

Best Spectacle Corrected Visual Acuity Loss of Michigan LASIK Patients

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What do you tell your patients when they ask if laser vision correction is safe? We all have our comfort level with refractive surgery and each of us will undoubtedly have a different answer for our patients in this situation. If one consults the literature, it would seem that laser in situ keratomileusis (LASIK) carries little risk and moreover is quite accurate. But in reading the current literature one can find two major flaws. First, much of the original research has been performed outside of the United States; this tells us nothing about our local surgeons. Second, most of the studies are written by surgeons. This paper does not question the objectivity of any researcher, but the combination of both these issues points to the need for some Optometry based research on a local level. This paper seeks to not only to comment on the safety of LASIK, but to take the next step and analyze the situation in Michigan to determine the amount risk facing our friends, family and patients as we refer them for this exciting procedure.

Let us take a few moments and define safety as it will be discussed in this paper. Once we have educated a patient on the surgery, and we feel that they have realistic goals for the procedure it is our duty to inform them of risks. There are literally a myriad of complications can arise from LASIK ranging from complete resection of a flap to overcorrection. We cannot list every one, but we do need a way to quickly and effectively illustrate how much they may be jeopardizing their eyesight. The most important may be potential acuity loss. This paper will yield a percentage of patients losing best spectacle corrected visual acuity (BSCVA) as a result of LASIK irrespective of its cause. It will not take into consideration subjective symptoms such as haloes/starbursting or such matters as under/over correction that are undesirable but not sight threatening.

Methods

A literature review was conducted to obtain data from a cross section of refractive surgeons. The only criteria for inclusion was that the article reported lines of BSCVA

lost due to the surgery. Inclusion of these statistics serves only as a measuring stick against which we can compare the local findings.

A brief survey was sent to random optometrists known to be co-managing LASIK patients and believed to have significant numbers of eligible patients. Eligible candidates were those that had undergone LASIK and were past their 6 month post operative visit. The six month mark was chosen because 80 percent of visual recovery in LASIK occurs within the first several postoperative days with the remaining 20 percent occurring over a 3- to 6- month period.¹ The survey also required that each patient be given an identification number by the OD so that patient anonymity could be maintained but original patient data could be reevaluated if necessary. The patient's pre- and post-operative refraction and BSCVA were also requested along with postoperative uncorrected visual acuity.

Results

Table 1 is a compilation of data taken from the studies utilized for this paper. It is by no means exhaustive, but represents a good cross section of the current literature on this subject. One will first notice that each of the studies is unique unto itself for a number of reasons that make direct comparisons and conclusions difficult. Chief among these is the fact that some of the researchers broke their patients down into subgroups based on refractive error and none of these categories correspond. A second consideration is the timing of the studies. While most of them compensated for their own learning curve, some of the later studies had a larger knowledge base and more choices regarding equipment and algorithms than some of the more pioneering studies. All these factors are confounding when trying to get a feel for the overall safety of this procedure from these reports. However, in analyzing the data some general conclusions can be discerned.

TABLE 1				
Overview of Studies Consulted				
Author	Eyes in Study	Pre-Op Myopia (Diopters)	Eyes with BSCVA Change (by degree of loss/gain**)	
(2)				
Guell et al.	43		- 1 line*	2.30%
Sala et al.	88		- 1 line*	3.40%
Helmy et al.	40		- 1 line*	5.00%
Tsai et al. (6)	A	29	<-7.00	Unchanged
			+ 1 line	89.66%
			+ 2 lines	3.45%
				6.89%
	B	26	<-10.00	Unchanged
				88.46%
			- 2 lines	7.69%
			+ 1 line	3.85%
	C	40	<-15.00	Unchanged
				37.50%
			-1 line	5.00%
			- 2 lines	5.00%
			+ 1 line	17.50%
			+ 2 lines	35.00%
	D	19	> -15.00	Unchanged
				21.05%
			-1 line	15.79%
			+ 1 line	10.53%
			+ 2 lines	52.63%
Jackson et al. (3)	122	<6.00	Unchanged	57.83%
			-1 line	16.39%
			- 2 lines	2.46%
			+ 1 line	20.49%
			+ 2 lines *	3.28%
	77	>6.00	Unchanged	44.16%
			-1 line	9.10%
			- 2 lines	5.19%
			+ 1 line	33.77%
			+ 2 lines*	7.08%
Marinho et al. (4)	34	10 - 22.50	Unchanged	44.11%
			-1 line	8.22%
			- 2 line	8.22%
			+ 1 line	11.67%
			+ 2 line	26.47%
Kremer et al. (5)	93	1- 5.00		
	59	5-8.00		
	50	8-23.00		
			Unchanged	75.82%
			- .5 line	9.90%
			-1 line	3.30%
			- 2 line	0.55%
			+ .5 line	6.04%
			+ 1 line	2.20%
			+ 2 line	2.20%
* or more				
** "+n line" = n lines of snellen visual acuity gained				
"-n line" = n lines of snellen visual acuity lost				

