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Testing a Novel Device for Accurate Ultrasound Delivery During Crystalline Lens Phacoemulsification Surgery

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Purpose: To assess whether the use of a patented, novel feedback device intended to accurately control phacoemulsification tip elongation is effective under varying machine settings and material resistance.

Methods: Sculpt mode phaco (550-mm Hg Venturi pump; elongations, 35 and 70 µm) and quadrant settings (550-mm Hg Venturi pump; elongations, 15, 30, and 60 µm) were used in agar gel of incremental density (1%, 2%, 3%, and 6% in demineralized water). Dispersed lens fragments were also simulated with 6% agar gel spherules (2–5 mm in diameter; 550-mm Hg vacuum, and 60-µm elongation). Actual phaco tip elongation was measured on voltage readings from the piezoelectric crystals and compared to nominal elongation with feedback control off and on.

Results: Mismatch between nominal and actual elongation when feedback control was off in sculpt mode varied between −13.51 µm and −23.07 µm of nominal elongation; in quadrant mode, mismatch varied between −2.79 µm and −20.41 µm. When the feedback control system was switched on, mismatch varied between −0.02 µm and +0.43 µm ($P < 0.001$ for all matchings). When the feedback system was off, the elongation mismatch among the 1%, 3%, and 6% agar was also statistically significant ($P < 0.001$). Elongation was 44.72 ± 4.16 µm with feedback control off and 60.02 ± 1.63 µm with it on (nominal elongation 60 µm; $P < 0.001$) when emulsifying agar 6% gel fragments. Dispersion of elongation data was also significantly wider when feedback control was turned off.

Conclusions: A novel feedback control system effectively controls elongation accuracy regardless of the resistance offered by incremental agar gel concentrations.

Translational Relevance: Implementing feedback control in phaco handpieces dramatically improves surgical accuracy. The translational value of this research relies on its immediate applicability to routine cataract surgery, resulting in a more appropriate use of ultrasound energy.

Introduction

Phacoemulsification is the state-of-the-art surgical technique for cataract extraction. It is the most prevalent procedure in all medical fields, with an estimated 3.6 million procedures per year in the United States, 7 million in Europe, and 20 million worldwide.[1] Lens material fragmentation and removal are achieved by means of a variously shaped hollow cylindrical titanium tip that hits the cataractous crystalline lens at an ultrasonic frequency, acting as a scalpel and aspirating fragments at the same time. Tip motion is actuated by piezoelectric crystals whose resonance frequency depends on their ceramic properties, and electric tension drives elongation. Ultrasonic energy depends on resonant frequency, elongation, and time.

Minimizing the amount of ultrasonic energy dissipated into the eye during the procedure reduces dreaded postoperative complications, including

corneal edema, iris inflammation, pain, and corneal decompensation. Because the lens material resists the motion of the tip, actual tip elongation is reduced, forcing the surgeon to increase the ultrasound (US) energy (i.e., elongation) until the nucleus fragments break and occlusion resolves. At this point, resistance drops dramatically and the tip runs free in the aqueous, dangerously dissipating energy until engagement of the next fragment. The purpose of this paper is to introduce a novel system that allows continuous and real-time tip elongation control via a feedback mechanism and to evaluate whether such a system increases the accuracy of tip elongation regardless of the resistance encountered.

Methods

Technical Background

Phacoemulsificator tip elongation is a consequence of vibration of the piezoelectric (πιέζειν [*piezein*] = to fold or compress and ἤλεκτρον [*ēlektron*] = amber) crystals when electric voltage is applied at a resonating frequency. Piezoelectric crystals, or ceramics, deform and vibrate when exposed to electric voltage and vice versa, generating an electric voltage when they deform. This reversible behavior allows them to alternatively drive the motion of phaco tips when fed with alternating voltage or generate voltage as a function of the elongation (i.e., crystal deformation) when the feeding voltage is temporarily stopped. The amount of voltage amplitude produced is proportional to elongation and represents an accurate measure of it.

The driving voltage at a resonance frequency is tested and recorded during priming and is continuously checked for reference throughout surgery. Phacoemulsification machines drive tip elongation based on priming data when the tip is vibrating against a balanced salt solution (BSS) resistance. It should be noted that, when the tip encounters the much denser lens material, the higher resistance significantly reduces tip elongation, limiting its efficiency and creating a mismatch between nominal elongation (tip displacement set by the surgeon, corresponding to elongation of the tip when immersed in water, such as during priming) and actual elongation, defined as the real tip oscillation amplitude determined by the same driving voltage when the tip is working against the variable resistance offered by the lens material. Actual elongation can nonetheless be accurately calculated based on crystal polarization produced by vibrating ceramics when the driving voltage (100 Hz) is periodically halted for a short time interval (250 ms).

Feedback Control System

In response to the need for consistent tip elongation and accurate ultrasound energy emission regardless of resistance, Optikon 2000 Spa (Rome, Italy) filed a patent for its Minimal Stress technology (referred to here as the feedback control system) for continuous feedback control of tip elongation (US6175180B1). The control system halts tension to the piezoelectric crystals 100 times per second and measures the voltage created by ceramic oscillation, calculating actual elongation in real time. Thus, the mismatch between the requested elongation (nominal elongation) and instantaneous actual elongation during surgery (which continuously varies due to lens material properties) is monitored in real time, and the tension is corrected as necessary to guarantee that the actual elongation equals the nominal elongation, regardless of the variable resistance.

