



Implantable Miniature Telescope (By Dr. Isaac Lipshitz) **For End-Stage Macular Degeneration**

Reference Publications

Implantable miniature telescope for the treatment of visual acuity loss resulting from end-stage age-related macular degeneration: 1-year results.

Hudson HL, Lane SS, Heier JS, Stulting RD, Singerman L, Lichter PR, Sternberg P, Chang DF, IMT-002 Study Group. *Ophthalmology*. 2006 Nov;113(11):1987-2001.

PURPOSE: To evaluate the safety and efficacy of an implantable visual prosthetic device (IMT; VisionCare Ophthalmic Technologies, Saratoga, CA) in patients with bilateral, end-stage age-related macular degeneration (AMD).

DESIGN: Prospective, open-label, multicenter clinical trial with fellow eye controls.

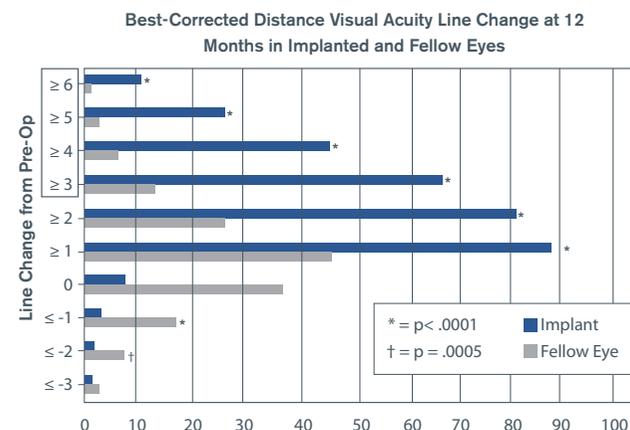
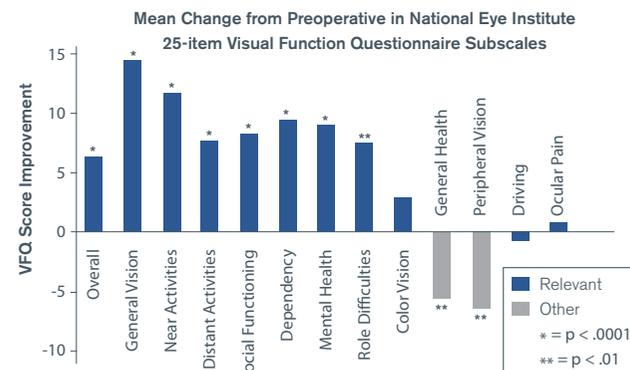
PARTICIPANTS: A total of 217 patients (mean age, 76 years) with AMD and moderate to profound bilateral central visual acuity loss (20/80-20/800) resulting from bilateral untreatable geographic atrophy, disciform scars, or both were enrolled.

METHODS: A visual prosthetic device (implantable telescope), designed to enlarge retinal images of the central visual field, was implanted monocularly in the capsular bag after lens extraction. Fellow eyes were not implanted to provide peripheral vision and served as controls. Study patients participated in 6 visual rehabilitation visits after surgery.

MAIN OUTCOME MEASURES: Best-corrected distance visual acuity (BCDVA) and best-corrected near visual acuity (BCNVA), quality-of-life scores from the National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) and the Activities of Daily Life scale, endothelial cell density (ECD), and incidence of complications and adverse events.

RESULTS: At 1 year, 67% of implanted eyes achieved a 3-line or more improvement in BCDVA versus 13% of fellow eye controls ($P < 0.0001$). Fifty-three percent of implanted eyes achieved a 3-line or more improvement in both BCDVA and BCNVA versus 10% of fellow eyes ($P < 0.0001$). Mean BCDVA and BCNVA improved 3.5 lines and 3.2 lines, respectively, in implanted eyes versus 0.8 lines and 1.8 lines, respectively, in fellow eyes ($P < 0.0001$). Change in visual acuity was not related to lesion type. Mean NEI VFQ-25 scores improved by more than 7 points from baseline ($P < 0.01$) on 7 of 8 relevant subscales. Eleven eyes did not receive the device because of an aborted procedure. Endothelial cell density was reduced by 20% at 3 months and 25% at 1 year. The decrease in ECD was correlated with postsurgical edema ($P < 0.0001$), and there was no evidence that endothelial cell loss is accelerated by ongoing endothelial trauma after implantation.

