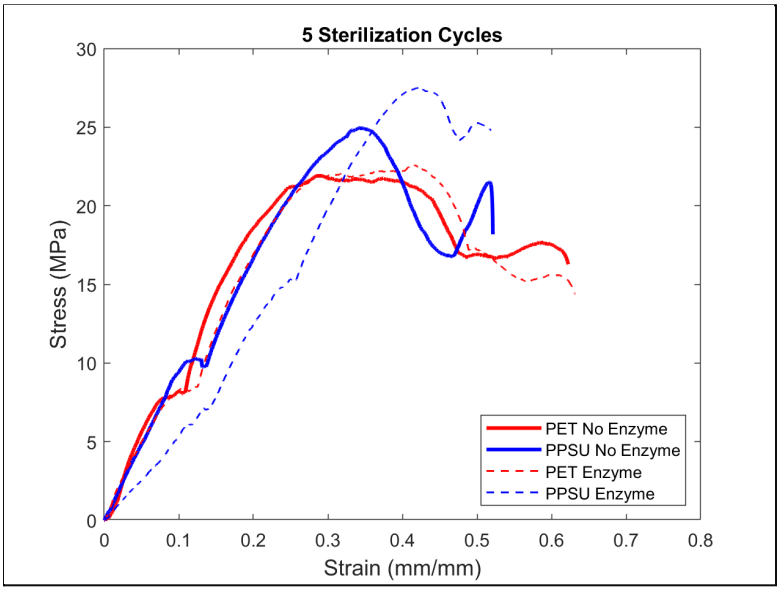

Figure 2. Stress vs Strain curve for hubs with five sterilization cycles.

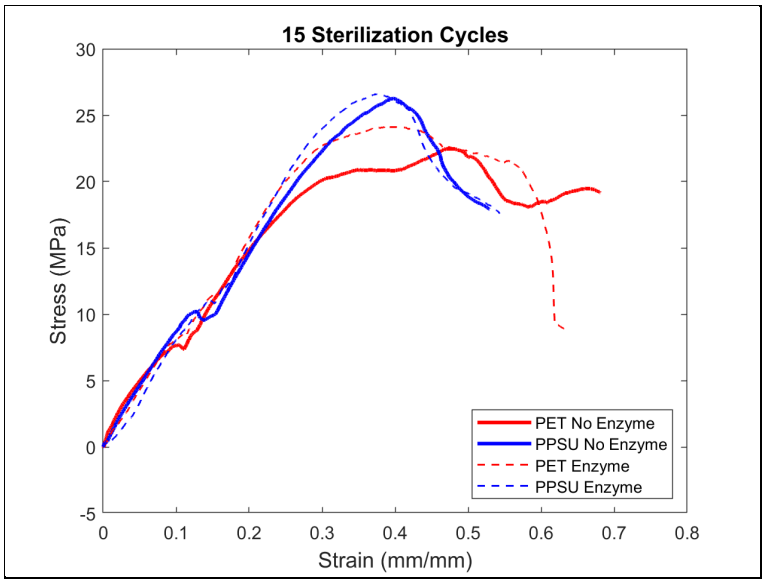

Figure 3. Stress vs Strain curve for hubs with fifteen sterilization cycles.

The ultimate strength of PPSU is higher than that of PET in all cases, as observed in Figures two, three, and four. Based on Figures three and four, the enzyme cleaning process increased the ultimate strength of both materials. However, these results need further testing to ensure accuracy due to the small sample size. Therefore, PPSU is projected to last longer than PET.

Conclusions

The team was tasked with increasing product lifespan by 100%. The team created prototype hubs with both PET and PPSU using CAD and machining equipment to accomplish this. An orthogonal design of experiments was created to test these prototypes to save time and obtain more useful quantitative data. The parameters varied for these experiments included material, number of cycles, and if there was enzyme cleaner used prior to autoclaving. Qualitative data was obtained after autoclave cycling by visually looking to see if there was any crack propagation in the hub. Quantitative data was obtained from mechanical proof testing. The results show the amount of sterilization cycling related to the force required for hub failure. The team hypothesized that the hub reusability would increase if the PET hub material were changed to PPSU. This hypothesis was proven to be true. These tests' results are valuable because they show the difference in PET and PPSU mechanical properties after product use and whether the change in material increases product lifetime.