Step by Step Manual for Advanced Surface Ablation (ASA)

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INTRODUCTION

Although lasers have been in use around the world since 1964 for various scientific and medical purposes it was not until 1987 that an ophthalmologist first used the laser for refractive purposes. Applying excimer laser photo ablation directly to the central surface of the cornea became known as "photo refractive keratectomy" or PRK and became widely used around the world to correct nearsightedness. The first PRK procedure on a patient was performed in 1987 at Columbia University and was on a blind eye. Photorefractive Keratectomy (PRK) was born.

The accuracy of the laser led to more accurate results than previous techniques. But in the beginning of Photorefractive Keratectomy in 1988 this method suffered from 2 severe complications: severe postoperative pain and increased corneal haze formation. These factors limited its effectiveness and reputation ever since. So as a matter of fact, the popularity of PRK, however, was slow to catch on. It wasn't until the development of microkeratome technology and introduction of laser-in-situ keratomileusis (LASIK) in 1991 for vision correction that popularity soared. With LASIK, patients experience little if any pain and see well quickly. Due to the fact that the LASIK procedure has its complications and disadvantages, like e.g. intraoperative microkeratome-related complications (thin, irregular, dislocated, free or perforated flap; entry into eye; diffuse intralamellar keratitis; epithelial ingrowth; interface problems and corneal keratectasie) the initial problems of PRK did not seem too severe. That is the reason for the revival of PRK. Haze formation, pain and slow recovery have almost disappeared by the introduction of Advanced Surface Ablation (ASA). This method is basically the PRK technique with following modifications: development of a special distribution pattern of laser shots and various postoperative treatment modifications.

PRE- AND POSTOPERATIVE PROCEDURES

Before the laser surgery with the MEL 70 or MEL 80 spot-scanning laser (Carl Zeiss Meditec AG), Novesine 0.4% (Oxybuprocain-HCL 4mg) eye-drops are applied for topical anesthesia. A lid speculum is inserted.

The eye has to be marked with an optical zone marker. The diameter of this marker depends on the pupil diameter of the patient.

The epithelium is then removed mechanically with an Amoil epithelial scrubber.

This Brush should be moisturized with 1 or maximum 2 drops BSS with room temperature before being used.

Afterwards an Epithelium Spatula is used immediately to clean any debris from the stromal surface.

The stroma is then ablated using a treatment diameter of 5.5 mm to 8.0 mm. If the pupil diameter is very large, we rather prefer a treatment diameter of up to 8.0 mm. In order to prevent an increase of corneal temperature we have developed a special distribution pattern of laser shots.

The complete procedure should be performed continuously because the longer the procedure, the higher the risk for the cornea to dehydrate and to get traumatized with the consequence of more haze formation. Additionally the use of the optional cone from Carl Zeiss Meditec AG is essential from our point-of-view because of following reasons: during the ablation the plum will not be sucked away directly above the surface of the cornea but only inside the cone.

This is also a decisive factor for minimizing the dehydration of the cornea.

Following the ablation the corneal treatment zone has to be cooled with -8 °C chilled BSS which has to be applied 3 to 4 times onto the corneal surface for the duration of 10 seconds each. The solution is sucked away by a sponge after each cooling procedure. It is most important, that before the cooling procedure a metal ring or funnel is applied to the treatment zone to ensure, that only this area is being cooled in order to avoid spill-over onto the adnexa due to the fact, that if the chilled BSS gets in contact with the conjunctiva the patient would suffer from pain due to coldness of BSS.

Then we apply one drop of NSAID (Non-Steroidal-Anti-Inflammatory-Drugs) such as Voltaren (Diclofenac Sodium 0.1%, Ciba Vision). Voltaren is an anti-inflammatory drug to reduce pain and the initial inflammatory response.

A bandage contact lens is applied (disposable soft contact lens, 1-Day-Acuvue® Johnson & Johnson Vision Products, Inc.). With one hand we use a Merocel sponge to remove the bandage lens from its packaging. With the other hand we use another sponge to correctly position the lens onto the eye.

