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Corresponding Author: Dr. Randall Olson, MD

Corresponding Author's Institution: University of Utah Health Sciences Center

First Author: Jason P. Brinton, BA

Order of Authors: Jason P. Brinton, BA; Wesley Adams, MD; Rajiv Kumar, MD; Randall Olson, MD

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Abstract: ABSTRACT

Purpose: To determine the thermal characteristics of the Legacy Advantec (LEG) and Sovereign (SOV) WhiteStar™ (WS) phacoemulsification machines during different clinically relevant scenarios.

Setting: In Vitro Study

Methods: In water, temperature was continuously recorded on the sleeve in an artificial chamber, and the increase in temperature over baseline after 60 seconds of ultrasound was determined. This was done for continuous ultrasound (CONT), 50-ms on and 50-ms off (PULSE), 6-ms on and 12-ms off (WS; SOV only) with aspiration blocked and not blocked, and with 100-gm and 200-gm weights suspended from the sleeve.

Results: Comparing temperature increase per 20% machine power increments, SOV ran hotter than LEG for CONT (2.31 X) and PULSE (2.23 X). Blocking aspiration increased temperature over the unblocked state. Pulsing decreased temperature 51% (LEG, PULSE), 52% (SOV, PULSE) and 64% (WS). Weights had much more effect on LEG: 3.5X more going from baseline to 100-gm weights and 3.2X more going from 100 to 200-gm weights. For all these comparisons, "P" is less than 0.0001.

Conclusion: The machines behave fundamentally differently with LEG controlling stroke length and SOV controlling a fixed power at any setting. Therefore, workload has a much bigger impact on LEG thermal characteristics. Pulsing will decrease heat produced directly related to the duty cycle. The most dangerous incision burn scenario is with continuous ultrasound, aspiration blocked and a heavy workload.

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Randall J Olson, M.D.
John A. Moran Presidential Professor
and Chair of Ophthalmology
Director, John A. Moran Eye Center
50 North Medical Drive
Salt Lake City, Utah 84132
Phone: (801) 585-6622
Fax: (801) 581-3357
Email: randall.olson@hsc.utah.edu

March 24, 2005

Douglas Koch, MD
Editor
Journal of Cataract & Refractive Surgery
4000 Legato Rd, #850
Fairfax, VA 22033

Re: Two Original Articles: 1) A Survey of Incision Thermal Contraction in Phacoemulsification: Incidence and Causal Relationships and 2) A Comparison of Thermal Features Associated with Two Phacoemulsification Machines.

Dear Doug:

I know this is an unusual request; however, the two papers having to do with the thermal aspects of phaco machines, as well as the wound burn study, I feel go together. As Section Editor, I felt that I should submit it to AJO, who accepted the wound burn study but not the phacodynamics study, and I feel that the two really deserved to be paired. The phaco dynamics study represents close to 1,500 hours of work and is the only definitive work on this subject. Please compare it with the very brief study that I published (Journal Cataract Refract Surg 2004;30:1109) and the one that Kevin Miller has in press with you to see that this is twenty times the work and the definitive answer.

Needless to say, I don't want to lose a potential acceptance so I am asking if you could consider a relatively rapid review and I would love to see these published together. If this is the case, then I will notify AJO and not submit the revision as requested.

I do appreciate your consideration.

Sincerely,

Randall J Olson, M.D.
John A. Moran Presidential Professor
and Chair of Ophthalmology
Director, John A. Moran Eye Center

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A Comparison of Thermal Features Associated with Two Phacoemulsification Machines

Jason P. Brinton, B.A.

Wesley Adams, M.D.

Rajiv Kumar, M.D.

Randall J Olson, M.D.

Department of Ophthalmology and Visual Sciences

University of Utah Health Sciences Center

Salt Lake City, Utah USA

Corresponding Author:

Randall J Olson, M.D.