Agar Gel Preparation

In order to evaluate phacoemulsification tip functioning against incremental resistance with feedback control either on or off, we prepared four different agar gel concentrations by dissolving 1, 2, 3, or 6 grams of agar powder in 100 mL of demineralized water and heating the solution at 95°C while stirring for 5 minutes. Each solution was then poured into a glass container to form a 10-mm-thick layer and left at 22°C for 24 hours until complete gelation. Agar gel in various concentrations (1%–6%) was chosen as the reference material because its resistance can be varied according to the agar powder concentration, and its known mechanical properties are comparable to those of the aging crystalline lens.[2] It is also used to simulate cataract surgery on artificial eyes.[3]

For the purposes of this study, part of the gel was left as a 10-mm-thick single layer and part was used to create small cylinders 10 mm in diameter using a Franceschetti trephine. Part of the denser 6% agar gel was minced to create irregular spherules 2 to 5 mm wide to simulate lens fragments which were then dispersed in BSS (Beaver-Visitec International, Warwickshire, UK). All gel used for this study was generated at the same time and used 24 hours after gelation in order to guarantee consistency of mechanical properties of the same agar concentration.

Study Design

The study aimed at replicating the surgical maneuvers of phacoemulsification: sculpting (phase 1) and quadrant removal (phase 2). To simulate

Table 1. Phaco Machine Settings

	Vacuum (mm Hg)	Elongation (µm)	Ultrasound Mode
Phase 1. Sculpting	550	15, 30, 60	Continuous
Phase 2. Quadrant removal	550	35, 70	Continuous
Fragment removal	550	60	Continuous

Note that both vacuum and elongation were set to panel mode (i.e., the machine instantaneously reached the desired value).

Table 2. Settings for Phase 1, Sculpting

		Agar				
Feedback Control	BSS	1%	2%	3%	6%	*P*
35-µm elongation						
Off	35.17 ± 0.41	18.11 ± 2.53	20.40 ± 3.61	21.49 ± 7.22	12.90 ± 3.21	<0.01
On	35.01 ± 0.78*	35.04 ± 1.38*	35.00 ± 1.63*	35.03 ± 2.06*	35.02 ± 1.61*	n.s.
70-µm elongation						
Off	70.24 ± 0.89	47.87 ± 4.13	51.71 ± 2.49	52.73 ± 4.58	46.93 ± 2.73	<0.01
On	69.87 ± 1.32*	70.04 ± 2.39*	70.09 ± 2.14*	70.06 ± 2.29*	70.02 ± 1.79*	n.s.

Actual tip elongation with feedback control off or on at requested (nominal) elongations of 35 µm and 70 µm. When feedback control was off, there was a significant difference between nominal and actual elongation, as well as among the various agar concentrations displayed in the table.

*The differences in actual elongation between feedback control off and on are significant ($P < 0.001$) at each elongation level.

n.s., not significant.

the sculpting phase, an experienced surgeon (T.R.) engaged the agar layer 10 times per each phacoemulsificator setting and agar concentration, while recording the data. Quadrant removal was replicated by aspirating agar gel cylinders until the tip perforated them or for at least 20 seconds if this did not occur. Every setting used three different agar gel cylinders. To simulate surgery more accurately, further testing was performed by immersing the phaco tip in BSS saturated with the small chunks of 6% agar gel (2–5 mm in diameter; see Table 1 for phaco settings) and recording data for 30 seconds to simulate random tip occlusion by lens fragments and resolution, a scenario often occurring toward the end of the quadrant removal phase when small pieces of lens nucleus move freely in the anterior chamber.

The machine used a Venturi effect (rotary vane) pump to guarantee a consistent vacuum. The agar gel cylinders (and spherules) were aspirated and lifted in BSS in order to exclude from the data the surgeon's force in impaling the material. The same was not possible for sculpting maneuvers that necessarily reflect the surgeon's manipulation. All measures were repeated with feedback control switched on and off, with the agar gel submerged in BSS using a 20-gauge straight 15° beveled tip connected to a R-Evo smart® phacoemulsification machine (Optikon 2000 Spa). Nominal elongation (requested tip elongation, expressed in µm) and actual elongation (elongation calculated based on the electricity produced by the piezoelectric crystals when driving tension stopped) throughout agar gel engagement and emulsification were recorded, together with vacuum, flow, and electric tension driving the phaco tip.

Main Outcome Measures

Nominal and actual tip elongation, amplitude of the alternating electric tension, and vacuum were recorded and used for analysis. The time average over the sampling interval represented overall tip elongation, which, in turn, is proportional to the delivered ultrasound energy.

Statistical analysis

All continuous variables were recorded as mean ± standard deviation. Analysis of variance compared elongation with and without feedback control. Mean squared error was also used to show data dispersion. All tests were two sided, and a level of statistical significance was set at $P < 0.05$.

