



SING IMT™ Product Monograph

February 2025

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Table of Contents

Table of Contents	2
Abbreviations	3
1.0 Executive Summary	4
2.0 Disease Overview and Burden.....	5
2.1 Disease Overview, Epidemiology, Risk Factors, and Diagnosis	5
2.1.1 Disease Overview	5
2.1.2 Epidemiology.....	6
2.1.3 Risk Factors	6
2.1.4 Diagnosis	7
2.2 Humanistic, Clinical, and Economic Burden	7
2.2.1 Humanistic Burden.....	7
2.2.2 Clinical Burden	8
2.2.3 Economic Burden.....	8
3.0 Current Treatments and Limitations in the Management of Late-stage AMD	10
3.1 Pharmaceutical Treatments and Procedures.....	10
3.1.1 Geographic Atrophy	10
3.1.2 Wet AMD.....	11
3.2 Implantable Devices	12
3.3 Opportunity to Address Current Unmet Needs with SING IMT™	15
4.0 SING IMT™	17
4.1 Overview and Key Features.....	17
4.2 Device and Implantation Specifications	19
4.3 Visual Rehabilitation.....	20
4.4 Clinical and Humanistic Value.....	21
4.4.1 Best-Corrected Distance and Near Visual Acuity	22
4.4.2 Functional Outcomes (Reading Acuity, Reading Speed, Fixation Stability)	24
4.4.3 Patient-Reported Outcomes and Quality of Life	25
4.4.4 Safety	25
4.4.5 Visual Rehabilitation.....	27
4.5 The Economic Value of SING-IMT	29
4.5.1 Offsetting the cost of blindness.....	29
4.5.2 Cost-utility of an Intraocular Miniature Telescope.....	30
4.5.3 Pricing Rationale and Patient Accessibility	30
5.0 References	32

Abbreviations

Abbreviations or Specialist Term	Explanation
ACD	Anterior chamber depth
AE	Adverse event
AMD	Age-related macular degeneration
Anti-VEGF	Anti-vascular endothelial growth factor
BCVA	Best-corrected visual acuity
BCDVA	Best-corrected distance visual acuity
BCNVA	Best-corrected near visual acuity
CE	Conformite Europeenne
ECD	Endothelial cell density
EMA	European Medicines Agency
ETDRS	Early treatment for diabetic retinopathy stud
FDA	United States Food and Drug Administration
GA	Geographic atrophy
IMT	First-generation implantable miniature telescope
IOL	Intraocular lens
IOL-VIP	Intraocular lens for visually impaired people
IOP	Intraocular pressure
LMI	Lipshitz macular implant
LMI-SI	Sulcus-implanted lipshitz macular implant
LogMAR	Logarithm of the minimum angle of resolution.
LVQoL	Low vision quality of life questionnaire
nAMD	Neovascular age-related macular degeneration
NEI VFQ-25	National eye institute 25-item visual function questionnaire
QALY	Quality adjusted life year
QoL	Quality of life
RPE	Retinal pigment epithelium
SING IMT™	Smaller-incision new generation implantable miniature telescope
SML	Scharioth macula lens
UK	United Kingdom
US	United States
USD	United States Dollar

1.0 Executive Summary

Age-related macular degeneration (AMD) is a chronic eye disorder of the macula that results in gradual vision impairment and central vision loss.^{1; 2} The estimated world-wide prevalence is 8.7%,³ with cases expected to increase 46% by 2040.⁴ Patients with AMD experience reduced visual acuity, in addition to poor functional outcomes such as slow reading speed and unstable fixation,^{5; 6} with risk of irreversible vision loss increasing as the disease progresses.^{2; 7} Both subtypes (dry AMD and wet or neovascular AMD [nAMD]) progress to late-stage AMD characterized by geographic atrophy (GA),⁸ where patients experience blurry or black spots in central vision, diminished colours, and vision impairment in low lighting.^{9; 10} Present in an estimated 60% of all patients with late-stage disease, treatment of GA is extremely challenging.¹¹

Central vision loss from GA interferes with critical everyday activities and impacts patient quality of life (QoL) and independence,^{1; 12; 13} with progression from late-stage AMD to loss of central vision occurring in just 1.4 to 2.5 years.¹⁴ QoL for patients with late-stage AMD has been reported as comparable to some severe health states or conditions, including late-stage prostate cancer or catastrophic stroke.¹⁵ Late-stage AMD also contributes substantial clinical and economic burden through direct and indirect costs.¹⁶ In Spain, vision loss or blindness due to AMD is estimated to cost €10,634 per patient per year as of 2021, and is expected to grow to €11,432 by 2030.¹⁷ The average annual economic burden (encompassing direct, indirect, well-being and productivity costs) for an individual living with GA for those over the age of 65 years was €17,958 and €27,733 in Germany and the United States (US), respectively.¹⁶

Currently, only injectable therapeutics such as anti-VEGF or anti-complement therapies have demonstrated efficacy in reducing neovascularization and scotoma progression.¹⁸⁻²⁰ However, once irreversible vision loss of late-stage disease begins, options to reduce the impact of GA are extremely limited.^{9; 21} Alternatively, many patients seek treatment for AMD at the time of cataract surgery, but experience minimal benefit from standard intraocular lenses (IOLs), since these are not designed to improve vision in patients with late-stage AMD.²²⁻²⁴ Recently, two implantable IOLs have been developed that are designed to improve vision in patients with AMD, however, limited clinical evidence is available to support their clinical efficacy and safety in patients with late-stage disease.²⁵ Unfortunately, **neither of these devices can provide improved vision at near and distance simultaneously, highlighting a serious unmet need for late-stage patients with GA.**²⁶⁻²⁹ Finally, although external visual aids such as magnifiers, spectacles, reading stands, and telescopes may help patients with AMD optimize the use of their remaining vision,^{30; 31} they do not compensate for the central scotoma, and as such, fail to reduce the impact of GA.

