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ALLEGRETTO WAVE Excimer Laser

Refractive surgeons from the US and international markets discuss the transition from customized-wavefront to optimized-wavefront ablation.

Meet The Panel



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Allegretto Wave Excimer Laser

Refractive surgeons from the US and international markets discuss the transition from customized-wavefront to optimized-wavefront ablation.



The Allegretto Wave excimer laser (WaveLight Technologie AG, Erlangen, Germany) recently received FDA approval for the treatment of myopia and hyperopia. This laser system received the largest initial approval range of any laser in the US, ranging from -12.00 D of myopia through +6.00 D of hyperopia. The laser has significant technical advances, including a fast, accurate tracker that does not require pupil dilation, an ablation rate of less than 5 seconds per diopter, and a Gaussian spot of 0.95 mm in diameter. Outcomes from the FDA study were comparable to or better than any series submitted to date, including those performed using customized ablations.

Guy M. Kezirian, MD, FACS, Moderator

BUYING AN ALLEGRETTO LASER

Kezirian: The decision to upgrade your excimer laser technology depends on many considerations that go beyond technical advances and improved outcomes. How do you justify buying an Allegretto Wave excimer laser system in today's marketplace? What are some of the different considerations you would make in purchasing the Allegretto at this time?

Alexander: I think the decision to buy the Allegretto can be multifactorial. We are an exclusive refractive center and our longer-term success depends on good outcomes and patient satisfaction. We decided that if we are going to play in the game we want the best technology in order to give our patients the highest quality of vision. And, when we evaluated the Allegretto, we found that it offered the highest level of technology, so the decision was simple.

Kezirian: Does anyone factor enhancement rates into their cost calculation of having the laser?

Moore: Enhancement rates do factor in, especially because we have to pay a click fee when performing an enhancement. I agree with Dr. Alexander's comments, but patients today have become very sophisticated.

They surf the Internet, they are aware of new technology, and I think that recent patients in particular are very technologically oriented. I have a STAR S4 excimer laser system (VISX Inc., Santa Clara, CA) in my office, as well as an Allegretto. I think the return on investment is going to be generated from the new patients that will make the leap to LASIK based upon their knowledge of the new technological advances.

Brint: I try to focus on increasing throughput. I remember the days when we were involved in the FDA clinical study and we would spend a whole day, or at least a whole morning, doing nothing but WaveLight patients. The fact is we were able to move the patients through the system so much more quickly than wavefront-guided systems, with dilating, then the wavefront, the aberrometry, and such. I have not quite gotten back to that improvement in flow now that we are using the Allegretto commercially. The Allegretto is a user-friendly, quick, and easy laser to use. I think, if we can use our marketing skills and adjust our price point, we can have a much higher throughput with the laser and end up being happier, getting the staff out quicker and on time. We obviously need to be able to offer the best platform for each patient's needs, but the Allegretto Wave certainly is great for patient flow.

"I think the decision to buy the Allegretto can be multifactorial. When we evaluated the Allegretto, we found that it offered the highest level of technology."

— Dr. Alexander



Abell: To answer your question regarding enhancements, there are notably fewer enhancements with the Allegretto versus other laser platforms from Alcon Laboratories, Inc. (Fort Worth, TX), and VISX. The lower-enhancement rate is a cost savings to the practice. In my practice, an enhancement costs about \$500. I attribute the low enhancement rate of the Allegretto to its better laser platform and to its better laser nomograms.

Stonecipher: I want to complement Dr. Abell on his point regarding enhancements. We as surgeons never want to admit that we aren't perfect, and so we diminish the costs of enhancements. My enhancement rate with the VISX and Alcon conventional platforms ranges between 3% and 4%. Since starting the US trials with the Allegretto on May 5, 2000, I have yet to enhance a WaveLight patient. It will happen, but to date it has not. If we use Dr. Avery's example of 1,000 patients per year, that is a savings of \$15,000 to \$20,000 per year.

