ABSTRACT

The Fugo Blade™ is a battery-powered electrosurgical device to perform anterior capsulotomy for cataract surgery, employing an incising filament as thick as a human hair. With this US Food and Drug Administration-approved unit, surgeons can perform anterior capsulotomy without the need of viscoelastic or a red reflex, as well as enlarge the anterior capsulotomy with radial or arcuate incisions into the capsulotomy margin. Multi-mini-sphincterotomies for small pupils and iridotomies are off-label uses.

ORIGINAL ARTICLE

The Fugo Blade™: The Next Step After Capsulorhexis

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Over the last 30 years, great advancements have been seen in the field of cataract surgery. Many of the senior ophthalmic surgeons of today have seen their cataract procedures change from intracapsular cataract surgery to planned extracapsular cataract surgery and most recently phacoemulsification cataract surgery. Phacoemulsification itself has changed dramatically with the introduction of technology such as viscoelastic solution and small sutureless incisions with foldable implants. These changes have improved the safety of surgery as well as the capability of the surgeon. Nonetheless, there has been a slowing of significant innovation over the last several years, possibly related to major cutbacks in reimbursement for cataract surgery and funds available to perform research in our field.

Capsulorhexis versus Bipolar Radiofrequency (RF) Capsulotomy

Early phacoemulsification and extracapsular cataract extraction employed "Christmas tree" or "can-opener" style capsulotomies. Over the last decade, this approach has largely been supplanted by another technique know as capsulorhexis capsulotomy. The word *capsulorhexis* is derived from the Greek word meaning "a tearing." This technique employs a perforation of capsule followed by a maneuver to tear a circular or quasi-circular hole in the anterior capsule.[1] The force vectors of a capsulorhexis tear are unpredictable, often making the procedure difficult, and capsulorhexis too frequently results in catastrophic surgical complications.[2-4]

Reprints:

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Both authors have a financial interest in this product.

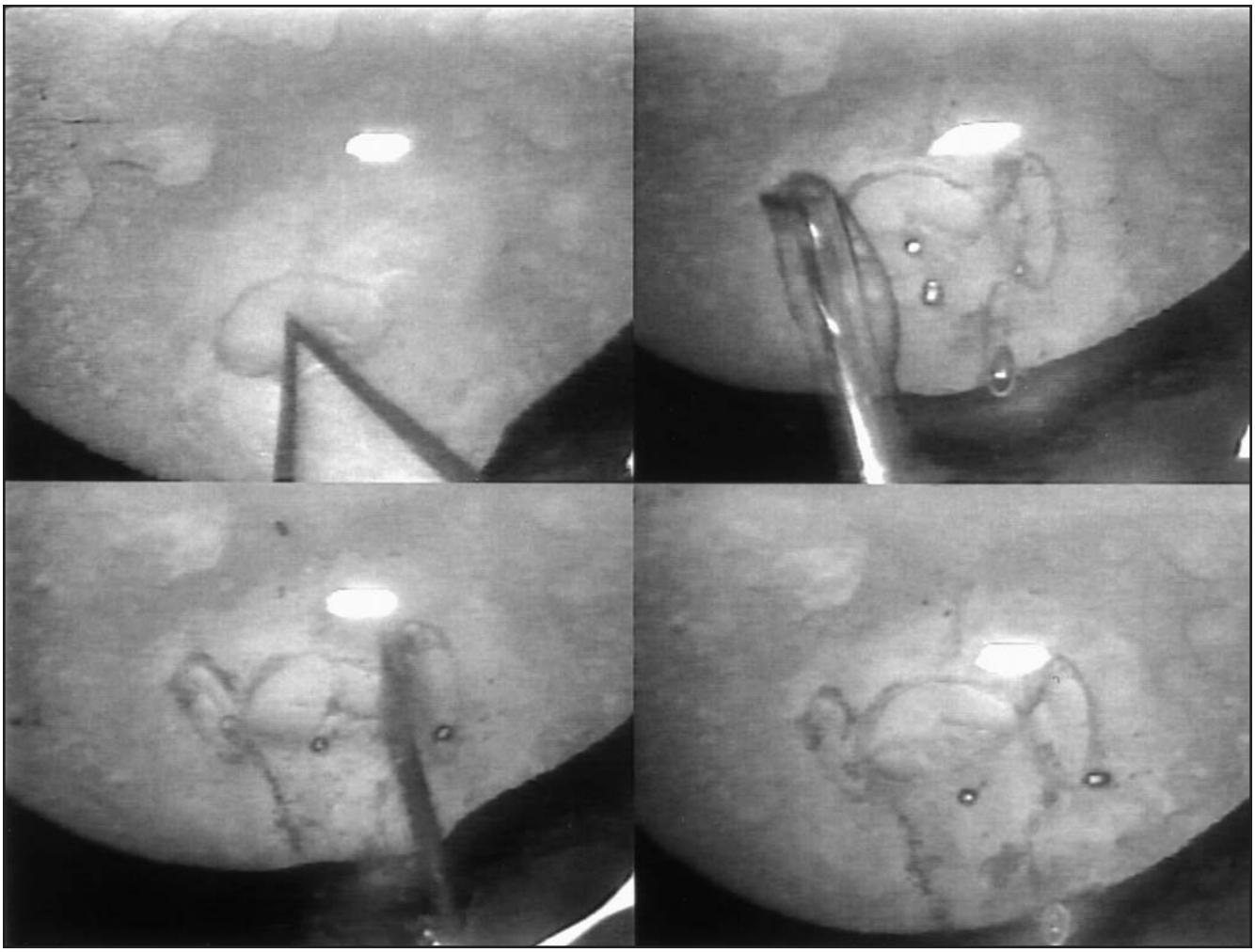

Fig 1.—Repairing a tear in lens capsule with the Fugo Blade™ capsulotomy device. **Upper left:** A keratome has just cut an oval tear in the capsule. **Upper right:** An incision has just been made with the Fugo Blade™ in capsule perpendicular to the right side of the original keratome tear, and the Fugo Blade™ probe is about to put a similar incision on the left side of the keratome tear. **Lower left:** A 30-gauge needle is placed through the original keratome capsule tear and is used to pull on the thin band of capsule between keratome tear and the Fugo Blade™ incision on the right side. **Lower right:** The keratome hole in capsule tears up to but stops at the Fugo Blade™ margin.