Department of Ophthalmology and Visual Sciences

University of Utah, John A. Moran Eye Center

50 North Medical Drive, Salt Lake City, Utah 84132

Phone (801) 585-6622, Fax (801) 581-3357, E-mail: randall.olson@hsc.utah.edu

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INTRODUCTION

Phacoemulsification is the most commonly performed surgical procedure in the United States, and complications resulting from the frictional heat generated (incision burn) during phacoemulsification have been well documented[1,2]. A series of wound temperature studies has implicated position of the needle[3], low-flow conditions[4,5,6,7,8,9], and use of full-power, non-pulse settings[8,9]. Until now it has been unclear to what degree machine settings and operating conditions contribute to the elevation of temperature at the phaco tip. By performing simulated phaco procedures in a highly-controlled environment, we have been able to quantify the contribution of each variable.

MATERIAL AND METHODS

Setting: The LEG phacoemulsification unit (Alcon, Ft. Worth, TX) was used in conjunction with a standard, 30° round 0.9-mm needle and 375/40 U/S TurboSonic hand-piece. The SOV phacoemulsification unit (AMO, Santa Ana, CA) was also tested with a round, 0.9-mm needle and their standard hand-piece. Each hand-piece was fitted with the sleeve provided by the manufacturer. The Alcon test chamber was used for both devices to control for any difference in heat sink attributable to chamber size. Test runs were done with the test chamber placed over the needle and sleeve such that the flat, open edge of the test chamber was flush with the flat, large end of the phaco sleeve, as shown in Figure 1.

Phaco hand-pieces were placed in a horizontal position on a table. Measuring tapes were fastened to each bottle so that “bottle height,” or the vertical distance from the level of the balanced salt solution (BSS) in each bottle to the level of the phaco needle, could be measured. After each run, the bottle height was readjusted to 70-cm.

Temperature was continuously measured using a subminiature microthermister sensor (T164A Thermocouple; Physitemp Instruments, Inc; 154 Huron Avenue, Clifton, NJ 08013), which was connected by a Type T Copper-Constantan mini-connector wire to a high-accuracy isothermal block (Physitemp Instruments, Inc.) with an accuracy of ±0.1°C. The microthermister wire was glued to the phaco sleeve such that the end of the thermo coupled sensor was positioned at a distance of 1.0-mm from the middle of the sleeve irrigation ports, as measured along the long axis of the needle and sleeve. The standard irrigation/aspiration and tuning cycles were run on each machine at the beginning of the day. Holding the foot pedal in “position 2,” normal saline

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was flushed through the test system (comprised of the needle, sleeve, and test chamber) until temperature leveled out at a constant 23.0 C ± 0.4 C for long enough to be assured that any residual heat had been dissipated from the handle (usually 20-30 seconds). Small variations in temperature (up to ± 0.2 C) were permitted at this point only if fluctuations were bidirectional (i.e. not trending in any particular direction). When a trend was observed, the temperature usually trended up due to residual heat in the hand-piece metal. Appreciable heat buildup in both hand-pieces (particularly in the Alcon hand-piece) required up to 30 to 45 minutes of cooling in air to maintain a constant baseline temperature. When aspiration-block runs increased the temperature to over 50 C, an hour or more was often required for the hand-piece to equilibrate with the room temperature of 23.0 C ± 0.4 C. Flushing fluid through the hand-piece at any point before the hand-piece was fully cooled resulted in a steady increase in temperature at the phaco tip. Flushing/aspirating saline through the chamber also served to eliminate bubbles that occasionally entered the chamber through the irrigation line.

Temperature data were recorded at the start of each run, and every 10 seconds thereafter until the end of the run. The phaco pedal was fully depressed (foot position 3) throughout the duration of each run, which lasted 60 seconds. Parameters tested were:

1) CONT and PULSE, unoccluded- and occluded (hemostat was used to clamp the aspiration line at a distance of about 1-cm from its attachment to the phaco hand-piece).

2) SOV for 6-ms on; 12-ms off (WS) both unoccluded and occluded.

3) CONT (unoccluded) with 100 and 200-gm weights suspended from the sleeve at the same position to create friction on the tip (2.0 Prolene used), as shown in Figure 2.

4) CONT (60% power setting); flow was increased from 12-ml/min to 30-ml/min in 2-ml/min steps for LEG and SOV.