Chotiner: It is hard to justify not having the Allegretto Wave excimer laser, especially for me, because I was involved in the clinical trials and know how this laser performs. Our clinical and marketing staffs constantly remind me how well the Allegretto patients do. I agree with Steve that the patients are moved through the process very quickly. My practice's results with the wavefront-optimized system are at least equal to if not better than what we achieve with the wavefront-guided system.

Bond: The cost of an enhancement is not only based on the direct cost of the actual mechanical things, but also the perceived hassle experienced by the patient. Patients tend to see the need for an enhancement as a failure of the initial treatment. Enhancements cost a lot

more than their direct cost. They cost in patient perception, in word-of-mouth referrals. Anything that reduces the enhancement rate is extremely important.

Maus: Being a primary advisor for WaveLight it has been a question for me what laser to use in my practice. However, I am part of the advisory board of the largest German laser center chain. With every new laser purchase the board evaluates the return on investment. One strong financial consideration is the retreatment rate that we see with different platforms. The low enhancement rate of the Allegretto definitely reduces our costs and gets us more word-of-mouth referrals. In addition, the low maintenance cost makes the system financially even more attractive. However, the main decision factors are safety and quality of the treatment. We feel that, if you invest in the best, it will pay itself off.

KEY FEATURES

Kezirian: From the surgeon's perspective, what one key feature would you describe as being your favorite to distinguish the Allegretto Wave excimer laser from the others that you have used or are using?

Bond: My favorite feature is the smaller platform, which easily fits into a room, allows you more space, and provides more patient comfort. The smaller platform also allows for easier maneuvering around the OR.

Alexander: The ability to vary the optical zone size is one of my favorite features. First, we get a true optical zone size of 6.0, 6.5, and 7.0 mm for the full diameter with a blend out to 9.0 mm. This allows us to match the patient's pupil size with the corresponding optical zone

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— Dr. Abell

size and hence, eliminate or minimize glare or halos. This is important in addressing patients' fears of night driving after laser vision correction.

Moore: My favorite feature is the speed of the delivery system, 200 Hz, and the speed of the tracker. I see patients sigh with relief when I tell them that the average patient treatment time is less than 30 seconds and the tracker can respond in less than 6 milliseconds. The slit-lamp feature of the laser is also a splendid addition.

Bond: I agree with Dr. Moore, but I also like the tracker. The tracker is a peace-of-mind mechanism. When you have these little movements or you are continually telling your patients undergoing LASIK via your VISX system to "look at the light, hold still," and you are wondering to yourself, "just how much of that treatment is actually going where I want it to go," watching the Allegretto's tracker perform is a marvelous thing.

Chotiner: I think the patients and the staff appreciate the laser's speed, and the laser's speed contributes directly to the consistency of the results. When patients have to fixate for a shorter period of time, they are less likely to become fatigued and lose fixation. Even with a good tracker, ablation speed is a real asset. I am constantly amazed by the Allegretto's speed, having used other lasers that do not have that kind of speed.

Brint: The speed of the treatment, the throughput, and the excellent optics are all great features. Most other lasers have these capabilities, but it seems like the Allegretto is the only laser where we are actually using those capabilities, where we will preprogram the morning's or the day's entry into the laser computer. That is another ergonomic efficiency-type of issue.

Maus: The eye tracker is wonderful and makes it much easier for the patient to relax during the treatment. Also, due to the stability and reproducibility of the system, we can expect consistent energy delivery throughout the entire treatment day. All patients achieve consistent results.

Stonecipher: Coming from the south, I like the phrase, "If momma ain't happy, ain't nobody happy." Well, let's take that one step further. My staff enjoys the simple pre-operative setup. Having had five different laser platforms, the staff seems to enjoy the ease of the start-up and calibration of the Allegretto's laser platform.

WHAT'S MISSING

Kezirian: What would you like to have in the Allegretto excimer laser system that might not be there at this point?

Brint: The current WaveLight laser is a little bit higher off the floor than the original model we used in the clinical trials, but I'd like even a little bit more elevation. I'd like the bed to move faster in and out of operating position.

Alexander: I'd like to see mixed astigmatism treatment become an option.

