In-Vitro Thermal Study of Different Tips in Various Operating Modes of the Sina Phacoemulsification System

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1. Introduction

Ultrasonic surgery units operating in the frequency range 20-60 kHz for tissue fragmentation and removal have been available for over 20 years. Such devices are widely used in phacoemulsification (phaco), in the recanalization of coronary arteries and related procedures and in a range of soft tissue procedures, in particular neurosurgery. Cataract consists of opacification of the crystalline lens, causing a decrease in vision. To restore transparency and vision to the eye it is necessary to proceed surgically, removing the lens and restoring the eye's refractive power by inserting an artificial lens. A foldable intraocular lens implant (IOL) is placed into the remaining lens capsule. Phacoemulsification refers to modern cataract surgery in which the eye's internal lens is emulsified with an ultrasonic hand piece, and aspirated from the eye. Three components constitute the heart of all phaco systems: irrigation, aspiration and ultrasound. This surgical procedure requires eye-hand-foot coordination. The ultrasound generating mechanism of the phaco hand piece causes the tip attached to it to vibrate rapidly back and forth. Sharpness of the tip is directly proportional to the tip angle and its selection is dependent on aspirated fluids being replaced with irrigation of balanced salt solution, thus maintaining the anterior chamber, as well as cooling the hand piece.

Phacoemulsification is the preferred technique because of the lower incidence of wound-related complications and quicker healing times than with other surgery methods. So the patient's recovery time is usually faster.

One of the primary challenges is managing the heat generated be the tip at the incision site. With an increase in the use of phacoemulsifiation concern about the potential for thermal wound injuries during surgery has increased, such as burns on the cornea and the sclera. These are due mainly to a rise in heat in the area around the phaco tip. In some cases burns can result in fusion of the cornea or the sclera, wound gape, and damage to the corneal endothelium.

It is important to note that the aim of this chapter is to compare and analyze in vitro the changes of temperature around the different tips for three operating modes of the Sina Phacoemulsification System which is one of the products of an Iranian medical engineering company (Aali-Payam Corporation).
This chapter is based on study in which two different types of thermocouples, digital and thin wires, have been used as instruments for measuring and monitoring the temperature changes around different tips for three operating modes of the system (Constant, Linear and Pulse). The proposed in-vitro approach has been investigated in detail.
Phacoemulsifier tips come in a number of variations; the three common ones are named for the angle of the cutting area. These are the 15 degree, the 30 degree and the 45 degree tips. Some surgeons like to vary the tip depending on the density of the cataract: using a 45 degree tip for a hard cataract and a 30 degree tip for softer cataracts – as these latter are the most popular all of the measurements and comparisons have been done for these two tips.
On the other hand bubbles which form at the tip during surgery by phacoemulsification damage the corneal endothelium. The principal source of them is the degassing of the irrigation solution by ultrasonic agitation.
In part 5 of the chapter, it will be shown that the quantity of bubbles is modulated by the partial pressure of air in the irrigation solution and the intensity of the ultrasonic energy.

2. How a phacoemulsification system works

When the natural lens of eye becomes cloudy, usually because of the aging process, it blocks light rays from passing through or diffuses the light in such a way that vision becomes fuzzy or hazy. This cloudy lens is called a cataract. The object of cataract surgery is to remove this hazy lens and to replace it with a plastic prescription lens that is permanently implanted in the eye.
At present, the most widely used surgical technique is phacoemulsification, developed by Charles Kelman (Kelman, 1967), in which ultrasonic emissions are utilized to fragment the crystalline lens inside the eye, the fragments then being drawn out through a very small incision – about 2.8-3 mm – at the zone where the cornea meets the sclera. This technique has several advantages such as faster surgical times, smaller incisions which make healing times quicker and increased surgeon control (Packer et a1., 2005; Corvi et a1., 2006).
Three components constitute the heart of all phaco systems which are irrigation, aspiration and ultrasound (Yow et al., 1997). According to the position of operator's foot on the pedal of system, four positions are defined (Maloney et al., 1988)
Position 0: Foot is off the pedal, no action.
Position 1: Initial depression of foot pedal. Fluid flows from the bottle, no aspiration or emulsification.
Position 2: Pedal pushed to the detent. Aspiration now accompanies irrigation.
Position 3: Pedal pressed to the next detent. With phaco hand piece, emulsification now is added to irrigation and aspiration.
Three operating modes were analyzed;

- **Linear mode**, in this mode the power of ultrasound waves are increased gradually from zero to the preset power of the system and it directly depends on how far down the pedal is pushed
- **Constant mode,** in this mode the power of ultrasound emissions are equal to the preset power of system immediately in the stages in which waves were used

- **Pulse mode,** in this mode the ultrasonic stream is not continuous but pulsed (Aali-Payam Corporation, 2006)

The ultrasonic hand piece (**Figure 1**) incorporates a transducer for converting high frequency, alternating current in to mechanical vibrations. By piezoelectric crystals electrical energy converts to mechanical energy and causes the hollow cylindrical tip attached to oscillate at a frequency around 40 KHz to break up (emulsify) the cataract into tiny pieces (Bond et a1., 2003; Packer et a1., 2005).