The aim of this technique is to minimize potential sources of infection to the corneal wound by avoiding any contact with the surgeon's glove and to apply the lens a traumatically.

Since the cornea surface gets plainer with higher myopic corrections, we hold the opinion, that one should develop bandage lenses especially for refractive surgeries with high oxygen permeability as well as a plainer base curve.

After the lens is positioned the lid-speculum has to be removed.

Postoperatively all patients should be treated with Ofloxacin 0.3% eye drops 4 times a day until complete re-epithelialization (usually on the second postoperative day).

During this time you must not give any therapeutic ointment.

After removing the contact lens, fluorometholone eye drops 0.1% are instilled 3 times a day for 1 month, tapered by 1 drop every month over the next 3 months.

Postoperative management of the patients: we emphasize following outpatient handling: all patients can reach us 24 hours a day for the following 3 days to ensure, that we can treat any unexpected circumstance such as infiltrates as well as answer all questions of the patients during this time. The patients feel totally being taken care of professionally.

[1] Preoperatively: Novesine 0.4% (Oxybuprocain-HCL 4 mg)
[2] Inserting a lid-speculum
[3] Marking of the eye with an optical zone marker
[4] Epithelium removal with an Amoil Brush
[5] Debris removal with an Epithelium Spatula
[6] Ablation with a special distribution pattern of laser shots
[7] Cooling of the cornea with chilled BSS
[8] Applying Voltaren eye drops
[9] Applying bandage lens
[10] Applying Ofloxacin 4x/day until complete re-epithelialization
[11] After lens removal: mild cortisone
[12] Postoperative management

STEP BY STEP INSTRUCTION

ADDITIONAL POSTOPERATIVE INSTRUCTIONS

- It is recommended that eye make-up be avoided for one week before and after surgery.
- It is important to rest your eyes as much as possible during the first 24 hours.
- Do not rub or squeeze the eye for at least one week post laser surgery.
- Don't drive after surgery until you are accustomed to your changed vision, especially distance judgment (usually days).
- Sunglasses with a proper UV-protection are recommended when outdoors for protection from glare, trauma, and extreme drying of the eyes. Nagy et al demonstrated in animal experiments, that by refraining from proper UV protection haze formation increased.
- Vigorous exercise, swimming and contact sports should be avoided for about 1 month postoperatively.
- Medications:

	VOLTAREN	Ofloxacin	LUBRICANTS	Cortisone
LASER DAY	1x	4x	2-4 hrly	
DAY 2		4x	2-4 hrly	
DAYS 3-6			2-4 hrly	
WEEK 2			4-8 hrly	3x
WEEKS 3+4			4-8 hrly	3x
WEEKS 5+6				2x

RESULTS OF A COMPARATIVE STUDY OF ASA VS. PRK

Considering Advanced Surface Ablation (ASA) we used a special distribution pattern of laser shots, which was developed by us, to avoid a summation of thermal effects. We also modified our postoperative treatment regarding new handling of bandage lenses, postoperative cooling with chilled BSS and a different medication.

This study was a prospective Cohort Study. We compared the pre- and postoperative BCVA, Spherical Equivalent (SE), postoperative UCVA, safety, stability, predictability, pain and re-epithelialization of 54 ASA eyes with 358 PRK eyes. Mean SE was -5.10 ± 2.71 D ranging from -0.75 D to -13.50 D. The above mentioned parameters were evaluated after 1 week, 1, 6 and 12 months postoperatively. The statistical analysis was performed with SPSS. Statistical methods were for paired data Wilcoxon Test, for impaired data with two variables Man-Whitney-U Test and for impaired data with more than two variables Kruskal-Wallis-Test. All test used were nonparametric, tested with Kolmogorov-Smirnov-Test. We set the level for significance at $p< 0.05$.

RE-EPITHELIALIZATION

The mean time for complete re-epithelialization was 2.25 ± 0.43 days in the ASA group whereas in the PRK group it was 3.15 ± 0.5 days.

Postoperative day 1 ratings of pain in the group with PRK was 5.24 ± 0.65 on a scale of 0 to 10 (10 = severe pain) and in the group with ASA 0.94 ± 0.88.