The machines were set to maximum aspiration of 20-ml/min, vacuum limit of 100-mm Hg, and the appropriate phaco mode. Five runs were completed on each machine for 20%, 40%, 60%, 80%, and 100% power settings for each parameter noted, except for the flow experiment which was kept at 60%.

The beginning temperature was subtracted from the temperature at 60 seconds to determine the increase in temperature. Temperature increases were plotted and found to be linear in all experiments, except the flow experiment. Every other run was reduced to temperature increase (in degrees centigrade) over baseline at 60 seconds per 20% power setting. This means that 40% power results were divided by 2, 60% runs by 3, etc.

5) The phacoemulsification foot pedal was held in "position 2" so that irrigation and aspiration proceeded without ultrasound. At 12-ml/min (100-mm HG vacuum limit) the machines were run at 0% power for 3 minutes. At 20-ml/min (100-mm Hg vacuum limit), the machines were run at 0% power for 2 minutes. Flow was measured by diverting outflow from the bag into a graduated cylinder (± 0.5-ml) and recorded after each run. The 12-ml/min and the 20-ml/min flow runs were repeated 10 times on each machine.

In the final experiment, the hand-pieces were autoclaved for 3 minutes and air-cooled for 60 seconds, following which temperature at the phaco tip was recorded for 240 seconds (at 15

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second intervals) from the time irrigation fluid began to flow through the tip. Flow was set at 26-ml/min; vacuum limit at 100-mm Hg.

All linear results were compared by independent sample T-tests as were the non-ultrasound flow results. Statistical significance was set at p=0.05.

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RESULTS

For all comparisons, the "P" values were less than 0.0001 except where noted. This isn't a surprising finding for a physics experiment. In a water workload SOV was 2.31 times hotter than LEG for CONT and 2.23 times hotter for PULSE (i.e. the dynamic range was about 2.3 times more for SOV). The decrease of temperature buildup in comparison to CONT for all PULSE and WS was directly correlated to the duty cycle. So at a 50% pulsed duty cycle, LEG was 49.4% of continuous heat build up and SOV was 47.8%. WS at a 33% duty cycle (6-ms on and 12-ms off) had 35.6% of the continuous temperature increase. Blocking aspiration increased the temperature at 60 seconds by 104% (LEG CONT), 208% (LEG PULSE), 64% (SOV CONT), 107% (SOV PULSE) and by 124% (WS).

Weight had a significantly different impact on the temperature increase between the two machines. The 100-gm weight increased the temperature in comparison to the unweighted runs more for LEG (52%) than SOV (15%; p=0.007 in comparison to SOV no weight), which difference was even more dramatic when going from 100-gms to 200-gms (LEG 115% and SOV 23%; Tables 1 and 2).

Increasing flow decreased the sixty-second temperature increase at 60% power for both machines with the difference more dramatic for SOV because the stroke length and power (dynamic range) was 2.3 times more. The results were non-linear with a largely steady state reached by LEG at 18 to 20-ml/min flow, but not reached for SOV at 30-ml/min flow (figure 3).

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Measured flow was greater for LEG in comparison to machine setting than SOV (at 12-ml/min setting; LEG 13.0 +/- 0.24 ml/min vs. SOV 11.8 +/- 0.25 ml/min, and at 20 ml/min setting; LEG 21.5 +/- 0.0 ml/min and SOV 19.5 +/- 0.0 ml/min actual flow; $p<0.0001$ for both). Temperature recorded 3.5 minutes after removal from the autoclave, which includes 2 minutes of priming at 26-ml/min flow, showed a tip temperature of 28 C for SOV and 29 C for LEG. By 120 seconds of further irrigation, both tips were approximately 1 C greater than room temperature.

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DISCUSSION

It is well known that comparisons are difficult to interpret if all variables except for the one being tested are not controlled. It is clear from our experiment these two machines behave completely differently in regard to a load, so comparisons to each other must be carefully considered. Furthermore, flow, although very consistent for each machine, was different with LEG having greater flow at the same machine setting. It is well known and confirmed by our flow experiments that increasing flow will decrease temperature buildup, which would inherently favor LEG in our experiments.

