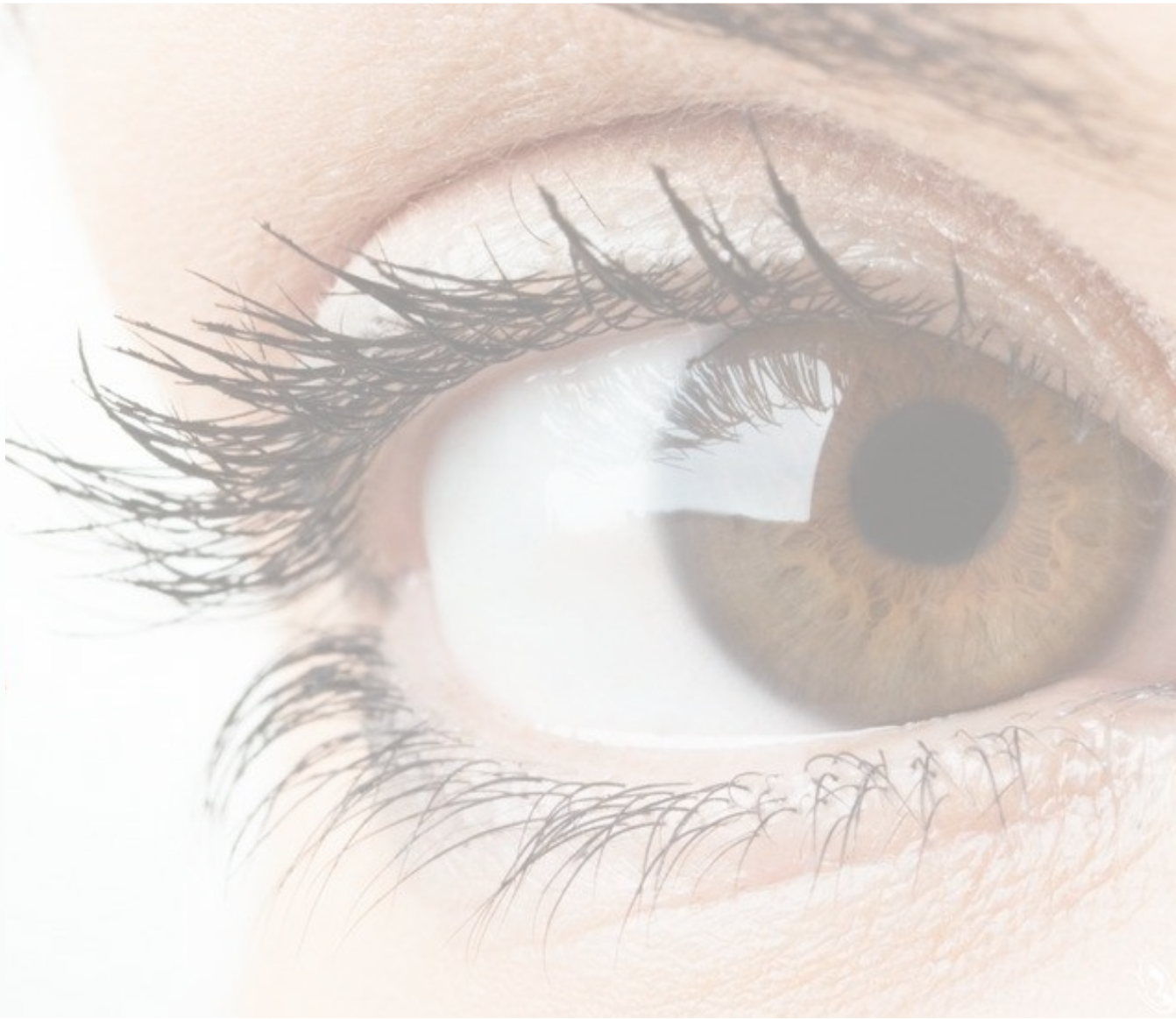
EYETRONIC® - Restoring Vision

EYETRONIC® Presentation

June 2024

eyetronic
restoring vision



Glaucoma

Progressive Loss of Vision

#1 cause for irreversible blindness

80 million -> 100 million by 2040

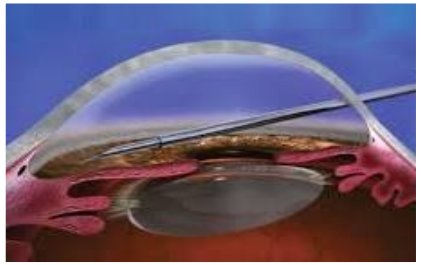
2% prevalence age 40+

3% in Asia

Quigley & Broman, Br J Ophthalmol 2006; 90:262–267, 2006; Tham et al., Ophthalmol 2014; 121:2081-2090

