Sports Medicine

Evidence matters

Stryker SWEEP probes

Top-level summary

In order to evaluate the performance of Stryker's 50-S SWEEP and 50-S SWEEP XL relative to competitor products, comparative testing was performed. **The 50-S SWEEP and 50-S SWEEP XL probe exhibited high idle speed, mass ablation rates, shaft strength, stiffness and resistance to clogging.**

Methods

The idle speed,[a] mass ablation rate,[b] shaft strength,[c] stiffness,[d] and resistance to clogging[e] of the 3.5 mm 50-S SWEEP and 50-S SWEEP XL probes with Stryker's CrossFire II Energy System were compared to four competitive radiofrequency (RF) probes:[1,2,3]

- 4.0 mm Arthrex Apollo RF, Aspirating Ablator 90˚, Extra Large (Arthrex Apollo XL) – Arthrex Synergy Resection System
- 4.7 mm Smith & Nephew Ambient HipVac 50 IFS (SNN HipVac) – Smith & Nephew Quantum 2 Resection System
- 3.75 mm Smith & Nephew MultiVac 50 XL (SNN MultiVac XL) – Smith & Nephew Quantum 2 Resection System
- 3.75 mm Smith & Nephew Ambient Super MultiVac 50 (SNN MultiVac) – Smith & Nephew Quantum 2 Resection System

The competitor probes were selected based on similarities in probe style, use, environment and market share.

During the testing of idle speed, mass ablation rate and clogging, probe operation was controlled by an automated test fixture. In each test, the respective power supply console was set to the maximum power level. Probes ablated simulated tissue in order to repeatably evaluate test criteria. Idle speed testing was conducted by steadily increasing the speed of the probe while ablating through tissue, until a speed was reached at which the probe could no longer efficiently ablate tissue. Mass ablation rate testing was conducted by measuring the mass removed by ablation over a set period of time. Clog testing was performed by ablating tissue in a repeatable pattern and speed, while tracking the amount of tissue ablated before clogging occurred.[2]

During the testing of shaft strength and stiffness, probes were loaded into a load application fixture. Max compressive load,[c] the compressive load at yield (when the probe starts to bend/kink permanently) and the slope were calculated. The slope is reflective of the material stiffness.[d] Given that the strength metrics are directly proportional to cross-sectional area of the probe, the shaft strength and stiffness were normalized for each competitive probe.

Results

Stryker's 50-S SWEEP XL probe outperformed all competitors tested with respect to idle speed, mass ablation rates, shaft strength, stiffness, and resistance to clogging.

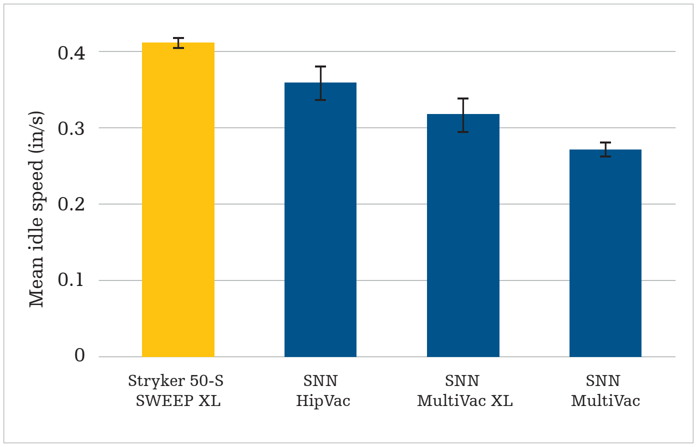

Figure 1

Comparative summary of idle speed data.[1] With respect to idle speed performance, Stryker's 50-S SWEEP XL outperforms the SNN HipVac, SNN MultiVac XL and SNN MultiVac by 14%, 30% and 51%, respectively. Error bars are the standard error of the mean, significance level of 0.05.

