New phacoemulsification technologies

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To examine recent developments in the field of phacoemulsification, a literature review was conducted for each system described. The review included peer-reviewed articles, information from manufacturers, and meeting presentations by surgeons. Our personal experience with systems we have used forms the underlying basis of our evaluation. Data for erbium:YAG laser phacoemulsification came from an interim summary of the U.S. Food and Drug Administration monitored study. Data for NeoSoniX came from a prospective evaluation of phacoemulsification in 25 eyes performed at the Oregon Eye Surgery Center. The development of new technology has allowed safer, more efficient phacoemulsification. Each surgeon should evaluate new developments to achieve the greatest possible benefit for patients.

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New technology brings challenges and opportunities to the anterior segment surgeon. The drive toward less traumatic surgery and more rapid visual rehabilitation after cataract surgery has spawned various modalities for reducing incision size and decreasing energy use.

Although ultrasonic phacoemulsification allows for relatively safe removal of cataractous lenses through astigmatically neutral small incisions, current technology has drawbacks. In ultrasonic phacoemulsification, piezoelectric crystals convert electrical energy into mechanical energy, which emulsifies the lens material by tip vibration. Ultrasonic tips create both heat and cavitational energy. A conventional phaco tip moves at ultrasonic frequencies between 25 KHz and 62 KHz. The amount of heat generated is directly proportional to the operating frequency. In addition, cavitational effects from the high-frequency ultrasonic waves generate even more heat.

Because of the liberation of heat, phacoemulsification needles have required an irrigation sleeve for cooling. This irrigation sleeve carries heat away from the tip and necessitates an incision larger than the tip alone would require. Nevertheless, standard ultrasonic phacoemulsification with an irrigation sleeve has the potential for thermal injury to the cornea in case of diminished flow. Flow and aspiration problems may be caused by compression of the irrigation sleeve at the incision site, kinking of the sleeve during manipulation of the handpiece, tip clogging by nuclear or viscoelastic material, and inadequate flow rate or vacuum settings.[1] Heating of the tip can create corneal incision burns.[2] When incision burns develop in clear corneal incisions, there may be a loss of self-sealability and corneal edema and severe induced astigmatism may result.[1]

Cavitational energy results from pressure waves emanating from the tip in all directions. Although increased cavitational energy can allow for phacoemulsification of dense nuclei, it can also damage the corneal endothelium and produce irreversible corneal edema in compromised corneas with preexisting endothelial dystrophies. Reduction in average phaco power and effec-

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tive phaco time has been correlated with improved patient outcomes after cataract surgery.[3] Low-power phaco technology will have an important advantage in minimizing intraoperative damage to ocular structures and maximizing the level and rapidity of the patient's visual rehabilitation.

The past decade has given rise to profound advances in phacoemulsification technique and technology. Techniques for cataract removal have moved from those that use mainly ultrasound energy to emulsify nuclear material for aspiration to those that use greater levels of vacuum and small quantities of energy for lens disassembly and removal. Advances in phacoemulsification technology and fluidics encouraged this ongoing change in technique by allowing for greater amounts of vacuum to be safely used. In addition, power modulations have allowed for more efficient use of ultrasound energy with greater safety in the delicate intraocular environment.[4]

Elimination of the frictional heat produced during ultrasound phacoemulsification and reduction of the power required for cataract extraction represent important steps toward the goal of atraumatic surgery. Laser technology, including the erbium:YAG (Er:YAG) (Phacolase, Zeiss-Meditec) and neodymium:YAG (Nd:YAG) such as photon phacolysis (Paradigm) and Dodick photolysis (ARC), offers 1 approach to the elimination of thermal energy and reduction of power during phacoemulsification. The sonic phacoemulsification system (Staar Wave, Staar Surgical) is another new approach to the elimination of heat and the danger of thermal injury to the cornea. Modification of ultrasound energy through refinement of power modulation offers yet another route leading to elimination of heat and reduction in incision size (WhiteStar, Allergan). The introduction of innovative oscillatory tip motion in coordination with power modulation permits further reduction of average phaco power and effective phaco time (NeoSoniX, Alcon). Other new modalities under investigation, which promise low-energy, nonthermal cataract extraction, include vortex phacoemulsification (Avantix, Bausch & Lomb) and Aqualase (Alcon), a fluid-based cataract extraction system.