Samsara Vision has developed the Smaller-Incision New Generation Implantable Miniature Telescope (SING IMT™), which addresses the major areas of current unmet needs for patients with profound vision loss in late-stage AMD. SING IMT™ provides the highest magnification (2.7X) with the largest coverage (54° from the foveal centre),^{25; 32} accommodating for central vision loss even in severe and progressed late-stage cases. Patients with SING IMT™ experienced clinically and statistically significant improvements in visual acuity for near and distance, with 97.1% of patients improving distance visual acuity by at least 1 line, and 51.4% improving 3 lines or more at 6-months follow-up relative to baseline.³³ Multiple clinical studies have reported the SING IMT™ in combination with visual rehabilitation therapy to be safe and effective at improving visual acuity, visual function (reading acuity, speed, fixation stability), and QoL in patients with late-stage AMD.³³⁻³⁹ SING IMT™ is also safe and well-tolerated by patients, with no unexpected safety signals.^{33-36; 38; 39} As a one-time, front-loaded cost, this device is expected to confer economic benefits over the long-term.⁴⁰ Overall, the improvement in visual acuity with SING IMT™ for patients with late-stage AMD, and the anticipated maintenance of these gains over time, is expected to contribute substantial clinical and economic benefits to patients and society.

2.0 Disease Overview and Burden

2.1 Disease Overview, Epidemiology, Risk Factors, and Diagnosis

2.1.1 Disease Overview

Age-related macular degeneration (AMD) is a chronic eye disorder of the macula, leading to gradual vision impairment and irreversible central vision loss in the late stage.

Age-related macular degeneration (AMD) is a chronic eye disorder, characterised by irreversible and progressive loss of central vision, that primarily affects adults over the age of 50.^{1; 2; 29} Visual impairment in AMD results from degradation or degeneration of the macula, the most central area of the retina, or the back of the eye.^{2; 9; 14} The macula, a 5.5 mm diameter region highly saturated in photoreceptors, is responsible for detailed focused central vision.⁴¹ While painless, AMD results in irreversible central vision loss (while peripheral vision remains intact) and often interferes with activities of daily living such as reading, seeing faces, watching television and driving.^{1; 2; 14} In addition to reduced visual acuity, patients with AMD also often exhibit poor functional outcomes, such as slow reading speed and unstable fixation.^{5; 6}

There are two distinct types of AMD; the dry form, which constitutes approximately 80% of cases, and the wet (neovascular) form which comprises the remaining 20% of cases.² In wet AMD, abnormal blood vessels leak blood or other fluids such as serum into the macula, causing damage and ultimately vision loss.^{41; 42} Conversely, dry AMD does not result from serum or blood leakage;⁴¹ rather, this disease manifests as humans age mainly from the accumulation of extracellular lipid- and protein-containing debris, called drusen, under the retina.^{43; 44} In elderly individuals, a restricted number of small drusen are common.^{7; 18} The presence of many small drusen, or large drusen, along with other changes such as pigmentary abnormalities, are characteristic signs of dry AMD.^{7; 41; 45}

AMD is typically categorized by severity into three major stages based on the risk of vision loss; early, intermediate, and late-stage AMD.⁷ Characteristics of each stage are outlined in

Table 1. Patients with mild AMD are often asymptomatic, and mild symptoms such as blurriness or trouble seeing in low lighting, may develop as patients progress to the intermediate stage.⁹ In late-stage AMD, patients often experience blurry or black spots in their central vision, diminished colours, and challenges with vision in low lighting.^{9; 10} Geographic atrophy (GA) is the late-stage form of dry AMD, where the progressive loss of photoreceptors, retinal pigment epithelium (RPE), and underlying choriocapillaris leads to the development of atrophic lesions of the retina and loss of visual function.⁸ Notably, GA accounts for approximately 60% of late-stage AMD and has proven the more challenging subtype to treat.¹¹ Wet or neovascular AMD is always considered late-stage and can be in an active (ongoing damage and vision loss) or inactive state, however reactivation can occur.⁴⁶ Both GA and wet AMD result in irreversible vision loss and can progress to the development of central scotoma, or blind spot in the central vision, as well as legal blindness.^{14; 18; 47}

Table 1: Characteristics of Severity Stages of AMD

AMD Stage	Classification Description
Early*	Multiple small (diameter < 63 µm) or intermediate drusen (diameter ≥ 63 µm to < 125 µm)
Intermediate*	Numerous intermediate drusen or large drusen (diameter ≥ 125 µm) and retinal pigment epithelium abnormalities
Late-stage	Presence of: <ul style="list-style-type: none"> • Geographic atrophy or • Neovascular age-related macular degeneration <ul style="list-style-type: none"> ○ Active state ○ Inactive state

*Early and intermediate AMD criteria apply to dry AMD only. Wet AMD is always considered late-stage.