CONCLUSIONS: This implantable visual prosthesis can improve visual acuity and quality of life in patients with moderate to profound visual impairment caused by bilateral, end-stage AMD.



Implantable telescope for end-stage age-related macular degeneration: long-term visual acuity and safety outcomes.

Hudson HL, Stulting RD, Heier JS, Lane SS, Chang DF, Singerman LJ, Bradford CA, Leonard RE, IMT-002 Study Group. Am J Ophthalmol. 2008 Nov;146(5):664-673.²

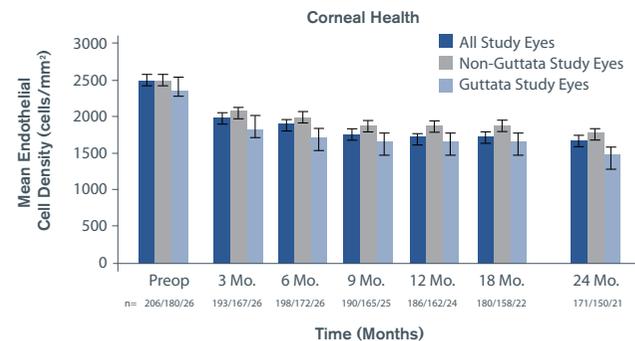
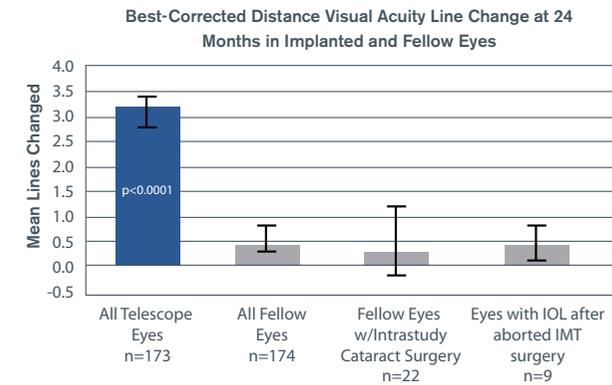
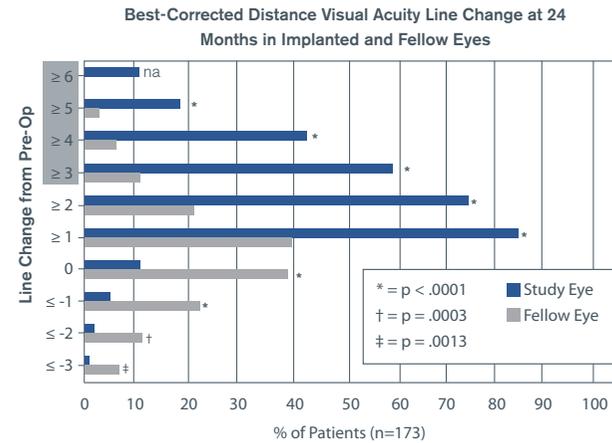
PURPOSE: To evaluate long-term safety and best-corrected visual acuity (BCVA) results of a telescope prosthesis in patients with end-stage age-related macular degeneration (AMD).

DESIGN: Prospective, open-label clinical trial with fellow-eye controls.

METHODS: Patients with end-stage AMD (bilateral geographic atrophy or disciform scars; BCVA, 20/80 to 20/800) received the telescope prosthesis at 28 centers. Methods were similar to those described in the one-year results, with follow-up visits continuing at 18 and 24 months. Main outcome measures included BCVA change from baseline, endothelial cell density (ECD) and morphometry, and incidence of complications.