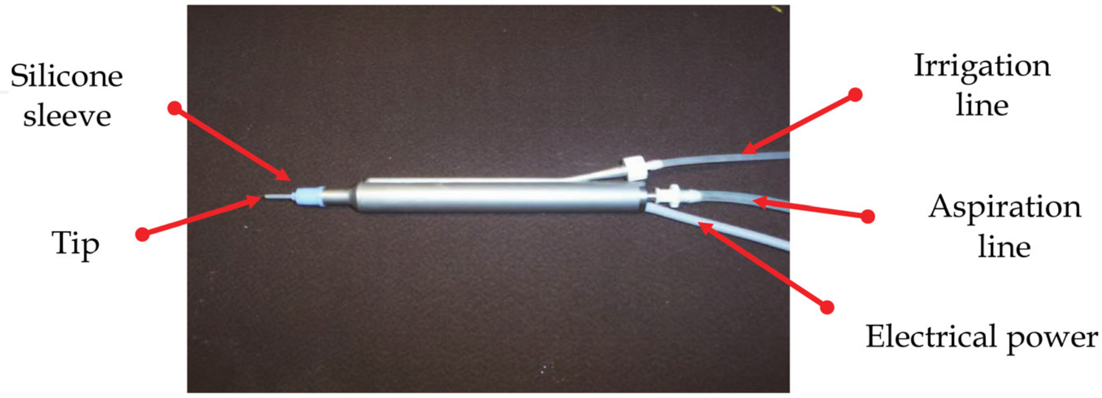

Fig. 1. Phacoemusification hand piece

The emulsified material is simultaneously suctioned from the eye by the tip. A special titanium alloy is the material of choice for such applications because of a favorable strength-to-weight ratio as well as biocompatibility and resistance to fragmentation. Phacoemulsifier tips come in a number of variations; the three common ones are named for the angle of the cutting area. They are the 0 degree, the 15 degree, the 30 degree and the 45 degree. The 45 degree tip has the longest bevel and therefore the sharpest tip, so it cuts most easily. Because of the large bevel of the aspiration port it occludes less easily. The 30 degree tip has a smaller bevel. Therefore the port is smaller and occludes more easily so it is more efficient for the aspiration. Some surgeons like to vary the tip depending on the density of the cataract: using a 45 degree tip for a hard cataract and a 30 degree tip for softer cataracts and they are the most popular so measurements and comparisons have been made for these two tips. The front (anterior) section of the lens capsule is removed along with the fragments of the natural lens. The back (posterior) portion of the capsule is left in place to hold and maintain the correct position for the implanted intraocular lenses.

2.1 Discussion

With an increase in the use of phacoemulsification concern about potential for thermal wound injuries during surgery has increased (Ernest et a1., 2001). Phacoemulsification requires more attention to detail than any other ophthalmic surgical procedure. The success of each step of the procedure is critically dependent upon how well each previous step was performed. Errors early in the procedure will almost inevitably result in subsequent problems. The small incision is what gives phaco most its advantages but, as with all steps in phacoemulsification, it must be fashioned very exactly (Osher et a1., 2006). The location, the size, the depth and configuration of the incision are all critical factors in determining the final outcome in phaco. In some cases burns can result in fusion of the cornea or the sclera, damage to the corneal endothelium, wound gape and delayed wound healing.

It is important to note that the aim of this study is to compare and analyze the changes of temperature around the different tips for three operating modes of the Sina Phacoemulsification System (**Figure 2**) which is one of the products of an Iranian medical engineering company (Ernest et a1., 2001; Tahvildari et a1., 2008).

Fig. 2. Sina Phacoemulsification System (Aali-Payam Co.)

3. Test instruments and methodology

In this study, for the purpose of monitoring in vitro the changes of temperature values are based on the utilization of two different types of thermocouples;

a. Digital Thermocouple
b. Thin wires Thermocouple

In all of the experiments the phaco tip is in the chamber with dimension of 10 cm $\times$ 18 cm $\times$ 23 cm and is full of serum solution (Sodium Chloride 0.9%). The size of chamber is big enough for it to act as a thermal bath. The power of the system was on its pre-set value of 50% and the intensity of waves for this power are about 155 W/cm^2 (Tahvildari et a1., 2008, 2007).

3.1 Digital thermocouple

The digital thermocouple has a probe and can measure temperatures near the phaco tip with sensitivity of 0.01 °C. In measurement with a digital thermocouple, each experimental test is repeated 5 times for every mode and the averages of temperature change in a period of 60 seconds are plotted.

3.2 Thin wires thermocouple

The thin wires thermocouple is made of two different metal wires with sealing wax on them for prevention of RF (radio frequency) waves (Jones & Chin, 1991) In our experiments thin wires themocouple had been made of Nickel-Nickel, Chrome (Ni-NiCr). With four thin wires thermocouple temperatures are measured in four different areas (**Figure 3**) near the tip indirectly by the changes of voltage with sensitivity of 1 μV and simultaneously are drawn by an X-Y recorder.

