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LEGACY ADVANTEC™ AND SOVEREIGN WHITESTAR™: A WOUND TEMPERATURE STUDY

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ABSTRACT

Purpose: To assess the wound temperature of the Sovereign WhiteStar™ and Legacy® Advantec™ phacoemulsification systems.

Setting/Venue: The John A. Moran Eye Center, Health Sciences Center, University of Utah.

Methods: Fresh cadaver eyes were obtained. 20-gauge, 30° straight tips were used with both the Legacy Advantec (L-ADV) and Sovereign WhiteStar™ (S-WS) phacoemulsification systems. Power was set at 50%, aspiration was 12 ml/min, L-ADV was run at 15 Pulses Per Second (pps), S-WS at WS CF (6 msec on, 12 msec off). Temperature was measured at 5-sec intervals for 60 seconds using a microthermistor placed in the wound. The phaco tip was angled 30° to increase wound tissue contact. At 10 seconds, flow was clamped to simulate occlusion. Five runs were averaged for the phaco tip, sleeved and unsleeved.

Results: The mean temperature was significantly higher for L-ADV compared to S-WS (from 10 seconds on in the sleeved condition and from 5 seconds on in the unsleeved condition after clamping the aspiration line). In 2 of 5 sleeved runs and 4 of 5 unsleeved runs, the L-ADV handpiece decreased power as the temperature increased. One run in the L-ADV with sleeve showed signs of wound burn. There were no signs of wound burn with the S-WS. The highest temperature recorded was 57.5°c for L-ADV and 38.6°c for S-WS. Power tests showed L-ADV protects the stroke length and S-WS has constant power except in air where it increases power.

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Conclusion: There was less increase in wound temperature over time with the S-WS compared to the L-ADV system for both sleeved and unsleeved simulated surgery in human eye-bank eyes. Because the ultrasound handpieces respond quite differently under different load scenarios, meaningful comparisons of pulsing features are difficult to create.

Synopsis: Ultrapulse ultrasound was cooler with the Sovereign unit than pulsed ultrasound with Legacy Advantec software. Comparisons are difficult to interpret due to proprietary differences in machine hardware and software.

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INTRODUCTION

We recently showed that incision burns are possible with microphaco (irrigation is separated from aspiration in phacoemulsification) using continuous and pulsed ultrasound at high power[1]. Under similar conditions, incision burn could be produced using micropulse technology (Sovereign® WhiteStar™, Advanced Medical Optics, Santa Ana, CA), only if flow and aspiration were occluded[2]. In the two eyes tested with micropulse phaco, the incision temperature did not exceed 32.4^{o}c after 3 minutes of ultrasound energy at 100% power with the aspiration line clamped. This suggests a decreased risk of incision burn with micropulse technology.

Thermistor monitoring of the incision temperature during microphaco using Sovereign WhiteStar™ micropulse technology in a series of patients using the “divide and conquer” approach also showed no incision temperature elevation above body temperature during ultrasound lens removal[3]. Our conclusion from these studies is that micropulse technology can decrease the risk of incision burn during lens removal.

At the Royal Hawaiian Eye Meeting 2003, Dr. Richard Mackool presented thermography data showing that at 30% and 50% power for 1 minute, Legacy® Advantec™ (Alcon, Inc., Ft. Worth, TX) at 15 pps in air, and in human eye- bank eyes, with fluid flow of 1 ml/minute was cooler than WhiteStar™ at the CF duty cycle (6 msec on, 12 msec off). This study is a comparison of the two technologies in human eye-bank eyes.

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MATERIAL AND METHODS

A fresh, unfrozen, human eye pair was obtained (45-years-old at death and only 18 hours from time of death to utilization) for our sleeved ultrasound study to specifically minimize the abnormal incision leakage often associated with frozen human eye bank tissue. For the unsleeved experiments done at the same time we utilized two human eyes frozen for less than 1 week and with less than 24 hours from time of death to enucleation.

Legacy with Advantec (L-ADV) and Sovereign with White Star (S-WS) were the phacoemulsification systems used. They were both set at 50% power and used a 20-gauge straight phaco needle with a 30^{o} angulated tip and no by-pass hole. L-ADV was set at 15 pps and S-WS at duty cycle CF (6 msec on, 12 msec off). Bottle height was at 90 cm above the eye measured to the top of the water level in the bottle for sleeved studies and 120 cm high for the unsleeved studies.

