Marketing Update Ophthalmology

August 31, 2006

Results from FDA Trials for wavefront-guided LASIK

Dear partners,

We are excited to announce that the U.S. Food and Drug Administration has granted approval to WaveLight to market and sell wavefront-guided procedures with the ALLEGRETTO WAVE in the United States. The approval is especially important since the study included not only eyes that received a wavefront-guided treatment, but also eyes that received a Wavefront Optimized™ treatment. Overall, the results from both groups were outstanding, but what is truly remarkable are some of the things that WaveLight was able to prove with this study and which NO other company so far has been able to show. Here are just some of the key findings:

- First laser system to show an actual reduction in higher order aberrations
- First laser to preserve and improve contrast sensitivity with ALL patients
- First laser to improve glare and night driving glare with ALL patients
- No patient required glasses for daily activities after Wavefront-Optimized™ surgery

There are many other key claims that our competition cannot match. Enclosed to this memo you therefore find in depth sales information that should help in your discussions with the surgeons:

- A summary sheet of all key outcomes and competitive comparison as PDF
- A PDF of a detailed Powerpoint with all results and competitive analysis

The original powerpoint is available for download from our Campus area (www.wavelight.com/campus).

You should familiarize yourself in detail with these outcomes and use them in discussions especially against VISX, B&L and Alcon. They all were unable to show that they can reduce aberrations and in case of VISX they were forced to include a statement in the documentation that specifically expresses that. All this is included in the powerpoint.

I will present these materials and review them in depth at the upcoming distributor meeting in London and look forward to see many of you there in person. If you have questions, please feel free to contact me.

Sincerely

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Director Global Marketing

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Custom LASIK with the ALLEGRETTO WAVE

Results from US Clinical Trials for wavefront-guided vision correction and comparison to wavefront-optimized correction

Study design

- Prospective, multi-center study
- 2 study groups (patient selection was random):
  - WFG: Wavefront-guided LASIK (“Study group”)
  - WFO: Wavefront optimized LASIK (“Control group”)
- Treatments up -7 dpt spherical equivalent with up to 3dpt astigmatism, optical zone: 6.5mm
- Keratome: exclusively Intralase
- Bilateral treatments only :
  both eyes received same treatment method

Study content

- Treatments conducted from Sept 2004 – Sept 2005
- 5 US study sites
- 374 eyes treated: WFG: 188 / WFO: 186
- Distribution of treatments at study sites:
  26% / 28% / 18% / 3% / 26%
- 332 eyes with 6 months follow up:
  WFG: 166 / WFO: 166
  Follow up > 92 %
- 5 eyes were retreated; WFG: 5 (3%); WFO: 0 (0.0%)

Most important clinical outcomes WFO/WFG

- 100% of patients could drive without glasses after treatment
- Over 87% of all patients (WFG and WFO) saw at least as good or better without glasses after treatment, then before with glasses
- 93% of patients achieved 100% visual acuity or more
- 0% enhancement rate in the WFO group
- No symptomatic increase in aberrations observed
- Slight improvement in contrast sensitivity and low contrast acuity seen for both WFG and WFO patients
- WFG LASIK proven to reduce aberrations, specifically trefoil and spherical aberrations (patients up to -4D or more than 0.4µ RMSh)