I haven't had a lot of trouble with the ergonomics of the machine. With all the machines I have used in the past, there's always been some little quirk, but I am thoroughly impressed with the Allegretto Wave excimer laser.

Maus: I would like the laser to have the capability to link to my electronic chart system so that data can automatically be up- and downloaded.

Stonecipher: I would like to expand on Dr. Maus' point here. I currently use the Refractive Surgery Consultant (Refractive Consulting Group, Inc., Paradise Valley, AZ) for my outcomes analysis. I would like to be able to enter my preoperative refractive data into a program like the Refractive Surgery Consultant and then go straight to the laser treatment profile. With the Allegretto's laptop platform, a technician or the physician could enter the preoperative data, and then the only requirement postoperatively would be a 1-month to 3-month visit to improve outcomes and optimize nomograms.



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— Dr. Moore

OPTICS, WORKING DISTANCE, AND SLIT LAMP

Kezirian: This laser has a couple of features that were installed specifically per surgeons' requests when it was first developed, including upgraded optics, a bigger working distance, and a slit-lamp attachment. Can any of you comment on the utility of those? Have they proven to be useful? How do you feel with your visualization and working distance in this laser compared to other platforms?

Abell: The slit lamp is an excellent option and a great improvement. It provides tremendous efficiency by enabling me to look at a patient's eye while he is on the bed. I can easily check the patient's flap position, and, if there is any debris or any misalignment, I can take care of it right then. I also use it when lifting flaps if I am going to do an enhancement.

Bond: The upgraded optics have also helped me to operate in a somewhat lower light, which I think is easier for the patients and not any harder for the surgeon once you get into the habit. Also, it helps make the pupils be more of a midrange size, which helps with your acquisition and your tracker. Having said that, the tracker can easily accommodate extremes of pupil size if necessary. We rarely do people the same day we do the cycloplegic refraction, but we did on one of our patients who had a huge pupil, and it was no problem at all. The tracker on the Allegretto is excellent.

Alexander: I want to echo Tom's comments. When I first looked at the laser, I did not pay much attention to the slit lamp in my evaluation of the machine, but it has proven to be invaluable. It helps with throughput and speed. It allows you to lift the flap at the laser as opposed

to at the slit lamp. I used to look at my flaps after the procedure, take them to another room, and look at each patient. I am able to do that right then and there, at the time of surgery, and it allows me to catch mistakes and misalignment in flaps that I probably would have missed or been reluctant to go back to change because of the time and hassle involved. So, having it there at the laser has been phenomenal.

Chotiner: I would agree that the optics are fantastic, and I also have had other surgeons comment on how good the view is through the optics in this laser.

Bond: At my center, there are three other surgeons that use the Allegretto now that did not use it during the clinical study. Those surgeons are invariably thrilled with it. They like the optics, and they like the tracker.

Maus: The slit lamp is also very useful for the repositioning of dislocated epithelium.

PATIENT'S PERSPECTIVE

Kezirian: Switching now from the surgeon's perspective to the patient's perspective, what do your patients tell you about this laser? Are there any differences from your previous platforms, and do you think that this laser is in their best interest?

Stonecipher: Dr. Kezirian and I have a paper in print at this time which shows an improvement in subjective mesopic patient outcomes with the Wavelight Allegretto laser. With the combination of the INTRALASE (IntraLase Corp., Irvine, CA) and the Wavelight laser, I have seen an improvement in postoperative day number 1 visions and and post-



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— *Dr. Stonecipher*

operative month 3 outcomes at the 20/15 level. Pretty much, all my lasers are comparable at the 20/20 level. With these additions of improved mesopic outcomes and improved predictability, applying a premium to this platform has been accepted more readily by patients.

Bond: I don’t hear patients say, “I can’t see at night” or “I am not happy with my 20/20 vision.” I was always struck by the study and the fact that, when you would ask the study patients if they were having trouble at night, they did not know what you were talking about.