Sleeved Studies

A 2.8-mm Storz steel keratome was used to make a straight in-and-out incision starting at the limbus. A mark was made at the limbus and then 2-mm inside the limbus such that the entry was at the first mark and the exit into the anterior chamber was at the second mark, making the incision approximately 2-mm long. The same blade for the same set of eyes was used throughout the study. A small protractor placed tangential to the wound was used to note a point at the opposite limbus 30^{o} to the right of the incision. This was marked with a methylene blue pen. The BAT 10 microthermistor tip (Physitemp, Clifton, New Jersey) was placed through the

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incision into the anterior chamber. After tuning the ultrasound handpiece, the tip with sleeve was also placed through the incision and the microthermistor tip brought back until it was midway into the wound. This was undertaken with the irrigation on to help facilitate this maneuver. The phaco tip was angled so the center of the tip pointed at the limbal marking 30^{o} to the right to increase frictional heat[4]. The microthermistor probe was at the far right side of the incision directly against the sleeve. In this fresh tissue the sleeve easily held the microthermistor probe in place throughout the experiment.

Irrigation and aspiration were used until the temperature was stable. An independent observer noted the temperature and timed the experiment. With the phacoemulsification system foot pedal fully depressed, the temperature was recorded every 5 seconds for 1 minute, while the operator monitored the procedure through an operating microscope. At 10 seconds the aspiration line was clamped to represent blockage during lens removal. Some leakage was always noted around the sleeve.

At the end of each 1 minute run, a double-bite 10-0 nylon suture was placed in the wound to make sure that it was water tight and then a new incision was made in the eye. The same procedure was carried out, alternating phacoemulsification systems for each run. 7 runs were performed with each system. The high and low runs were thrown out.

Non-Sleeved Temperature Studies

The same parameters were used for sleeveless phaco. Incisions were made with a 20-gauge steel blade (Microsurgical Technology, Redmond, WA). Due to the small size of the incision, trying to gauge the length of the wounds was difficult. We therefore simply went straight in parallel to the iris plane. Due to the more edematous nature of these corneas, it was difficult to determine exactly how long the wounds were. However, the process itself was consistent. The same 30^{o} mark to the right was made in the same fashion and a second incision was made for the irrigator. We did not make an additional incision for the irrigator for each run; we simply made new incisions for the phaco tip throughout this procedure.

The Microsurgical Technology 20-gauge Duet irrigator was placed in the irrigation wound. We had found that the microthermistor was usually damaged when it contacted the phaco tip. We made a small, superficial incision to the right of the phaco wound, approximately 200 microns in size and only halfway into the cornea. The microthermistor wire was placed in this small slit and was held in the tissue approximately one-wire width away (about 100 microns) from the ultrasound needle as observed at the highest magnification of our operating microscope. The experiments were then carried out in a fashion analogous to the sleeved experiments. When clamped, leakage was always noted around the ultrasound needle. Only a single-bite 10-0 nylon suture was used to close these small incisions.

To determine how fluid flow affected the operation of the two systems, an independent technical service (Intertek Testing Services) determined the energy utilization for both instruments using 15 pps for the L-ADV and CF for S-WS over the entire power range for operation in fluid, in air, and in air at 1 ml/min of flow (Figure 1).

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With each machine set at 12 ml/min the aspiration flow was measured for 3 minutes for 10 runs each. Bottle height was adjusted to 90 cm for each run.

Statistical comparison was by Student T-Test. Statistical significance was defined as $P<0.05$.

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RESULTS

There was a statistically significant difference in wound temperature between the L-ADV and S-WS systems for sleeved phaco after ten seconds and for unsleeved phaco after five seconds from the time of clamping the aspiration line (Figures 2 & 3). In all runs, L-ADV ran at a higher temperature than the S-WS after clamping the aspiration line. A clinical wound burn was noted in one L-ADV run of sleeved phaco. There were no wound burns with the S-WS. As each run progressed, particularly with sleeveless phaco (microphaco), the L-ADV system would often substantially decrease ultrasound power. In some instances, ultrasound output ceased. As soon as we noted the decrease or loss of ultrasound power, we stopped the run. This affected the power of our analysis in that we did not have many data points toward the end of our L-ADV experimental runs. This did not happen for the S-WS system.