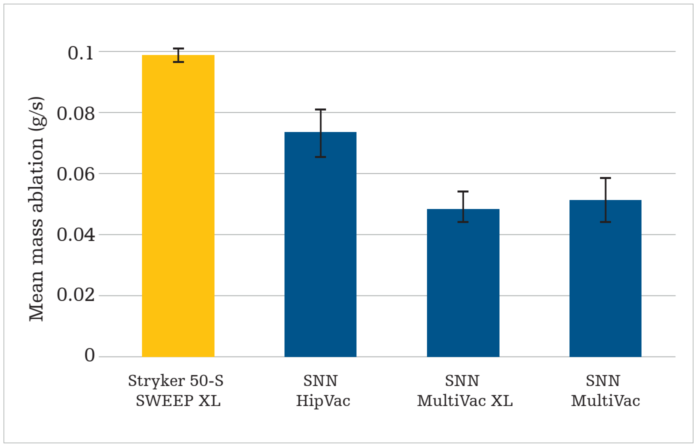

Figure 2

Comparative summary of mass ablation data.[1] With respect to mass ablation performance, Stryker's 50-S SWEEP XL outperforms the SNN HipVac, SNN MultiVac XL and SNN MultiVac by 34%, 102% and 90%, respectively. Error bars are the standard error of the mean, significance level of 0.05.

Results (continued)

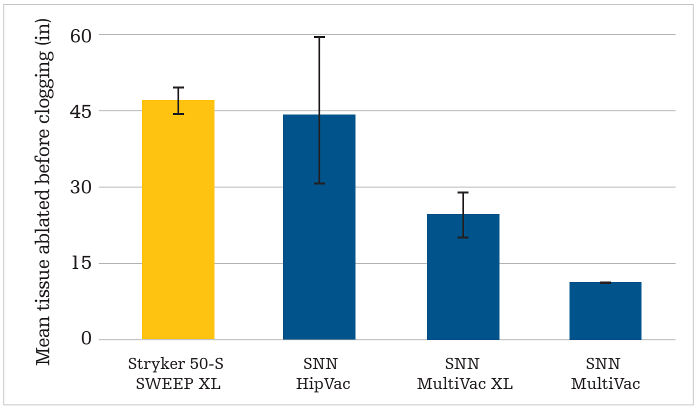

Figure 3

Comparative summary of clogging data.[1] With respect to clogging performance (tissue ablated before clogging), Stryker's 50-S SWEEP XL outperforms the SNN HipVac, SNN MultiVac XL and SNN MultiVac by 6%, 89% and 303%, respectively. Error bars are the standard error of the mean, significance level of 0.05.

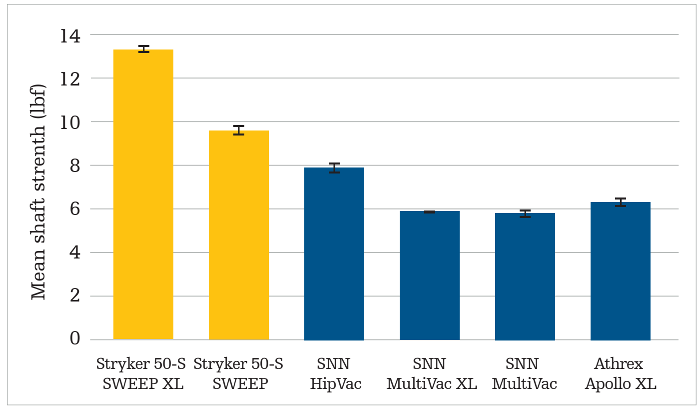

Figure 4

Comparative summary of normalized shaft strength data.[1,4] With respect to probe shaft strength, Stryker's 50-S SWEEP XL outperforms the SNN HipVac, SNN MultiVac XL, SNN MultiVac and Arthrex Apollo XL by 68%, 122%, 126% and 109%, respectively. With respect to probe shaft strength, Stryker's 50-S SWEEP outperforms the SNN HipVac, SNN MultiVac XL, SNN MultiVac and Arthrex Apollo XL by 22%, 61%, 64% and 51%, respectively. Error bars are the standard error of the mean, significance level of 0.05.