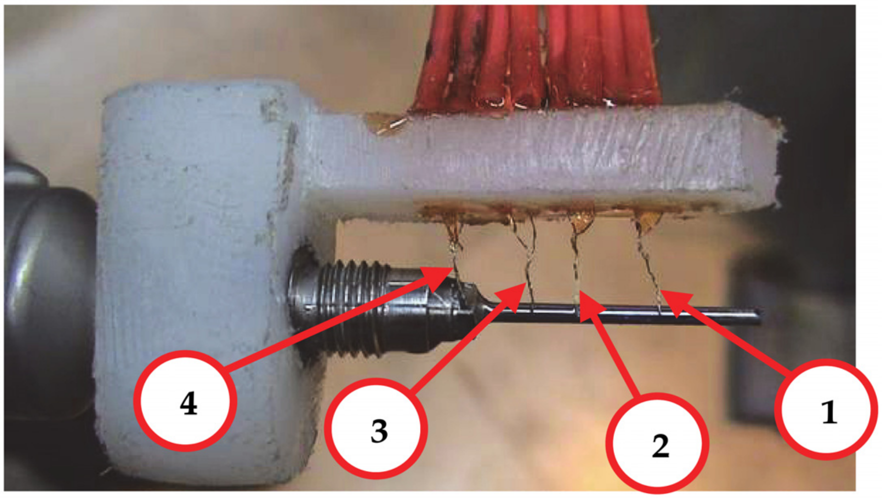

Fig. 3. Four different thin wires thermocouples monitor the temperature changes of the tip

On the next stage temperature changes are measured by the thin wires thermocouple for the same tip in a period of 60 seconds with the same initial conditions.
Because voltage changes are in the order of µV, then the numbers of peaks in a specific period of time are greater so in these graphs four points are important for us in comparison: the starting point, maximum, minimum and ending.

4. Analysis of results

In this study, for the purpose of monitoring in vitro the temperature values around two tips with the angle of 30 and 45 degree, first the measurements were performed using the digital thermocouple for different operating modes of the phaco system. In the next stage the same measurements were performed but with the thin wires thermocouple.

4.1 30 Degree tip – Digital thermocouple

Shown in **Figure 4** and **Table 1** are the temperature values monitored by digital thermocouple when the system is operating in linear and constant modes for the 30 Degree tip. In linear mode maximum temperature increase is 0.5 °C but in constant mode it is 0.47 °C.

	Average of Starting	Average of Maximums	Average of Minimums	Average of Endings
LINEAR MODE	21.62	22.12	21.87	22.1
CONSTANT MODE	21.65	22.12	21.87	22.12

Table 1. Temperature Values for Linear and Constant modes measured by Digital Thermocouple

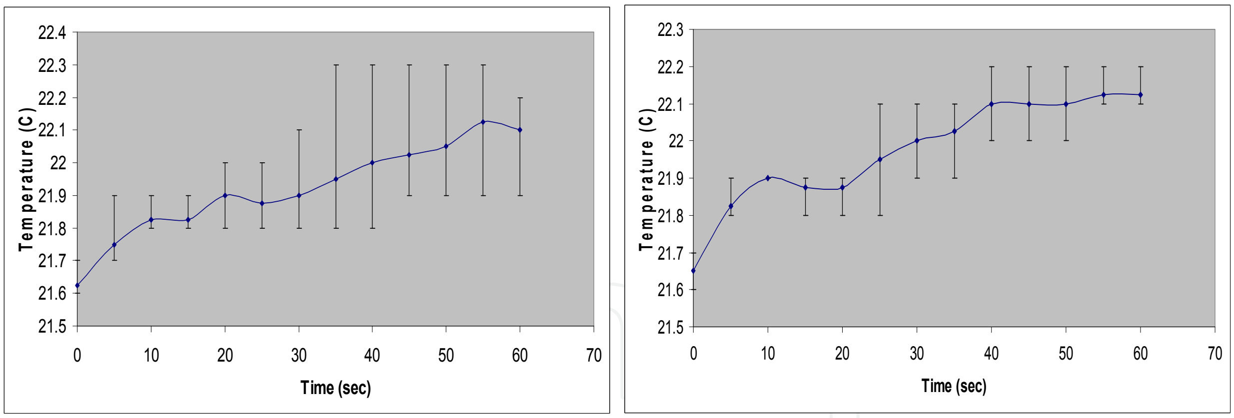

Fig. 4. Linear Mode – Temperature values versus Time [top]; Constant Mode – Temperature values versus Time [bottom]

Shown in **Figure 5** and **Table 2**, in pulse mode, when the system is set to emit 10 pulses per second (pps), maximum temperature increase for linear – pulse mode around the tip is 0.2 °C but for constant – pulse mode this value is 0.23 °C.

	Average of Starting	Average of Maximums	Average of Minimums	Average of Endings
LINEAR PULSE MODE	22.05	22.25	22.1	22.27
CONSTANT PULSE MODE	21.62	21.85	21.72	21.82

Table 2. Temperature Values for Linear – Pulse and Constant – Pulse modes measured by Digital Thermocouple

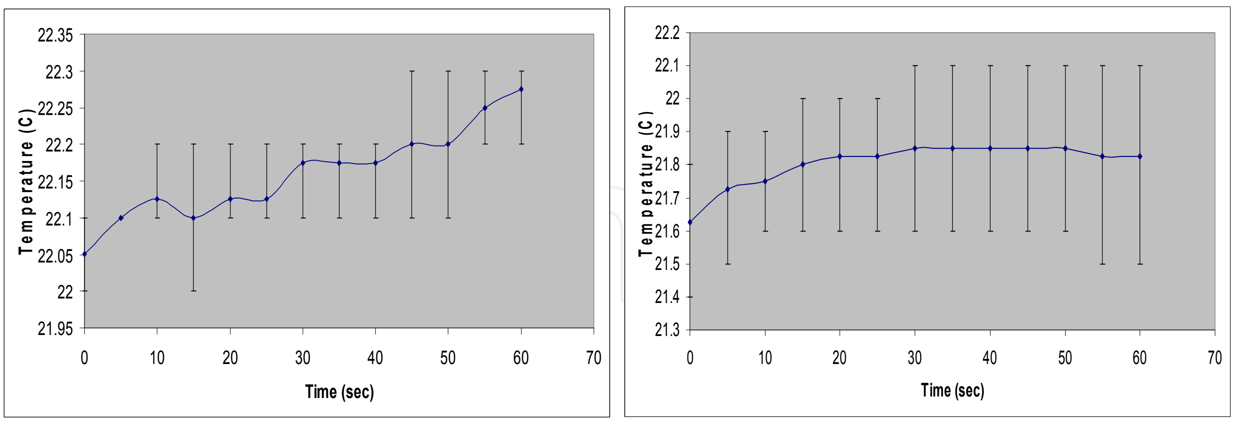

Fig. 5. Linear-Pulse Mode (10 pps) – Temperature values versus Time [top]; Constant-Pulse Mode (10 pps) – Temperature values versus Time [bottom]