Results

Elongation data are reported in Table 2 for the phase 1 (sculpt) settings and in Table 3 for phase 2 (quadrant removal) settings. When operating in BSS, the difference between requested and deployed

Table 3. Settings for Phase 2, Quadrant Removal

		Agar				
Feedback Control	BSS	1%	2%	3%	6%	*P*
15-µm elongation						
Off	—	12,20 ± 0.70	13.5 v 2.0	13.62 ± 0.66	6.94 ± 2.03	<0.001
On	15.01 0.2	15.0 ± 0.39*	15.0 ± 0.6*	15 ± 0.72*	15.01 ± 0.64*	n.s.
30-µm elongation						
Off	—	25.99 ± 2.28	19.25 ± 3.78	19.27 ± 2.12	9.59 ± 4.86	<0.001
On	30.1 0.61	30.02 ± 2.37*	30.01 ± 0.4*	30.03 ± 0.54*	30.02 ± 1.05*	n.s.
60-µm elongation						
Off	—	48.17 ± 5.89	47.43 ± 2.63	46.49 ± 3.62	44.06 ± 3.27	<0.001
On	59.91 0.75	60.23 ± 1.50*	60.03 ± 1.16*	60.08 ± 0.86*	60.03 ± 0.93*	n.s.

Actual tip elongation with feedback control off or on at requested (nominal) elongations of 15 µm, 30 µm, and 60 µm. When feedback control is off, there is a significant difference between nominal and actual elongation, as well as among the various agar concentrations shown in the table.

*The differences in actual elongation between minimal stress control OFF and ON are significant ($P < 0.001$) at each elongation level.

n.s., not significant.

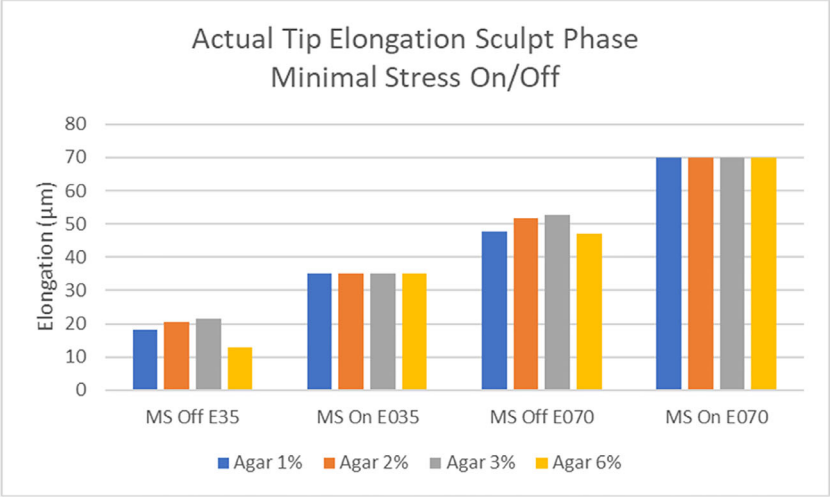

Figure 1. Actual tip elongation in sculpt mode with feedback control off or on when nominal elongation (requested elongation) was set to 35 µm (E35) or 70 µm (E70). Colored bars indicate increasing agar gel percentage.

elongation was not significant for either mode. In the sculpt phase (Table 2), the feedback system allowed much more accurate control of elongation at both 35- and 70-µm nominal elongation (Figs. 1 and 2). The difference in actual elongation between feedback control being off or on was significant at all agar gel concentrations ($P < 0.001$), exceeding 60% of requested elongation for the denser 6% agar (Fig. 2). When elongation feedback control was switched off, a significant reduction in elongation (nominal – actual elongation) occurred (Fig. 2), especially when increasing the nominal elongation from 35 µm up to 70 µm ($P < 0.01$). In the quadrant removal phase, feedback control allowed significantly higher accuracy, and elongation was almost perfectly on target, regardless of increasing agar gel resistance (1%–6%; $P < 0.001$ at all nominal elongations) (Table 3). In contrast, when feedback control was turned off, the difference between nominal and actual elongation changed significantly, both as agar gel resistance increased and as elongation rose ($P < 0.001$ in all cases) (Figs. 3, 4). The average elongation error with feedback control off also exceeded 60% at 30-µm elongation (Fig. 4).

When emulsifying 6% agar gel spherules dispersed in BSS (Figs. 5, 6), elongation accuracy proved significantly higher with feedback control on ($P < 0.001$), as shown in Table 4. Average actual elongation when the nominal value was 0 µm reached 44.02 µm with feedback control off compared to 60.02 µm when feedback control was turned on ($P < 0.001$). When feedback control was turned off, not only was the elongation accuracy much worse but the variability of elongation was also much greater, as shown in Figures 7 and 8. The mean squared error (Table 4) was 10.92