LEG foot pedal controls stroke length (like a cruise control in a car) so at any percent setting the power will increase for increasing workload while SOV maintains a similar power (like a gas pedal) so stroke length will vary depending on the workload (fixed gas pedal means going fast downhill and slow uphill). This means in a minimal workload environment (such as water), SOV has a dynamic range about 2.3 times greater than LEG. If this inherent bias is appropriately controlled, then the results will be exactly the same for both machines as would be expected in any physics experiment. For instance, in a water environment, stroke length equivalence will occur if LEG is set at 50% and SOV at approximately 22% power.

We added weights to model an increasing workload as clearly would occur when encountering cataractous material. The workload would also be increased with a tight wound and when twisting the instrument inside the wound by increasing friction on the tip. It is also clear that the workload can be directly related to the hardness of the materials so the hardest cataracts would produce the heaviest workload. So, with a 100-gm weight, LEG increased temperature 3.5 times

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more than SOV and with a 200-gm weight this difference was five fold. In fact, SOV temperature increase with a 200-gm weight was not statistically different than the corresponding increase with a 100-gm weight because as this workload increased at a fixed power setting, the stroke length decreased. LEG was adding power at a fixed foot pedal position to maintain the stroke length so temperature increase at 200-gm is roughly double the increase at 100-gm (115 vs. 52%).

Pulsing the power brought consistent and expected results when considering the laws of thermodynamics. Duty cycle -- time on versus time off -- was observed to have a direct, correlative impact on temperature increase. Pulse length had no impact. This means that any experimental results inconsistent with the laws of thermodynamics must not be taking control of instrument power (stroke length) into account.

Blocking aspiration always dramatically increased heat generation at the sleeve, which is no surprise. The “blocked” increase in temperature versus the “unblocked” increase at the same power setting was greater for LEG than SOV (24% more for LEG at continuous ultrasound setting and 44% more for LEG at pulse setting). While highly statistically significant ($p<0.0001$), this is probably due to the difference in dynamic range (SOV 2.3 times greater than LEG), and not anything inherently different in the instruments. In other words, LEG was still idling while SOV was working at its power limits. This is consistent with the greater standard deviation observed in SOV experiments when aspiration was blocked. In fact, the correlation with actual temperature increase was absolute (the lower the “unblocked” temperature increase, the higher the “blocked” temperature increase), strongly suggesting that differences had more to do with instrument fatigue in a true torture test (two hand-pieces were destroyed and one aspiration line melted during the aspiration blocked experiments). Furthermore, in a clinical setting, which will virtually always be less of a torture test, this means the increase in temperature when aspiration is blocked should be closer to the LEG PULSE results (tripled the unblocked temperature).

The importance of flow and the dynamic range difference of SOV are clearly illustrated in our flow experiments. As expected, this is a non-linear geometric function, which will reach a relatively steady state after a certain flow rate. So any temperature experiments must control for flow, especially in low flow situations, because minute differences in flow can have a dramatic impact on temperature results. When trying to measure flow with ultrasound on, we found that flow always decreased and was much less consistent than our flow experiments without ultrasound. It certainly should not be surprising that linear flow characteristics would be altered in the presence of an ultrasound-generating tip. This finding deserves further scrutiny because of its potential impact on any temperature experiments.

Autoclave experiments showed that residual heat can increase sleeve temperature, especially if minimal time elapses from when the hand-piece is removed from the autoclave. All clinicians during a hurried turnover have certainly had a hand-piece that was hot to the touch, so this finding is also not surprising. Any additional heat would be additive to ultrasound-related heat increases and could dramatically decrease the safety margin relative to the risk of incision burn.