Erbium:YAG Laser Phacoemulsification

Laser phacoemulsification represents an emerging technology in cataract surgery. Several potential advantages over ultrasound as a modality for cataract extraction have maintained interest in the laser. These advantages include a relative reduction in the energy requirement for cataract extraction and the absence of the potential for thermal injury to the cornea. However, investigation has demonstrated that the efficacy of the laser is limited to extraction of nuclear sclerosis of grades 0 to 3 and that phacoemulsification time with the laser, although dependent on the surgeon's level of experience, tends to be longer than with ultrasound.

The Er:YAG laser produces a wavelength of 2.94 μm, which lies in the infrared spectrum and is highly absorbed by water. In water, cavitation bubbles form and collapse instantaneously. However, the collapse of the bubbles occurs more slowly in the nuclear material of the lens. The laser beam can travel across the first bubble and form a second bubble in line with the first. If a third bubble forms, it increases the effective range of the laser to 3.0 mm. Direct concussive effects of the laser energy propagation wave disrupt the lens material, creating an emulsate that is aspirated from the eye.

As mentioned, a principle advantage of laser cataract extraction in general and of the Er:YAG system in particular is the absence of thermal energy. Because the tip of the Er:YAG laser system does not produce relevant heating effects, the risk of corneal burn is eliminated and the potential for reduced incision size is created.[5]

The Phacolase Er:YAG laser has variable pulse energy from 5 to 50 mJ as well as variable frequency from 10 to 100 Hz. In its present form, the Phacolase system is coupled to a Megatron irrigation/aspiration (I/A) pump (Geuder, Heidelberg). The Megatron has a peristaltic pump with venturi-like effect. The Phacolase handpiece incorporates the laser fiber inside the aspiration port. A bidirectional foot switch is used that separates infusion and aspiration from laser energy. Moving the foot pedal laterally increases the repetition rate in a linear fashion. Pushing the pedal down provides linear control of vacuum.

One method of nuclear disassembly with the Phacolase involves prechopping the nucleus with a device developed by Takayuki Akahoshi, MD. This prechopper can be used to segment the nucleus before phacoemulsification with the Phacolase. For denser grades of nuclei, prechopping reduces the total operating time. Further evolution of the technique will likely emphasize separation of irrigation from aspiration and laser in the

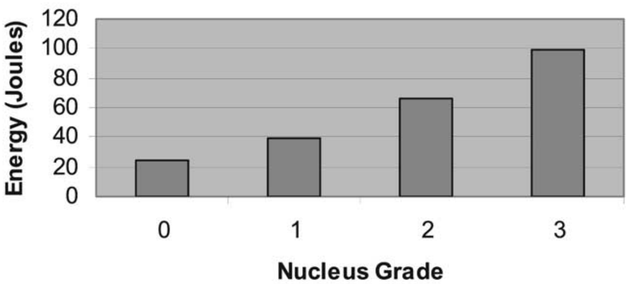

Figure 1. (Fine) Mean Er:YAG energy in joules by nucleus grade.

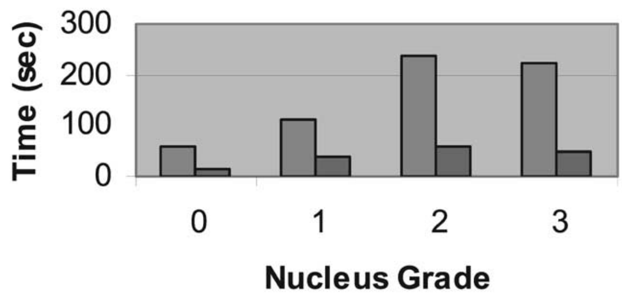

Figure 2. (Fine) Time required for Er:YAG phacoemulsification as compared to ultrasound phacoemulsification by nucleus grade (light bars = Phacolase; dark bars = ultrasound).

development of a bimanual technique. Because of the absence of risk from thermal injury, the incision size may effectively be reduced to 1.0 mm. However, at present, all systems are limited by the incision sizes necessary for intraocular lens (IOL) implantation.

