


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

<b>Explanation of Terms:</b> This table is a breakdown (based upon FDA data) of the likelihood of seeing 20/16 (top table) or 20/20 (bottom table) without glasses or contact lenses after LASIK based on pre-treatment prescription. NR = Not Reported						
<b>Uncorrected Vision &gt;= 20/16 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent</b>						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
<b>Uncorrected Vision &gt;= 20/20 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent</b>						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
	<b>Eyes with &gt;0.50D Astigmatism Pre-Op</b>		<b>Retreatments?</b>	<b>Treatment Zone</b>	<b>Approved Treatment Range</b>	
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						
<b>Source Document References: FDA "Summary of Safety and Effectiveness Data"</b>						
Autonomous LadarVision CustomCornea	PMA# P970043/S10: Table 6					
B+L Zyoptix	PMA# P990027/S6: Table 6					
VISX CustomVue	PMA# P930016/S16: Table 6c					
				All source documents available for public download from the FDA website: <a href="http://www.fda.gov/cdrh/">www.fda.gov/cdrh/</a>		
 <b>StrongVision</b> University of Rochester Eye Institute						