It is important to consider how all of this is related to the clinical situation. We have confirmed that incision burn is most likely to occur in a no or low-flow situation, especially with a high workload (hard nucleus ± tight wound or torqueing the tip in the wound) while using continuous

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ultrasound energy. Pulsing the energy should decrease this risk commensurate with the duty cycle if the power is held at a constant level. Any loss of efficiency would result in more power used, so this direct relationship may not be seen clinically. Because the temperature difference between a burn and near burn (near burn probably a much more common event) is minimal in worse case scenarios, it would seem that almost instantaneously ramping up the power with LEG without changing foot pedal position in response to removing an impaled nuclear fragment, particularly with aspiration blocked, may increase the overall risk of wound burn versus a gas pedal-type power approach. Certainly, rushing surgery with a hot hand-piece fresh out of the autoclave is an additional and totally avoidable risk for incision burn.

We also conclude that unless flow and instrument stroke length are strictly controlled that machine to machine feature comparisons are fraught with error. Such comparisons, generally, should be made to the same machine or conclusions are lost in the uncontrolled variables.

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FIGURE LEGEND

Figure 1. The microthermister wire is positioned 1-mm from the sleeve opening in exactly the same position for both Legacy and Sovereign with the same test chamber placed flush with the end of the phacoemulsification sleeve.

Figure 2: A weight is hung with 5-0 Prolene suture around the artificial test chamber at the same point throughout producing consistent friction of the sleeve against the phaco tip.

Figure 3: Flow is plotted on the X-axis and increase in temperature after one minute is plotted on the Y-axis. The effect of decreasing temperature with increased flow is obvious as is the much greater power in water of the Sovereign unit.

* Synopsis

SYNOPSIS

Legacy uses much less power than Sovereign in water, but responds to workload with a much greater temperature increase. In pulsing ultrasound, temperature increase is directly related to duty cycle.

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Figure 1
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Figure 2
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Figure 3
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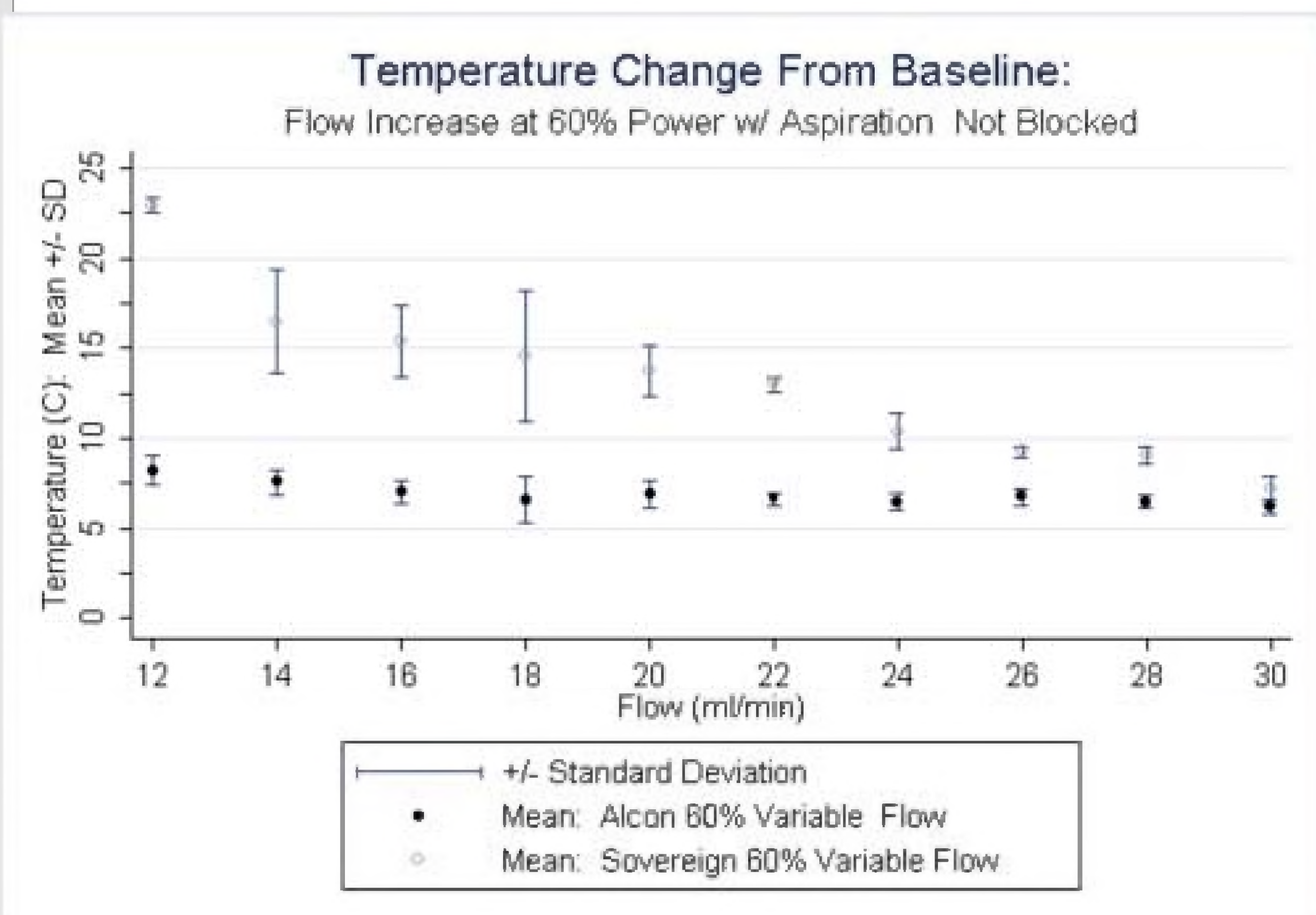