Phase III U.S. Food and Drug Administration (FDA) clinical trials are currently ongoing in the United States. Preliminary data from the multicenter randomized comparison of Er:YAG and ultrasound phacoemulsification were reported at a 2001 meeting (M. Packer, MD, "Safety and Efficacy of the Erbium Yttrium Aluminum Garnet (Er:YAG) Laser for Cataract Extraction," presented at the XIX Congress of the European Society of Cataract & Refractive Surgeons, Amsterdam, The Netherlands, September 2001).

At the time of this writing, 101 eyes of 72 patients have been enrolled in the study at 7 treatment centers, with 78 eyes randomized to laser phacoemulsification. Intraoperative performance parameters revealed mean energy requirements ranging from 24.7 J for extraction of grade 0 nuclei to 99.1 J for extraction of grade 3 nuclei (Figure 1). The mean laser phacoemulsification time varied from 56.1 seconds for grade 0 to 222.5 seconds for grade 3 nuclei (Figure 2).

In summary, Er:YAG laser phacoemulsification represents an emerging technology with several promising attributes. These include the reduction of energy required for phacoemulsification, absence of risk for thermal injury, and potential reduction of incision size.

Neodymium:YAG Laser Phacoemulsification

Dodick Photolysis

Dodick[6] introduced the pulsed Q-switched Nd:YAG laser in 1991. The FDA has approved the laser for cataract extraction. This 1064 nm Nd:YAG laser system uses plasma formation and shock-wave generation to produce photolysis of lens material. The shock wave results from the impact of laser radiation on a titanium plate. Alzner and Grabner[7] have shown that there is no heat production at the laser tip. As with the other nonthermal modalities discussed here, the Nd:YAG laser does not require a cooling sleeve and therefore permits cataract extraction through a 1.25 mm incision (Figure 3).

In the Dodick system, laser light does not emerge from the tip. Rather, the shock waves are produced by a titanium block within the tip. Therefore, the eye is not directly exposed to laser energy.

Neodymium:YAG photolysis represents a low-energy modality for cataract extraction. Kanellopoulos[8] reports a mean intraocular energy use of 5.65 J per case. This level of energy compares favorably with values previously reported for ultrasound phacoemulsification and approximates the level of energy reported for the choo-

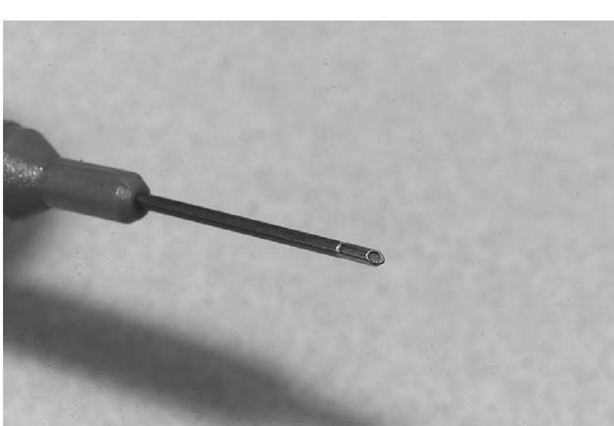

Figure 3. (Fine) The Dodick photolysis laser tip.

choo chop and flip phacoemulsification technique using power modulations.[4]

Surgeons usually use a groove-and-crack technique with the laser, sculpting in a bimanual fashion and cracking as soon as possible. Alternatively, a prechopping technique may be used as described by Wehner (W. Wehner, MD, "Enhancing the Dodick Laser Photolysis with the Wehner Spoon," presented at the XIXth Congress of the European Society of Cataract & Refractive Surgeons, Amsterdam, The Netherlands, September 2001). Residual fragments are then removed by laser emulsification. The total time the tip is in the eye varies with the grade of the nucleus, from 2.15 minutes for 1+ nuclear sclerosis to 9.8 minutes for 3+ nuclear sclerosis.

The absence of thermal energy and the consequent ability to extract a cataract through an incision smaller than 2.0 mm await the development of IOLs capable of insertion through smaller incisions to achieve a real advantage.