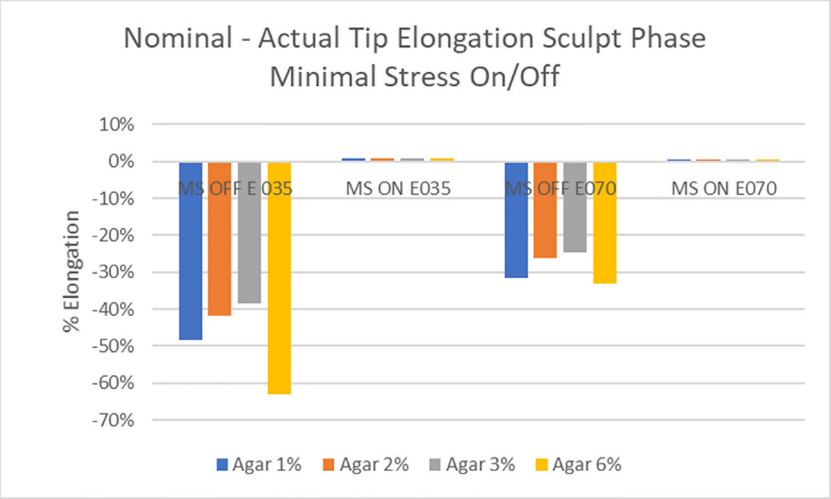

Figure 2. Difference in actual tip elongation (requested elongation – actual elongation expressed as a percentage) in sculpt mode with feedback control off or on when nominal elongation was set to 35 µm (E35) or 70 µm (E70). Colored bars indicate increasing agar gel percentage.

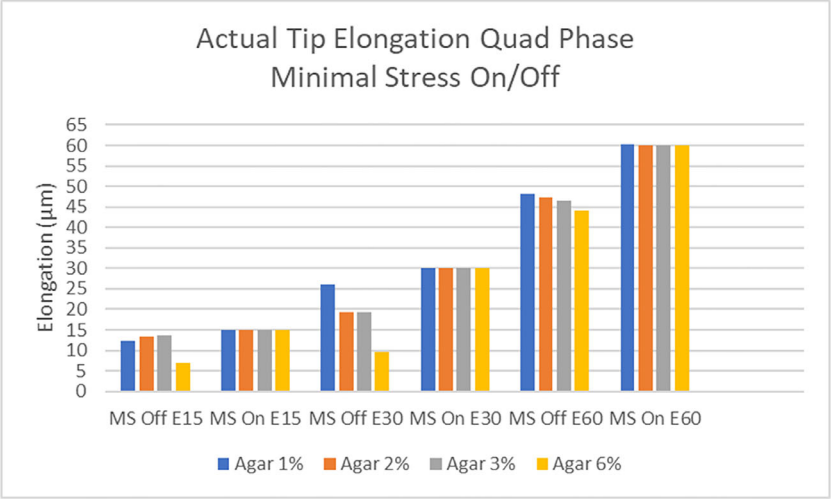

Figure 3. Actual tip elongation in quadrant removal mode with feedback control off or on when nominal elongation (requested elongation) was set to 15 µm (E15), 30 µm (E30), or 60 µm (E60). Colored bars indicate increasing agar gel percentage.

Table 4. Fragment Removal Settings (see also Table 1)

	6% Agar	*P*	Mean Squared Error
MS OFF E60	44.72 ± 4.16	—	10.92
MS ON E60	60.02 ± 1.63	< 0.001	2.67

Average actual tip elongation with feedback control off or on at requested (nominal) elongation of 60 µm. The difference in actual elongation between feedback control off and on is significant ($P < 0.001$).

with feedback control off and 2.67 when on. The much wider distributions of data around the average and related to requested elongation are clearly visible in Figures 7 and 8, where the histograms show a much taller and narrower Gaussian curve when feedback control was turned on (Fig. 8) compared to off (Fig. 7).

Figures 9 and 10 "explode" 100 milliseconds of Figures 5 and 6, respectively, in order to show in detail how the elongation and driving tension data changed as the tip engaged fragments of varying density. With feedback control off, elongation dropped well below nominal values to rebound as occlusion resolved (Fig. 9), while tension remained unchanged. When the control mechanism was switched on, actual elongation remained consistently at nominal values, and the