Energy utilization experiments showed clear differences when the machines functioned in air (no or 1 ml/min flow) or a fluid environment (12 ml/minute fluid flow). L-ADV sharply decreased energy utilization particularly in air but also with 1 ml/minute flow while S-WS substantially increased energy utilization with the highest energy utilization at 50% power while in air and at 1 ml/minute flow in air (Figure 1). The L-ADV had significantly more fluid flow than S-WS. (For 3 minutes S-WS 35:4±0.25 ml; L-ADV 38.9±0.24 ml; P<.0001). S-WS was closer to the stated 12 ml/min flow (11.8 vs. 13.0 ml/min).

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DISCUSSION

The laws of thermodynamics are absolute, therefore, all believable results must exist within their framework. If all other parameters are equivalent then equal stroke length must result in equal frictional heat generation, which is the culprit in wound burn. Frequency differences can be counterbalanced by changes in stroke length to again produce equivalence. If all of these factors have then been brought to equivalence a shorter duty cycle (percent of time on) will always produce less frictional heat than a longer duty cycle over time. Any results contrary to this suggest some other factors must have come into play.

While we have not determined all of the differences, a very important one is how these two machines behave under load. The L-ADV handpiece protects its stroke length so it idles in air and will work increasingly harder with increasing load. The S-WS handpiece protects its power output except our results show it races in air actually increasing the power and stroke length and under increasing load will have an increasingly shorter stroke length with comparatively less frictional heat generation. So incisional temperature comparisons without a load (ie: in air) will dramatically favor L-ADV, while with increasing load S-WS will come out ahead. These differences are inherent in the machines and have nothing to do with ultrapulse or 15 pps Advantec software.

There are other important potential issues. Fluid flow is very effective in removing frictional heat generation. Parameters, as listed machine to machine and even cassette to cassette, are bound to vary as they did in our case. Although set at 12 ml/min, L-ADV pulled an average of

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13.0 ml/min of aspiration (statistically more than S-WS) which would lower the L-ADV temperature, all else being equal. This must be considered in any incisional temperature study. Incision leakage is another way of changing fluid flow. Reproducible incision creation is therefore very important. A further example is an ultrasound needle by-pass port that effectively creates a leak under occlusion and will thereby indirectly cool the incision.

Our two Legacy machines, when occluded, would often drop power or cease operation after 15-30 seconds in an admittedly torture situation. This is a laudable safety feature to protect against incision burns, however, when it comes in to play, any feature comparison is further rendered meaningless because such events were not noted with the S-WS unit.

To further complicate the picture there are no industry standards so power at any setting does not necessarily have any equivalence between machines from different manufacturers. Furthermore, there are probably other factors we have not considered which makes any comparison problematic

So with this information as a background we can conclude:

1. Under the increased frictional load (friction directly increases ultrasound tip work) of our experiments (tight wound and angled tip) a stroke length protected instrument (L-ADV) will always generate more frictional heat than a power protected instrument (S-WS) if stroke length is about equal in an unloaded fluid environment.

2. Air as a medium is both clinically irrelevant and distinctly favors the L-ADV handpiece irrespective of any other handpiece feature.

3. All else being equal, frictional heat from a pulse will be the same no matter who the instrument maker might be.

4. Although our results showed a clear thermal advantage for S-WS, no meaningful direct thermal comparison of White Star™ and Advantec™ features can be made from our study. Furthermore, a study to compare the two features would be exceedingly difficult for all of the reasons discussed.

The only way to accurately understand the features of ultrapulse technology are to eliminate all of these uncontrollable variables and compare these features with the same machine. This is only possible with S-WS (or Alcon Infiniti with its ultrapulse feature) as L-ADV does not have this feature. In a small experiment (2 runs per setting) we found S-WS (6 ms on and 12 ms off) produced much less incisional frictional heat than pulse mode (50 ms on and 50 ms off), all using the same instrument[1,2]. Why this may be so is not entirely clear. It is possible that frictional heat retention and elimination is not a linear function in corneal tissue in such a way that it aids ultrapulse in heat dissipation.