Bipolar diathermy capsulotomies, although not approved for marketing in the United States, are employed by a substantial percentage of surgeons throughout the world.[5] Oertli of Switzerland has been the most prominent manufacturer of bipolar diathermy radiofrequency (RF) capsulotomy units. This unit employs standard bipolar diathermy. It produces sufficient electrical current to pass through the tip to cause a dielectric hysteresis, creating a heating of capsule sufficient to burn a path through the capsule. In effect, these units use the biologic tissue of the capsule as a bioelectric resistor, which restricts passage of the electrons through capsule material, thereby generating heat. The problem with these bipolar units is that they cut in an inefficient fashion and often have their cutting tips stick to the capsule surface. This problem is an innate limitation of a standard bipolar approach to electrosurgical capsulotomy. Therefore, these bipolar cutting tips must be used in a very specific manner, namely, that they are moved in a slow fashion and at a constant velocity.[6] They also require viscoelastic solution as a conductor path for

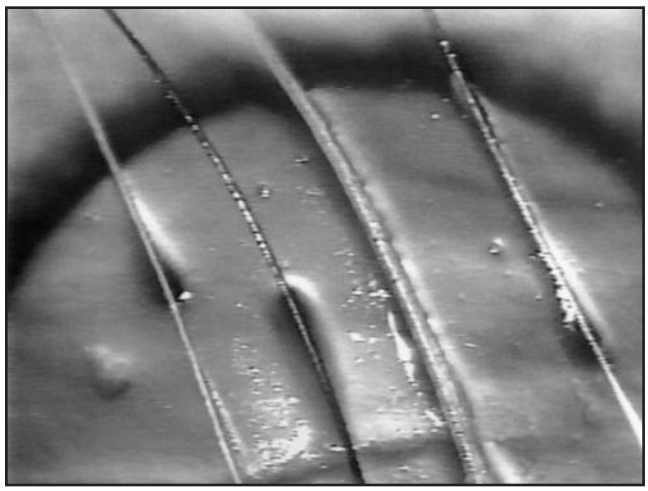

Fig 2.—Four strands, visualized through an operating room microscope, lie across a cornea, with the pupil margin seen superiorly. The 2 strands on the left are human hairs. The third strand from the left is a pig hair. The strand on the far right is the Fugo Blade™ incising filament.

Fig 3.—When the Fugo Blade™ incising tip is activated, one may visualize the RF energy field around the tip with an optically modified operating room microscope (left). When one filters spurious light from around the activated tip, it is evident that the energy field is closely compressed next to the incising filament (right).

Fig 4.—When one filters light to visualize the incising filament itself, the cutting filament itself remains dark while there is a glow around it, as seen under ultrahigh magnification. This demonstrates a lack of blackbody glow from the tip, indicating that the tip remains cool (left). The amount of energy visualized around the cutting tip appears substantial, yet small rechargeable batteries in the unit console can power this unit for a total cutting time of about 1 hour (right).

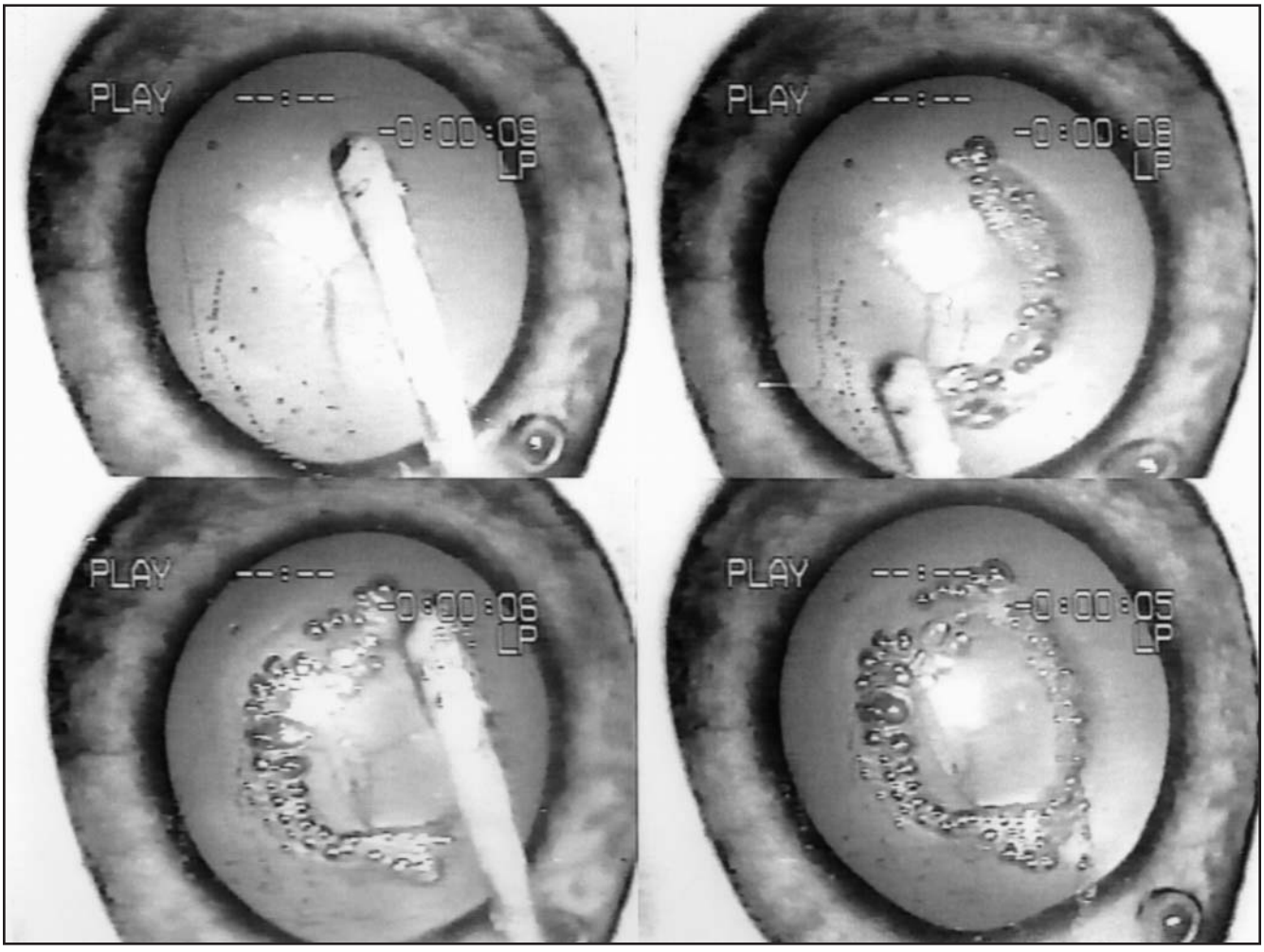

Fig 5.—A 3-second Fugo Blade™ capsulotomy. **Upper left:** The capsulotomy begins at –09 seconds on the counter. **Upper right:** Half of the capsulotomy is performed after 1 second (ie, –08 seconds on the counter). **Lower left:** The second half of the capsulotomy is performed in 2 seconds (–06 seconds on the counter). **Lower right:** A completed Fugo Blade™ capsulotomy.