Photon Laser Phacolysis

The photon laser phacolysis system by Paradigm Medical uses a 1064 nm Nd:YAG laser to produce photoacoustic ablation of cataract material under aspiration. The ski-shaped distal tip of the probe curves up to provide the laser light emitted from the optical fiber (Figure 4). The aspiration inlet is placed in the face of the tip, creating a photon trap. Thus, all rays of laser photons that enter the aspiration port are internally reflected and kept within the probe tip. Although some minimal heating of tissue occurs, the heat is rapidly removed by aspiration and the temperature of the probe tip only rises by about 1°C.

Figure 4. (Fine) The Paradigm photon phacolysis ski-shaped distal tip.

The peak intensity of the photon system is more than 10 000 times below that required for the onset of plasma generation, the operative action during posterior capsulotomy. Therefore, phacolysis represents an exceptionally safe modality in terms of capsule integrity. In the wet lab using pig eyes, one can actually place the anterior lens capsule directly in the line of the laser beam and fire repeatedly without causing discernible damage to the capsule.

A pilot study with the Paradigm phacolysis system has shown promising results, and a clinical study protocol is now underway in the U.S. The laser is coupled to the Mentor SIStem peristaltic I/A pump. The study is restricted to the softer grades of nuclear sclerosis, for which this technology is most advantageous.

Sonic Phacoemulsification

Sonic technology offers an innovative means of removing cataractous material without the generation of heat or cavitational energy by using sonic rather than ultrasonic technology. Its operating frequency is in the sonic rather than the ultrasonic range, between 40 Hz and 400 Hz. In contrast to ultrasonic tip motion, the sonic tip moves back and forth without changing its dimensional length. The tip of an ultrasonic handpiece can exceed 500°C, while the tip of the Staar Wave handpiece in sonic mode barely generates any frictional heat. In addition, the sonic tip does not generate cavitational effects. Thus, fragmentation, rather than emulsification or vaporization, of material takes place.

The same handpiece and tip can be used for both sonic and ultrasonic modes. The surgeon can alternate between the 2 modes using a toggle switch on the foot pedal when more or less energy is required. The modes can also be used simultaneously with varying percentages of both sonic and ultrasonic energy. We found that we can use the same chopping cataract extraction technique in sonic mode as we use in ultrasonic mode with no discernible difference in efficiency.

The Staar Wave also allows improved stability of the anterior chamber with coiled SuperVac tubing, which increases vacuum capability up to 650 mm Hg (Figure 5). The key to chamber maintenance is a positive fluid balance between infusion flow and aspiration flow. When occlusion is broken, vacuum previously built in the aspiration line generates a high aspiration flow that

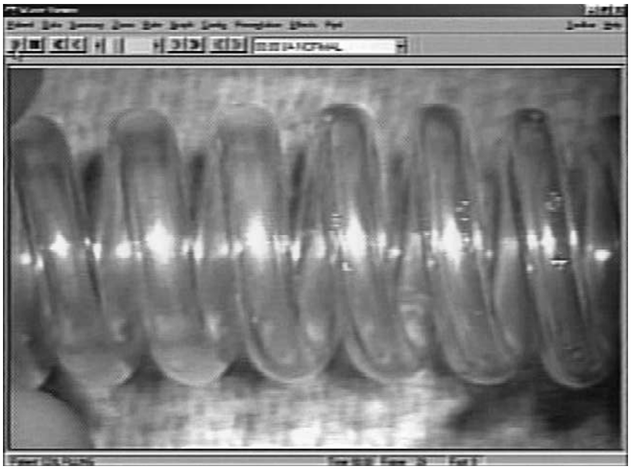

Figure 5. (Fine) Coiled SuperVac tubing available with the Staar Wave system.

can be higher than the infusion flow. This results in anterior chamber instability. The coiled SuperVac tubing limits surge flow resulting from occlusion breakage in a dynamic way. The continuous change in direction of flow through the coiled tubing increases resistance through the tubing at high flow rates such as on clearance of occlusion of the tip (Figures 6 and 7). This effect only takes place at high flow rates (greater than 50 cc/min). The fluid resistance of the SuperVac tubing increases as a function of flow, and unoccluded flow is not restricted (Alex Urich, Staar Surgical, personal communication, March 2002).[9]

The Staar Wave combines important innovations in phacoemulsification technology that satisfy the demands of nonthermal, low-power cataract extraction.