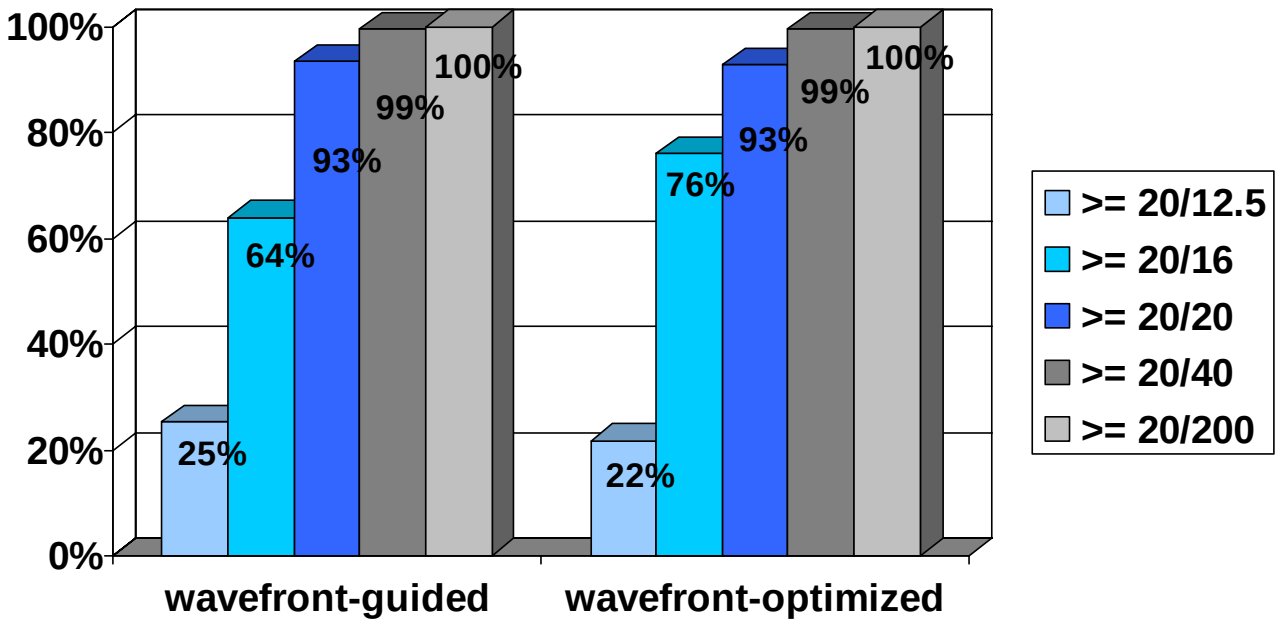
Important distinctions in the FDA approval Custom Monovision

- ALLEGRETTO WAVE first system to be able to perform custom monovision treatments for presbyopia using wavefront-guided treatments
  - Surgeon can alter the sphere target by up to 3 D
  - Other systems allow only 0.75 D
- ALLEGRETTO WAVE first system to allow surgeon-adjustment of the cylinder treatment

Most important subjective outcomes

- At stability, most patients (over 88.9%) would highly recommend the treatment to a friend
  - 97.5% would probably or highly recommend it
- No patients (0%) required glasses anymore after WFO treatment (1.8% WFG)
- Over 90% of patients rated their visual quality good or excellent after treatment (WFG 94.5%/WFO 92%)
- Glare and night driving glare all improved

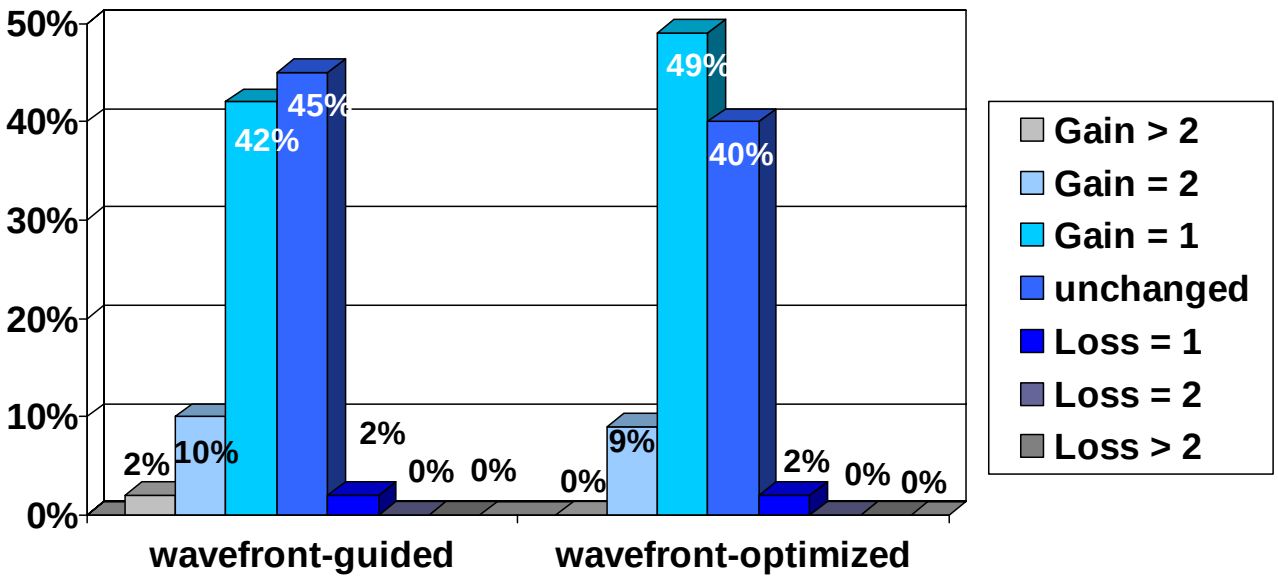
Effectiveness: UCVA (Uncorrected visual acuity)