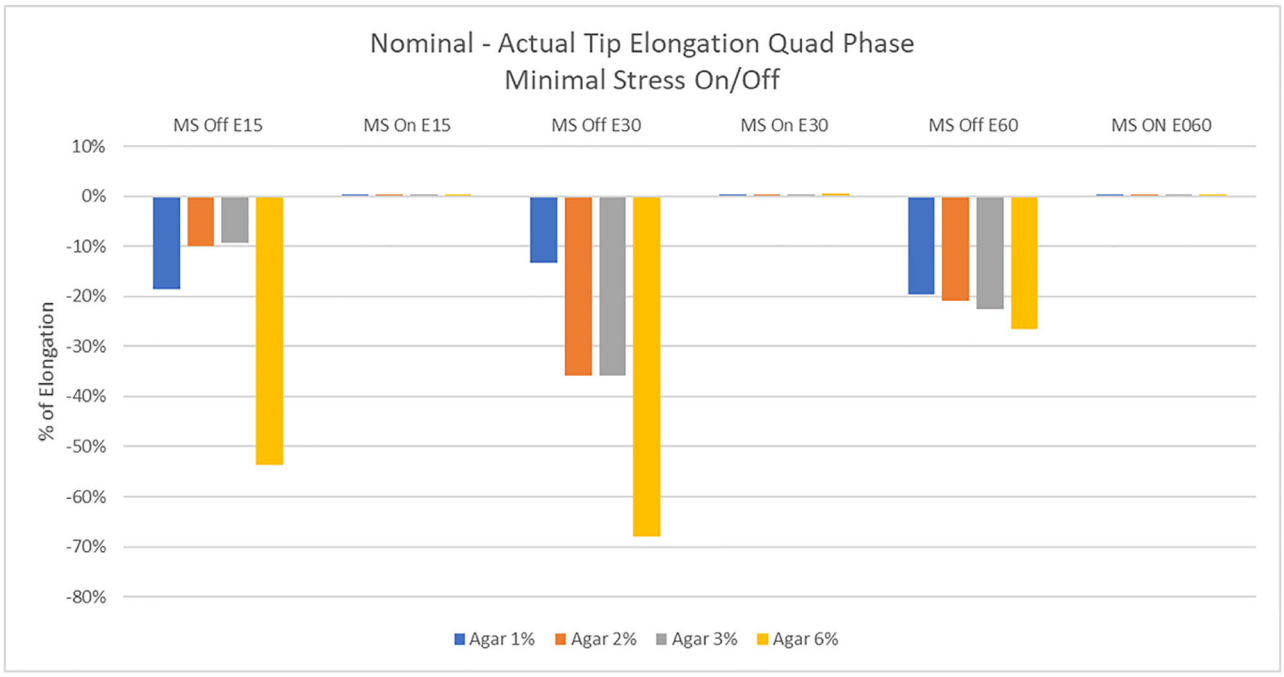

Figure 4. Difference in actual tip elongation (requested elongation – actual elongation expressed as a %) in quadrant removal mode with feedback control off or on when nominal elongation was set to 15 µm (E15), 30 µm (E30), or 60 µm (E60). Colored bars indicate increasing agar gel percentage.

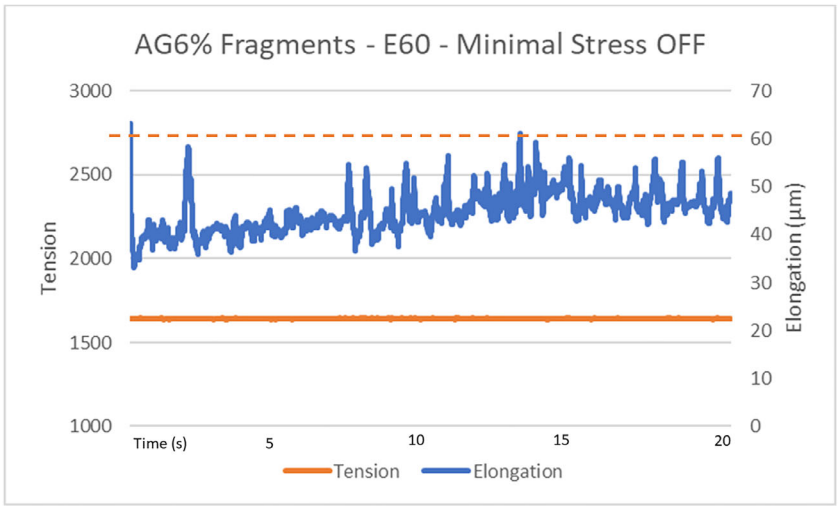

Figure 5. Actual tip elongation and driving electric tension (voltage) recorded while aspirating 6% agar spherules dispersed in BSS with feedback control off. Note that voltage is constant while elongation is extremely variable due to inconsistent resistance of engaged agar spherules mimicking lens material. Average elongation is also reported in Table 4. Red dashed line at the 60-µm level indicates requested (nominal) elongation.

driving tension adjusted continuously to guarantee the requested elongation (Fig. 10).

Figure 11 reports actual tip elongation in 6% agar gel fragments with feedback control off (blue curve, same as Fig. 5) and simulates two possible scenarios depending on the actions the surgeon might take to compensate for elongation mismatch:

1. The surgeon increases nominal elongation exactly by the average decrease dictated by resistance (60 µm – 44.72 µm = 15.28 µm; gray curve in Fig. 9). This improves effectiveness but is not sufficient to break the harder fragments (because the probability distribution is symmetrical, for about 50% of the surgical time elongation will not reach the desired