4.2 30 Degree tip – Thin wires thermocouples

In **Table 3**, the temperature values reached in linear and constant modes around the tip which are measured by thin wires thermocouples in four different areas around the 30 Degree tip is shown.

		Starting	Maximum	Minimum	Ending
LINEAR MODE	THERMO NO.1	-10	38	8	22
	THERMO NO.2	-3	12	-1	-2
	THERMO NO.3	-10	102	35	80
	THERMO NO.4	-4	65	41	50
CONSTANT MODE	THERMO NO.1	-2	54	12	31
	THERMO NO.2	-2	17	1	2
	THERMO NO.3	3	100	59	89
	THERMO NO.4	1	84	21	67

Table 3. Temperature Values for Linear and Constant modes measured by thin wire thermocouples

Figure 6 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in linear mode.
The maximum temperature increase in this mode for thermocouples No.1 is 48, No.2 is 15, No.3 is 112 and No.4 is 69 μV.

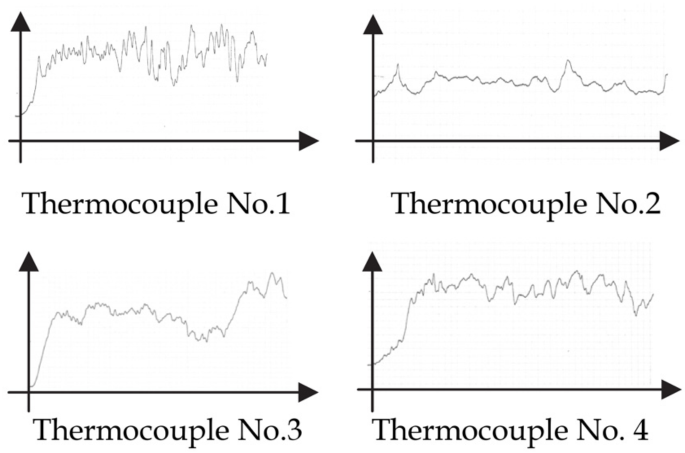

Fig. 6. Linear Mode – Voltage changes (μV) versus Time (sec.) for each thermocouple

Figure 7 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in constant mode.
The maximum increase in this mode for thermocouples No.1 is 56, No.2 is 19, No.3 is 97 and No.4 is 83 μV.

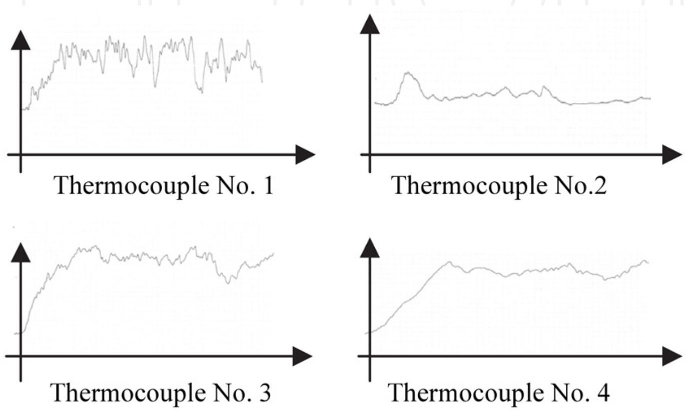

Fig. 7. Constant Mode – Voltage changes (μV) versus Time (sec.) for each thermocouple

In **Table 4**, the temperature values reached in linear – pulse and constant – pulse modes around the tip which are measured by thin wires thermocouples in four different areas around the tip is shown.

		Starting	Maximum	Minimum	Ending
LINEAR PULSE MODE	THERMO NO.1	2	31	18	27
	THERMO NO.2	-8	8	1	2
	THERMO NO.3	-3	57	38	37
	THERMO NO.4	-5	61	53	52
CONSTANT PULSE MODE	THERMO NO.1	-11	21	8	10
	THERMO NO.2	-2	17	9	11
	THERMO NO.3	12	63	48	57
	THERMO NO.4	6	90	78	9

Table 4. Temperature Values for Linear – Pulse and Constant – Pulse modes measured by thin wire thermocouples

Figure 8 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in linear – pulse mode when the system is set to emit 10 pulses per second (10 pps). The maximum increase in this mode for thermocouples No.1 is 29, No.2 is 16, No.3 is 60 and No.4 is 66 μV.