What is certain is that neither this study nor our previous studies can answer these questions. We can only conclude that with equal stroke length at low load in fluid, that increasing load will favor S-WS over L-ADV in prevention of wound burn due to the energy algorithm differences of

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the two machines. A direct comparison of 15 pps Advantec and ultrapulse (6 ms on and 12 ms off) features is not possible from this study, and it will be difficult to isolate for direct feature comparisons their impact on incisional, frictional temperature.

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FIGURE LEGEND

Figure 1. Comparison of handpiece power at different system power settings and different flow levels for the L-ADV and S-WS systems. Dotted lines indicate the L-ADV system, solid lines the S-WS system. Note that as the load decreases, handpiece power decreases with the L-ADV system and increases with the S-WS system.

Figure 2. Mean temperature scores for Legacy Advantec and Sovereign with WhiteStar™ (sleeved experiments). Power was 50%, flow 12 m./min, and the phaco tip angled at 30° to mimic a possible wound burn situation for all runs. Aspiration line was clamped to stimulate occlusion at 10 seconds. Legacy Advantec was set for 15 pps, Sovereign WhiteStar™ for duty cycle CF, 6 msec on:12 msec off. * indicates significant difference between the two groups at $P \leq 0.05$. † indicates signs of wound burn. Dotted line indicates times at which the Legacy Advantec handpiece detuned during the run, and was excluded from the analysis.

Figure 3. Mean temperature scores for Legacy Advantec and Sovereign with WhiteStar™ (unsleeved, bimanual experiments). Power was 50%, flow 12 m./min, and the phaco tip angled at 30° to mimic a possible wound burn situation for all runs. Aspiration line was clamped to stimulate occlusion at 10 seconds. Legacy Advantec was set for 15 pps, Sovereign WhiteStar™ for duty cycle CF, 6 msec on:12 msec off. * indicates significant difference between the two groups at $P<0.05$. Dotted line indicates times at which the Legacy Advantec handpiece detuned during the run, and was excluded from the analysis.

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FIGURES

Figure 1.