Abbreviations: AMD = age-related macular degeneration

Source: Coleman et al 2008;⁷ Amini et al 2023,² American Academy of Ophthalmology.⁴⁶

2.1.2 Epidemiology

AMD is the third leading cause of blindness globally, following cataracts and glaucoma.²⁵ Approximately 9% of all blindness cases worldwide are attributed to AMD, and the prevalence is expected to continue to grow in alignment with the aging population.⁴¹ Globally in 2020, an estimated 196 million people had AMD, with this number projected to increase to 288 million by 2040.^{4; 41} Over 8 million people are affected with GA worldwide, making up approximately 20% of patients with AMD.⁴⁸ Approximately 1 in 5 people aged 85 years and older have GA, or late-stage dry AMD, in at least one eye.⁴⁹ A prevalence of 0.44% for GA has been estimated for the worldwide population in 2020.⁵⁰ Across the globe, the highest prevalence of GA exists in Europe, at 1.11%, followed by Africa and Asia, at 0.14% and 0.21%, respectively.⁴ The prevalence of GA significantly increases with age, with rates increasing from 0.1% in those less than 65 years of age, to 3.2% in those 75 years of age or older in Europe.⁵⁰

A late-stage global AMD pooled incidence rate of 0.23 per 100 person-years has been estimated, with the number of new cases projected to increase to 6.41 million by 2050.³ By 2050, the number of Europeans with late-stage AMD is expected to increase from 67 to 77 million and grow to 700 000 incident cases per year.⁵⁰ Comparatively in Australia, the Australia National Eye Health Survey reported a late-stage AMD prevalence of 0.96% and 0.17%, in nonindigenous and indigenous Australians, respectively.⁵¹ A 15-year incidence of GA was estimated at 3.6% based on the Blue Mountains Eye Study.⁴⁹ In the United States, an annual incidence rate of 1.9 per 1000 people aged 50 years or older estimated for GA, with approximately 160,000 cases occurring each year.⁵² Along with AMD, the incidence of GA is expected to rise in the coming decades due to the aging population worldwide.^{4; 14}

2.1.3 Risk Factors

A variety of demographic, genetic, and lifestyle factors are associated with the development of AMD. The risk of AMD increases with advancing age, and previous studies have found that the late stages of AMD are more common among Caucasians, compared to other ethnicities.^{18; 53} Genetics and family history have a significant influence on the development of AMD; currently, approximately 103 AMD-associated genes and loci have been identified and this value is expected to continue to increase.^{2; 41} Lifestyle factors such as smoking, physical activity level, and diet have also been linked to the risk and progression of AMD.^{2; 18; 54} Smoking is considered the strongest modifiable risk factor for AMD and significantly increases the risk of AMD, with an apparent dose-response relationship.^{18; 53; 55} Conversely, smoking cessation has been associated with a reduced risk of AMD progression.^{18; 53} Additional evidence suggests that the intake of

dietary fat, low antioxidant levels, cardiovascular disease, hypertension, atherosclerosis, and obesity may also be risk factors contributing to the development of AMD.^{2; 10; 18; 41}

2.1.4 **Diagnosis**

The diagnosis of AMD is typically made considering the patients age and history, signs and symptoms (if present), physical examination results, and diagnostic testing.^{18; 53} An initial history of the patient should be taken, including medical history, family history of AMD, current medications and quantitative smoking history.¹⁸ Signs and symptoms of AMD may not be present, particularly if the patient is in the early or intermediate stages.^{42; 53} Clinicians may use an Amsler grid, to assess a patient's central vision and line detection; patients with AMD may see wavy or distorted lines, with holes or dark areas in their vision.¹⁴ Following this, a comprehensive eye examination should be conducted, including stereoscopic biomicroscopic examination and/or a dilated fundus examination.^{18; 53} The examiner should look for key clinical AMD signs such as drusen, GA, subretinal fibrosis, RPE changes, and subretinal fluid or haemorrhage.^{41; 53} Specific key diagnostic procedures can also be performed, such as optical coherence tomography, or fundus fluorescein angiography.^{18; 53} Other diagnostic tests that may be considered include colour fundus photography, fundus autofluorescence, optical coherence tomography angiography, and indocyanine green angiography.^{14; 18; 56} Importantly, early detection, proper monitoring, and prompt treatment can improve visual outcomes for patients with AMD.¹⁸

2.2 **Humanistic, Clinical, and Economic Burden**

2.2.1 **Humanistic Burden**

Through deterioration of central vision, late-stage AMD interferes with critical everyday activities and substantially impacts patient quality of life.

In developed countries, AMD is the most common cause of blindness, confirmed by one of the most important healthcare databases from United Kingdom (UK) with an estimated 26% of legal blindness attributed to GA.¹³ In a large study (N=1,901) of patients with GA in the UK, approximately 7.1% of patients met the threshold for blindness registration, and over time 16% of the remaining patients became legally blind (per UK specifications) in a median of 6.2 years; furthermore, the loss of central vision may occur rapidly with the median time from GA without subfoveal involvement to GA with subfoveal involvement ranging from just 1.4 to 2.5 years.^{14; 57} The annual incidence of blindness registration due to AMD in Australia among those 50 years and older, reached 8.2 cases per 100,000 populations years in 2016.⁵⁸

The quality of life (QoL) observed for patients with late-stage AMD is comparable to some severe health states or conditions.¹⁵ AMD and its associated vision loss have far-reaching negative impacts QoL and activities of daily living, with evidence suggesting that vision-related QoL is worse in patients with AMD compared to those without, and declines over time as AMD progresses.^{10; 54; 59} Late-stage AMD has been associated with a 60% reduction in QoL,¹⁵ importantly, this is analogous to the QoL reported for individuals with serious systemic conditions such as late-stage prostate cancer or catastrophic stroke.¹⁵

Anxiety and depression, as well as falls and injuries resulting from poor vision are also known to be common in those with AMD.^{60; 61} In patients with AMD, prevalence estimates range from 15.7% to 44% for depressive symptoms and 9.6% to 30.1% for anxiety symptoms.⁶¹ Vision impairment has been found to be associated

with a 16% greater rate of falls and 23% higher rate of multiple falls compared to those without vision impairment, based on an analysis of 2,822 older adults in the US.⁶²