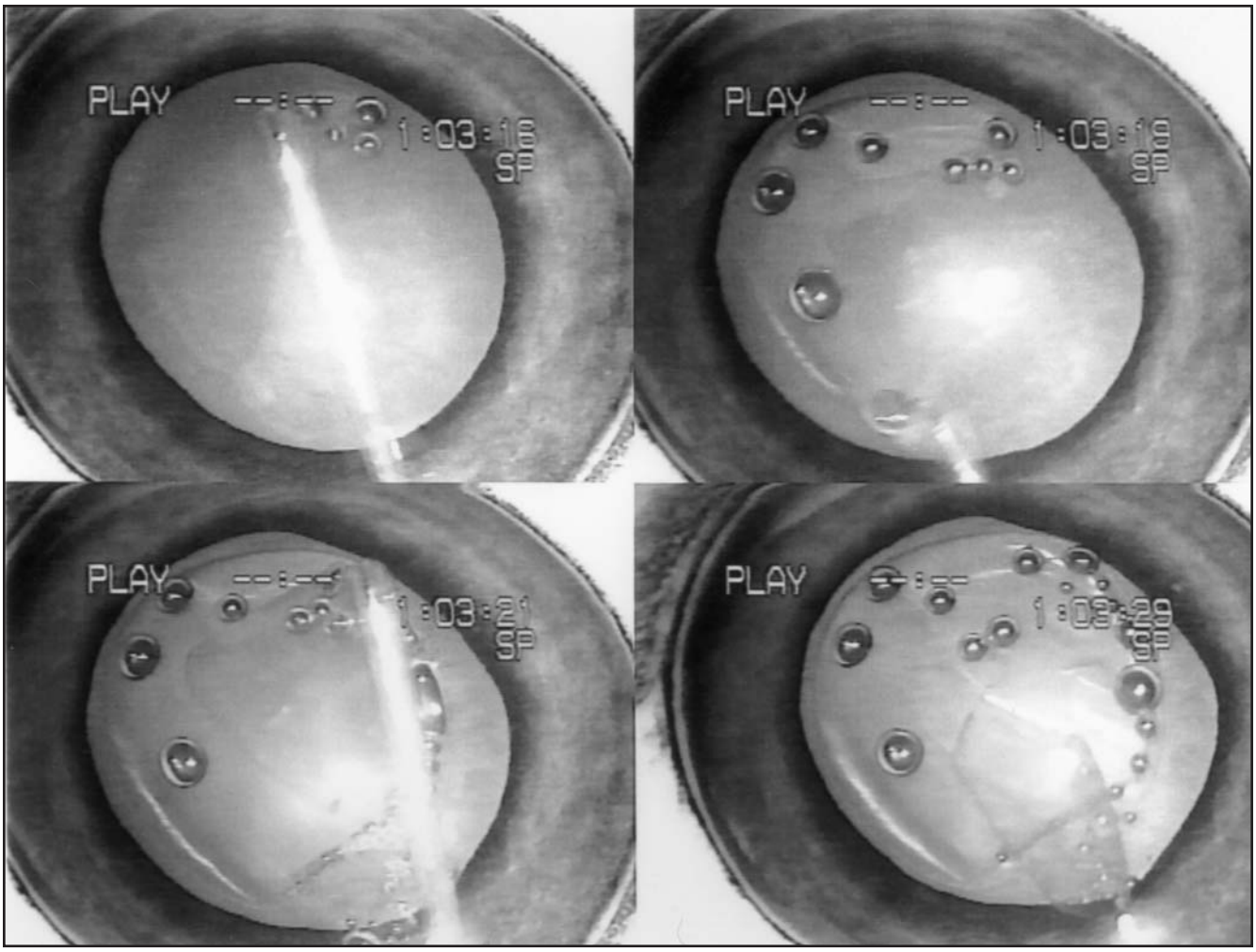

Fig 6.—Fugo Blade™ capsulotomy. **Upper left:** The capsulotomy begins at 16 seconds on the video timer. **Upper right:** In a counterclockwise motion, the left half of the capsulotomy is completed in 3 seconds (19 seconds noted on the timer). **Lower left:** The capsulotomy is completed in a total of 5 seconds (21 seconds on the video timer). **Lower right:** The completed Fugo Blade™ capsulotomy.

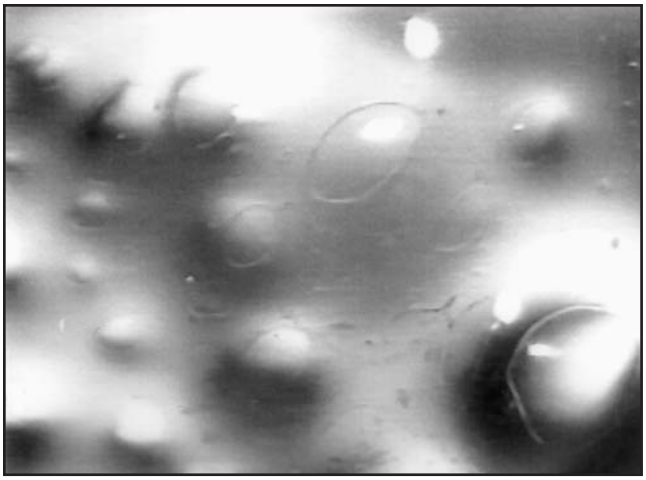

Fig 7.—Under very high microscopic magnification, holes about 100 µm (average diameter) are seen in the posterior capsule. These were created by momentarily touching the activated Fugo Blade™ tip against the posterior capsule. Note in the lower right hole in the capsule, vitreous is slightly bulging through the hole but cannot pass through it because the hole aperture is too small. Also, these small capsule openings made with the Fugo Blade™ will not spontaneously continue to tear.

electrons to pass from one of the bipolar tips to the second bipolar electrode.

