

CustomVue™ LASIK
Correction of Presbyopia
with Monovision:
Results of the
US Clinical Trial

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Chicago, Illinois
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Participating Centers

Bascom-Palmer Eye Institute <i>W. Culbertson, S. Yoo</i>	Coleman Vision <i>S. Coleman</i>
Baylor College of Medicine <i>D. Koch, M. Weikert</i>	Kraff Eye Institute <i>C. Kraff, M. Kraff</i>
Clearview Eye and Laser Medical Center <i>S. Feldman</i>	Maloney Vision Institute <i>R. Maloney</i>
	Wilmer Eye Institute <i>R. Chuck, A. Kim, N. Jabbur, T. O'Brien</i>

Treatment Design:
CustomVue LASIK Monovision

- Presbyopic patients with myopia
 - Dominant eye targeted for emmetropia
 - Non-dominant eye under-corrected
 - Targeted up to -2.0 D myopia to provide near vision
 - Monovision acceptance evaluated preoperatively with contact lens trial

CustomVue LASIK Monovision
Inclusion Criteria

- M/F, any race, >40 years old at preop
- BSCVA of $\geq 20/20$ in both eyes
- $\leq -6.0D$ MRSE with astigmatism $\leq -3.0D$
- Non-dominant eye
 - Pre-op myopia at least as great as targeted post-op myopia
 - Planned laser treatment $\leq 0.75D$ MRSE
 - May not require treatment
- Preop Refractive stability within $\pm 0.50D$
- WaveScan pupil measurement $> 5.0mm$ in dim light

CustomVue LASIK Monovision
Exclusion Criteria

- Intolerance to monovision correction
- Concurrent use of medications which impair healing
 - topical /systemic steroids, antimetabolites, isotretinoin, amiodarone HCl
- Systemic disease
 - Diabetes, collagen vascular disease, autoimmune disease, endocrine disorders, immunodeficiency, lupus, rheumatoid arthritis
- Ocular disease
 - Prior surgery, active ophthalmic disease, dry eye, atopic disease, IOP $> 21mm$ Hg, abnormal topography, corneal irregularity
- Pregnant, nursing, intent to become pregnant
- Participating in any other clinical trial

Surgical Targets & Parameters

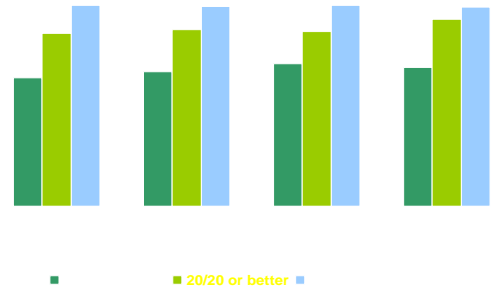
- Physician Nomogram Used
- 6 mm minimum optical zone
- 8 mm ablation zone
- Intralase, Hansatome, and Amadeus keratomes used
- Iris Registration released during study enrollment period
 - About 1/3 of eyes treated with IR

Cohort Description

- 296 eyes of 160 patients treated
 - 24 fellow eyes did not require laser treatment
- Mean Age: 50 ± 5 years (40 to 65 years)
- Gender: 35% male, 65% female
- Pre-Operative Refractive Error (MRSE)
 - Dominant Eyes: -3.82 ± 1.25 D
 - Non-dominant Eyes: -4.15 ± 1.05 D

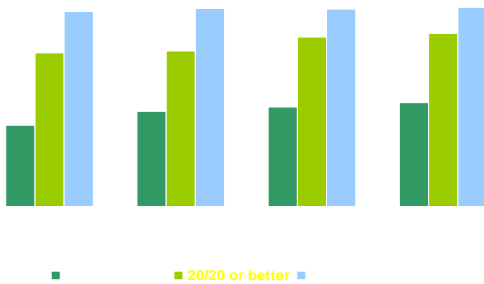
Binocular UCVA: Distance at 4 meters

At 12M: 93% were 20/20 or better distance UCVA.



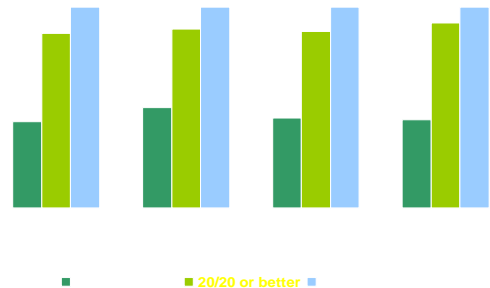
Binocular UCVA: Intermediate at 60 cm

At 12M: 87% were 20/20 or better intermediate UCVA.



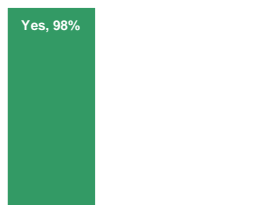
Binocular UCVA: Near at 40 cm

At 12M: 92% were 20/20 or better near UCVA.