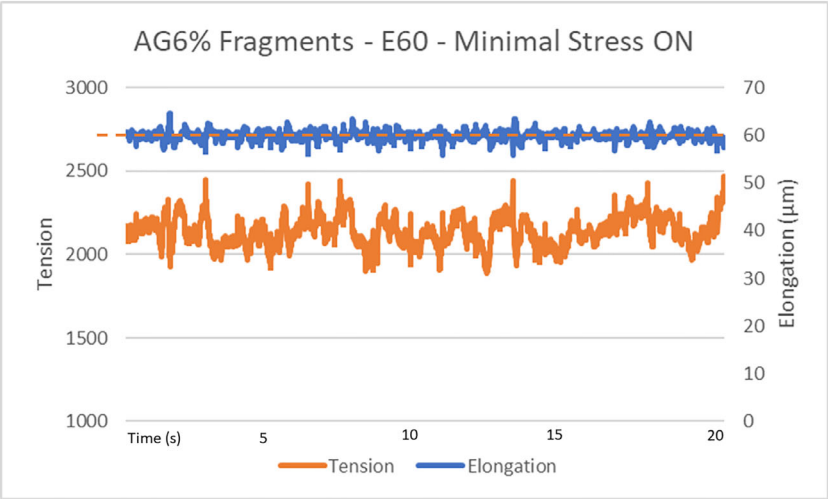

Figure 6. Actual tip elongation and driving electric tension (voltage) recorded while aspirating 6% agar spherules dispersed in BSS with feedback control on. Note that the voltage is now extremely variable in order to keep elongation consistently around the nominal (requested) value of 60 µm highlighted by the red dashed line. See also Table 4.

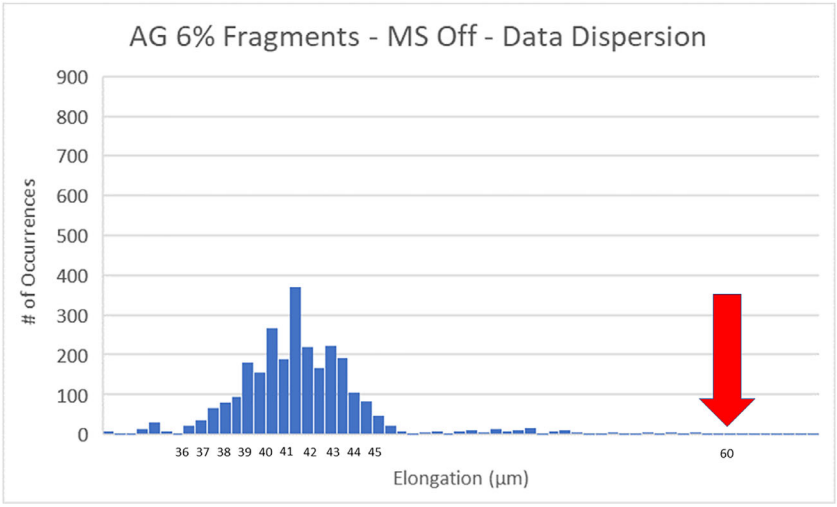

Figure 7. Histogram of elongation values recorded while engaging 6% agar fragments with feedback control off. The Gaussian curve is flat and dispersed compared to Figure 8 (see also Table 4 for mean squared error comparison). Red arrow at 60 µm indicates requested (nominal) elongation.

value). For this reason, the second scenario appears more reasonable.

2. The surgeon increases elongation to completely compensate for the elongation loss due to resistance until all of the harder fragments break. This results in an increase equal to the maximum difference between nominal and actual elongation (27.92 µm; red curve in Fig. 9).

An estimate of dissipated energy with and without feedback system control was calculated as follows. The area under the curve (AUC; the integral of elongation function over time) covered by the blue line in Figure 11 (feedback control off) was 69.5% of the AUC calculated when feedback control was switched on (but was an average of 15 µm less efficient) (Table 4). When elongation was increased by the average loss (gray line in Fig. 9), the AUC was equal to 99.6% of the AUC calculated with feedback control on (but elongation did not reached nominal value in about 50% of cases). When elongation was increased to entirely compensate for the maximum loss due to resistance (red line in Fig. 11), the AUC was 1.2096 times the AUC when feedback control was switched on. Therefore, the amount of excess US energy necessary to achieve complete fragmentation of 6% agar gel spherules was

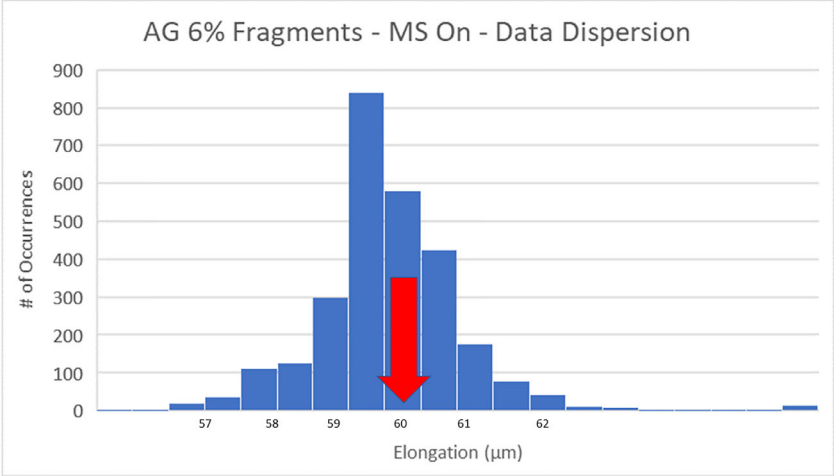

Figure 8. Histogram of elongation values recorded while engaging 6% agar fragments with feedback control on. The Gaussian curve is much higher and narrower compared to Figure 7, meaning that the elongation data cluster very close to the requested 60 µm of elongation, indicated by the red arrow. See also Table 4 for mean squared error comparisons.

