Macular Photocoagulation Study

Extrafoveal Study

Purpose: Randomized controlled clinical trial to determine whether argon laser is effective for preventing or delaying SVL in eyes with EFCNVM secondary to ARMD, OHS, INVS.

Eligibility: Patients:

- ☞Angiographic evidence of CNVM with foveal edge 200 to 2500 μ from center of FAZ. "Well defined NVM"
- ☞Best corrected VA 20/100 or better. Age ≥50 years
- ☞Peripapillary lesions only if spared 1.5 clock hours of NFL
- ☞ARMD must have drusen, OHS must have one other atrophic scar, INVS had nothing else.

Stuff:

- ☞12 centers, Bailey-Lovie chart, full exam, photos, angio.
- ☞Argon blue green laser. Angio within 72 hours. Laser settings: 200μ spot size, 0.2-0.5 sec duration surround NVM 100 to 125 μ (if NVM within 350μ, 100μ used), start with 200mW with test burn.
- ☞Retrobulbar used
- ☞Uniform whitening

Patient Follow Up:

- ☞Tx'd pts 3 to 9 weeks post tx. Nontx'd 3 to 6 mths.

Outcome measured:

- ☞Best correct VA.
- ☞SVL (defined as loss of 6 lines, 4 fold ↑ in visual angle).

Results:

ARMD

Visual Acuity 20/200 or worse

Time	Treated	Non Treated	Difference
18 months	14%	33%	2X
3 years	31%	52%	1.7X

Risk of SVL

Time	Treated	Non Treated	RR
18 months	21%	43%	2.0 (50% reduc)
3 years	47%	62%	1.4 (24% reduc)
5 years	46%	64%	1.4 (24% reduc)

☹ Recurrence rate in treated eyes 54% (75% within first year) in five years.

OHS

VA 20/200 or worse

Time	Treated	Non Treated
3 years	5%	39%
5 years	?	?

☺ Recurrence rate 26%.

Risk of SVL

Time	Treated	Non Treated	Difference
18 months	9%	36%	3.6X (60% reduc)
3 years	10%	48%	4.8X (78% reduc)
5 years	12%	42%	4X

Idiopathic Neovacularization

VA 20/200 or worse

Time	Treated	Non Treated
3 years	7%	26%
5 years	?	?

Risk of SVL

Time	Treated	Non Treated	Difference
18 months	13%	38%	2.9X
3 years	20%	36%	1.8X

5 years	23%	48%	

Juxtafoveal Study

Purpose: Multi center controlled clinical trial designed to determine whether krypton red laser photocoagulation is of value in preventing vision loss in eyes with ARMD in eyes with CNVM 1 to 199μ from center FAZ or CNVM 200μ or farther from center of FAZ with blocked florescence or blood extending within 200μ of the FAZ center.

Eligibility: Patients:

☞Angiographic evidence of edge of CNVM between 1 to 199μ from center FAZ or CNVM 200μ or farther from center of FAZ with blocked florescence or blood extending within 200μ of the FAZ center.

☞Best corrected VA 20/400 or better. Age ≥50 years

☞Peripapillary lesions only if spared 1.5 clock hours of NFL

☞ARMD must have drusen.

Stuff: ☞13 centers, Bailey-Lovie chart, full exam, photos, angio.

☞Krypton red laser. Angio within 72 hours. Surround NVM by 100 to 125μ on non foveal side and up to center of FAZ.

Patient Follow Up: ☞Tx'd pts 2,4 & 6 weeks post tx. Nontx'd 3 to 6 mths.

Outcome measured: ☞Best correct VA.
☞SVL (defined as loss of 6 lines, 4 fold ↑ in visual angle).

Results:

Best Corrected VA 20/200 or worse

Time	Treated	Non Treated
3 years	31%	49%
Avg. VA	20/200	20/250

Proportion with SVL

Time	Treated	Non Treated	Difference
1 year	31%	41%	1.5X

3 years	50%	61%	1.2X
5 years	55%	65%	1.1X

Proportion with SVL in relation to hypertension (3 years)

Hypertension	Treated	Non Treated	Difference
Normotensive	31%	64%	2X
Suspect HTN	46%	70%	1.5X
Definite HTN	58%	58%	0X

☹ 55% developed recurrence within 1 year.

Fellow eye risk factors.

1. 5 or more drusen (RR 2.1)
2. Focal hyperpigmentation (RR 2.0)
3. Large drusen (RR 1.5)
4. Hypertention (RR 1.7)

One risk factor 7%, two 30%, three 60%, four 87%.
Only 10% without RPE hyperpigmentation & soft drusen.

Note: To be eligiable the lesion had to be well defined only. It could therefore be occult or classic. Parts can be obscured by blood or pigment. 10-15% of all lesions qualify based on these criteria.

Subfoveal Study

Purpose: A clinical trial conducted to evaluate the effect on vision of laser treatment (argon green or krypton red) compared with no treatment of eyes with subfoveal CNVM associated with ARMD.

Eligibility: Patients:

1) Angiographic evidence of edge of CNVM under the center of the FAZ. "Classic CNVM under FAZ center and may have occult elsewhere". No larger than 3.5 DA.
2) Component of classic CNV
3) CNV with classic and occult (as long as part well defined)
4) Boundaries well demarcated
5) Entire lesion ≤3.5 MPS DA (recurrent arm of study 6 DA allowed)
6) BCVA 20/40 - 20/320
7) Age ≥50 years
8) ARMD must have drusen.

Stuff: ☞13 centers, Bailey-Lovie chart, full exam, photos, angio.

1. Either Krypton red laser or argon green (pts randomly assigned).
2. Angio within 96 hours.
3. Surround NVM by 100μ. Treat entire lesion both classic and occult.
4. Treat features that block (blood, blocked flour, serrous PED)
5. 200-500μ
6. 0.5 sec
7. 300 μ into prior tx, cover all feeder 100μ sides

Patient Follow Up: ☞For all pts 3 & 6 months.

Results:

Three year outcome for recurrent CNVM with ARMD

	SVL	Lost lines	Median VA	Reading Speed

Treated	17%	2.6	20/250	35 wpm
Untreated	39%	3.9	20/320	15 wpm

Three year outcome for new CNVM with ARMD

	SVL	Lost lines	Median VA	Reading speed
Treated	23%	3.5	20/320	22 wpm
Untreated	45%	5.0	20/500	13 wpm

☺ By 12 months untreated group caught up to treated.

NB. Same trend for reading speed.

<u>Follow up studies identified key factors associated with good out come.</u>

Lesion size: small ≤1 DA
medium 1-2 DA
large 3 DA

VA: good ≥20/125
moderate ≥20/160
poor 20/200

<u>Size</u>	<u>VA</u>	<u>Group</u>	<u>Otcome</u>
< 1DA	>20/125	A	Benefit throughout follow-up
< 1DA	<20/100	B	Tx worse year 1, substantially better thereafter
1-2DA	>20/200	A	
1-2DA	<20/160	B	
> 2DA	>20/200	C	Slightly better throughout
> 2DA	<20/160	D	Worse 18 months, no difference thereafter

<u>Key factors influencing outcomes:</u>

8. Larger lesion had smaller benefit.
9. ≤1DA earlier tx benefit.
10. VA 20/40 to 20/100 did not show benfit till 18 months.

NB. No difference between Argon vs, Krypton.