Glaucoma Treatment Today

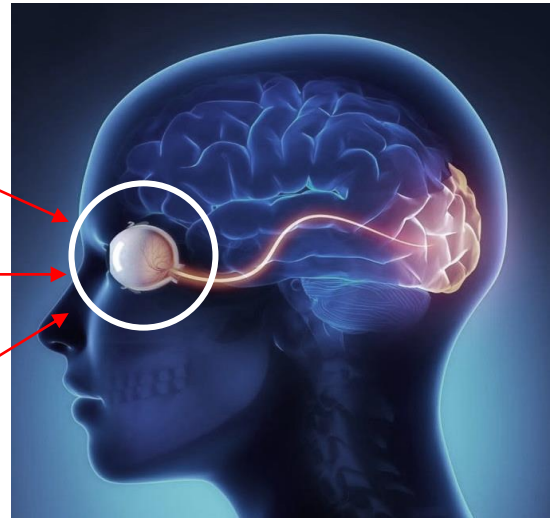
Standard-of-Care has focus on the eye



Drops

Surgery

MIGS



Management of **IOP** is **necessary**

But **not sufficient**

Patients continue to **lose vision**

#1 cause for irreversible blindness

80 million -> 100 million by 2040

40% have **NTG** - Normal Tension Glaucoma

70% in Asia have NTG

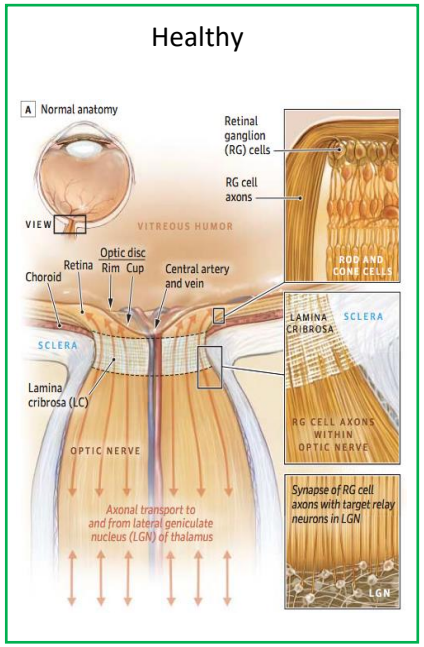
Quigley & Broman, Br J Ophthalmol 2006 90: 262-267; MJ Chen et al., Taiwan J Ophthalmol 2020; 10(4):250-254