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TABLES

Table 1: Results based on 25 runs per category. Results are at 60 seconds with the increase over baseline (room temperature) recorded. Five runs were done at 20%, 40%, 60%, 80% and 100% power setting, then results determined by dividing the results by 2 at 40%, 3 at 60%, etc. Temperature is recorded on the phaco sleeve.

Category	Aspiration	Machine	C° ± Standard Deviation Temperature Increased at 60 seconds in 20% Power Increments
Continuous ultrasound	Unblocked	Legacy	1.99 ± 0.49
		Sovereign	4.59 ± 0.70
	Blocked	Legacy	4.06 ± 0.55
		Sovereign	7.55 ± 2.42
Power 50-ms on and 50-ms off	Unblocked	Legacy	0.98 ± 0.25
		Sovereign	2.20 ± 0.45
	Blocked	Legacy	3.03 ± 0.45
		Sovereign	4.54 ± 1.76
Power 6-ms on and 12-ms off	Unblocked	Sovereign	1.64 ± 0.19
	Blocked	Sovereign	3.67 ± 0.69
Continuous Ultrasound 100-gm weight suspended from sleeve	Unblocked	Legacy	3.03 ± 0.62
		Sovereign	5.27 ± 0.97

Continuous Ultrasound	Unblocked	Legacy	4.27 ± 0.76
200-gm weight suspended from sleeve		Sovereign	5.65 ± 0.72

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Table 2: Comparative ratios of temperature increases as outlined. All comparison have a p<0.0001 except where noted. (Legacy=LEG, Sovereign=SOV, Pulsed=50-ms on and 50-ms off. WS=6-ms on and 12-ms off.

Category	Ultrasound Setting	Aspiration	Ratios
SOV/LEG	Continuous	Unblocked	2.31
SOV/LEG	Pulsed	Unblocked	2.23
LEG/LEG	Pulsed/Continuous	Unblocked	0.494
SOV/SOV	Pulsed/Continuous	Unblocked	0.478
SOV/SOV	WS/Continuous	Unblocked	0.356
LEG/LEG	Continuous	Blocked/Unblocked	2.04
SOV/SOV	Continuous	Blocked/Unblocked	1.64
LEG/LEG	Pulsed	Blocked/Unblocked	3.08
SOV/SOV	Pulsed	Blocked/Unblocked	2.07
SOV/SOV	WS	Blocked/Unblocked	2.24
LEG/LEG	Continuous	100-gm Weight/No Weight	1.52
SOV/SOV	Continuous	100-gm Weight/No Weight	1.15*
LEG/LEG	Continuous	200-gm Weight/No Weight	2.15
SOV/SOV	Continuous	200-gm Weight/No Weight	1.23

* P=0.007