RESULTS: At two years, data from 174 (92.6%) of 188 available patients were analyzed. Overall, 103 (59.5%) of 173 telescope-implanted eyes gained three lines or more (doubling of visual angle) of BCVA compared with 18 (10.3%) of 174 fellow control eyes ($P < .0001$). Mean BCVA improved 3.6 lines (standard deviation [SD], 1.9 lines) and 2.8 lines (SD, 2.3 lines) from baseline in eyes with the 3X and 2.2X device models, respectively. Mean ECD stabilized through two years, with 2.4% mean cell loss occurring from one to two years. There was no significant change in coefficient of variation or percentage of hexagonal endothelial cells from within six months to two years after surgery. The most common complication was inflammatory deposits.

CONCLUSIONS: Long-term results of this telescope prosthesis show the substantial BCVA improvement at one year is maintained at two years. Key indicators of corneal health demonstrate ECD change that reflects remodeling of the endothelium associated with the implantation procedure. ECD stabilizes over time, and there is no evidence of any ongoing endothelial trauma.



Long-term (60-month) results for the implantable miniature telescope: efficacy and safety outcomes stratified by age in patients with end-stage age-related macular degeneration.

Boyer D, Freund KB, Regillo C, Levy MH, Garg S. Clin Ophthalmol. 2015

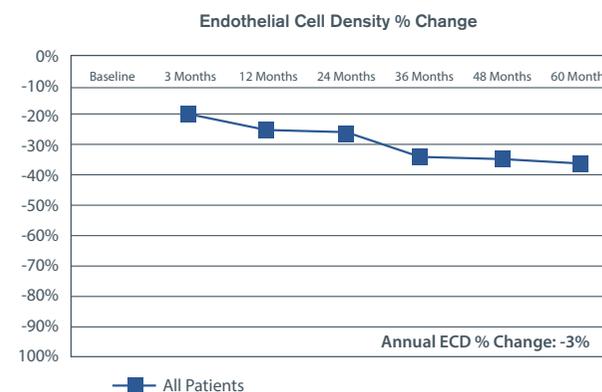
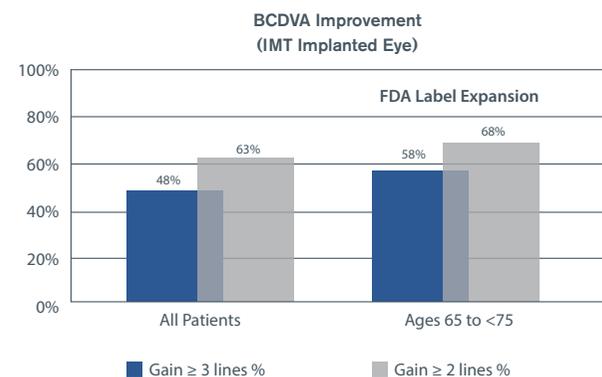
Jun 17; 9:1099-1073

BACKGROUND: The purpose of this study was to evaluate the long-term results of an implantable miniature telescope (IMT) in patients with bilateral, end-stage, age-related macular degeneration (AMD).

METHODS: A prospective, open-label, multicenter clinical trial with fellow eye controls enrolled 217 patients (mean age 76 years) with AMD and moderate-to-profound bilateral central visual acuity loss (20/80–20/800) resulting from untreatable geographic atrophy, disciform scars, or both. A subgroup analysis was performed with stratification for age (patient age 65 to <75 years [group 1; n=70] and patient age ≥75 years [group 2; n=127]), with a comparative evaluation of change in best-corrected distance visual acuity (BCDVA), quality of life, ocular complications from surgery, adverse events, and endothelial cell density (ECD). Follow-up in an extension study was 60 months.