NeoSoniX Phacoemulsification

NeoSoniX technology represents a hybrid modality involving low-frequency oscillatory movement that may be used alone or in combination with standard high-frequency ultrasonic phacoemulsification (Figure 8). Softer grades of nuclear sclerosis may be completely addressed with the low-frequency modality, while denser grades will likely require the addition of ultrasound.

In the NeoSoniX mode, the phaco tip has a variable rotational oscillation up to 2 degrees at 120 Hz. As with sonic phacoemulsification, this lower frequency does not produce significant thermal energy and thus minimizes the risk of thermal injury.

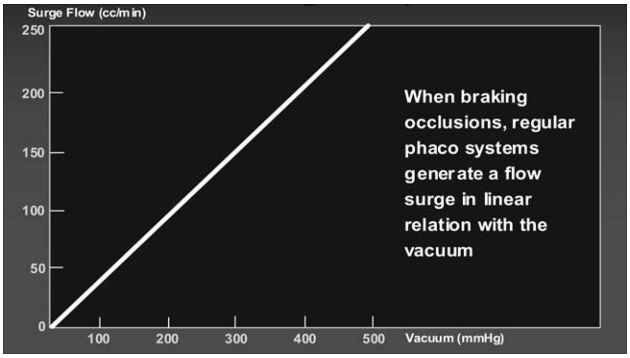

Figure 6. (Fine) Surge flow versus vacuum for regular tubing.

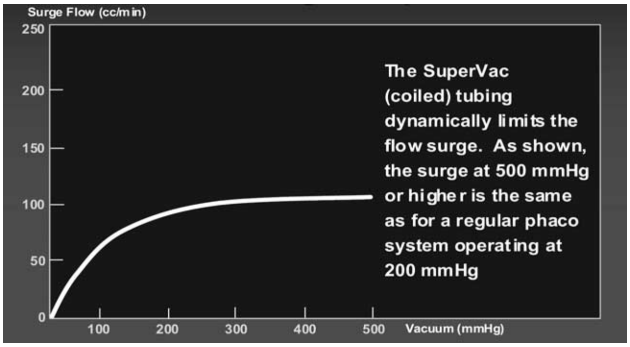

Figure 7. (Fine) Surge flow versus vacuum for coiled tubing.

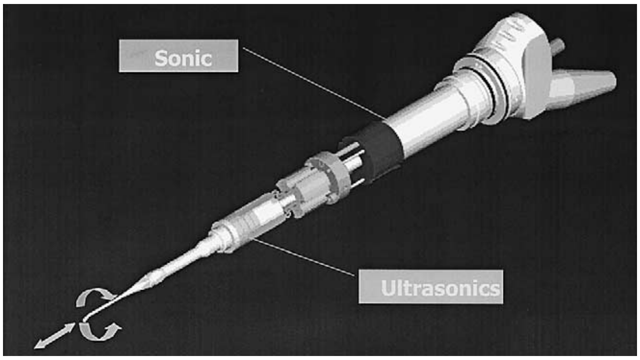

Figure 8. (Fine) Schematic diagram of NeoSoniX handpiece.

The Legacy system may be programmed to initiate NeoSoniX at any desired level of ultrasound energy. Thus, the surgeon may use the low-frequency mode to burrow into the nucleus for stabilization before chopping by setting the lower limit of NeoSoniX to 0% phaco power. This approach works best with a straight tip, which acts like an apple corer to impale the nucleus. Alternatively, NeoSoniX may be initiated as an adjunct to ultrasound at the 10% or 20% power level.

We have found NeoSoniX most efficacious at 50% amplitude with a horizontal chopping technique in the AdvanTec burst mode at 50% power, 45 mL/min linear flow, and 450 mm Hg vacuum. A 0.9 mm microflare straight ABS tip rapidly impales and holds nuclear material for chopping. During evacuation of nuclear segments, the material flows easily into the tip with little tendency for chatter and scatter of nuclear fragments. With refinement of our parameters, we have found a 57% reduction in average phaco power and an 87% reduction in effective phaco time compared with data we previously published on the Legacy system.[4]

NeoSoniX has permitted further reduction in the application of ultrasonic energy to the eye when used in conjunction with ultrasound and allowed nonthermal cataract extraction when used alone. It represents an important new modality in phacoemulsification technology.

