

Rx Stratified Summary of FDA Results for all Customized LASIK Approved Systems Nearsightedness and Nearsightedness with Astigmatism

Uncorrected Vision \geq 20/16 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent n = number of eyes treated

	-1.00 to -1.99D	-2.00 to -2.99D	-3.00 to -3.99D	-4.00 to -4.99D	-5.00 to -5.99D	-6.00 to -6.99D
Autonomous LadarVision CustomCornea	NR	NR	NR	NR	NR	NR
B+L Zyoptix	73.2% n=41	77.9% n=86	70.7% n=82	66.7% n=57	61.5% n=39	66.7% n=27
VISX CustomVue (3 mo post-op)	NR	NR	NR	NR	NR	NR

Uncorrected Vision \geq 20/20 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent n = number of eyes treated

	-1.00 to -1.99D	-2.00 to -2.99D	-3.00 to -3.99D	-4.00 to -4.99D	-5.00 to -5.99D	-6.00 to -6.99D
Autonomous LadarVision CustomCornea	82.6% n=23	75.0% n=40	90.3% n=31	81.5% n=27	69.2% n=13	50.0% n=4
B+L Zyoptix	97.9% n=41	95.3% n=86	92.7% n=82	91.2% n=57	84.6% n=39	81.5% n=27
VISX CustomVue (3 mo post-op)	98.1% n=54	89.8% n=59	89.8% n=59	75.6% n=41	70.0% n=20	NR

	Eyes with $>0.50D$ Astigmatism Pre-Op	Retreatments?	Treatment Zone	Approved Treatment Range
Autonomous LadarVision CustomCornea	287/426	67.4%	*	6.5mm up to -7.00D sphere; $<0.50D$ cylinder
B+L Zyoptix	223/340	65.6%	None	up to 7mm up to -7.00D sphere; -3.00D cylinder
VISX CustomVue	141/351	40.2%	12 eyes	6.0mm up to -6.00D sphere; -3.00D cylinder

* First 40 eyes treated were excluded from the final data after the treatment software was modified