RESULTS: Data were available for 22, 38, and 31 patients in group 1 and 42, 46, and 32 patients in group 2 at 36, 48, and 60 months, respectively. Mean BCDVA improvement from baseline to 60 months was 2.41 ± 2.69 lines in all patients (n=76), with 2.64 ± 2.55 lines in group 1 and 2.09 ± 2.88 lines in group 2. Quality of life scores were significantly higher in group 1. The most common significant surgery-related ocular complications in group 1 were iritis >30 days after surgery (7/70; 10%) and persistent corneal edema (3/70; 4.3%); and in group 2 were a decrease in BCDVA in the implanted eye or IMT removal (10/127 each; 7.9%), corneal edema >30 days after surgery (9/127; 7.1%), and persistent corneal edema (6/127; 4.7%). Significant adverse events included four corneal transplants, comprising two (2.9%) in group 1 and two (1.6%) in group 2. At 60 months, one patient in group 1 (3.2%) and three patients in group 2 (9.4%) had lost ≥2 lines of vision. The IMT was removed in one (1.4%) and ten (7.9%) patients in group 1 and group 2, respectively. Mean ECD loss was 20% at 3 months. Chronic loss was 3% per year. ECD loss was less in group 1 than in group 2 (35% versus 40%, respectively) at 60 months.

CONCLUSION: Long-term results show substantial retention of improvement in BCDVA. Chronic ECD loss was consistent with that reported for conventional intraocular lenses. The IMT performed as well in group 1 (the younger group) as it did in group 2 through month 60. Younger patients retained more vision than their older counterparts and had fewer adverse events. Although not a specified outcome for this study, patients younger than 65 years also fared better than those in group 2 and retained more vision with fewer adverse events through month 60.



Anti-vascular endothelial growth factor injection technique for recurrent exudative macular degeneration in a telescope-implanted eye.

Joondeph BC. Retin Cases Brief Rep. 2014 Fall;8(4):342-4.⁴

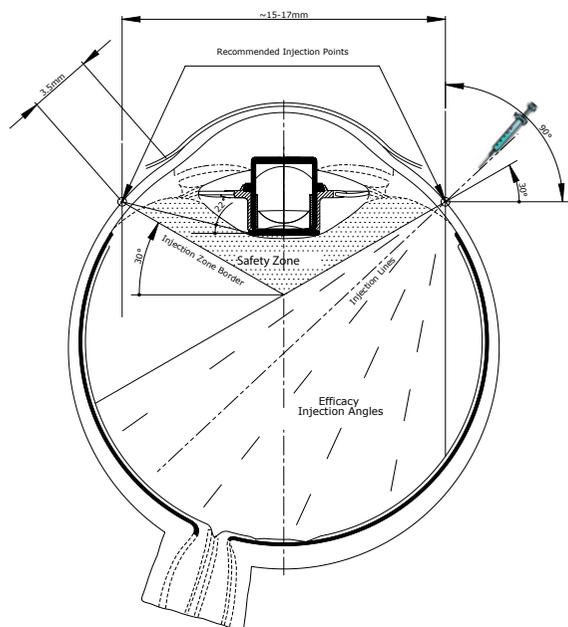
PURPOSE: To describe the management of a patient with neovascular age-related macular degeneration and an implantable miniature telescope.

METHODS: Clinical case report.

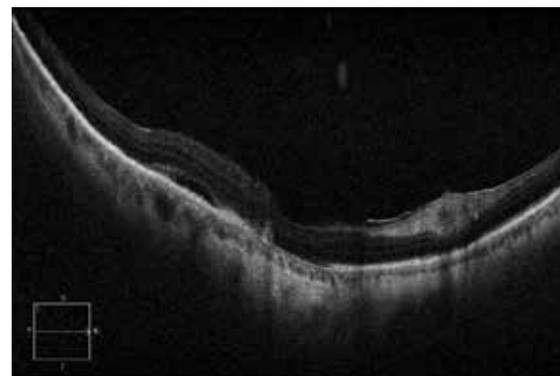
RESULTS: The patient developed recurrent choroidal neovascularization after telescope implantation and was successfully managed with a series of anti-vascular endothelial growth factor injections and serial ocular coherence tomography through the telescope.