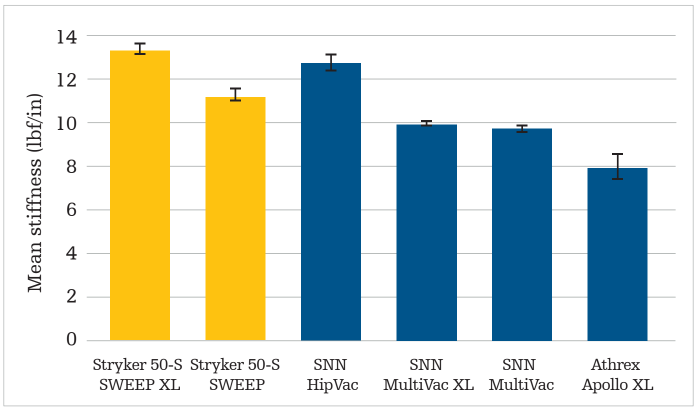

Figure 5

Comparative summary of normalized stiffness data.[1,4] With respect to probe stiffness, Stryker's 50-S SWEEP XL outperforms the SNN HipVac, SNN MultiVac XL, SNN MultiVac and Arthrex Apollo XL by 8%, 38%, 40% and 73%, respectively. With respect to probe shaft strength, Stryker's 50-S SWEEP outperforms the SNN MultiVac XL, SNN MultiVac and Arthrex Apollo XL by 12%, 14% and 41%, respectively; Stryker's 50-S SWEEP is outperformed by the SNN HipVac by 14%. Error bars are the standard error of the mean, significance level of 0.05.

Clinical relevance

Idle speed and mass ablation rate are performance characteristics that determine the maximum speed and maximum tissue ablation rate of RF probes without generating bubbles or failing to form plasma.[1] Bubbles could potentially cloud the field of view during surgical procedures and ablation of tissue without plasma is an indicator that the tissue is not fully ablated and could cause a potential clog of the probe. Stryker's 50-S SWEEP XL produced equal or higher mass ablation rates and idle speed, and exhibited a greater resistance to clogging than the four competitive RF energy systems tested, meaning that tissue resection can be achieved more quickly, making the most efficient use of surgical time.

Shaft strength is a measure of the maximum force that the probe shaft is able to withstand.[c] Although the SNN HipVac outperformed Stryker's 50-S SWEEP XL by 7%, the 50-S SWEEP XL is a 3.5 mm probe while the SNN HipVac is a 4.7 mm probe. Thus, the mechanical strength of the larger shaft would be expected to be much greater. Still, while the SNN HipVac has a shaft cross-sectional area that is 80% greater than Stryker's 50-S SWEEP XL, the shaft strength of the SNN HipVac is only 7% greater than the 50-S SWEEP XL. Normalized data reveals that Stryker's 50-S SWEEP outperforms all competitive probes with respect to shaft strength and stiffness. Additionally, with the smaller diameter, surgeons are able to ablate tissue in tighter spaces.

References:

[1] Data on file, Stryker DHFD14167 2018 Rev A, Marketing Collateral Testing Overview

[2] Data on file, Stryker TR18517 2018 Rev A, Idle Speed, Mass Ablation, & Clogging Test Report

[3] Data on file, Stryker TR18080 2018 Rev A, Shaft Strength Test Report

[a] Idle speed – the maximum linear speed at which the probe can effectively ablate tissue without generating bubbles or failing to form plasma[2]

[b] Mass ablation rate – a metric used to measure the rate of tissue ablation when the probe is moved at 50% of the calculated idle speed for that specific probe style[2]

[c] Shaft strength – the maximum force that the shaft is able to withstand[3]

[d] Stiffness – the rate that the probe bends with respect to the force applied to the distal end of the probe[3]

[e] Clogging time – the time a probe is continuously run through tissue media before the suction path is blocked and bubbles are consistently formed[2]

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