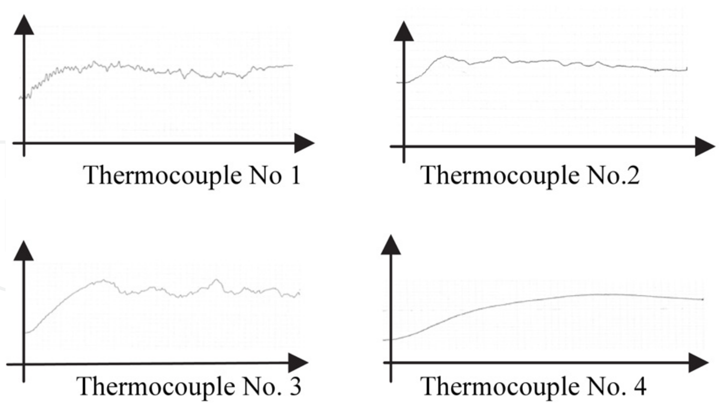

Fig. 8. Linear – Pulse Mode (10 pps) – Voltage changes (μV) versus Time (sec.) for each thermocouple

Figure 9 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in constant – pulse mode when again the system is set to emit 10 pulses per second (10 pps). The maximum increase in this mode for thermocouples No.1 is 32, No.2 is 19, No.3 is 51 and No.4 is 84 μV.

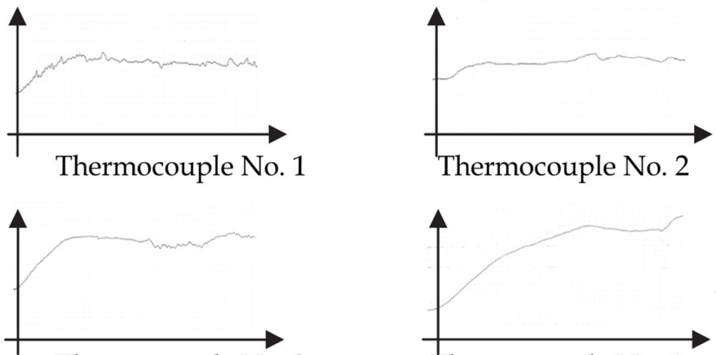

Fig. 9. Constant – Pulse Mode (10 pps) – Voltage changes (µV) versus Time (sec.) for each thermocouple

4.3 45 Degree tip – Digital thermocouple

Shown in **Figure 10** and **Table 5** are the temperature value monitored by digital thermocouple during the system is operating in linear and constant modes for the 45 Degree tip. In linear mode maximum increase is 0.72 °C but in constant mode it is 0.67 °C.

	Average of Starting	**Average of Maximums**	**Average of Minimums**	**Average of Endings**
LINEAR MODE	20.35	21.07	20.92	20.97
CONSTANT MODE	20.35	21.02	20.85	21.12

Table 5. Temperature Values for Linear and Constant modes measured by Digital Thermocouple

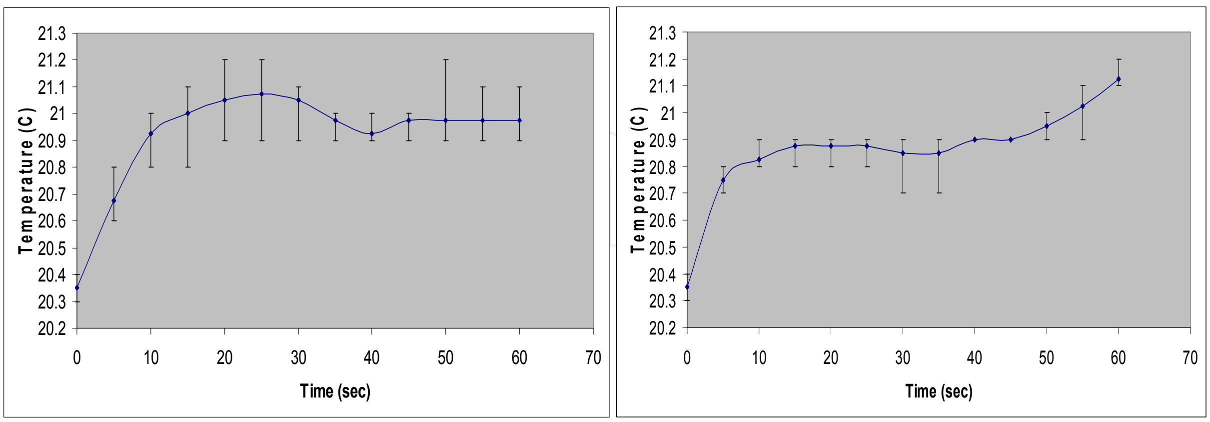

Fig. 10. Linear Mode – Temperature values versus Time [top]; Constant Mode – Temperature values versus Time [bottom]

Shown in **Figure 11** and **Table 6**, in pulse mode, when the system is set to emit 10 pulses per second (10 pps), maximum increase for linear – pulse mode around the tip is 0.17 °C but for constant – pulse mode this value is 0.13 °C.