WhiteStar Technology

WhiteStar represents a new power modulation within ultrasonic phacoemulsification that virtually eliminates the production of thermal energy. Analogous to the ultrapulse mode familiar to users of carbon dioxide lasers, WhiteStar extrapolates pulse-mode phacoemulsification to its logical limit. As the duration of the energy pulse is reduced, it eventually becomes less than the thermal relaxation time of ocular tissue. Thus, it is theoretically impossible to produce a corneal wound burn.

WhiteStar technology sets the stage for bimanual cataract extraction with the Sovereign phacoemulsification machine (Allergan). The absence of thermal energy obviates the need for an irrigation sleeve on the phaco tip, permitting a reduction in incision size and allowing irrigation through a second instrument, such as an irrigating chopper, placed through the side port. With an incision for cataract extraction smaller than 1.0 mm, the challenge becomes production of IOLs capable of insertion through such microphaco incisions.

Olson, Soscia, and Packard reported exciting results using a 21-gauge irrigating chopper and a 21-gauge bare phaco needle with the bimanual technique (R.J. Olson, MD, W.L. Soscia, MD, "Safety and Efficacy of Bimanual Phaco Chop Through Two Stab Incisions with the Sovereign," and R. Packard, MD, "Evaluation of a New Approach to Phacoemulsification: Bimanual Phaco with the Sovereign System Rapid Pulse Software, both presented at the XIII Congress of the European Society of Ophthalmology, Istanbul, Turkey, June 2001). Olson and Soscia's study of cadaver eyes demonstrated that thermal injury does not occur even in the absence of aspiration with 100% power for 3 minutes. Packard reported an absence of wound burns with excellent surgical ease and efficiency via sub-2.0 mm incisions.

WhiteStar technology demonstrates important advantages in improved safety and efficiency of cataract extraction, whether used in standard fashion or with the microphaco technique.

Advantix

Vortex phacoemulsification involves placement of a tiny rotary impeller inside the capsular bag through a 1.0 mm capsulorhexis. The impeller rotates at 60 kHz and causes expansion of the capsular bag with rotation of the nuclear complex, allowing extraction of the cataract from a nearly intact lens capsule. Expansion of the capsular bag minimizes the risk of capsule rupture.

The tiny circular capsulorhexis is constructed with a round diathermy instrument, reducing the technical demands of such a surgical feat. The I/A tube containing the rotary impeller is placed over the capsulorhexis while hydrodissection is performed with gentle irrigation. The tube is then inserted in the capsular bag through the 1.0 mm capsulorhexis before rotation is initiated, completely isolating the anterior chamber from the activity of cataract extraction. Nuclear material is effectively removed from the capsular bag with vortex action, after which cortex is actually stripped away and extracted.

The advantages of leaving nearly the entire capsular bag in situ after cataract extraction will not be realized until an injectable artificial crystalline lens becomes available and the problem of capsule opacification is eliminated. Nishi and Nishi[10] as well as others are currently investigating these devices and may soon have a prototype available.

Aqualase

The Aqualase is a fluid-based cataract extraction system. Another nonthermal modality, Aqualase uses pulses of a balanced salt solution at 50 to 100 Hz to dissolve the cataract. This modality may demonstrate advantages in terms of safety and prevention of secondary posterior capsule opacification. Still early in its development, Aqualase represents an innovative and potentially advantageous modality for cataract extraction.

Conclusion

Since the time of Dr. Charles Kelman's inspiration in the dentist's chair (while having his teeth ultrasonically cleaned), incremental advances in phacoemulsification technology have produced ever-increasing benefits for patients with cataract. The modern procedure simply was not possible even a few years ago, and until recently prolonged hospital stays were common after cataract surgery.

The competitive business environment and the wellspring of human ingenuity continue to demonstrate synergistic activity in the improvement of surgical technique and technology. Future advances in cataract surgery will continue to benefit our patients as we develop new phacoemulsification technology.

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