Abrasion Resistance of the Arthrex Apollo^{RF®} H50 and Smith & Nephew HipVac[®] 50 Ablation Probes

Arthrex Research and Development

Purpose

During arthroscopic hip procedures, RF probes are commonly inserted through an open cannula to access the hip joint. The insulation on RF probes must be resistant to abrasion and wear in order to sustain contact with the cannula and particularly the cannula tip during use. A search of the US FDA MAUDE database shows that insulation wear can cause particulate and surgical delay due to inoperable probes.¹ The purpose of this testing was to compare the abrasion resistance of the insulation on the Arthrex Apollo^{RF} H50 and Smith & Nephew HipVac 50 ablation probes.

Methods and Materials

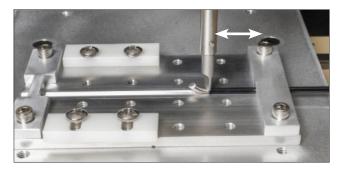
A reciprocating abrasion testing machine (TABER[®] Reciprocating Abraser, Model 5900) was used to determine the maximum cycles before insulation breach for each hip probe. The probe test sample was secured to the specimen table such that approximately 1-inch of insulation was exposed as shown in Figure 1.

Figure 1. Test setup.



To simulate aggressive use, a weight was added to the test machine weight holder so the 20° angled stylus applied a 7 N load at the point of contact on the probe. The stylus on the counterbalanced arm of the abrasion testing machine was in contact with the probe throughout the test with the initial position shown in Figure 2, where the specimen table was advanced to the right.

Figure 2. Stylus and probe test setup.



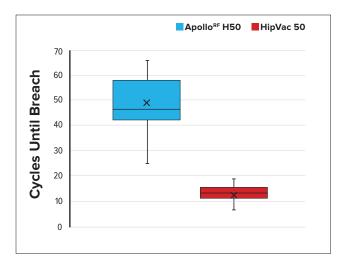
As illustrated in Figure 2, the test machine specimen platform moved in a 1-inch reciprocating motion along the long axis of the probe while under the stationary tool holder at a speed of 20 cycles per minute until there was a breach in the insulation of the test sample. The number of cycles until breach was recorded.

Fifteen test samples of the Arthrex Apollo^{RF} H50 probes and 15 test samples of the Smith & Nephew HipVac 50 ablation probes were tested.

Results

The number of cycles before insulation breach was (48 \pm 11) for the Arthrex Apollo^{RF} H50 test samples and 13 \pm 3 for the Smith & Nephew HipVac 50 test samples. Figure 3 graphically displays the distribution of data and Figure 4 shows the samples before and after the abrasion cycles.





Data were normally distributed and a 2-sample *t* test was conducted to compare the results. The cycles before breach of the Arthrex Apollo^{RF®} H50 device was statistically greater than that of the Smith & Nephew HipVac[®] 50 (48 ± 11 vs 13 ± 3 cycles, respectively) at the 0.01 level of significance.

Figure 4. Test samples before and after insulation breach.



Conclusions

While minor insulation wear is visible, the results of this test show that none of the samples with insulation wear caused a loss of function to the Arthrex Apollo H50 probes. Arthrex RF probes are designed to have sufficient abrasion resistance to withstand contact with the cannula during hip arthroscopy procedures. The results of this testing show that the Arthrex Apollo^{RF} H50 probe can withstand a statistically significantly greater number of cycles than the Smith & Nephew HipVac 50 ablation probe.

References

1. FDA's Medical Device Adverse Events (MAUDE) search. https:// www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search. cfm from June 2015 through July 2017 for brand names: AMBIENT HIPVAC 50 IFS, TURBOVAC 90 XL ICW, MULTIVAC 50 XL, SUPER MULTIVAC 50 IFS, COOLPULSE 90 ELECTRODE, VAPR ARCTIC SUCTION ELECTRODE, VAPR ARCTIC SUCTION ELECTRODE, VAPR ARCTIC SUCTION ELECTRODE, 50-S XL, 50-S, 90-S XL, and APOLLO RF 90.