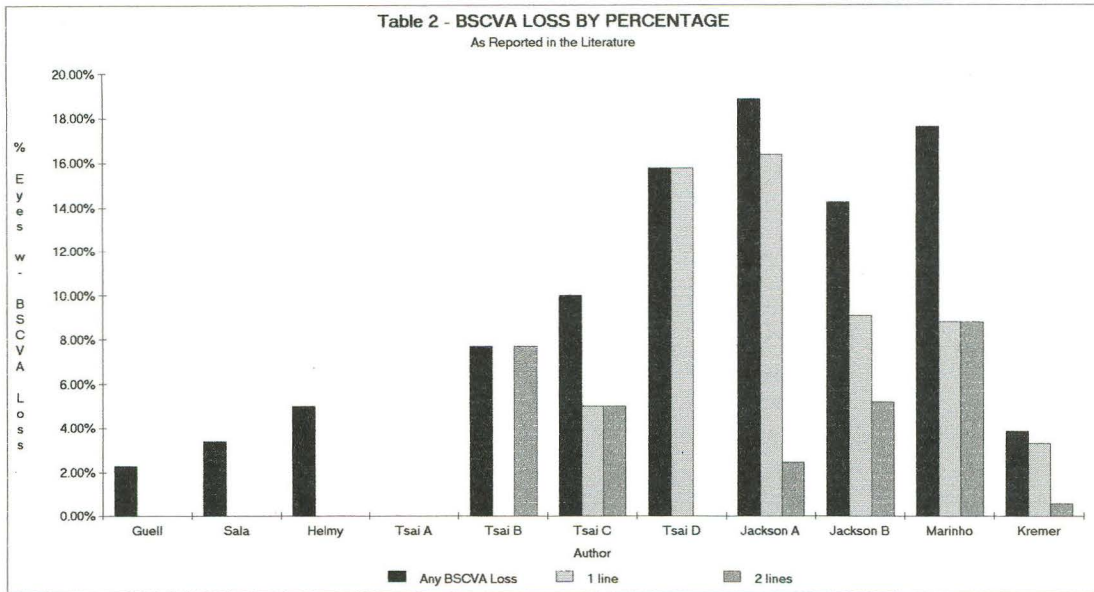
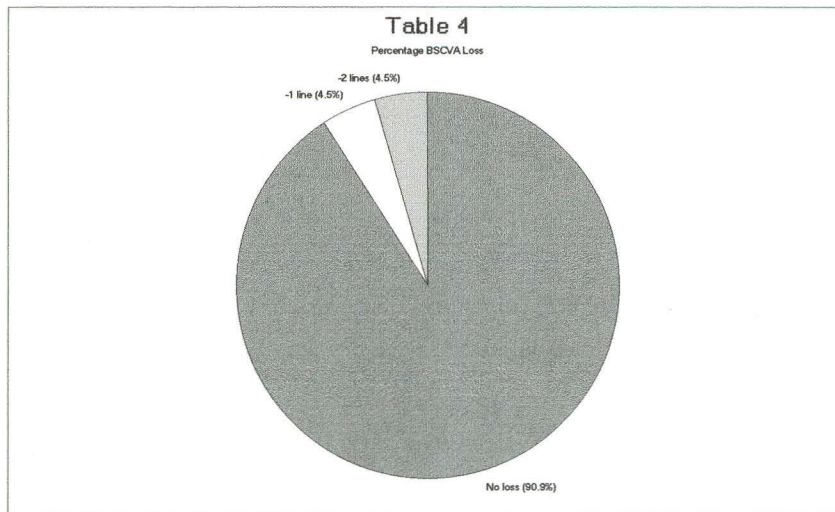


Table 2 first illustrates the percentage of patients that lost any amount of BSCVA. It also breaks those percentages down by the number of lines of snellen acuity lost. You will note that in every study, save one, there were patients that did loose at least one line of BSCVA. However, the percentages of lost acuity vary greatly from 2 percent to over 18 percent. These values also seem to vary with the extent of myopia treated as illustrated by Tsai⁶. In group A, where the myopia was less that 7.00 D, no patients lost BSCVA; however, as the myopia crept to 15.00 D in group D, 15.79% of the patents suffered some acuity loss. An equally interesting and important trend that should be brought to light at this point is that many patients, especially the higher myopes, gained lines of BSCVA. (Please refer back to Table 1 for specific numbers.)

Raw data gathered from our own study is summarized in table 3 below. You will note that we received surveys from four Optometrists utilizing three different surgeons and that twenty-two eyes were included in the study. Included in this table is information regarding pre- and post-operative refractive error which ranged from -13.25D to +.75 with a mean value of 4.77 Diopters of myopia.