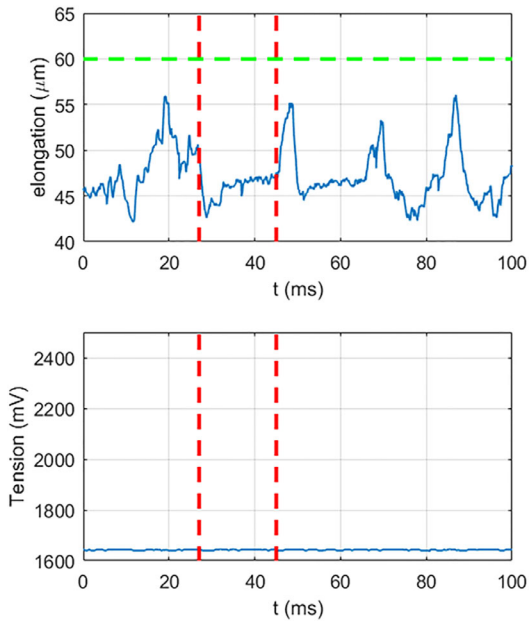

Figure 9. Detail of Figure 5 spanning 1 second. Feedback control is off, and the tip is engaging 6% agar fragments dispersed in BSS. The green dashed line shows nominal (requested) elongation of 60 µm, and the two vertical dashed red lines isolate one single event of fragment engagement. (Upper panel) Elongation is reduced to about 45 µm until the fragment is emulsified, occlusion resolves, and elongation unnecessarily spikes up to 55 µm. The nominal elongation is never reached, but the fluctuation is very high. (Lower panel) Driving tension remains stable due to the absence of any feedback control.

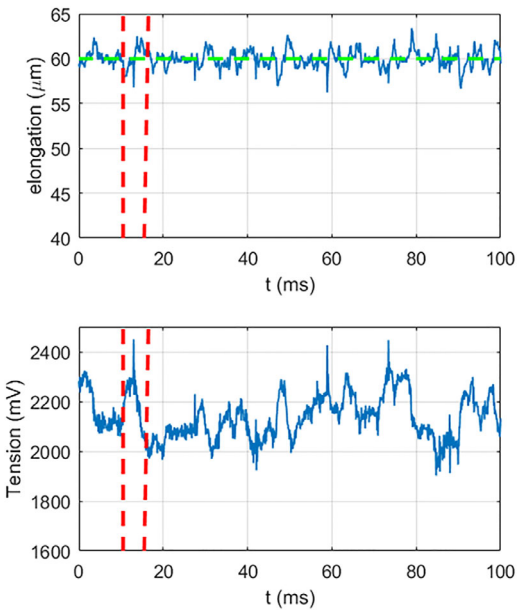

Figure 10. Detail of Figure 6 spanning 1 second. Feedback control is on, and the tip is engaging 6% agar fragments dispersed in BSS. The green dashed line shows nominal (requested) elongation of 60 µm, and the two vertical dashed red lines isolate one single event of fragment engagement. Elongation remains very stable just around the requested 60 µm (upper panel), and the event of fragment engagement is visible only in the lower panel, where tension is increased due to the feedback control mechanisms sensing the increase in resistance requiring more tension to keep elongation stable at the nominal value.

on average 20.96% less when active feedback control for elongation was switched on.

Discussion

The accuracy of phacoemulsification tip elongation retains great clinical importance, as inappropriate

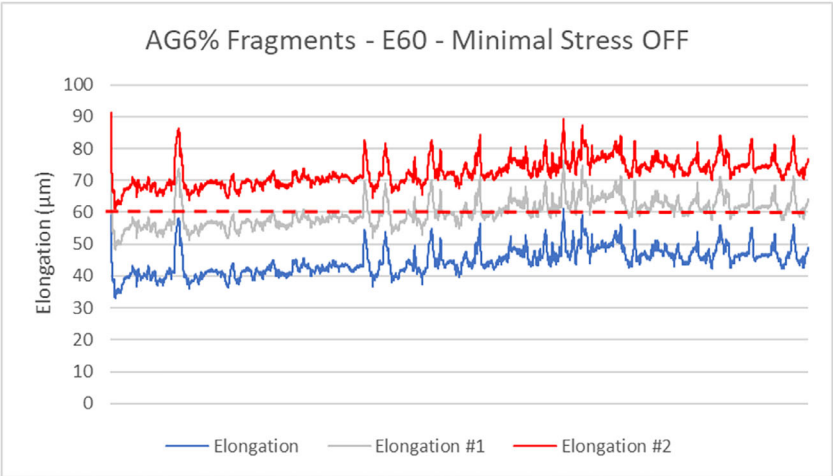

Figure 11. Actual tip elongation while removing 6% agar fragments dispersed in BSS with feedback control off (blue line). Nominal elongation is 60 µm. The average loss of elongation due to resistance is 15.30 µm, and the maximum loss is 27.92 µm. The gray curve (elongation 1) represents the actual elongation (blue curve) translated over the average loss (15.30 µm), and the red curve is the actual elongation (blue curve) translated over the maximum elongation loss (29.92 µm).

ultrasound dispersion in the anterior chamber results in iris inflammation, endothelial cell damage,[4] and corneal decompensation[5] that may eliminate the benefits of surgery and increase its risks.[6,7] Elongation accuracy improvement offered by feedback control was apparent in both sculpt and quadrant modes (Table 1). In no single case when the system was on did the elongation error reach 0.5%, regardless of agar gel density and requested elongation (Tables 2–4, Figs. 2, 4). The difference between feedback control being on or off was highly significant in all cases ($P < 0.001$).