	Average of Starting	Average of Maximums	Average of Minimums	Average of Endings
LINEAR PULSE MODE	21.40	21.57	22.55	21.62
CONSTANT PULSE MODE	20.57	20.70	20.65	20.72

Table 6. Temperature Values for Linear – Pulse and Constant – Pulse modes measured by Digital Thermocouple

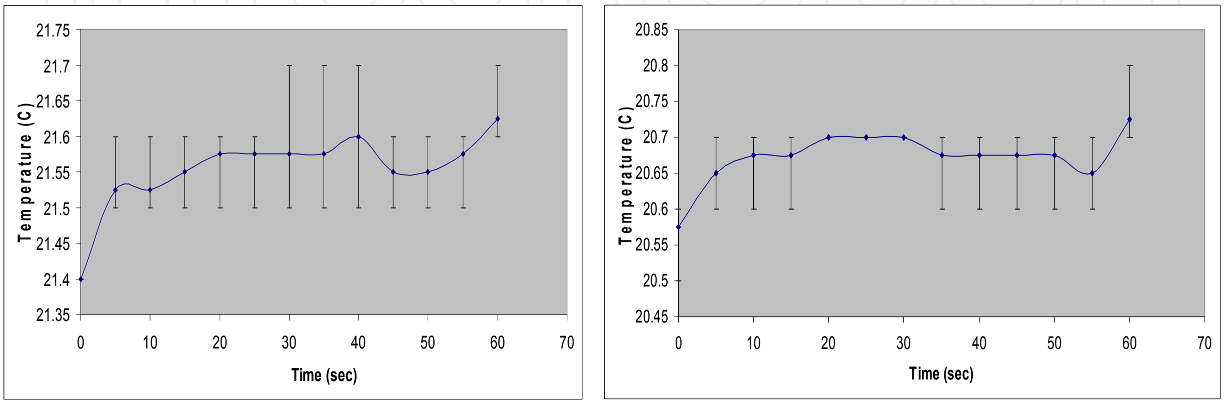

Fig. 11. Linear -Pulse Mode (10 pps) – Temperature values versus Time [top]; Constant - Pulse Mode (10pps) – Temperature values versus Time [bottom]

4.4 45 Degree tip – Thin wires thermocouples

In **Table 7**, the temperature values reached in linear and constant modes around the tip which are measured by thin wires thermocouples in four different areas around the tip is shown.

		Starting	Maximum	Minimum	Ending
LINEAR MODE	THERMO NO.1	0	40	-2	9
	THERMO NO.2	-9	23	7	18
	THERMO NO.3	-7	40	0	8
	THERMO NO.4	-7	6	0	2
CONSTANT MODE	THERMO NO.1	-5	4	-10	2
	THERMO NO.2	-8	11	-2	2
	THERMO NO.3	-14	50	10	15
	THERMO NO.4	-5	62	32	56

Table 7. Temperature Values for Linear and Constant modes measured by thin wire thermocouples

Figure 12 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in linear mode.

The maximum increase in this mode for thermocouples No.1 is 40, No.2 is 32, No.3 is 47 and No.4 is 13 µV.

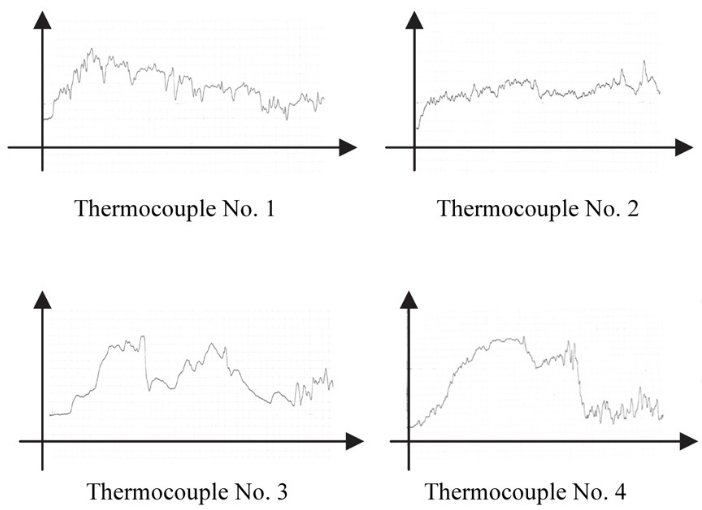

Fig. 12. Linear Mode – Voltage changes (μV) versus Time (sec.) for each thermocouple

Figure 13 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in constant mode. The maximum increase in this mode for thermocouples No.1 is 9, No.2 is 19, No.3 is 64 and No.4 is 67 μV.

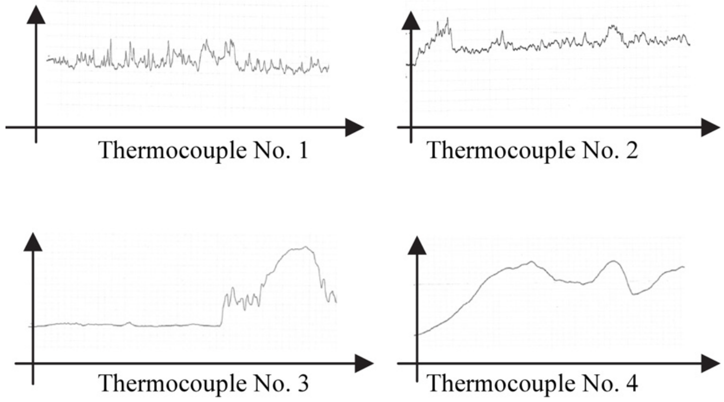

Fig. 13. Constant Mode – Voltage changes (μV) versus Time (sec.) for each thermocouple

In **Table 8**, the temperature values reached in linear – pulse and constant – pulse modes around the tip which are measured by thin wires thermocouples in four different areas around the tip is shown.