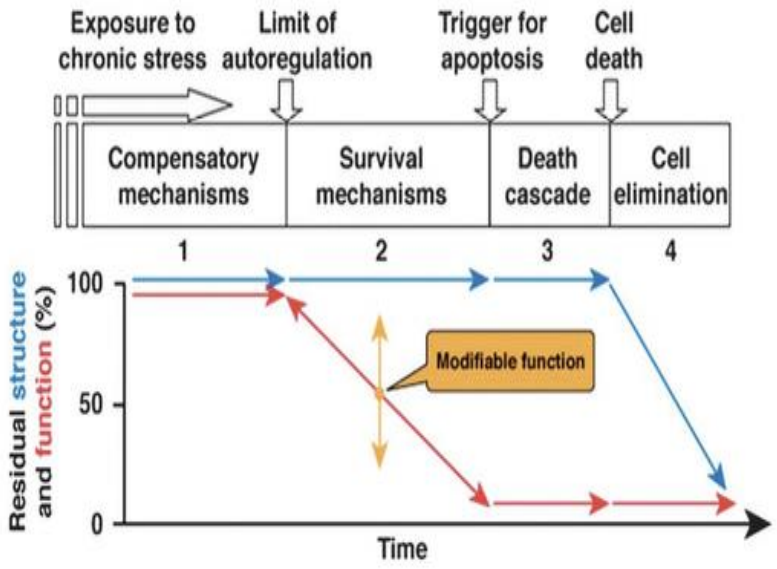
Glaucoma Treatment Tomorrow

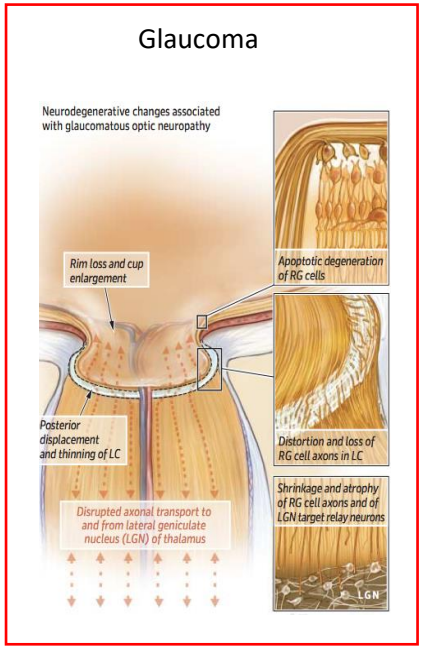
New paradigm needs focus on the optic nerve

Glaucoma is a **neuropathy** of the optic nerve

Electricity activates **nerves**







Oxidative stress **terminates metabolism** → **Nerve cells** become **inactive** and will later lose their function - **vision is lost** → Nerve cells die - **apoptosis**

Stimulate before structure is lost

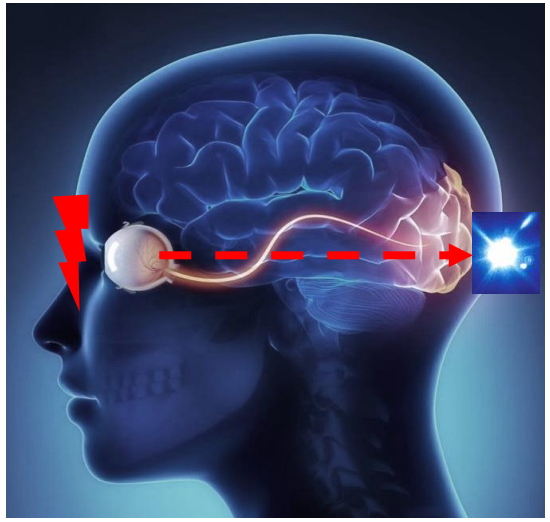
Weinreb et al., JAMA 311: 1901-11, 2014, Porciatti & Ventura, J Neuroophthalmol 32: 354-8, 2012; Cordeiro et al., Brain 140: 1757-67, 2017

Optic Nerve Stimulation (ONS)

Re-engaging non-active cells with electrical current

EYETRONIC®

CE



Stimulates from **eye to cortex**

Reactivates cellular metabolism

Phosphenes as **biomarker**

900 patients in **9.000 sessions**

No SAE (Serious Adverse Event)

