A Benchtop Model for Comparison of Abrasiveness between Surgical Devices

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Statement of Purpose: Surgical staplers are a commonly used surgical device that enables a surgeon to simultaneously cut and staple, providing a hemostatic cut line. These devices are frequently used in lung resections, colorectal cancer, and bariatric surgery. In some cases layers of staple line reinforcement material, or buttress, may be added to opposing sides of the stapler to add compression to the staple line and reinforce fragile tissue. A benchtop test was developed to model the use of buttress on the lungs and investigate the effects of dynamic, cyclical contact between buttressed staple lines and surrounding tissue. The following benchtop model was designed to obtain quantitative data in a repeatable method to allow for objective comparisons between various configurations of staplers and buttress products. To model worst-case, each staple line specimen was formed by firing two sequential buttressed staple lines, forming a 90° angle, in synthetic media. Each wedge was applied against a soft gel abrasion substrate for a set duration using a programmable linear actuator. Five groups representing various stapler-buttress combinations were included in this study: Groups A, B, C, D, and E, with mean defects of 32.1, 185.7, 134.4, 86.6, and 552.5 mm^3, respectively. Based on the 95% Bonferroni confidence intervals, there was a statistically significant difference between E and all other groups, while there was not enough evidence to detect a difference between Groups B, C, and D.

Methods: In this benchtop model synthetic materials were used in place of tissue and electro-mechanical test systems were used to produce cyclic motion between the staple lines and the abrasion substrate. To create the staple line wedges, two sequential buttressed staple lines were fired at a 90° angle in synthetic media with uniform thickness. Excess buttress at the apex of the wedge was trimmed to 1 cm for all groups. Wedges were held in pneumatic grips on an Instron to precisely control the vertical position of the wedge. The abrasion substrate was made by polymerizing an agarose gel with aluminum oxide in suspension, which enabled the surface topography to be mapped using a 3-dimensional laser scanner. A linear actuator with a custom tray was used to hold the abrasion substrate and the Instron was used to lower the apex of the wedge 0.200" sub flush to the gel surface. The actuator cycled the gel across the wedge with a 2 inch stroke for five minutes. This process was repeated for each new wedge in an undisturbed area. Agarose gels were shipped over- night for processing at ImageIQ, Inc (Cleveland, OH) where they were scanned with a high resolution 3-dimensional laser scanner. The surface of each gel was analyzed then each defect was isolated and analyzed as a solid volume (mm^3). Data were pooled by group (A, B, C, D, and E) as there were no significant differences detected between gels.

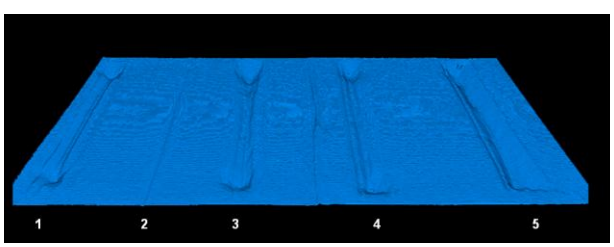

Figure 1: Surface rendering of an agarose gel after treatment with five specimens, produced at ImageIQ, Inc (Cleveland, OH)

Results: The mean defect volume and standard deviation for Groups A, B, C, D, and E were 32.1 ± 16.6, 185.7 ± 132.5, 134.4 ± 127.7, 86.6 ± 71.5, and 552.5 ± 198.8 mm^3, respectively. Furthermore, all groups followed a normal distribution (p-value ≥ 0.05).

Table 1: Summary table with sample size, mean, standard deviation and the p-value for normality, by group A-E

Group	Sample Size	Mean (mm^3)	Standard Deviation (mm^3)	Normality (p-value)
A	9	32.1	16.6	0.515
B	9	185.7	132.5	0.857
C	6	134.4	127.7	0.136
D	9	86.6	71.5	0.184
E	9	552.5	198.8	0.245

Based on the 95% Bonferroni confidence intervals, there was a statistically significant difference in mean defect volume between E and all other groups, while there was not enough evidence to detect a difference in means between Groups B, C, and D.

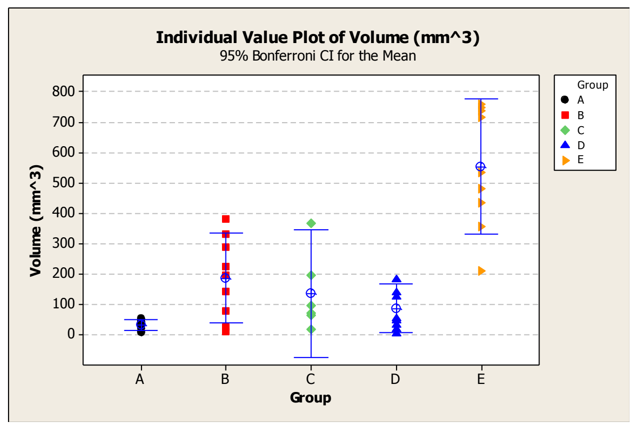

Figure 2: Individual value plot shown with mean symbols and 95% Bonferroni confidence intervals

Conclusions: Initial testing has shown feasibility of the method and provided data with statistically significant differences between groups. Going forward, additional samples may be evaluated to increase sample size and measurements such as depth and length may be analyzed. Although this model cannot be used to directly evaluate safety, as there is patient interaction or healing response; the method produced objective data that allowed for direct and objective comparisons between groups. This provides a new tool to evaluate abrasion for use throughout new product development, from benchmarking the performance of predicate products with known clinical safety profiles to comparison of new product concepts and various design iterations. In the future this method may be adapted to model the interaction between other devices and surrounding tissue in their respective applications. In this way, the method described herein may provide an additional tool in new product development across various specialties and applications.