Both groups demonstrated similar performance for visual acuity

Data reflects 6 months post-operative results

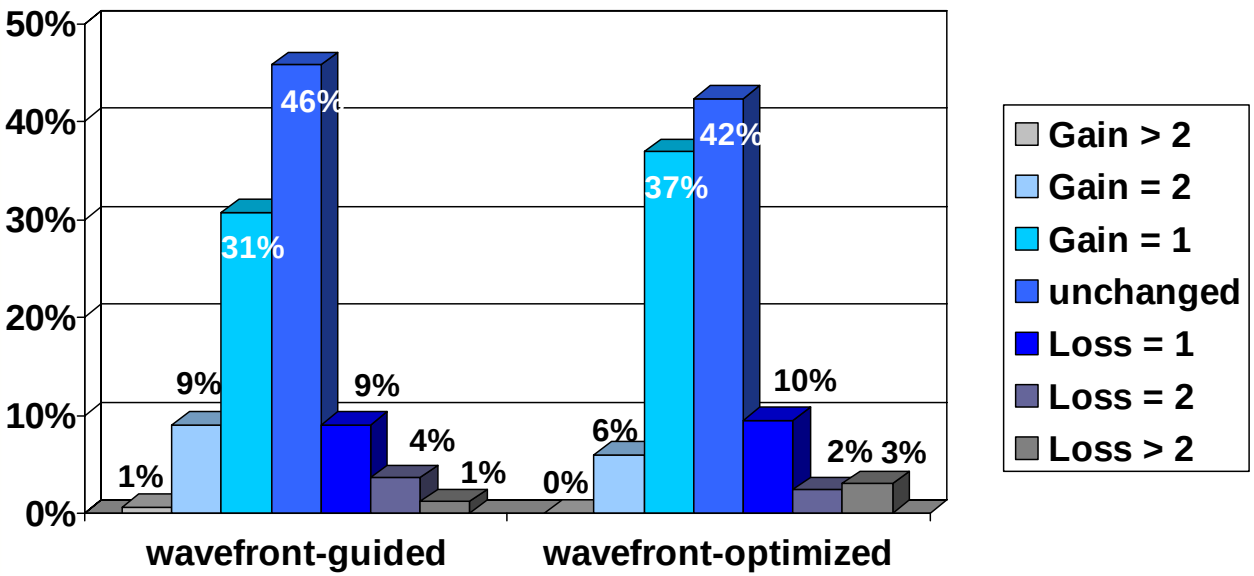
Safety – Change in BSCVA (Best corrected visual acuity)



Over 97% in both patient groups remained unchanged or gained one, two or more lines of vision, **over 50% of all patients gained at least one line of BSCVA**