An ethnographic study of 16 patients with GA reported significant impacts to regular functioning and activities of daily living, including difficulty reading, watching television, challenges with social and leisure activities, and physical or financial impacts.¹² Patients also expressed frustration regarding their lack of independence, difficulty with household activities, and requiring support from others.^{1; 12} Late-stage AMD also impacts functional vision outcomes, such as reading speed and fixation.^{5; 6; 37} Among patients diagnosed with GA in the UK, 71.1% are considered ineligible to drive based on visual acuity; among those that remain eligible to drive, 66.7% will become ineligible to drive in a median of only 1.6 years.⁵⁷ Adapting to vision loss has been cited as key to maintaining QoL for patients with AMD.¹

2.2.2 Clinical Burden

High healthcare resource utilization rates for patients with late-stage AMD result in significant clinical burden.

Late-stage AMD is associated with significant clinical burden; incurring high healthcare resource utilization (HCRU), with the burden and associated costs accelerating with late-stage disease.^{63; 64} According to a UK-based burden of illness study, annual healthcare costs were found to be over seven times higher in patients with AMD compared to age-matched controls without AMD.⁶⁵ Patients with AMD were 3.8 times more likely to require assistance with activities of daily living, versus controls.⁶⁵ In relation to HCRU and disease severity, a large analysis (N=28,773) of patients with AMD in the United States (US) found that those with GA require, on average, between 2.57-2.63 outpatient visits per year, 16%-19% higher relative to those with early-to-intermediate AMD.⁶³ An additional retrospective study found that patients with GA had higher rates of hospitalizations, outpatient visits, and falls with head injuries than patients without GA, contributing higher annual health care utilization and associated costs.⁵⁴ Similarly, a cohort study of 75 patients with wet AMD in the UK found they had significantly more visits to ophthalmologists and optometrists, compared to elderly controls without AMD.⁶⁵

2.2.3 Economic Burden

Late-stage AMD contributes substantial economic burden to the healthcare system through direct and indirect costs.

As a result of the humanistic and clinical burden described above, AMD imparts substantial economic burden to both patients and the healthcare system.¹⁶ A comprehensive report examining the cost impact of GA in Germany and the US, demonstrated substantial direct, indirect, wellbeing, and productivity costs associated with both conditions.¹⁶ The average annual economic burden (encompassing direct, indirect, wellbeing and productivity costs) for an individual living with GA for those over the age of 65 years was €17,958 and €27,733 in Germany and the US respectively.¹⁶ A summary of the annual per-patient direct, indirect, wellbeing, and productivity costs for GA in Germany and the US, is presented in **Table 2**. The

estimated total societal costs when assuming mid-prevalence rates across all ages for GA were €3.7 billion in Germany and €19.2 billion in the US.¹⁶

Impactful drivers of direct costs include eye imaging exams, while indirect medical cost drivers included assistive technology, formal care, and nutraceuticals.¹⁶ While generalized European cost data is lacking, annual direct and indirect costs associated with GA in Germany was found to range from €178 to €751 (**Table 2**).¹⁶ Relatedly, in Australia, AMD is estimated to contribute AU\$19.4 million in direct costs each year.⁶⁶ Wellbeing costs in Germany account for the majority of the overall individual costs, while costs associated with productivity loss had the largest impact in the US.¹⁶ Low vision, anxiety, and depression were reported as major wellbeing cost drivers, with many patients and caregivers also experiencing job loss, job reduction, and leisure time loss, contributing to productivity costs.¹⁶ Up to 75% of patients reported job reduction, and up to 36% job loss related to GA across the two countries.¹⁶

Table 2: Annual individual costs of GA in Germany and the US

Cost Category	Germany	US
Direct Costs	€178	€327 (\$326 USD)
Indirect Medical Costs	€751	€12,736 (\$12,702 USD)
Wellbeing Costs*	€16,939	€11,944 (\$11,912 USD)
Productivity Costs [◇]	€4,702	€23,319 (\$23,256 USD)
Average Annual Individual Cost (under 65 years of age) [†]	€22,571	€48,326 (\$48,133 USD)
Average Annual Individual Cost (over 65 years of age)	€17,958	€27,733 (\$27,622 USD)

* Wellbeing costs capture costs associated with low vision, anxiety, and depression.

[◇] Productivity costs capture costs associated with individual job loss, individual job reduction, caregiver job reduction due to care, caregiver job reduction due to travel to appointments and leisure loss.

[†] Does not include costs associated with patient job reduction or job loss.

Abbreviations: AMD = age-related macular degeneration; GA = geographic atrophy; US = United States; USD = United States Dollar.

Source: Adapted from Retina International, 2022.¹⁶ US values converted to USD using the Bank of America Foreign Exchange Rate for US Dollar.⁶⁷

3.0 Current Treatments and Limitations in the Management of Late-stage AMD

Treatment options for patients with early or intermediate AMD are often aimed to avoid neovascularization or slow the progression of the disease. Recommendations in current clinical guidelines for the treatment of AMD vary depending on the type of AMD (wet vs. dry) and the stage of disease (early/intermediate/late). Nutritional supplementation is recommended in the early and intermediate stages, while anti-VEGF treatment is suitable for some patients with wet AMD.¹⁸ The applicability of external low vision aids should be assessed throughout the patient journey.^{21; 68} Clinical guidelines note a dearth of treatment options for patients with GA,^{18; 21; 68; 69} indeed, several remain under investigation. Please refer to the subsections below for a description of available therapies for patients with AMD.