Alexander: I think this relates back to the previous question, why get this laser? Is it cost-justified? Patients’ expectations today are higher, and I feel that this laser allows us the ability to meet those expectations at a higher degree. The higher myopes that had undergone surgery on a different platform used to complain about glare and halo; their quality of vision wasn’t as high as that of those who received surgery from an Allegretto system. The quality of vision in Allegretto patients is at a higher level. I’ve done enhancements on patients that have had surgery from other laser systems, and they prefer the Allegretto eye.

Maus: A few years ago, I used the Allegretto and the MEL 70 (Carl Zeiss Meditec AG, Jena, Germany) parallel in my office. There was a significant different in patients’ satisfaction between the two platforms. With the MEL 70, we had close to no patients telling us that their night vision had improved whereas with the Allegretto about 20% of patients reported improved night vision, even

before wavefront-optimization. The Allegretto treatment with its large, true optical zones is especially beneficial for high myopes with wide pupils.

Chotiner: Patients do appreciate the difference from one platform to another. In our facility, we encourage patients’ family members to come into the laser suite. They sit 10 feet from the patient and right across from a large video monitor. Our practice sees a lot of referral patients, particularly referrals from family members. Patients who have had their LASIK on older platforms and watch their family members’ surgery on the Allegretto will, more often than not, comment about how fast the procedure is with the Allegretto. They recognize that this is something better, newer, and more sophisticated.

Moore: We have more than 50% of patients on postoperative day 1 exams voluntarily reporting they have never had visual quality of this type before surgery, with either glasses or contact lenses.

Chotiner: I’m seeing a significant percentage of patients on postoperative day 1 with 20/16 vision, and, again, making the same comment, “I never saw this well even with my glasses or contacts.”

Abell: My patients say the same thing, and I think they have confidence in the laser system. Another thing is the monitor itself where the patients’ families can view a surgery. The monitor is very clear, it’s high definition, and I prefer it.

CUSTOMIZED TREATMENTS

Kezirian: The WaveLight Allegretto Excimer Laser was the first to perform a wavefront-guided LASIK treatment, and yet, today, in the US, the laser has not been approved for custom treatments. In your practice, whether you have other platforms that can do custom or not, how do you handle a patient who says, “I want to have custom ablation. I’ve read about it in the newspaper.”

Brint: We do have custom capability. If the patient falls within the FDA guidelines, which is, for us, less than 1.00 D of cylinder, then they can get custom. But, for those patients with more than 1.00 D of cylinder, and we have a lot of them, we discuss the possibility of a two-stage process. We’ll do a traditional treatment first, and then we’ll come back and do a custom enhancement if the patient feels it’s necessary. I think we’ve

done one custom enhancement because the particular patient felt it was necessary. I don't think that's an issue, but I have found it quite easy with this laser for those people that come in with more than 1.00 D of astigmatism that want custom. The biggest problem we've had with quality of vision is spherical aberration. But, the Allegretto has the spherical aberration problem essentially taken care of. One of the major components of any custom treatment is to not induce spherical aberration. But, since the Allegretto laser is already wavefront-optimized and designed to minimize the induction of spherical aberration, I am quite comfortable offering the Allegretto to those patients who currently do not fit the FDA inclusion criteria for true custom ablations.

Alexander: First of all, I don't have that question posed to me. But, I do have the ability to do customized treatment. However, most of the patients, when they come in, are looking for our recommendation, and as physicians it is our job to tell them what is best for them. We tell them what the Allegretto does, how it is designed, and I tell them that it is the best platform available. Typically, that is enough.

Chotiner: I have the LADARWave (Alcon Laboratories, Inc., Fort Worth, TX) platform. As I said earlier, my results with the WaveLight equal or exceed the results that I get with the custom wavefront-guided laser. I would agree with Dr. Alexander that patients are looking to you to direct them to the platform that works well for you, the surgeon. In our hands, the Allegretto is the platform that works the best.

Maus: One thing we have to keep in mind is that many people mix up the words *wavefront-guided* and *custom*. A custom treatment in the broader sense of the definition means that the best possible treatment is chosen individually for a given patient based on the personal and clinical indications. So, if a wavefront-optimized treatment creates similar or better results than wavefront-guided treatments with other platforms, but the surgeon still customizes the treatment to the patients needs, the wavefront-optimized treatment would be the best custom treatment available today.