		Starting	**Maximum**	**Minimum**	**Ending**
Linear Pulse mode	Thermo No.1	0	12	-4	6
	Thermo No.2	0	26	16	23
	Thermo No.3	-2	12	-1	0
	Thermo No.4	4	58	33	54
Constant Pulse mode	Thermo No.1	-12	4	-8	2
	Thermo No.2	6	30	8	21
	Thermo No.3	-5	18	-7	-3
	Thermo No.4	9	40	16	33

Table 8. Temperature Values for Linear – Pulse and Constant – Pulse modes measured by thin wire thermocouples

Figure 14 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in linear – pulse mode when the system is set to emit 10 pulses per second (10 pps). The maximum increase in this mode for thermocouples No.1 is 12, No.2 is 26, No.3 is 14 and No.4 is 54 μV.

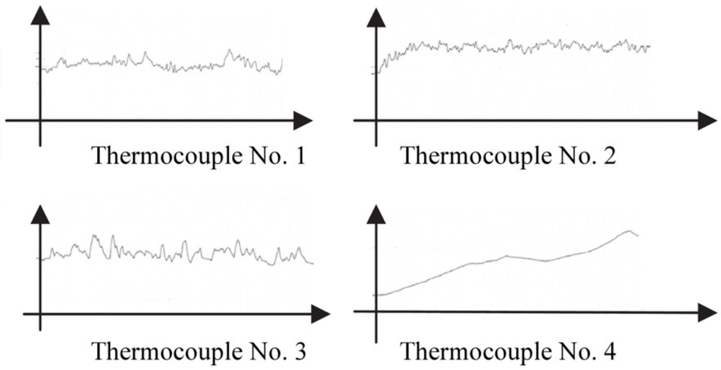

Fig. 14. Linear – Pulse Mode (10 pps) – Voltage changes (μV) versus Time (sec.) for each thermocouple

Figure 15 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in constant – pulse mode when the system is set to emit 10 pulses per second (10 pps).
The maximum increase in this mode for thermocouples No.1 is 16, No.2 is 24, No.3 is 23 and No.4 is 31 μV.

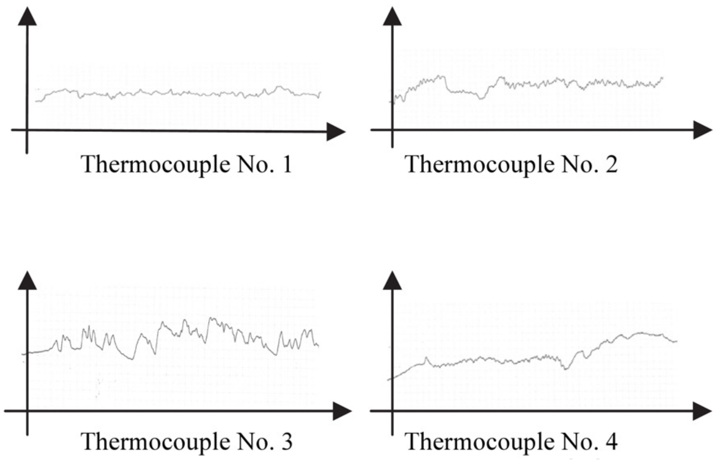

Fig. 15. Constant – Pulse Mode (10 pps) – Voltage changes (μV) versus Time (sec.) for each thermocouple

5. Air bubble effects on temperature changes

Bubbles generated during phacoemulsification damage the corneal endothelium. The principal source of the bubbles is the degassing of the irrigation solution by ultrasonic agitation. The quantity of bubbles is modulated by the partial pressure of air in the irrigation solution and the intensity of the ultrasonic energy. Bubbles reaching the endothelium can destroy cells (Kim et a1., 2002).

In this study all experiments were done in 60 seconds for the 45 degree tip using three solutions with different partial pressures of gas: ordinary, low-gassed and high-gassed. The phaco system was operating in constant mode with 50% power.

In **Table 9**, the temperature changes around the tip which are measured by digital thermocouple for three solutions is shown.

	Average of Starting	**Average of Maximums**	**Average of Minimums**	**Average of Endings**
ORDINARY	21.9	22.6	22.4	22.7
LOW-GASSED	21.9	22.9	22.6	22.9
HIGH- GASSED	22.1	22.8	23.3	23.3

Table 9. Temperature changes for different solutions measured by digital thermocouples shown in **Figure 16** the temperature value monitored by digital thermocouple during the system is operating in constant modes and the 45 Degree tip for three different solutions.