CONCLUSION: Intravitreal injections can be safely performed in an eye with a telescope using standard ocular coherence tomography imaging and taking into consideration the unique geometric dimensions of the telescope.

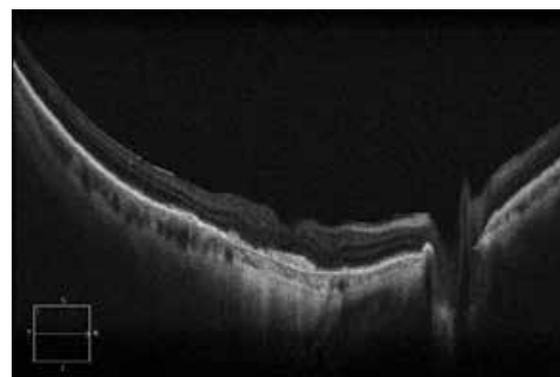
Telescope Injection



Schematic diagram showing the geometry of the telescope and the recommended points and direction of intravitreal injection.



Pretreatment spectral domain optical coherence tomography image demonstrating the central geographic atrophy and a small pocket of subretinal fluid.



Posttreatment spectral domain optical coherence tomography demonstrating the resolution of subretinal fluid.

Comparative effectiveness and cost-effectiveness of the implantable miniature telescope.

Brown GC, Brown MM, Lieske HB, Lieske PA, Brown KS, Lane SS. Ophthalmology. 2011 Sep;118(9):1834-43.⁵

OBJECTIVE: To assess the preference-based comparative effectiveness (human value gain) and the cost-utility (cost-effectiveness) of a telescope prosthesis (implantable miniature telescope) for the treatment of end-stage, age-related macular degeneration (AMD).

DESIGN: A value-based medicine, second-eye model, cost-utility analysis was performed to quantify the comparative effectiveness and cost-effectiveness of therapy with the telescope prosthesis.

PARTICIPANTS: Published, evidence-based data from the IMT002 Study Group clinical trial. Ophthalmic utilities were obtained from a validated cohort of >1000 patients with ocular diseases.

METHODS: Comparative effectiveness data were converted from visual acuity to utility (value-based) format. The incremental costs (Medicare) of therapy versus no therapy were integrated with the value gain conferred by the telescope prosthesis to assess its average cost-utility. The incremental value gains and incremental costs of therapy referent to (1) a fellow eye cohort and (2) a fellow eye cohort of those who underwent intra-study cataract surgery were integrated in incremental cost-utility analyses. All value outcomes and costs were discounted at a 3% annual rate, as per the Panel on Cost-Effectiveness in Health and Medicine.

MAIN OUTCOME MEASURES: Comparative effectiveness was quantified using the (1) quality-adjusted life-year (QALY) gain and (2) percent human value gain (improvement in quality of life). The QALY gain was integrated with incremental costs into the cost-utility ratio (\$/QALY, or US dollars expended per QALY gained).

RESULTS: The mean, discounted QALY gain associated with use of the telescope prosthesis over 12 years was 0.7577. When the QALY loss of 0.0004 attributable to the adverse events was factored into the model, the final QALY gain was 0.7573. This resulted in a 12.5% quality of life gain for the average patient during the 12 years of the model. The average cost-utility versus no therapy for use of the telescope prosthesis was \$14389/QALY. The incremental cost-utility referent to control fellow eyes was \$14063/QALY, whereas the incremental cost-utility referent to fellow eyes that underwent intra-study cataract surgery was \$11805/QALY.

CONCLUSIONS: Therapy with the telescope prosthesis considerably improves quality of life and at the same time is cost-effective by conventional standards.

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www.CentraSight.com/Important_Safety_Information

Additional References

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US Patents 5,354,335;5,391,202;5,928,283;6,569,199B1;6,596,026B1