Moore: On the other side of the coin, when we went to wavefront-guided technology with the Star S4, we were limited to 6.00 D of myopia and 3.00 D of cylinder. If somebody came into our practice that had read about



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— Dr. Bond

wavefront technology and did not qualify for the treatment, a lot of times that would turn people off, they were disappointed and sometimes wouldn't schedule. The large approval ranges of the Allegretto allow me to tell patients that we can do wavefront-optimized for virtually anybody that is a good candidate for LASIK.

Chotiner: I agree with Charlie. It was a major problem when you were limited to 1.49 D of cylinder and you got a patient who exceeded those parameters. Prior to WaveLight's FDA approval, we were frequently confronted with patients to whom we had marketed custom treatments but who exceeded custom parameters. It was sometimes even embarrassing. Since WaveLight's approval, we are now able to say that, in our opinion, wavefront optimized ablation works as well, if not better, than actual custom.

Stonecipher: Currently, I offer the customized VISX Star S4 platform and the wavefront optimized Allegretto platform at the same price. As has been said, the expanded FDA approval with the Allegretto laser allows me to offer this to an expanded range of patients. When the platforms overlap, I discuss both options, but obviously the WaveLight platform is much easier to implement and more cost effective.

POSTOPERATIVELY INDUCED DRY EYE

Kezirian: This laser does induce less spherical aberration and does deliver an optical zone size that is 6.5 mm. But, the cost of that optical zone is wider, deeper ablations. There has been a lot of work and discussion during the past few years about the etiology of dry eye after LASIK. Clearly, wider and deeper ablations result in a lower recovery time of

corneal sensations and more dry eye symptoms. Have you experienced this in your clinic? If you have, what do you do to anticipate or treat this?

Moore: I have experienced this problem. You can really see a topographical postoperative increase in the optical zone size in an Allegretto eye versus other laser platform eyes. We have had to consequently become very sensitive about ocular surface management. We are very careful about treating blepharitis preoperatively as well as starting patients on artificial tears 2 or 3 days or 1 week before surgery and by using collagen punctal plugs that dissolve during a 90-day period of time rather than 24 to 48 hours. We are much more sensitive about ocular surface management using preservative-free tears and gels at bedtime in these patients, in particular, the hyperopic patients that are older than the myopic group of patients.

Abell: In addition to what Charlie does, we also use Restasis (Allergan Inc., Irvine, CA) and flaxseed oil. I have not had an increase in postoperative dryness, but I think that's because we are more aggressive with treating it preoperatively.

Bond: I believe we have seen additional dryness, and I had wondered if that were due to its being January in Illinois, when and where there's less humidity. We are doing the things Dr. Moore described, and they do work. More aggressive plugging with the 90-day plugs, ocular surface management, and Restasis tears have worked well.

Stonecipher: I agree with Dr. Abell. I don't see an increased risk of dry eyes, but when it occurs it is usually a patient we have selected out preoperatively. For example,

they had dry eyes prior to surgery with their contact lens wear. I have become much more proactive in these patients, aggressively treating their dry eye preoperatively with tears, punctal plugs, Restasis, and oral supplements when indicated. I, like Dr. Bond, also see more of a dry eye issue in the winter or less humid months. Those patients with preoperative issues I tend to suggest that they have surgery in the summer or more humid months.

Kezirian: How long do you have to maintain ocular surface therapy after LASIK with this laser, say, in a -6.00-D myope?

Bond: We maintain ocular surface therapy for approximately 3 to 6 months. The patients titrate and tailor their own treatment much more than we give them credit for.

Chotiner: We've moved away from using a mechanical keratome, and that's been extremely helpful with flap thickness and bed thickness issues. There is some indication that INTRALASE flaps induce fewer dry eye symptoms than mechanical flaps. Now that we've also been using the WaveLight on a regular basis, I have not seen an increase in dry eye complaints; in fact, we've probably seen a decrease.