Although bipolar RF capsulotomy offers distinct advantages, capsulorhexis produces the strongest capsular rim of any technique employed today. The reason and physiologic basis of the strength of the capsule is controversial, and the data presented in the literature to date are contradictory. Authors have indicated that capsulorhexis provides full capsular strength, whereas bipolar radiosurgical capsulotomy produces a decrease in strength in the capsule rim. Nonetheless, the data that are used to support these contentions are even contradictory between authors, and histologic techniques employed are highly susceptible to artifact.[7-9]

Histologic Studies on Anterior Capsulotomy Rims

The histologic studies of our research group do not agree with classically accepted articles in the field. It is our belief that much of what has been presented in the past is heavily weighed with specimen artifact. Techniques are available, however, which minimize

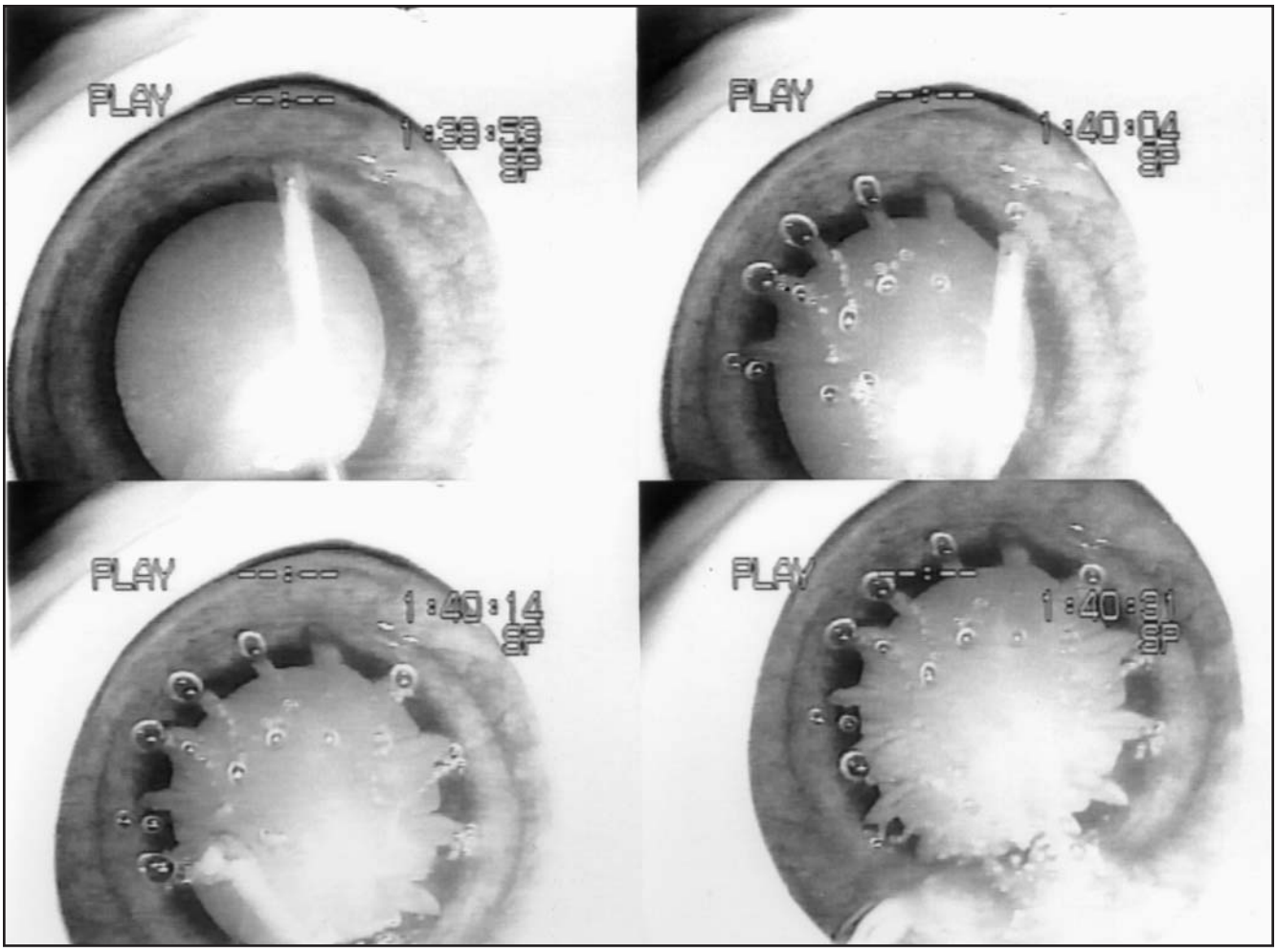

Fig 8.—Multi-mini-sphincterotomies (MMS) are used to enlarge the pupil diameter. This can be performed with vitrectomy scissors but requires costly equipment and requires significant time. A Fugo Blade™ MMS is an off-label use, as it would be for an iridotomy. **Upper left:** Beginning of a Fugo Blade™ MMS. **Upper right:** After 11 seconds, 6 sphincterotomy incisions have been made. **Lower left:** Progress with the MMS procedure after 21 seconds of surgical time. **Lower right:** Completed MMS procedure, which required about 30 seconds. We are now ready to infuse viscoelastic solution into the anterior chamber to further dilate the pupil. Note that the effect would be more dramatic with a smaller pupil diameter.

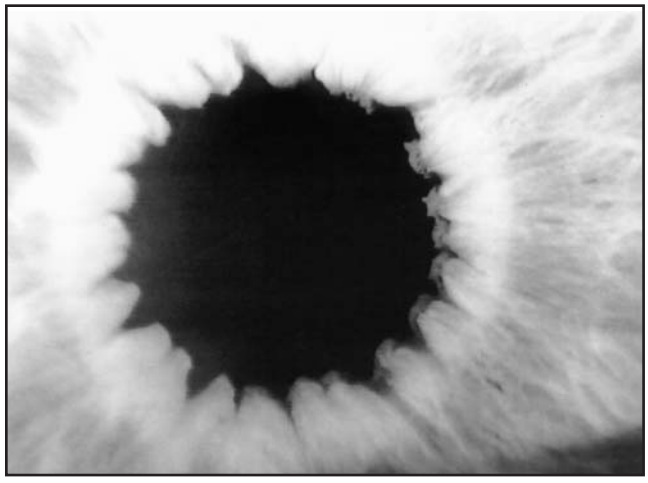

Fig 9.—When multi-mini-sphincterotomies (MMS) are performed properly, they produce excellent visualization during surgery as well as superb cosmetic appearance postoperatively. This is a slit-lamp high-magnification view of a MMS several weeks postoperatively.

the issue of artifact from data collection of anterior capsule histologic specimens.