PAIN

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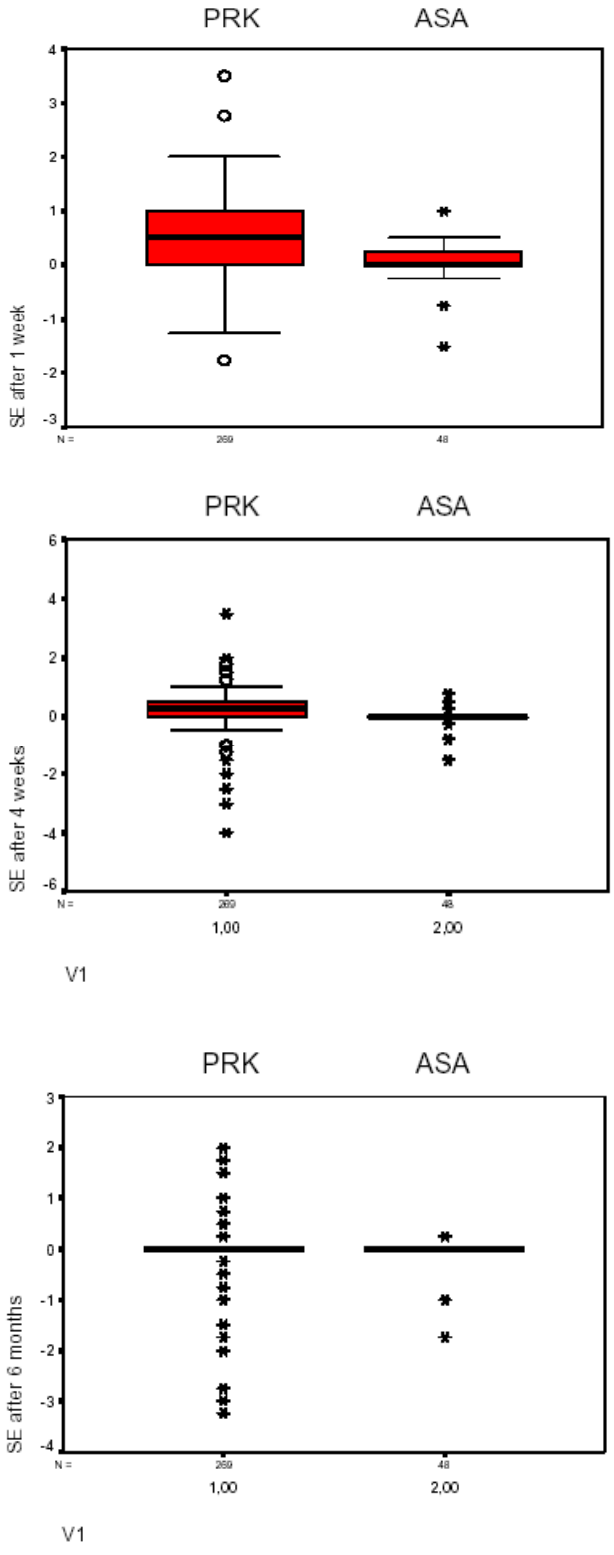
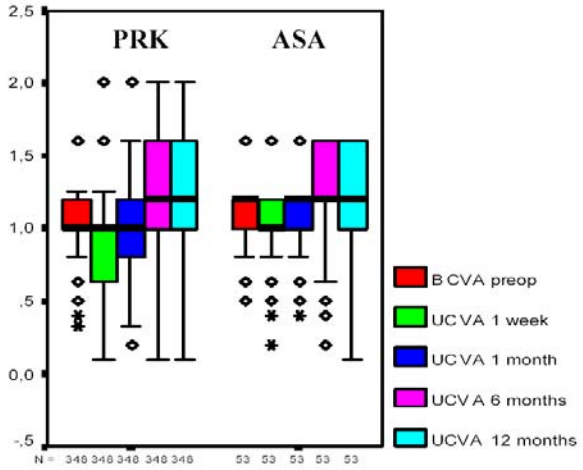
TIME COURSE OF SPHERICAL EQUIVALENT (SE)