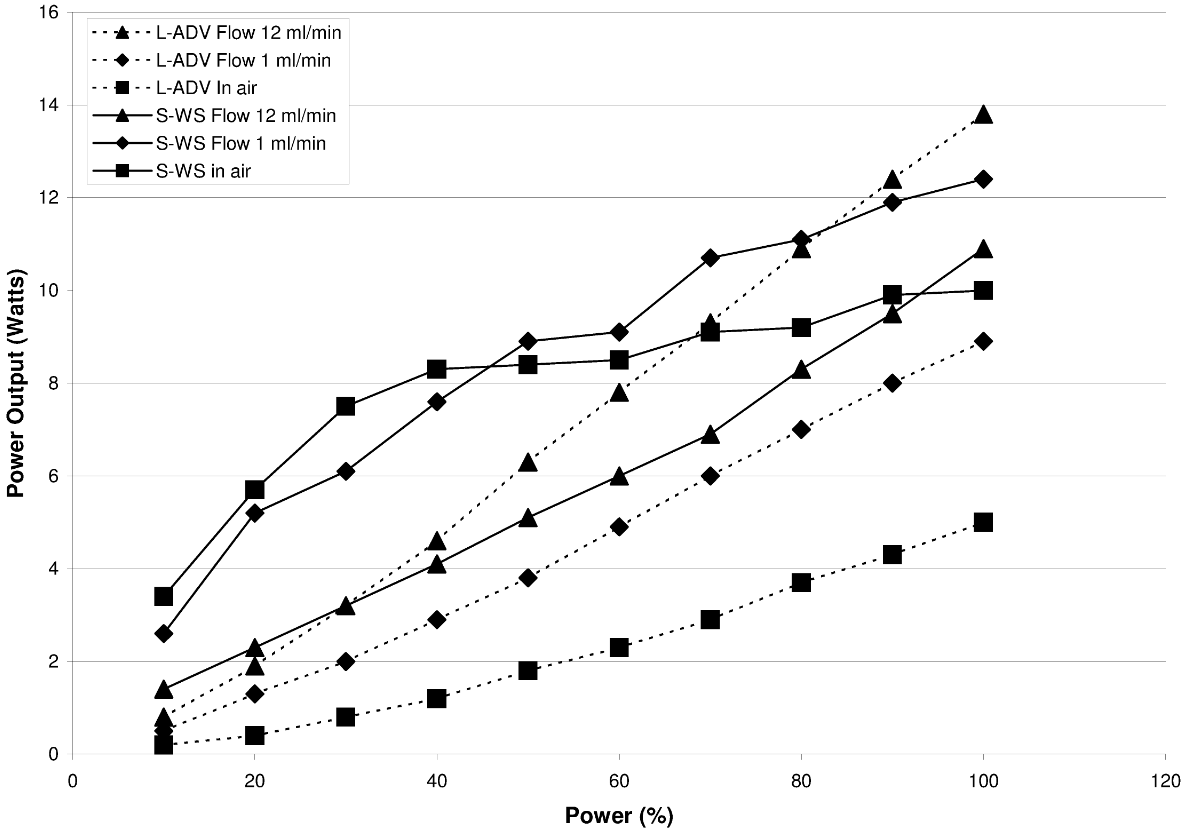

Figure 2.

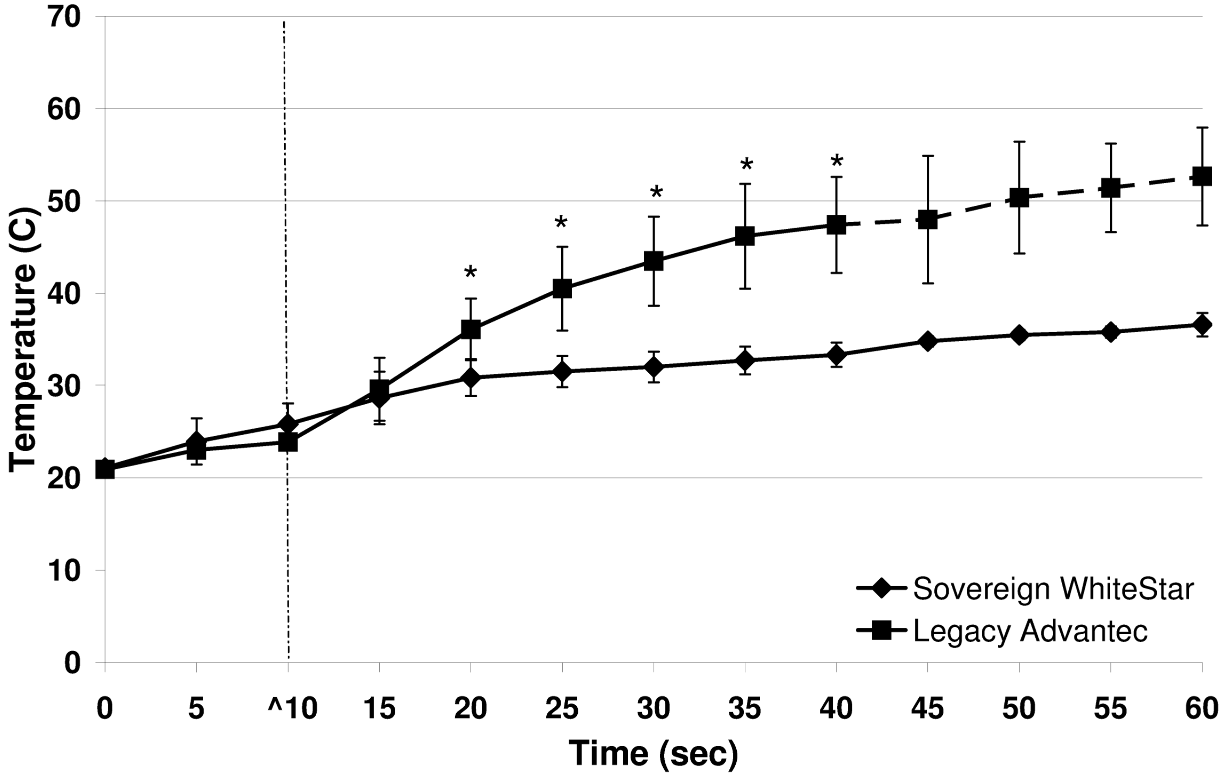

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Figure 3.