Fugo Blade™ Capsulotomy

The Fugo Blade™ capsulotomy device is produced by Medisurg Research and Management Corporation, Norristown, Pennsylvania, USA. The unit is housed in a 10 × 8 × 6-inch electronic console. The device has a high-tech solid-state design and is powered by internally housed rechargeable batteries. The unit also comes with an activation foot switch, an electromagnetic shielded handpiece, and a recharger unit for the rechargeable batteries. The unit can operate only from the power of the internal rechargeable batteries since switching the console button to the ON position will simultaneously disconnect the unit from the wall charger/transformer power. This feature provides ultimate patient safety.

The electronic console has 2 settings to control cutting characteristics: cutting intensity and cutting power. Cutting power includes 3 levels: low, medium,

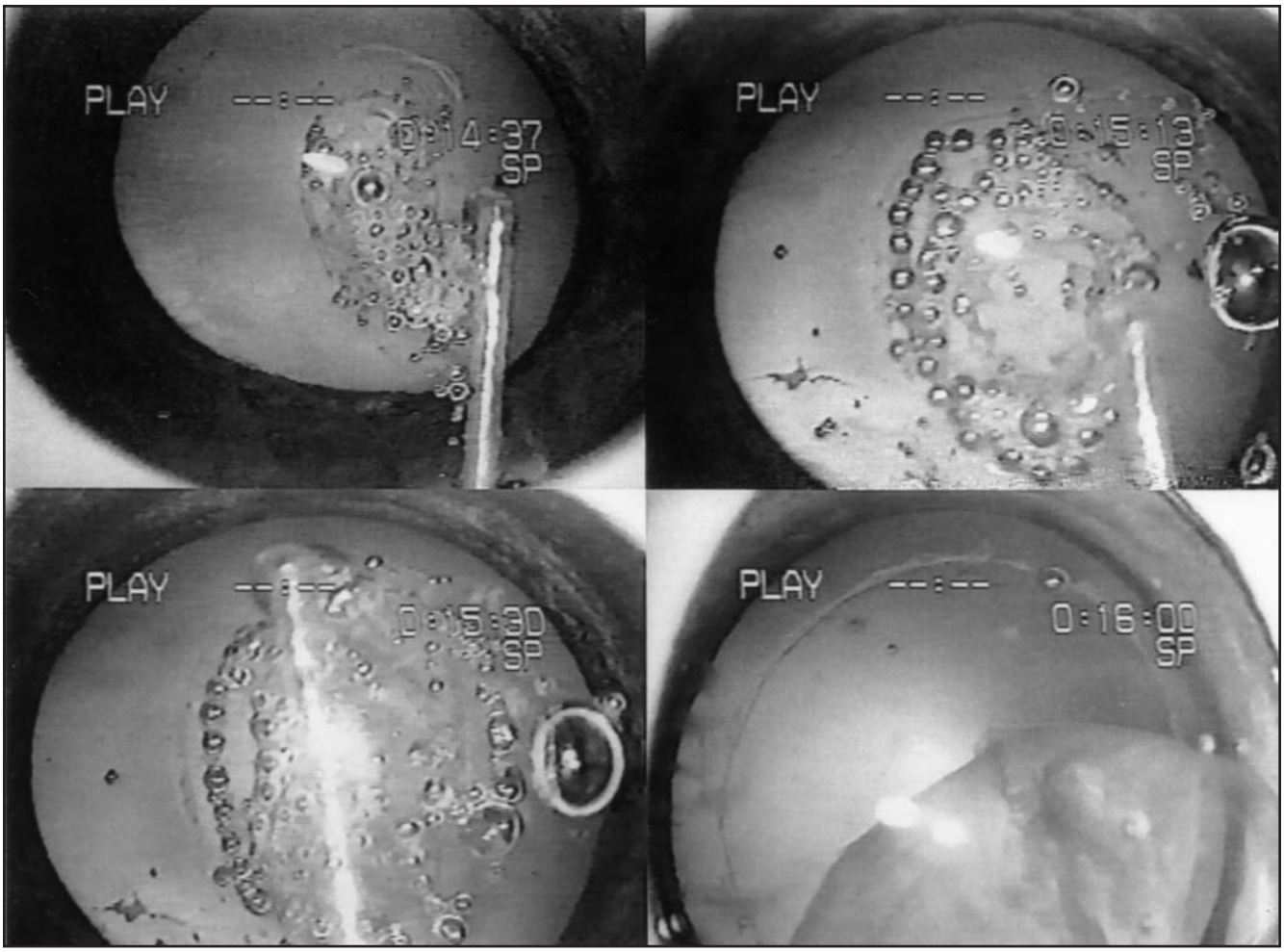

Fig 10.—To demonstrate the cutting efficiency of the Fugo Blade™, one may place several capsulotomies around each other. **Upper left:** A small central capsulotomy is created. **Upper right:** A second capsulotomy is created around the first capsulotomy. **Lower left:** A third capsulotomy is being created in a counterclockwise fashion around the second capsulotomy. **Lower right:** The third capsulotomy rim is seen after partial evacuation of corticonuclear material, with a small amount of residual cortex noted inferiorly.

and high. The cutting intensity is controlled with a vernier control knob, which rates the cutting intensity from 1 through 10. Any combination of cutting power may be used with any level of cutting intensity; therefore, the number of combinations is quite extensive since the cutting intensity has a linear control. Surgeons will find that different combinations of these 2 console factors will provide variations in cutting characteristics. It has been our experience that surgeons tend to prefer a combination of these 2 characteristics. For example, one surgeon may prefer medium power with a cutting intensity of 5. This surgeon preference will emulate the surgeon preference now seen in phacoemulsification. For example, surgeons prefer various combinations of phaco aspiration and phaco vacuum settings.