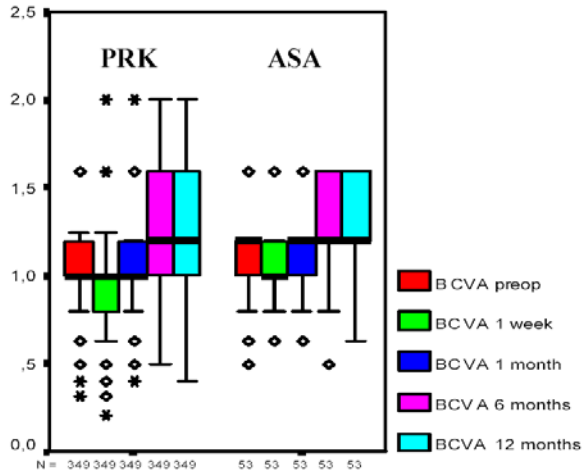
The above shown Boxplots illustrate, that the stability of the SE in the ASA is significantly higher than in PRK with less variance and extreme values after 1 and 4 weeks (p< 0.05 Man-Whitney-U), whereas after 6 and 12 months there is no significant difference between ASA and PRK.

COMPARISON OF PREOPERATIVE BCVA WITH POSTOPERATIVE UCVA



PRK: UCVA after 1 week is significantly worse than preoperative BCVA (p<0.05 Wilcoxon). Recovery of BCVA is within 4 weeks. After 6 and 12 months UCVA is significantly better (p<0.05 Wilcoxon) than preoperative BCVA.
ASA: Recovery of BCVA is achieved within 1 week. After 6 and 12 months UCVA is also significantly better (p<0.05 Wilcoxon) than preoperative BCVA.
After 1 and 4 weeks UCVA is significantly better (p<0.05 Man-Whitney-U) than PRK. After 6 and 12 months no significant changes were found between both groups.

COMPARISON OF PRE- AND POSTOPERATIVE BCVA



PRK: BCVA after 1 week is significantly worse than preoperative BCVA (p<0.05 Wilcoxon). Recovery of BCVA is achieved between 1 to 4 weeks. After 6 and 12 months BCVA is significantly better than preoperative BCVA (p<0.05 Wilcoxon).
ASA: Recovery of BCVA is achieved within 1 week. After 6 and 12 months BCVA is also significantly better (p<0.05 Wilcoxon) than preoperative BCVA.
After 1 and 4 weeks BCVA is significantly better (p<0.05 Man-Whitney-U) than PRK. After 6 and 12 months no significant changes between PRK and ASA can be found.

SUMMARY: ASA - PRK

	ASA	PRK
UCVA	After 1 and 4 weeks better than preoperative BCVA ($p<0.05$ Wilcoxon)	After 1 and 4 weeks worse than preoperative BCVA ($p<0.05$ Wilcoxon)
	Better than PRK ($p<0.05$ Man-Whitney-U)	
	After 6 and 12 months better than preoperative BCVA ($p<0.05$ Wilcoxon)	After 6 and 12 months better than preoperative BCVA ($p<0.05$ Wilcoxon)
	No differences to PRK	
BCVA	After 6 and 12 months better than preoperative BCVA ($p<0.05$ Wilcoxon)	After 6 and 12 months better than preoperative BCVA ($p<0.05$ Wilcoxon)
	Better than PRK after 1 and 4 weeks ($p<0.05$ Man-Whitney-U) and no differences to PRK after 6 and 12 months	
Recovery of BCVA	Within 1 week	Between 1 to 4 weeks
Efficacy (within ± 0.5 D)	98%	98%
Safety (BCVA unchanged or improved)	98%	93%
Predictability	96% (± 0.5 D) 98% (± 1.0 D)	92% (± 0.5 D) 95% (± 1.0 D)
Regression	-0.03 D	- 0.28 D
Pain	0.94 ± 0.88	5.24 ± 0.65
Re-epitheliazation time	2.25 ± 0.43 days	3.15 ± 0.5 days

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Publication No. 000000-1275-084