CE certified based on 3 RCTS

Mode-of-Action and Effects of ONS

Preclinical data after optic nerve injury

Mode-of-Action

Neurotrophic factors

↑ IGF-1, BDNF, CNTF, FGF-2; ↓TNF-α

Immunomodulation

↑ IL-10; ↓ IL-6, COX-2, NF-kB

Glutamine synthetase ↑

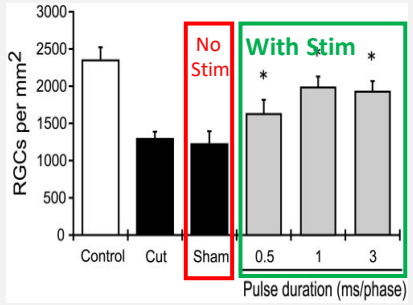
Intracellular Ca^{2+}↑

Caspase 3 ↑

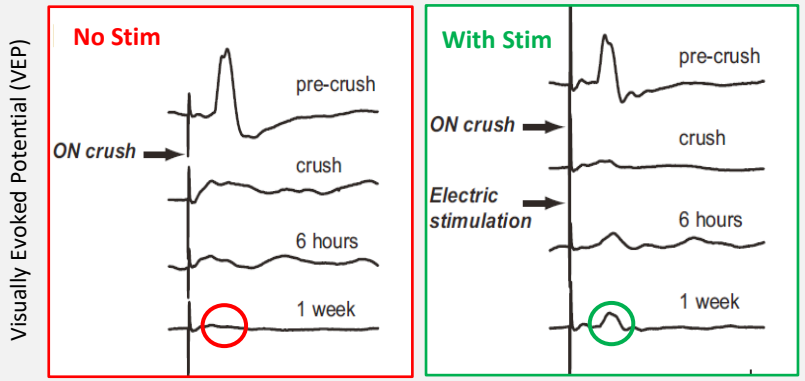
Perfusion ↑

3 Effects

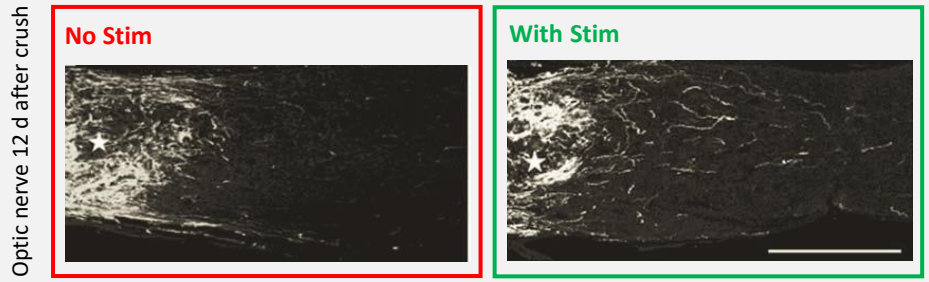
Neuroprotection



Functional Neurorestoration



Structural Neurorestoration



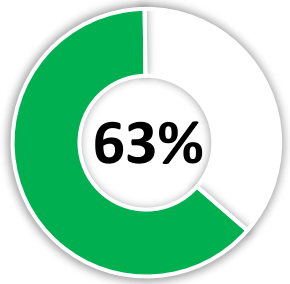
Miyake et al., Invest Ophthalmol Vis Sci 48: 2356-61, 2007, Tagami et al., Jpn J Ophthalmol 53: 257-66, 2009, Morimoto et al., Invest Ophthalmol Vis Sci 46: 2147-55, 2005

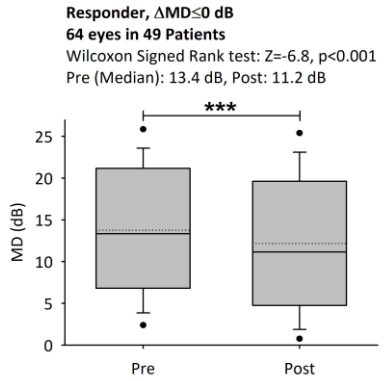
Results with EYETRONIC®

12-month clinical outcomes in IOP patients

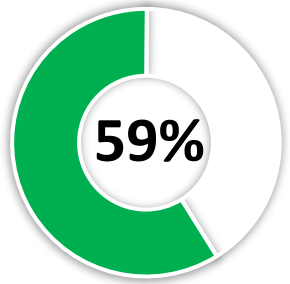
Elevated IOP Eyes (n=101)

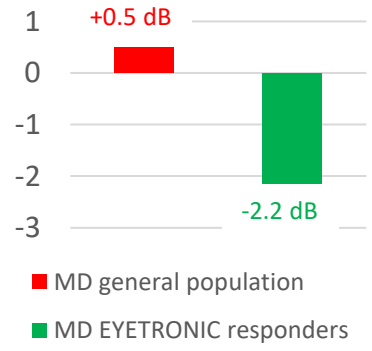
Halt in Visual Field loss





Improved Visual Field






Erb et al. Bioelectronic Medicine (2022) 8:6
https://doi.org/10.1186/s42234-022-00089-9