The cutting handpiece is an ergonomically designed handpiece the size of a large pencil. The distal end of the autoclavable handpiece possesses a nonpolar electrical connector into which one inserts a disposable cutting tip. It is imperative that this cutting tip be used in 1 procedure only. The unit handpiece with the disposable cutting tip should be kept on the surgical field until the end of the case in the event that a rent is created inadvertently in the capsule and the surgeon wishes to employ the unit to perform a Fugo Blade™ repair of a capsular tear (Fig 1). Nonetheless, at the end of each case, this tip must be replaced in order to provide maximum cutting efficiency. Many of the same reasons apply for single use of the Fugo Blade™ disposable tip as are seen with such devices as the phacoemulsification unit tip. To ensure that the tips are not reused, the electrical connector in the disposable tip contains an electrical pin connector that is heat sensitive and which has an operational temperature below that of standard autoclave or flash autoclave.

The disposable cutting tip contains a cutting filament at its very distal portion, which has the thickness approximately equivalent to a human hair (Fig 2). When the unit is activated by depressing the surgeon's foot switch, the electrical energy of the rechargeable batteries is processed through the solid-state electronics inside the unit console and is passed down the cable of the handpiece and through the handpiece. This energy is concentrated at the cutting filament tip.

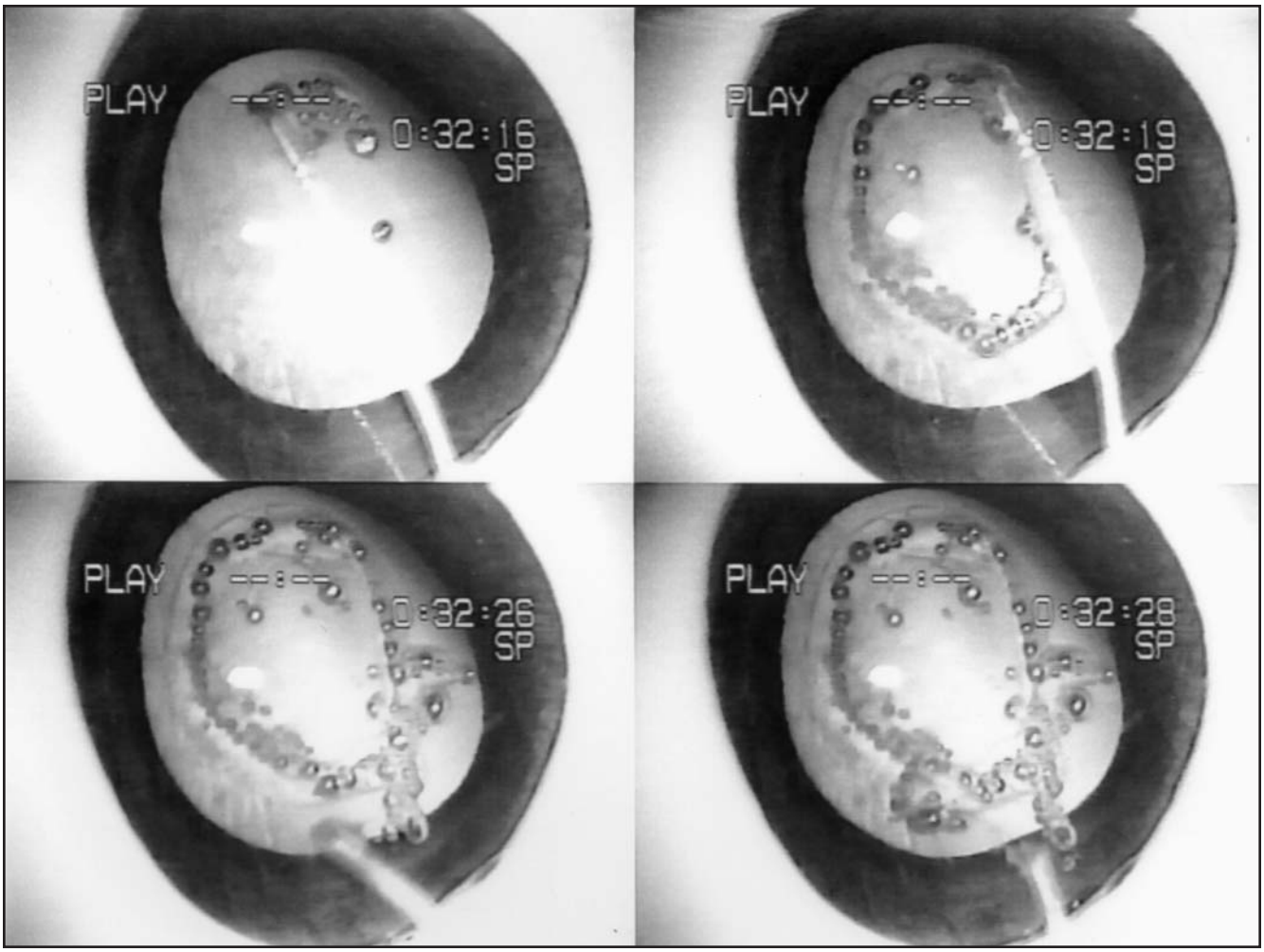

Fig 11.—A Fugo Blade™ capsulotomy is created in 3 seconds, followed by radial incisions to enlarge the capsulotomy. **Top left:** the capsulotomy begins at 16 seconds on the counter. **Top right:** The capsulotomy is completed at 19 seconds on the counter. **Bottom left:** To enlarge the capsulotomy, radial incisions are placed at the 4-o'clock and 5-o'clock positions along the capsulotomy margin. **Bottom right:** To further enlarge the capsulotomy, another radial incision is placed at the 7-o'clock position along the capsulotomy margin. Infusion of viscoelastic solution into the anterior chamber would now create a significant enlargement of the capsulotomy diameter.

The output power at the cutting tip is variable from 1.25 to 3.50 W of average output power. The operation frequency is higher than in most electrosurgical units. This signal, however, is highly modulated in order to present efficient energy transfer at the cutting tip, thereby producing efficient incision into capsule. The efficiency of RF energy transfer at the cutting tip allows one to visualize the energy field around the hair-thin cutting filament under filtered, high-magnification visualization (Figs 3 and 4). We refer to this visible energy field as a resonant energy maze.