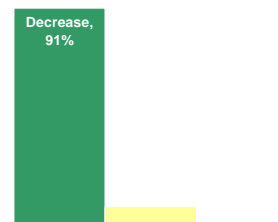
Satisfaction with Monovision

At 12M: 98% of subjects would, if given the opportunity, elect to have CustomVue LASIK Monovision treatment again.

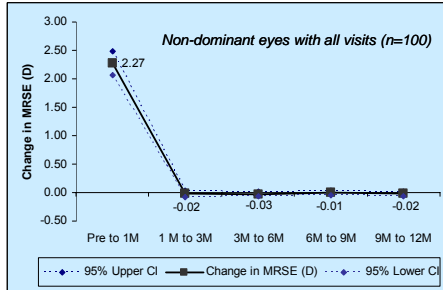


Spectacle Dependence

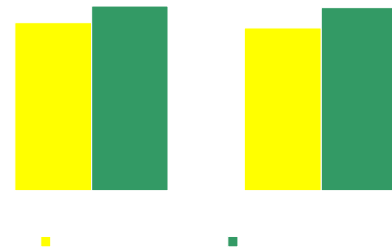
At 12M: 91% of subjects had a reduction in need for spectacles.



Refractive Stability *Change in MRSE*

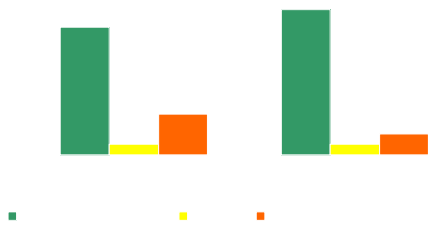


Intended vs. Achieved MRSE

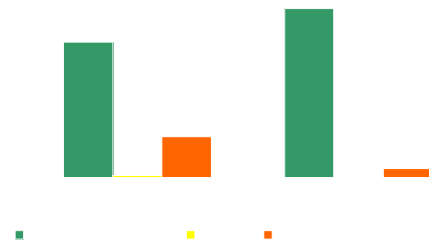


At 12M: 99% of dominant eyes and 98% of non-dominant eyes were within ± 1.0 D of intended correction.

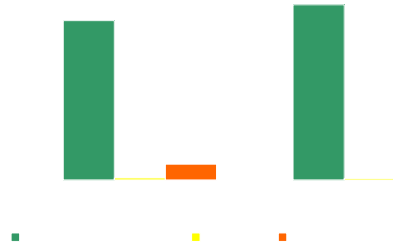
Distance Vision at Night *(Pre-Op BSCVA to 12M Post-Op UCVA)*



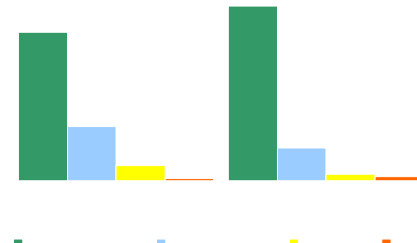
Near Vision (sustained) *(Pre-Op BSCVA to 12M Post-Op UCVA)*



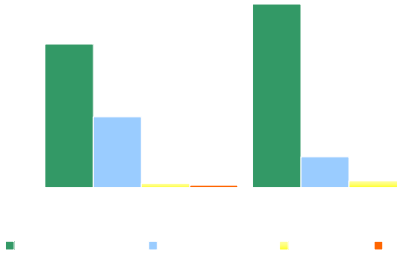
Depth Perception *(Pre-Op BSCVA to 12M Post-Op UCVA)*



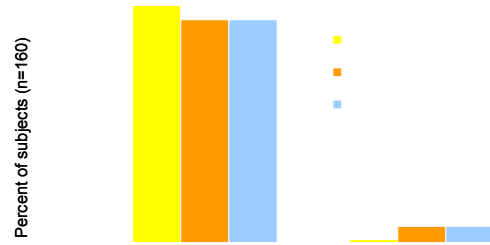
Halos Around Lights *(Pre-Op BSCVA to 12M Post-Op UCVA)*



Glare (Pre-Op BSCVA to 12M Post-Op UCVA)



Change in Contrast Sensitivity at 12 Months



Analyses of Safety

- No eye lost > 2 lines BSCVA at distance or near
- Adverse Events
 - DLK (n=12)
 - 11 prior to the 1 month exam
 - 1 at 9 months
 - IOP (n=2)
 - Corneal infiltrate (n=1)

Retreatments

- 8 eyes of 7 subjects (2%) had wavefront-guided retreatment
 - 7 dominant eyes were retreated to improve distance vision
 - 1 non-dominant eye was retreated to improve near vision

Summary of 12 Month Results

- **UCDVA**
93% of subjects 20/20 or better
69% were 20/16 or better
- **UCNVA**
92% of subjects 20/20 or better
44% were 20/16 or better
- **UCDVA and UCNVA**
86% of subjects achieved **both** with 20/20 or better
- 98% of subjects would elect to undergo monovision LASIK treatment again
- No eye lost more than 2 lines of BSCVA

Thank You