Switching the feedback control off in sculpt mode yielded an elongation error of up to over 60% for 6% agar; the error was significantly higher at 35 µm versus 70 µm, possibly due to the lower tip energy. Results were similar in quadrant removal mode. Feedback control ensured elongation within less than 0.5% of the requested elongation (Table 3, Fig. 3); when it was turned off, the average measured mismatch (nominal – actual elongation) was around 15% but exceeded 60% with the highest agar percentage samples (6% agar) (Fig. 4). The reason for such a difference, surgically relevant well beyond statistical significance, lies in the intrinsic functioning of the continuous feedback which becomes apparent when the driving tension and elongation are plotted together (Figs. 5, 6; see Figs. 9 and 10 for 100-ms detail, respectively).

When aspirating agar 6% fragments dispersed in BSS, the phaco tip randomly engaged solid and liquid material offering different resistance. With feedback control off (Figs. 5, 9), the average elongation was greatly reduced (average elongation of 44.72 µm compared to nominal elongation of 60 µm) to peak when occlusion resolved and the tip moved freely in BSS (Table 4). Tension (orange line in Fig. 5 and lower panel in Fig. 9), on the other hand, remained unchanged at values predetermined in BSS during priming or by the producer.

When feedback control was activated (Figs. 6, 10), tip elongation stayed consistent around the desired (nominal) elongation of 60 µm (average elongation 60.02 µm; Table 4) due to the continuous tension variation (orange line in Fig. 6 and lower panel in Fig. 10). In the absence of a feedback control system, therefore, elongation reduced when necessary (during solid material fragmentation) and spiked unnecessarily in aqueous, when the use of US is useless and dangerous. Conversely, when feedback control was active (Fig. 10), elongation remained nearly constant due to real-time control. A sudden increase of the driving tension was observed when the tip came into contact with the solid fragment. Accuracy of the feedback control system was also confirmed by the much narrower dispersion of elongation data (mean squared error, 2.67 vs. 10.92; Table 4) reported in Figures 7 and 8 for feedback control off and on, respectively.

Consistent tip elongation is the key to unnecessary ultrasound dispersion. During surgery, the surgeon is completely unaware of actual tip elongation and can only rely on surgical efficiency (ability to break lens fragments) and therefore will increase elongation until the desired macroscopic effect is reached. The two likely scenarios occurring when the surgeon realizes that actual elongation has not reached the desired effect (nominal elongation) are depicted in Figure 11. The most obvious reaction is to compensate completely for the maximum gap elongation (Fig. 11, red curve) in order to break the harder lens fragments. This would

result in unnecessary dissipation of 16% more US when feedback control is off, with peaks of 90-µm elongation.

More cautiously, the surgeon could increase elongation based on the average decrease dictated by the agar (lens material) resistance. This way, the dissipated energy would equal that with feedback control on (AUC of gray line in Fig. 9 = 99.6% of AUC of blue line in Fig. 6), but effectiveness would be only one-half because 50% of the time the tip would not reach the desired elongation and harder fragments would not be broken. Accurate estimation of actual in vivo elongation is far from being a mere technicality; indeed, it is necessary to measure the energy delivered to tissues and to evaluate biological consequences properly. It is also important for classification purposes and for surgical series or machine comparison.[8,9]

Elapsed phaco time, absolute phaco time, and cumulative dissipated energy[10] are different measures of dissipated US energy accounting for duty cycle (pulsed, burst, or continuous) and power percentage. All such quantities relate to power expressed as a percentage of voltage corresponding to maximum tip elongation (in water!), which is neither disclosed nor fixed among different instruments.

Unless actual in vivo elongation is measured, all such quantities represent only a gross approximation of dissipated energy, as shown in Figure 5, where the same phaco machine power setting results in actual elongation between 33.1 and 63.2 µm. On the other hand, correlating weak dissipated energy data to clinical features such as lens opacity[11] can be misleading or scarcely significant. For this reason, it would be highly desirable for different phacoemulsification machines to declare tip actual or at least nominal elongation, as the absence of such information makes any comparison impossible.[8,11–15]

In summary, our data demonstrate that actual tip elongation may differ as much as 60% in the absence of a feedback control mechanism that could significantly improve tip elongation accuracy regardless of resistance. Tip elongation consistency improves efficiency by reducing US energy dispersion. The translational research potential of the study is intuitive, as incorporating feedback control in phaco machines would allow more accurate US delivery and less dispersion of energy in the anterior chamber, offering immediate, relevant clinical benefit.

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