The cutting capability of the Fugo Blade™ capsulotomy unit is quite precise and efficient. The unit is approved in the United States for anterior capsulotomy only (Figs 5 and 6). By momentarily and gently touching the Fugo Blade™ incising tip against the capsule, one can create microscopic pore openings in the capsule (Fig 7). Any use of this device for such maneuvers as a multi-mini-sphincterotomy or an iridotomy would be considered an off-label application in the United States (Figs 8 and 9). Initially surgeons are encouraged to produce a slow and careful capsulotomy in order to minimize any complication. Surgeons are recommended to employ a capsulotomy time of approximately 5 to 20 seconds. The unit is employed by gently tracing over the location on the capsule in which the capsulotomy is desired. There is no attempt to physically tear or punch through or perforate the anterior capsule. This unit is a highly efficient incising device (Fig 10). The capsulotomy need not be performed in a single maneuver, wherein several arcuate incisions in the capsule can intersect and thereby create a capsulotomy. If the surgeon is not content with the initial capsulotomy, then it is recommended that the surgeon enlarge the diameter of the capsulotomy with arcuate incisions around the capsule margin or employ radial incisions into the capsule margin (Figs 11 and 12). Because the Fugo Blade™ capsulotomy rim is not as strong as capsulorhexis, it is advisable to avoid pulling a larger nucleus through a smaller capsulotomy opening. Many surgeons have had problems in the past with such a maneuver, and radial tears have developed in a capsulorhexis. This problem will be even more prominent should a surgeon attempt

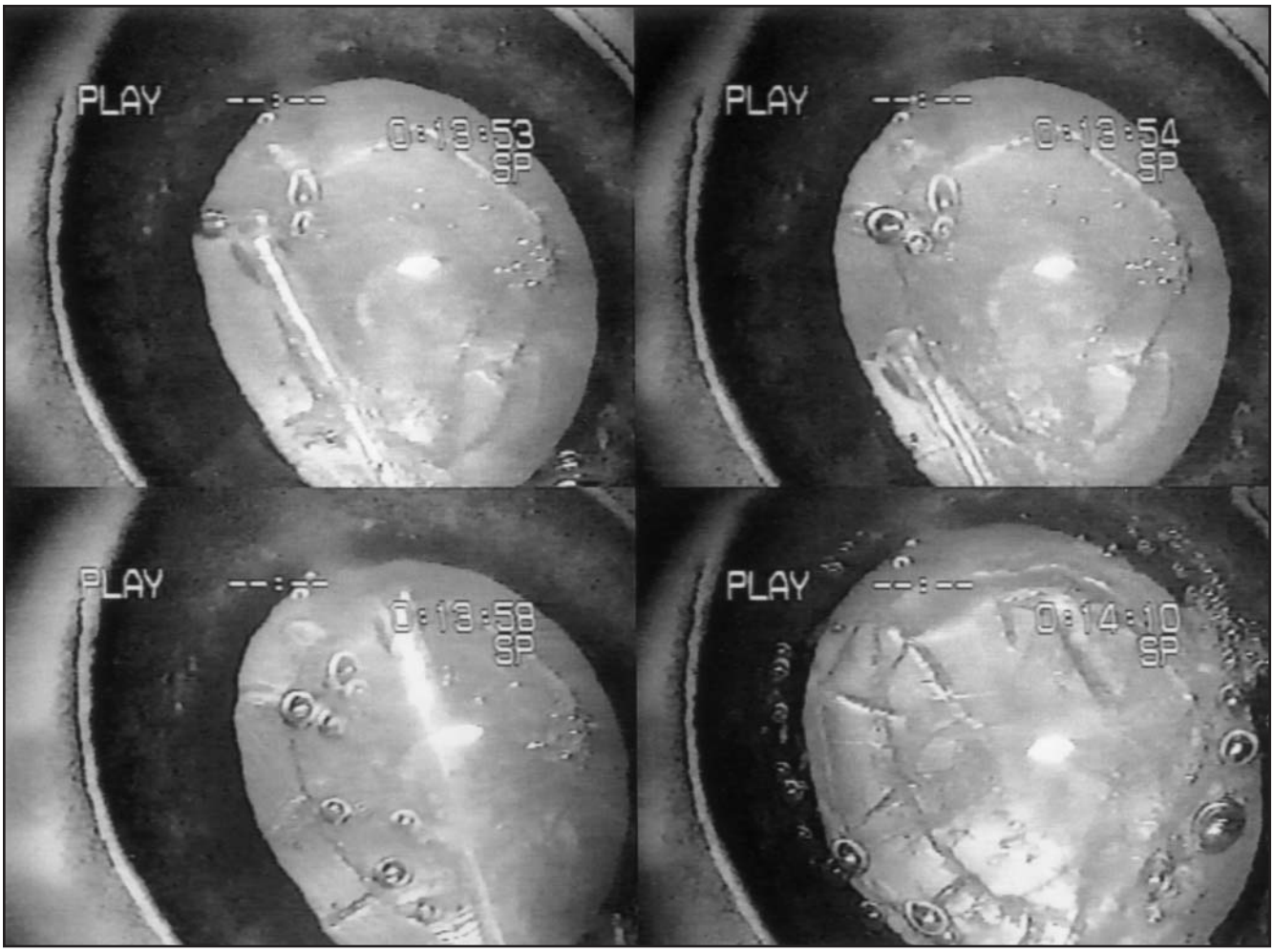

Fig 12.—The Fugo Blade™ may be used to enlarge the capsulotomy size. **Top left:** A radial incision was just placed at the 11-o'clock position along the capsulotomy, and is now about to be placed at the 10-o'clock position. **Top right:** Radial capsulotomy incisions were placed at 10 o'clock and 11 o'clock, and now is about to be placed at the 8-o'clock position. **Lower left:** Radial capsulotomy incisions were placed at the 6, 7, 8, 10, and 11-o'clock positions. We are about to place another radial capsule incision at the 12-o'clock position. **Lower right:** Following radial capsule incisions, viscoelastic solution is infused into the anterior chamber, pushing the small capsule flaps outward. Notice that the capsulotomy margin is now just inside of the pupil margin. Inside of the capsule margin, there are radial incisions in the cortex where the radial capsulotomy incisions were made.

pulling a larger nucleus through a smaller capsulotomy opening with the Fugo Blade™ capsulotomy rim.

Finally, it should be emphasized that being able to perform an anterior capsulotomy without a red reflex will present the surgeon with a great ability to control difficult surgeries (Fig 13).