Evidence suggests that nutritional supplements, including antioxidants, vitamins, and minerals may aid in slowing the progression of AMD.⁷⁰⁻⁷² However, since nutritional supplementation slows progression of AMD and is not curative, patients with early or intermediate AMD will still progress, eventually requiring treatment for late-stage AMD.

A variety of external aids or devices are available to improve visual performance in patients with low vision, which may include patients with AMD at any stage, and help them optimize the use of their remaining vision.^{30; 31} These devices may assist patients in improving their visual performance, while being non-invasive, and are available as-needed to perform specific tasks.^{30; 31} The aim of these devices is to make objects bigger, brighter, bolder, or closer, with higher colour and contrast to enhance vision.³⁰ The provision of external aids is also often accompanied by visual rehabilitation, to allow patients to use the aids effectively and optimize their impact.^{30; 73} Visual rehabilitation traditionally includes an assessment of current vision and function, offers patient strategies on optimal use of their remaining vision and completion of everyday tasks, trains patients on how to properly use prescribed external devices, as well as provides counselling and emotional support.^{73; 74}

Low vision aids can generally be categorized into optical, electronic, or non-optical devices.^{18; 31} Some examples include hand/stand magnifiers or telescopes, and spectacles to make objects larger and easier to visualize.^{30; 31} Although external visual aids may be useful for many patients to improve visual functioning, these devices can be cumbersome to use (requiring one or two hands at all times), may evoke cosmetic concerns, and require continuous head motion resulting in motion sickness or vestibular effects.^{29; 75} Furthermore, these aids do not directly improve or restore vision for patients with central vision loss resulting from GA.⁷⁶

3.1 Pharmaceutical Treatments and Procedures

The available and recommended pharmaceutical or procedural treatments for patient with late-stage AMD differ between the wet and dry forms. These treatments and procedures are detailed in the subsections below.

3.1.1 Geographic Atrophy

Currently, no pharmacologic therapies are approved for use in Europe for the treatment of geographic atrophy.

In contrast to wet AMD, the current treatment options for patients with GA (or late-stage AMD) are more limited. In 2023, two anti-complement component intraocular therapeutic agents, pegcetacoplan and avacincaptad pegol, were approved by the US Food and Drug Administration (FDA) for the treatment of late-stage dry AMD or GA,¹⁹ and in January 2025 pegcetacoplan was approved by Therapeutic Goods Administration (TGA) in Australia.⁷⁷ Both agents have been reported to reduce GA lesion growth and the rate of GA expansion over time in clinical trials; however, no functional improvement or visual benefit for patients has been observed.¹⁹ In fact, the European Medicines Agency (EMA) recommended refusal of the marketing authorisation for pegcetacoplan in June 2024, citing the lack of clinically meaningful benefits for patients as a main contributor.⁷⁸ Furthermore, Astellas withdrew its marketing authorisation application from the EMA for avacincaptad pegol.⁷⁹ As such, no pharmacologic therapies are currently approved for use in Europe for the treatment of GA.

A variety of additional treatments are currently being considered or investigated for the treatment of late-stage AMD, including neuroprotective agents, anti-inflammatory drugs, vasodilators (dry AMD), and gene therapy; however, their safety and efficacy have yet to be fully explored.^{41; 80} The prospect of personalizing treatments for patients with AMD, depending on the specific disease pattern occurring in each eye, risk factors, as well as the AMD-associated genetic variants a patient, is also growing, although has not yet become a reality.^{81; 82} Overall, additional and alternative treatments or management strategies to improve visual functioning, particularly for patients with GA, are needed.

3.1.2 Wet AMD

Effective treatments, such as anti-VEGF therapies, are available for patients with wet-AMD, however these treatments are not able to correct irreversible vision loss in patients who have progressed to a late-stage.

Wet AMD results in rapid vision loss and is considered late-stage AMD.^{2; 9} Photodynamic therapy and laser photocoagulation surgery were previously considered important treatments for the management of wet AMD; however, these have largely become antiquated with the introduction of anti-VEGF therapies.²⁰ Anti-VEGF agents are intraocular therapeutics delivered via intravitreal injections and are currently the accepted standard of care and first-line therapy for treating and stabilizing cases of wet AMD.^{18; 20} Prompt treatment with these agents is crucial to stabilize disease progression before significant irreversible vision loss has occurred.⁸³ Anti-VEGF therapy however, is not effective for all patients, with some being classified as poor responders, experiencing sub-optimal response following consistent dosing.²⁰ Patients can also develop anti-VEGF resistance over time following repeat injections, or additional complications resulting from frequent injections, including increased intraocular pressure, fibrosis or scarring, inflammation, or endophthalmitis.^{20; 41}

Furthermore, even with optimal treatment using anti-VEGF therapy, the disease and resulting vision loss may continue to progress in some patients over time.^{84; 85} A prospective study of close to 1000 patients with wet AMD receiving anti-VEGF therapies reported that the average visual acuity declined by an estimated 1.5 to 2 letters per year, with approximately one sixth of all eyes reaching $\leq 20/200$ acuity at 5-years.⁸⁵ An additional systematic review of population-based analyses found that the incidence of blindness due to wet AMD decreased by only 47% following the introduction of anti-VEGF treatments, suggesting that some patients with wet AMD continue to progress to blindness, despite the availability of these treatments.⁸⁴ Therefore, alternative treatments should be sought for cases where anti-VEGF therapies are ineffective, or for those who have progressed to severe irreversible vision loss.^{20; 86}

3.2 Implantable Devices

Effective treatment options to improve vision and retain visual benefit as central vision loss progresses for patients with late-stage AMD are lacking.