Bioelectronic Medicine

RESEARCH ARTICLE Open Access

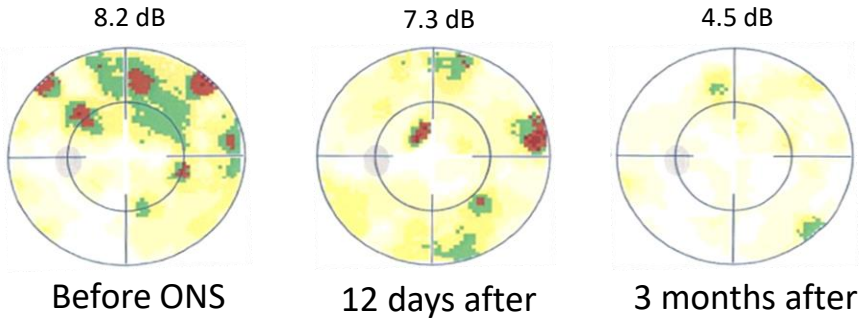
Electrical neurostimulation in glaucoma with progressive vision loss

Carl Erb[1], Sophie Eckert[2], Pia Gindorf[1], Martin Köhler[3], Thomas Köhler[3], Lukas Neuhann[4], Thomas Neuhann[4], Nadja Salzmann[3], Stefanie Schmickler[5] and Jens Ellrich[6*]

Abstract

Background: The retrospective study provides real-world evidence for long-term clinical efficacy of electrical optic nerve stimulation (ONS) in glaucoma with progressive vision loss.

Mean Defect (dB) Visual Field perimetries

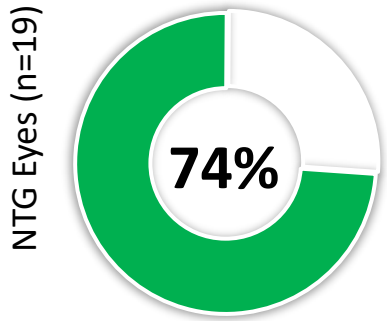


Neuromodtronic PMCF, Germany, 2022; Erb et al., Bioelectronic Medicine (2022) 8:6

Results with EYETRONIC®

12-month clinical outcomes in NTG patients

Improved Visual Field



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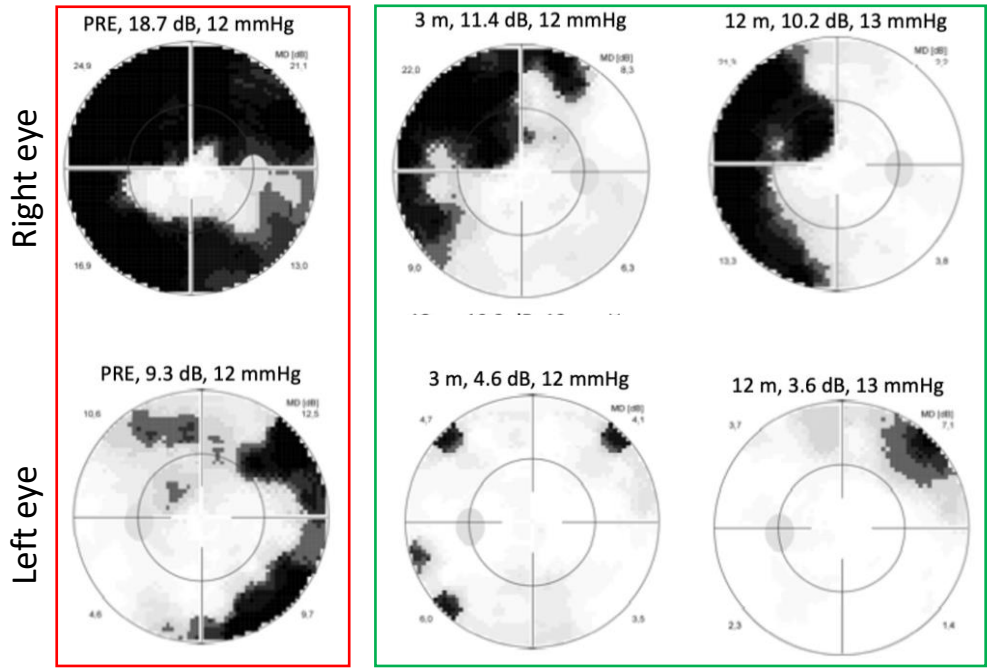