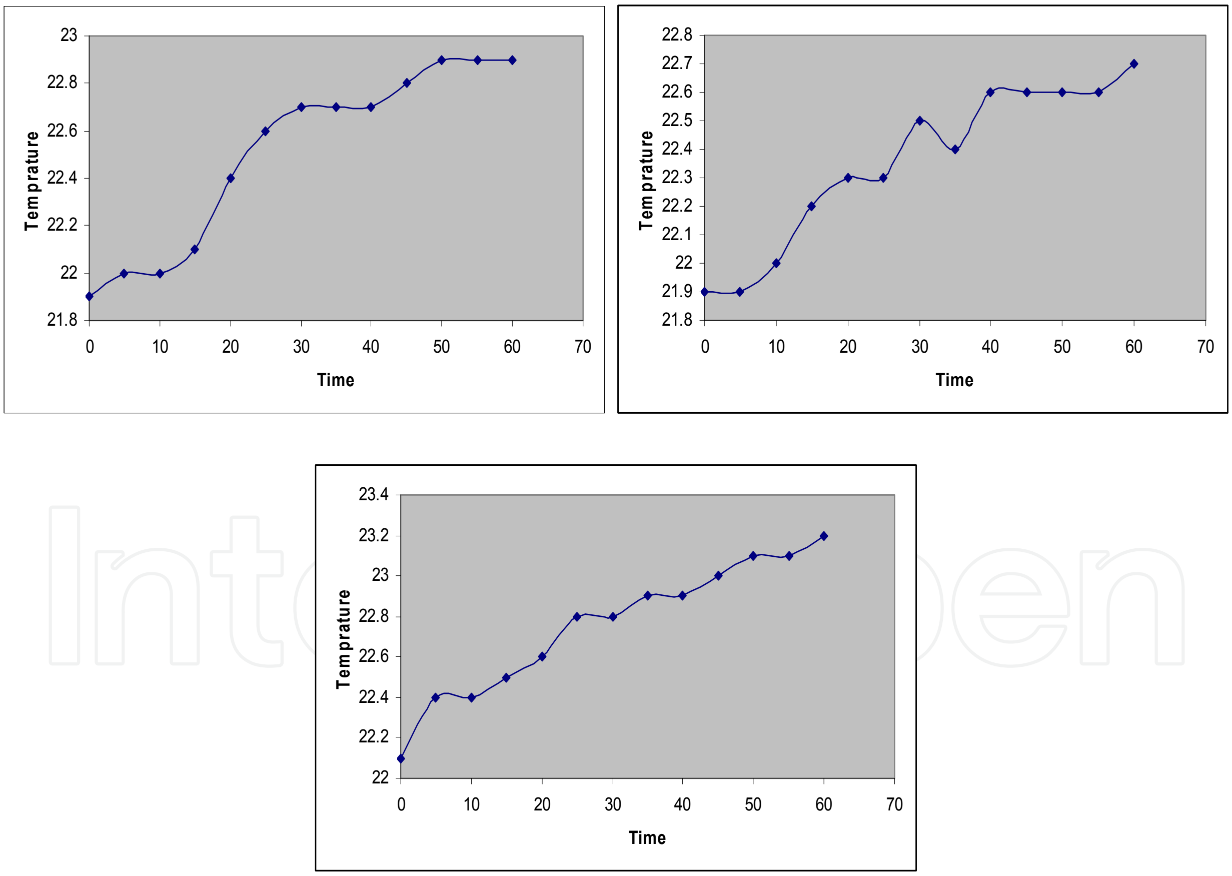

Fig. 16. Constant Mode – Temperature values versus Time for ordinary solution [top]; low-gassed solution [middle]; high-gassed solution [bottom]

According to these plots the changes of temperature for ordinary solution is is 0.7 °C, for low-gassed solution is 1.0 °C and for the high-gassed one is 1.2 °C.

In **Table 10**, the temperature changes around the tip where it is inserted to the eye exactly under the endothelium measured by digital thermocouple number 1 for three solutions is shown.

	Average of Starting	Average of Maximums	Average of Minimums	Average of Endings
Ordinary	68	75	71	73
Low-gassed	76	100	79	79
High- gassed	76	113	69	84

Table 10. Temperature changes for different solutions measured by thin wire thermocouple (Number 1)

Figure 17 are the temperature changes that are plotted according to the voltage changes of each thermocouple versus time in constant mode when the system is set to its 50% power.

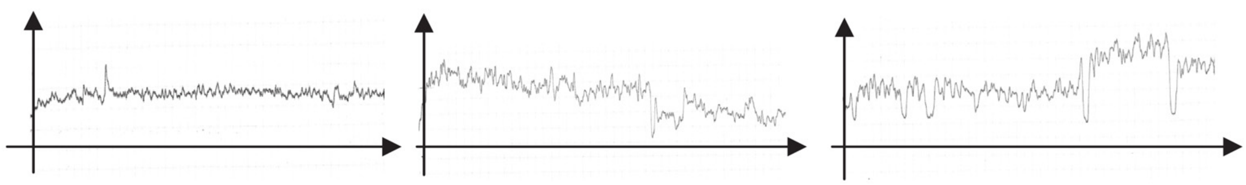

Fig. 17. Constant Mode – Temperature values versus Time for ordinary solution [left]; low-gassed solution [middle]; high-gassed solution [right] messured by thin wire thermocouples

According to these results the changes of temperature for ordinary solution is 7, for low-gassed solution is 23 and for the high-gassed solution is 27μV.

6. Conclusion

In this study thermocouples have been used as an instrument for measuring the temperature changes of different phaco tips for the purpose of monitoring and comparing three operating modes of a phacoemulsification system.

All in vitro measurements were done with the same initial conditions. In evaluating the maximum temperatures reached in each operating mode, it has been found that for both tips temperature changes in pulse mode (linear – pulse and constant – pulse) have fewer and lower peaks. The main reason for this is that the short periods of time between each pulsed wave allow the tip to cool between two successive emissions. Moreover, in these modes, the system produces a lower thermal increase with respect to the linear and constant modes.

It is strongly recommend that in cataract surgery employing the Sina phaco system only linear – pulse and constant – pulse modes should be used, so to reduce any possible surgical complications caused by the excessive release of heat.

Accordingly keeping the levels of partially dissolved gas in the irrigation solution low is a strategy for avoiding bubble formation and corneal endothelial damage.

Although all the experiments were performed in vitro, and increases in tip temperature during surgical operations is even higher than in these data, the results suggest the modern procedure of phacoemulsification can be performed at a safe temperature through an informed manipulation of surgeon-controlled parameters.

7. Acknowledgment

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At the end, I owe an immense debt of gratitude to my beloved parents (The late Louise Tahvildary and the late Amanollah Tahvildari) for all of their support.

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