Intraocular implantable devices have been developed as a surgical alternative to external visual aids in an effort to provide improvement in visual functioning for patients with AMD.^{29; 75} Due to common risk factors between the conditions, such as age, cataracts often occur in eyes with AMD, providing an opportunity to correct AMD at the time of cataract surgery. During cataract surgery, the eye's natural lens is removed and replaced with an artificial intraocular lens (IOL).^{22; 87} While the implant of a standard IOL may improve vision loss resulting from the cataractous cloudy lens, these lenses are not designed or optimized to improve central vision loss resulting from AMD.^{22; 24} As a result, patients with AMD, particularly those who have progressed to late-stage, often do not experience significant improvements in visual acuity following cataract surgery.²³ A report from the AREDS research group found that while eyes without AMD gained on average 8.4 letters of visual acuity, those with late-stage AMD only gained 1.9 letters following cataract surgery.²³

Recently, a number of IOLs specifically designed to improve vision in patients with AMD have been developed, including the EyeMax Mono and Scharioth Macula Lens (SML).^{25; 29; 75} A brief summary of these implantable intraocular devices is presented in **Table 3**. Initial research on these devices suggest they may provide clinical benefits to patients with AMD; however, the available clinical evidence remains limited with the majority of data obtained from case reports or case series, representing only a small number of patients over a short follow-up period.²⁵ Further, neither of these devices are supported by clinical data related to a significant improvement of both near and distance vision in patients with late-stage AMD.²⁵ The SML device has only demonstrated significant improvement in near vision in clinical studies, with no observed impact to distance vision for patients with late-stage AMD.^{25; 28; 88} In a study of 8 patients implanted with the SML, uncorrected near visual acuity was found to improve from an average of J13 preoperatively, to J4 at 6-months follow-up, with best corrected distant visual acuity (BCDVA) was found to remain stable (mean BCDVA of 0.26 preoperatively to 0.24 at 6-month follow-up).²⁸ For the EyeMax Mono, much of the available clinical evidence is conducted in patients with intermediate dry AMD, with often only a small subset of patients with severe vision loss or extensive atrophy.^{26; 89; 90} In a retrospective case series of 113 eyes, only 11 had AMD with extensive atrophy. Among these 11 eyes, although significant improvements in corrected distance visual acuity were observed (0.32 logMAR improvement in BCDVA from pre- to post-implantation; $p=0.004$), no significant differences in near visual acuity could be discerned (0.9 logMAR at baseline to 0.9 logMAR post-implantation).²⁶




Neither of these implantable devices for AMD are considered the standard of care.^{18; 25} Although these devices can be used in patients with late-stage AMD, none are currently recommended for patients with late-stage AMD presenting with profound vision loss from GA,^{25; 26; 28; 32} indicating a gap in treatment options for this patient population. For example, the SML is considered suitable for patients with BCDVA ≤ 0.32 decimal ETDRS (6/18) and ≥ 0.1 decimal ETDRS charts (6/60).⁹¹ Additionally, these devices have low magnification (less than 2x), which while beneficial immediately after insertion, can become insufficient as the disease progresses and vision further declines.²⁵ Devices with higher magnification can improve vision for a broader group of patients while also remaining effective over time as AMD and vision loss progress.²⁵ Additionally, the EyeMax Mono in particular is mainly effective for patients with sufficient remaining macular function within 10 degrees of the foveal centre and is not indicated for AMD patients with no functioning retina within 2-disc diameters of the anatomical centre.^{26; 27} Therefore, the EyeMax Mono is not a

recommended treatment option for patients with more severe vision loss, and may become ineffective for patients whose vision loss progresses beyond 10 degrees from the foveal centre and have already fully deteriorated the foveal area.^{26; 27}

Importantly, IOL insertion will impact a patient's eligibility to receive other implantable devices (with higher magnification) as AMD severity progresses, thereby restricting future treatment options in late-stage disease.^{25; 29; 32} As such, the current standard IOLs and implantable intraocular devices for AMD exhibit various limitations, including having to choose between near or distance vision improvement, and limited magnification across the foveal restricting long-term viability and effectiveness for those with severe vision loss. Thus, resulting in considerable unmet needs for patients with late-stage AMD affected by scotomas.

Samsara Vision has launched the **Smaller-Incision New Generation Implantable Miniature Telescope (SING IMT™)**; a novel next-generation injectable Galilean telescope implant designed to improve near and distant visual acuity and QoL for patients with GA. See **Sections 3.3** and **4.0** below to learn more.

Table 3: Summary of Implantable Devices for AMD

Device	Description/Mechanism of Action	Magnification	Projection on the retina	Recommended for late-stage AMD with profound vision loss
EyeMax Mono (Sharpview Ophthalmology) ^{25-27; 29}	Single lens; hyperspherical design to increase scope of focus and image quality supplied to the macula.	X1.2	Up to 10 degrees from the foveal centre.	
Scharioth Macula Lens (SML; Medicontur) ^{25; 28; 29; 88; 91}	Near Triad Reflex; single-piece lens with a central region that provides high refraction to achieve sharp vision.	X2.0	Not described	
SING IMT™ ^{25; 29; 32}	Galilean telescope; two optical elements with high positive and negative power to project objects onto larger area of the retina not degenerated by AMD.	X2.7	Up to 54 degrees from the foveal centre.	

^a Statistically significant improvement in near visual acuity in patients with late-stage AMD within clinical studies.

^b Statistically significant improvement in distance visual acuity in patients with late-stage AMD within clinical studies.

Abbreviations: AMD = age-related macular degeneration; SML= Scharioth Macula Lens.