Conclusion

In conclusion, the Fugo Blade™ capsulotomy unit employs a solid-state electronic system powered by rechargeable batteries to provide maximum patient safety. It allows the surgeon to perform anterior capsulotomy in a safe and repeatable fashion in seconds. It also allows the surgeon to easily and safely enlarge the size of the capsulotomy. Should a surgeon inadvertently tear the capsule during the procedure, this can be repaired by placing a Fugo Blade™ incision in front of the dissecting head of the tear. Use of the unit to perform multi-mini-sphincteroromies for small pupils or iridotomies would be considered an off-label use. As with phacoemulsification devices, the active incising tip is a disposable, one-time use item. Viscoelastic solution or a red reflex is not needed with this device. It is advised, however, that the novice surgeon employ viscoelastic for maximum safety in stabilizing the anterior chamber during the early learning curve. In general, surgeons should feel comfortable with this unit after about 10 to 20 cases. Although this unit greatly decreases the difficulty of opening the capsule as well as enlarging the size of the capsulotomy, it provides a capsulotomy opening which is not as strong as that of capsulorhexis. Therefore, treating this margin in a manner similar to a capsulorhexis is not appropriate. It is much wiser to enlarge the capsulotomy than to attempt to pull a larger nucleus through a smaller capsulotomy opening since this will most likely result in a tear of the capsular rim. It is thereby obvious that surgeons must retool their mental approach toward cataract surgery when employing the Fugo Blade™ capsulotomy unit. As such, the authors suggest using less physical force in removing cortex and nucleus while employing more surgical finesse in removing cortex and nucleus through capsulotomies created with the Fugo Blade™.

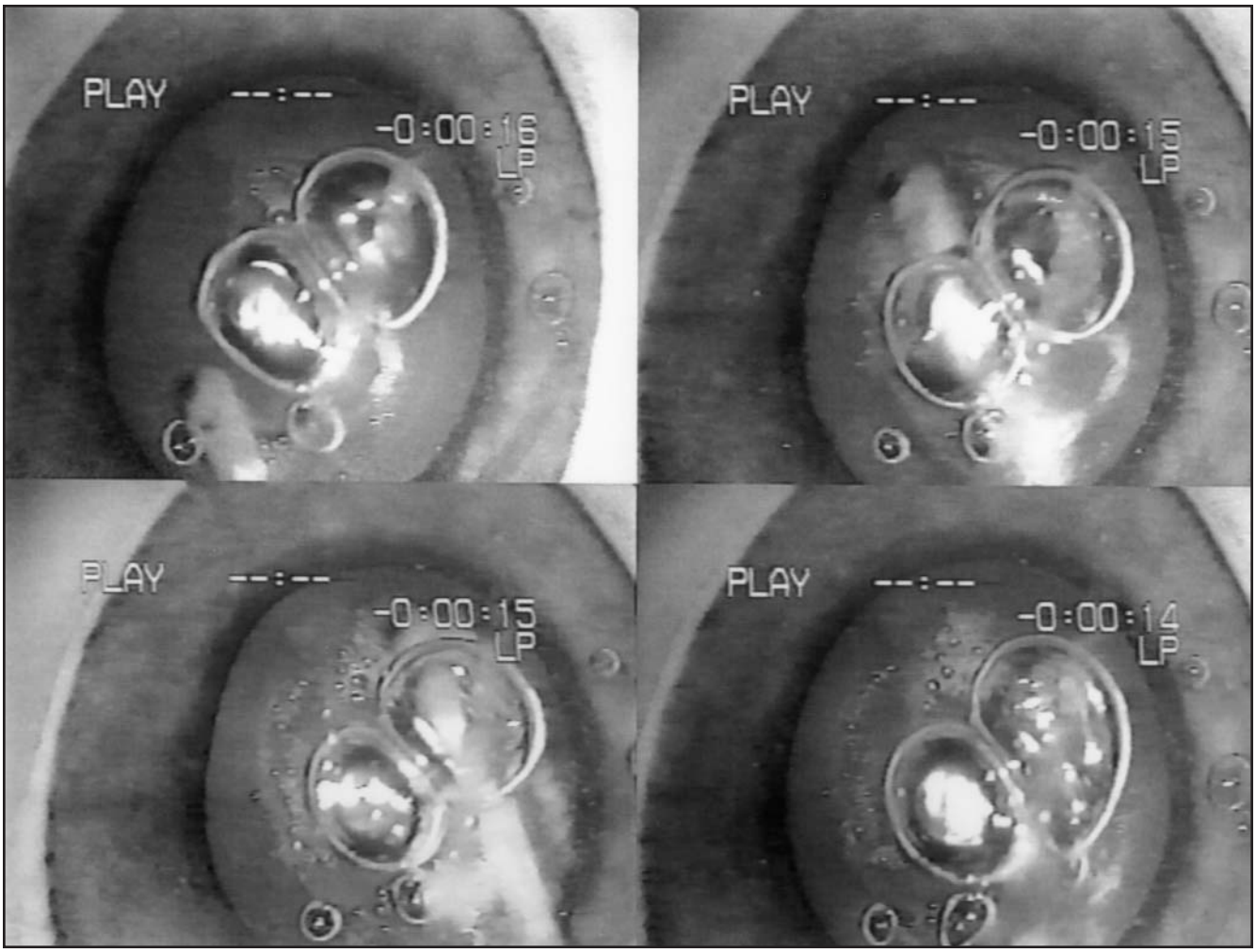

Fig 13.—Anterior capsulotomy performed without a red reflex. The Fugo Blade™ can also perform an anterior capsulotomy under air, balanced salt solution (BBS), or viscoelastic solution. Here, the anterior capsulotomy is performed with a combination of BSS and air in the anterior chamber. **Top left:** A Fugo Blade™ capsulotomy is being performed in a clockwise fashion. **Top right:** The capsulotomy continues, and one can see the slight granularity of the capsule margin just inside the pupil margin. **Lower left:** The capsulotomy continues with the cutting probe now under an air bubble. **Lower right:** The capsulotomy is complete but is difficult to visualize secondary to a lack of a red reflex. Note the granular-appearing margin of the capsulotomy rim just within the border of the pupil margin.

As technology changes, our approach to surgery must also change.

Educational courses with surgeon certification will be offered on use of the Fugo Blade™. More information about the Fugo Blade™ may be found on its Web site at www.fugoblade.com.

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