MIXED ASTIGMATISM

Kezirian: In the US, the Allegretto is not approved for mixed astigmatism. A full range of myopia and hyperopia is approved with astigmatism, but mixed astigmatism per se is not. Internationally, there is a mixed astigmatism algorithm and I wonder if Dr. Maus would comment on his experience with that. And in the US, I wondered if some of you would comment about how you treat mixed astigmatism. Are you using this platform, or are you using another?

Maus: We've used the mixed astigmatism algorithm for a little longer than 1 year. Before we received the new software, we also performed a two-step treatment. Now, it has become a single-step procedure. We are very satisfied with the outcomes of the single-step treatment, even for patients with up to -7.00 D of cylinder. Two weeks ago, I had a patient with +5.50 and -7.00 D of cylinder. At one day postoperatively, the patient was +0.25 and -0.50 D, which is an excellent result, especially because of the variances in refraction that we find common in mixed astigmatism patients.



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— Dr. Chotiner

Kezirian: Would anyone like to comment on how they manage mixed astigmatism in the US with the Allegretto?

Abell: I use a different platform, and I'm looking forward to having a mixed astigmatism approval on the Allegretto.

Alexander: I've used the Allegretto for mixed astigmatism treatments. You have to double card at present; however, the treatment results are still good. Basically, if you're in plus cylinder, you can use the first treatment, or the first card. I treat the sphere, and then I reprogram the laser for the cylinder component, with plano for the spheric component. There's not a great lag between the two treatments, and I've had surprisingly good results with the cylinder component, which I think is difficult to be done with other platforms.

Maus: When I still performed two-step treatments, I aimed for an average K reading between 42.00 and 45.00 D. The treatments were split between a myopic cylinder and a hyperopic cylinder treatment to save tissue and to end up with a normal, average, corneal K reading.

LEARNING CURVE

Kezirian: The Allegretto is a little different. The setup, mechanics, and ergonomics are different. What's the learning curve with this laser for you and for your staff?

Moore: I had a colleague from Houston that wanted to try the Allegretto. He brought two cases to my facility, and, unfortunately, one was a -8.00 D, and the other was -10.00, not the best cases to start on. It is a learning curve, and it is definitely a change in the ergonomics that we've been used to. Plus, the speed of the machine makes it imperative, just like transitioning from a motorized airplane to a jet airplane, to think ahead of the curve rather than wait until you get into trouble.

Alexander: I can echo what Dr. Moore said. I've had the Allegretto for a solid 2 months. It took me about a month to really feel comfortable. However, after you make the change, you realize this is a better platform. For example, the working distance is more comfortable, the overall ergonomics are more efficient, the calibration is easier and quicker, which all yield a faster throughput.

Maus: I had a period of 18 months in which I did not need service and another period of 7 months in which I did not have to adjust the energy. I checked it every morning and it was okay. It really gave me peace of mind.

KEY POINTS FROM THIS DISCUSSION

- The Allegretto Wave excimer laser (WaveLight Technologie AG, Erlangen, Germany) has received the largest initial FDA approval of any laser in the US, ranging from -12.00 D of myopia through +6.00 D of hyperopia. The laser has significant technical advances, including a fast, accurate tracker that does not require pupil dilation, an ablation rate of under 5 seconds per diopter, excellent optics with a laser-mounted slit lamp, and a Gaussian spot of 0.95 mm in diameter. Outcomes from the FDA study were comparable to or better than any series submitted to date, including those performed using customized ablations.
- Panelists felt that the initial laser costs are offset by lower per-procedure fees, lower enhancement rates, and faster throughput.
- Patients' night-driving symptoms are significantly reduced with this laser.
- The wavefront-optimized ablation permits most eyes to be treated without customized ablation, thus greatly reducing the workup time required per patient.
- Larger true optical zones require larger, deeper ablations. The treatment of dry eye symptoms is important.

Kezirian: Is the laser well suited for a high surgical volume environment?

Bond: The laser's extremely well suited for faster throughput and higher volumes.

Chotiner: I agree with that. In fact, our staff has commented how our turnover times, our throughput times, have improved with this laser due to its speed. □