Sources: Grzybowski et al 2020;²⁹ Borkenstein et al 2022;²⁵ SING IMT™ Instructions for Use,³² SharpView Ophthalmology Physicians Brochure,²⁷ Medicontur Ophthalmic Practitioners Guidebook,⁹¹ Badalà et al. 2024,²⁶ Nekolova et al. 2017,²⁸ Scharioth 2015.⁸⁸

3.3 Opportunity to Address Current Unmet Needs with SING IMT™

Only SING-IMT™ provides magnification to 54° from the foveal centre, accommodating for central vision loss longer than any other device on the market.

In comparison to other available implantable devices, the SING IMT™ provides the highest magnification (X2.7), and optimizes image quality up to 54 degrees° from the foveal centre,³² suggesting benefit for those with profound vision loss, or continued efficacy for patients whose vision loss may further progress over time.

- Contrarily, the EyeMax Mono provides relatively low magnification of X1.1-1.2 and is only effective for patients with sufficient remaining macular function within 10 degrees of the foveal centre.^{27; 29}
- Although the SML provides a higher magnification of 2X, light is not distributed away from the fovea and the central optic region works to provide high refraction to sharpen vision only in the range of 10 to 15cm from the eye.^{25; 29} As a result, the SML only acts to improve mainly near vision, with no impact or improvement in distance vision, as seen in clinical studies.^{25; 28; 29; 88}

Therefore, neither of these devices would be an effective treatment option for patients with severe or profound visual impairment, and may become ineffective for patients whose vision loss progresses beyond the capabilities of either device.

Only SING IMT™ can provide patients with late-stage AMD the opportunity to significantly improve near and distance vision following profound vision loss associated with GA.

The SING IMT™ represents the only treatment option for patients with GA with profound vision impairment. The safety and efficacy of the SING IMT™ or its predecessor device with identical optical component WA IMT has been demonstrated in multiple clinical studies, with reported improvements in visual acuity (BCNVA and BCDVA) and visual functional outcomes (reading acuity, reading speed, and fixation stability).^{34; 35; 37-39} Furthermore, multiple clinical studies have demonstrated the SING IMT™ to be safe and well-tolerated by patients, significantly improving both near and distance visual acuity, with no unexpected safety signals observed.^{34-36; 38; 39}

Other available implantable devices, such as the EyeMax Mono and the SML have not been demonstrated to significantly improve both near and far distance vision in patients with late-stage AMD:

- The SML is considered suitable for patients with BCDVA ≤ 0.32 decimal ETDRS (6/18) and ≥ 0.1 decimal ETDRS charts (6/60).⁹¹ Additionally, the device only provides near vision magnification with no changes in distance visual acuity observed in clinical studies.^{25; 28}
- Clinical evidence for the EyeMax Mono is primarily on patients with intermediate dry AMD, with only a small subset of patients included with severe visual impairment.^{26; 90} This is in alignment with the indication of the device, including only patients with sufficient remaining macular function within 10 degrees of the fovea.²⁷ Among those with severe vision loss, significant benefit was only observed with distance vision, with significant differences in near visual acuity not discernible.²⁶

Thus, the SING IMT™ is the only device that can benefit all aspects of vision, both near and far, filling a significant treatment gap for patients with late-stage AMD and severe vision loss.

In addition to its clinical value, the SING IMT™ also has humanistic and economic benefits.

For patients with vision loss resulting from AMD, improving visual acuity may have additional benefits including, but not limited to, improvement in QoL and reduction in overall economic burden (e.g., increased employability and productivity, and lower HCRU costs) over a patient's lifetime.^{16; 63; 65; 92} Indeed, a prospective study of 11 patients demonstrated significant improvement in QoL at 3-month follow-up relative to baseline. The expected economic value of the SING IMT™ is multi-faceted, and centres around its (a) one-time, front-loaded cost, reduced implantation procedure time relative to the predicate IMT device, and cost-effectiveness of the predicate IMT device that is expected to be maintained or improved upon for the SING IMT™.

Ultimately, introduction of the SING IMT™ provides patients with AMD-related bilateral central scotomas a therapeutic intervention with demonstrated clinical efficacy in improving visual acuity, functional visual outcomes, and patient QoL. In a time where assessing value for money for therapeutic interventions is paramount to counterbalance continually rising healthcare costs, considering the economic and humanistic value of such interventions is imperative. Access to the SING IMT™ is expected to allow patients to improve central vision and independence safely and economically, allowing them to visually reconnect with their world.

Please refer to Section 4.0 below for additional details and to learn how Samsara Vision's SING IMT™ is positioned optimally to meet the needs described above.

4.0 SING IMT™

4.1 Overview and Key Features

The **S**maller-**I**ncision **N**ew **G**eneration Implantable **M**iniature **T**elescope (**SING IMT™**) is a novel next-generation injectable Galilean telescope implant designed to improve visual acuity and QoL for patients with late-stage AMD.⁹³ The updated design directly improves on the established first-generation IMT device that has been successfully implanted in over 600 patients with late-stage AMD.⁹³ The device provides a surgical option for qualified patients with late-stage AMD, that previously have had no alternative treatments or therapies.⁹³