Data reflects 6 months post-operative results

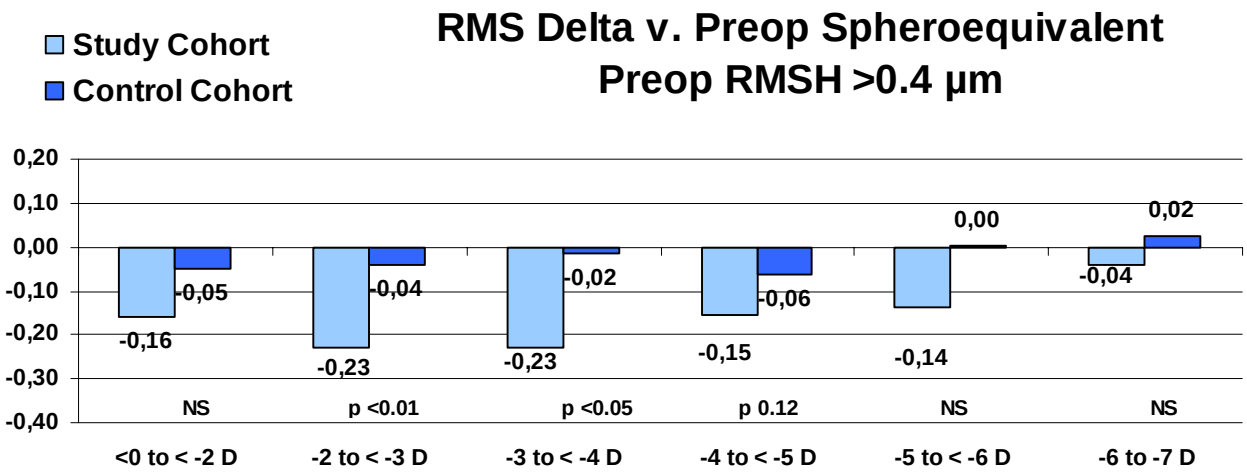
Efficacy – $UCVA_{post}$ vs. $BSCVA_{pre}$



85% of patients saw at least as good or better without visual aids after the treatment (WFO or WFG) than before with their glasses or contact lenses

Data reflects 6 months post-operative results

Patients with high pre-op higher order aberrations



Eyes with higher amounts of pre-operative aberrations do better with WFG LASIK, but the WFO method was also able to effectively reduce aberrations in most of those eyes.

Data reflects 6 months post-operative results

Recommended patient selection
Treatment matrix

RMSh $_{pre\text{-}op}$	Attempted spherical equivalent correction (dpt)					
	-1 to < -2	-2 to < -3	-3 to < -4	-4 to < -5	-5 to < -6	-6 to < -7
<=0,2 µ	**WFO** (WFG)	**WFO** (WFG)	**WFO** (WFG)	**WFO** (WFG)	**WFO** (WFG)	**WFO** (WFG)
>0.2 - 0.3µ	**WFG / WFO**	**WFG/ WFO**	**WFG/ WFO**	**WFG/ WFO**	**WFG/ WFO**	**WFG/ WFO**
>0,3 - 0.4µ	**WFG**	**WFG**	**WFG**	**WFG/ WFO**	**WFG/ WFO**	**WFG/ WFO**
>0.4 µm	**WFG**	**WFG**	**WFG**	**WFG**	**WFG**	**WFG**

The dark blue area shows patients that are likely to benefit more from a WFO treatment. The light blue area shows patients that will benefit equally from either a WFG or a WFO treatment. The grey area shows patients that are likely to benefit more from a WFG treatment.

Competitive comparison: Approval ranges

Wavefront based treatments - Sphere

-12D	WaveLight WFO	+6D
-7D	WaveLight WFG	
-11 D	VISX CustomVue	+3D
-7D	B&L Zyoptics	
-7D	Alcon Ladarvision	

Wavefront based treatments - Cylinder

-6D	WaveLight WFO	+5D
-3D	WaveLight WFG	
-3D	VISX CustomVue	+2D
-3D	B&L Zyoptics	
-4D	Alcon Ladarvision	

WFO also approved for mixed astigmatism up to 6D.
VISX CustomVue approved for mixed from 1D to 5D.

Competitive comparison – visual outcomes

Factor	WL WFO (old, myopia)	WL WFO (new)	WL WFG	Visx S4 low myopes	Visx S4 high myopes	B&L	Alcon Ladar
UCVA 20/20	94%	93%	93%	91%	84.3%	91.5%	81%
UCVA 20/16	72%	76%	64%	65%	65.2%	70.3%	Not reported
UCVA 20/12.5	28%	22%	25%	35%	14.6%	Not reported	Not reported
MRSE +/- 0.5 dpt	93%	95.2%	94.6%	86%	77%	75.9%	79%
MRSE +/-1 Dpt	100%	100%	98.2%	100%	95.5%	93.8%	96%
BSCVA loss of one line or more	19%	14.8%	13.9%	25%	No eyes lost more than two lines. No other information was included	21.8%	45%
Same or gain	81%	85.2%	86.1%	76%	Not included in the results	78.2%	55%
Retreatments	3.77%	0%	2.7%	3.4%	2.1%	Not included in protocol	Not reported