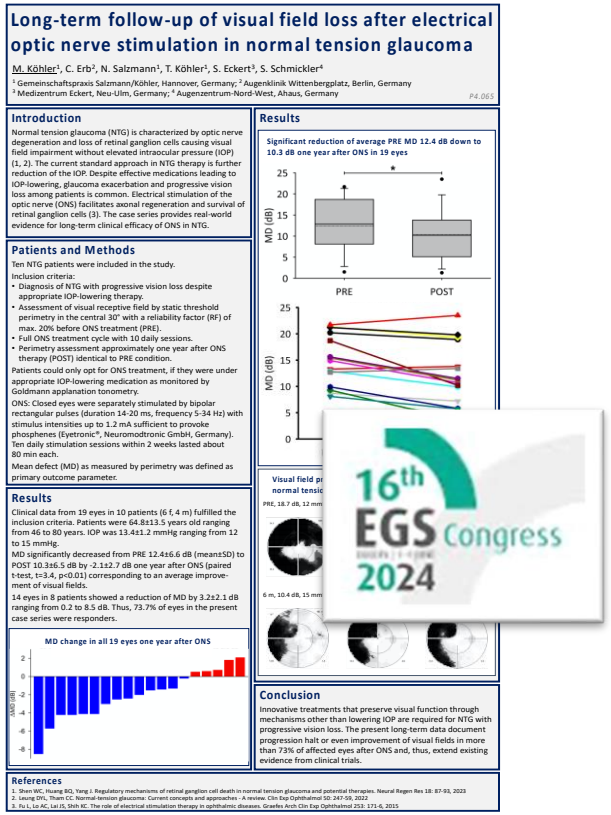

Long-term follow-up of visual field loss after electrical optic nerve stimulation in normal tension glaucoma

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P4.065

Introduction

Normal tension glaucoma (NTG) is characterized by optic nerve degeneration and loss of retinal ganglion cells causing visual field impairment without elevated intraocular pressure (IOP) (1, 2). The current standard approach in NTG therapy is further reduction of the IOP. Despite effective medications leading to IOP-lowering, glaucoma exacerbation and progressive vision loss among patients is common. Electrical stimulation of the optic nerve (ONS) facilitates axonal regeneration and survival of retinal ganglion cells (3). The case series provides real-world evidence for long-term clinical efficacy of ONS in NTG.

Patients and Methods

Ten NTG patients were included in the study.
Inclusion criteria:
- Diagnosis of NTG with progressive vision loss despite appropriate IOP-lowering therapy.
- Assessment of visual receptive field by static threshold perimetry in the central 30° with a reliability factor (RF) of max. 20% before ONS treatment (PRE).
- Full ONS treatment cycle with 10 daily sessions.
- Perimetry assessment approximately one year after ONS therapy (POST) identical to PRE condition.

Patients could only opt for ONS treatment, if they were under appropriate IOP-lowering medication as monitored by Goldmann applanation tonometry.
ONS: Closed eyes were separately stimulated by bipolar rectangular pulses (duration 14-20 ms, frequency 5-34 Hz) with stimulus intensities up to 1.2 mA sufficient to provoke phosphenes (Eyetronic®, Neuromodtronic GmbH, Germany). Ten daily stimulation sessions within 2 weeks lasted about 80 min each.
Mean defect (MD) as measured by perimetry was defined as primary outcome parameter.

Results

Clinical data from 19 eyes in 10 patients (6 f, 4 m) fulfilled the inclusion criteria. Patients were 64.8±13.5 years old ranging from 46 to 80 years. IOP was 13.4±1.2 mmHg ranging from 12 to 15 mmHg.
MD significantly decreased from PRE 12.4±6.6 dB (mean±SD) to POST 10.3±6.5 dB by -2.1±2.7 dB one year after ONS (paired t-test, t=3.4, p<0.01) corresponding to an average improvement of visual fields.
14 eyes in 8 patients showed a reduction of MD by 3.2±2.1 dB ranging from 0.2 to 8.5 dB. Thus, 73.7% of eyes in the present case series were responders.

MD change in all 19 eyes one year after ONS

Results

Significant reduction of average PRE MD 12.4 dB down to 10.3 dB one year after ONS in 19 eyes

Conclusion

Innovative treatments that preserve visual function through mechanisms other than lowering IOP are required for NTG with progressive vision loss. The present long-term data document progression halt or even improvement of visual fields in more than 73% of affected eyes after ONS and, thus, extend existing evidence from clinical trials.

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16th EGS Congress 2024

Neuromodtronic PMCF, Germany, 2022; EGS 2024 Eyetronic Poster, P4.065

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