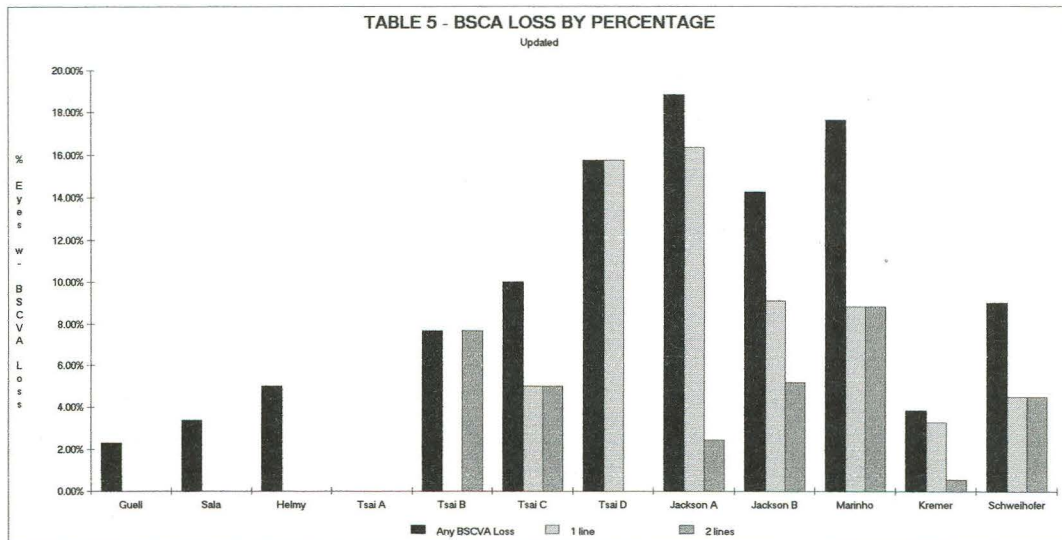
Table 3 - Survey Results							
Surgeon	Referring OD	Patient ID	Pre-Op Sph. Equiv.	BSCVA	Post-Op Sph. Equiv.	BSCVA	Net Gain/Loss
1	4	3001	-13.25	20/20	-0.75	20/20	0
1	4	3001	-12.75	20/20	-1.25	20/20	0
1	2	1616	-4.5	20/20	0.50	20/20	0
1	2	1616	-4.75	20/20	0.00	20/20	0
1	1	8095	0.75	20/20	1.25	20/25	-1
1	1	8095	-1.25	20/20	-1.00	20/20	0
1	2	7347	-3.5	20/20	-0.25	20/20	0
1	2	7347	-3.75	20/20	-0.25	20/20	0
1	1	9729	-9	20/20	0.00	20/20	0
1	1	9729	-9.5	20/20	0.25	20/20	0
1	2	9409	3.5	20/25	1.50	20/25	0
1	2	9409	1.75	20/25	0.50	20/25	0
1	2	9999	-6.5	20/20	0.00	20/20	0
1	2	9999	-6.25	20/25	-1.25	20/25	0
1	2	6790	-9	20/15	0.75	20/25	-2
1	2	6790	-8	20/15	0.75	20/20	0
2	3	3002	-2.5	20/20	0.50	20/20	0
2	3	3002	-3.5	20/20	0.00	20/20	0
2	3	3003	3.75	20/20	-0.25	20/20	0
2	3	3003	-3.25	20/20	-0.25	20/20	0
3	3	3004	-6.75	20/20	-0.50	20/20	0
3	3	3004	-6.75	20/20	-0.75	20/20	0

BSCVA loss is summarized in Table 4. One eye was found to have lost one line of BSCVA (8095), falling from 20/20 to 20/25. A second eye (6790) was found to have lost 2 lines of BSCVA, going from 20/15 to 20/25. Therefore, 9% of participating patients experienced some acuity loss as a result of the LASIK procedure.



Discussion

Table 5 is an updated version of Table 2 that now includes data from this study. This allows the reader to put this data into perspective and draw his/her own inferences.



Conclusion

While this paper was well conceived and that the methods and purpose are sound, reservations regarding its outcome remain. In essence, the study was conducted six months prematurely. At the time that the surveys were sent out, area Optometrists did not have the patient base to respond in large enough numbers to gather a sufficient sample. In addition, fewer surgeons were performing LASIK at that time. To illustrate this point refer to the "Surgeon" column of Table 3. Seventy-two percent of our procedures were performed by one ophthalmologist. This paper is more a report of his/her abilities than it is a statement of the surgical proficiency available to our patients.

Having made these statements and given all the data in Table 5, I do feel confident in making the following statements. First, it is rare for any LASIK patient to lose more than two lines of BSCVA. In fact, two lines seems to be the uppermost limit for VA loss with an incidence between one half to eight percent. Secondly, the overall risk of losing vision is probably quite close to **nine percent** and may in fact be lower.

Works Cited

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