Best performace in each category highlighted in blue
All information from data available on FDA website

Competitive comparison: Change in RMSh

ALLEGRETTO WAVE Wavefront Optimized
12% increase in RMSh in average across all eyes No significant change for patients with pre-operative RMSh of 0.4µ
ALLEGRETTO WAVE wavefront-guided
No significant increase of RMSh across all eyes and refractions 17% reduction in trefoil across all eyes 27.27% reduction for eyes with pre-operative RMSh of 0.4µ or more
Alcon Ladarvision
20.6% average increase of RMSh with CustomCornea 56.9% average increase of RMSh with conventional LASIK
VISX Star S4 CustomVue
No data about aberrations or aberration changes reported, only statement: „Average higher order aberrations did not decrease after treatment“ (see next slide)
Bausch and Lomb
13.4% average increase of RMSh with Zyoptics 45.3% average increase with conventional Planoscan treatment

FDA Disclaimer

- **Disclaimer for wavefront-guided treatment of Myopia:**
- a. Approval of the premarket approval application is for the WaveLight ALLEGRETTO WAVE® Excimer Laser System used in conjunction with the WaveLight ALLEGRO Analyzer. The device uses a 6.5 mm optical zone, a 9.0 mm ablation/treatment zone, and is indicated for wavefront-guided (WFG) laser assisted in situ keratomileusis (LASIK): 1) for the reduction or elimination of up to -7.00 diopters (D) of spherical equivalent myopia or myopia with astigmatism, with up to -7.00 D of spherical component and up to 3.00 D of astigmatic component at the spectacle plane; 2) in patients who are 18 years of age or older; and 3) in patients with documentation of a stable manifest refraction defined as ≤ 0.50 D of preoperative spherical equivalent shift over one year prior to surgery.
- b. LASIK is an elective procedure with the alternatives including but not limited to eyeglasses, contact lenses, photorefractive keratectomy (PRK), traditional LASIK and other refractive surgeries.
- c. Approval of the application is based on a randomized clinical trial in the United States with 374 eyes treated; 188 with Wavefront-Guided LASIK (Study Cohort) and 186 with Wavefront-Optimized LASIK (Control Cohort). 178 of the Study Cohort and 180 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.2%.
- d. The studies found that of the 180 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point in the Study Cohort, 100% were corrected to 20/40 or better, and 95.0 % were corrected to 20/20 or better without spectacles or contact lenses. In the Control Cohort, of the 176 eyes eligible for the uncorrected visual acuity (UCVA) analysis of effectiveness at the 3-month stability time point, 100% were corrected to 20/40 or better, and 93.8% were corrected to 20/20 or better without spectacles or contact lenses.
- e. The clinical trials showed that the following subjective patient adverse events were reported as "moderate to severe" at a level at least 1% higher than baseline of the subjects at 3 months post-treatment in the Study Cohort: light sensitivity (37.2% at baseline versus 47.8% at 3 months) and visual fluctuations (13.8% at baseline versus 20.0% at 3 months). In the Control Cohort, halos (36.6% at baseline versus 45.4% at 3 months) and visual fluctuations (18.0% at baseline versus 21.9% at 3 months).
- f. Long term risks of Wavefront-Guided LASIK for myopia with and without astigmatism beyond 6 months have not been studied.
- g. Note that the complete name for this ophthalmic laser is "WaveLight ALLEGRETTO WAVE® Excimer Laser System used in conjunction with the WaveLight ALLEGRO Analyzer. The device uses a 6.5 mm optical zone, a 9.0 mm ablation/treatment zone, and is indicated for wavefront-guided (WFG) laser assisted in situ keratomileusis (LASIK): 1) for the reduction or elimination of up to -7.00 diopters (D) of spherical equivalent myopia or myopia with astigmatism, with up to -7.00 D of spherical component and up to 3.00 D of astigmatic component at the spectacle plane; 2) in patients who are 18 years of age or older; and 3) in patients with documentation of a stable manifest refraction defined as ≤ 0.50 D of preoperative spherical equivalent shift over one year prior to surgery."