


Rx Stratified Summary of FDA Results for all LASIK-Approved Excimer Lasers: Farsightedness and Farsightedness with Astigmatism

Explanation of Terms: This table is a breakdown (based upon FDA data) of the likelihood of seeing 20/20 (top table) or 20/40 (bottom table) without glasses or contact lenses after LASIK based on pre-treatment prescription.						
Uncorrected Vision \geq 20/20 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent						
<i>n=number of eyes treated</i>						
	0.00 to +0.99D	+1.00 to +1.99D	+2.00 to +2.99D	+3.00 to +3.99D	+4.00 to +4.99D	Cumulative Total
Autonomous LadarVision	100% (n=2)	52.8% (n=72)	45.6% (n=79)	41.2% (n=34)	25.9% (n=27)	45.3% (n=214)
B+L Technolas 217	88.9% (n=9)	67.6% (n=111)	58.4% (n=77)	40.6% (n=32)	50.0% (n=4)	61.4% (n=233)
VISX S2 (12 mo post-op)	not reported	not reported	not reported	not reported	not reported	58.7% (n=167)
Uncorrected Vision \geq 20/40 at 6 Months Post-op per Pre-op Manifest Refractive Spherical Equivalent						
<i>n=number of eyes treated</i>						
	0.00 to +0.99D	+1.00 to +1.99D	+2.00 to +2.99D	+3.00 to +3.99D	+4.00 to +4.99D	Cumulative Total
Autonomous LadarVision	100% (n=2)	98.6% (n=72)	96.2% (n=79)	79.4% (n=34)	85.2% (n=27)	93.0% (n=214)
B+L Technolas 217	100% (n=9)	95.5% (n=111)	94.8% (n=77)	90.6% (n=32)	100% (n=4)	94.8% (n=233)
VISX S2 (12 mo post-op)	not reported	97.3% (n=37)	98.1% (n=53)	94.6% (n=37)	100% (n=26)	97.4% (n=153)
Source Document References: FDA "Summary of Safety and Effectiveness Data"						
Autonomous LadarVision	PMA# P970043/S7: Tables 13, 15					
B+L Technolas 217	PMA# P990027/S4: Table 16					
VISX S2	PMA# P930016/S10: Tables 16, 17					
						
All source documents available for download from: www.fda.gov/cdrh/lasik/lasers.htm						
University of Rochester Eye Institute						