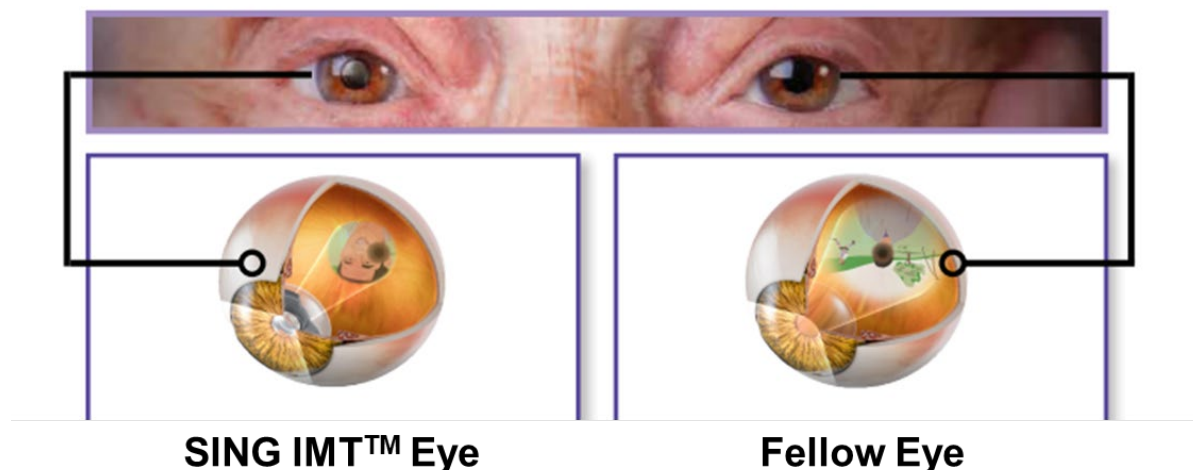
SING IMT™ is comprised of a glass telescope optical component, embedded in a haptic silicone carrier (**Figure 1**). The telescope contains two micro lenses which act to reduce the effective size of a patient's scotoma or blind spot, magnifying objects in the central field of vision and projecting the enlarged imaged onto the retina.³² The three silicone haptic wings act to hold the telescope in the ocular capsular bag following insertion.³² Implanted in one eye, images are magnified **2.7X** and projected onto healthy photoreceptors surrounding the macula, reducing the impact of the scotoma and allowing patients to see objects that may have previously been unrecognizable at both near and far distances.^{32; 94}

Figure 1: The SING IMT™



Source: SING IMT™ Instructions for Use.³²

While optimized for intermediate vision between 3 to 10 meters, the device can also aid vision at both near and far distances with the use of conventional glasses.^{25; 32} The device provides sufficient image resolution to allow for a variety of detailed tasks such as reading, face recognition, and TV watching.³² The placement of the implant directly inside the eye allows for scanning of objects and materials with natural eye movements as opposed to head movements, eliminating any accelerated motion or vestibular effects.³² Following implantation, the SING IMT™ implanted eye is used for central vision or detailed visual needs, including recognizing faces, watching TV, reading, and dining, while the fellow eye without the device provides peripheral vision, including appropriate orientation and context to ensure safe mobility (**Figure 2**).⁹⁴

Figure 2: Illustrative representation of vision in the SING IMT™ implanted and fellow eye

Source: Samsara Vision SING IMT™ Physician Brochure.⁹⁴

Key features of SING IMT™ include its high magnification (2.7X) and novel haptic design enhancing stability and centring of the device, along with heightened corneal clearance from posterior vaulting.^{25; 29} The implantation of the device is performed with the pre-loaded SING IMT™ delivery system, which is designed to provide consistent and predictable device delivery.^{93; 94} The three foldable haptics, small device diameter, and delivery system allow for a streamlined surgical procedure, enabling a short procedure time of 25 minutes.^{25; 29; 94} An incision up to 7.5mm with few sutures is required, limiting surgical trauma and potentially permitting faster healing and earlier initiation of rehabilitation training relative to the predicate IMT device.^{29; 32; 94}

The new generation SING IMT™ device received a Conformite Europeenne (CE) mark for the European Union in 2020.⁹⁵ The device is not currently FDA approved.⁹⁵

Indications for Use^{32; 94}

The SING IMT™ device is indicated for patients 55 years of age or older, with bilateral central scotomas resulting from late-stage AMD, with stable moderate to severe visual impairments.

Eligible patients must:

- Be 55 years of age or older
- Have bilateral irreversible, late-stage AMD (either inactive wet AMD or dry AMD)
- Have evidence of geographic atrophy or disciform scar
- Have best-corrected distance visual acuity between 20/80 and 20/800 (0.25 – 0.024 or 6/24 – 6/240 meters)
- Be willing to participate in a post-operative training program
- Have adequate peripheral vision in the eye not receiving the device
- In the eye scheduled to receive the device, have:
 - Evidence of a cataract
 - Anterior chamber depth of ≥ 2.5 mm
 - Endothelial cell density $> 1,600$ cells per square mm

4.2 Device and Implantation Specifications

SING IMT™ is comprised of two components, a quartz glass optic component and a medical grade silicone carrier. The device exhibits a 10.8mm haptic diameter, 4.4mm axial length and a 3.6mm optic diameter. The implant is sterilized by ethylene oxide. A brief summary of device and implantation procedure specifications for SING IMT™ is included in **Table 4**.^{32; 94}

In comparison to the proven first-generation IMT device, SING IMT™ has a smaller overall diameter (13.5mm vs. 10.8mm for the IMT and SING IMT™, respectively) with foldable haptics and a preloaded delivery system, resulting in a simpler surgical procedure, smaller incision size, fewer sutures, and a shorter surgical duration (60 minutes vs. 25 minutes for the IMT and SING IMT™, respectively).^{25; 29} Notably, the magnification, optical diameter, and axial length are similar for both IMT and SING IMT™.

Table 4: Summary of device and implantation specification of SING IMT™

Characteristic	SING IMT™
Magnification	$\times 2.7 \pm 10\%$
Optical diameter	3.6 mm
Axial length	4.4 mm
Overall diameter	10.8 mm
Weight in air	121 mg $\pm 10\%$
Weight in aqueous medium	63 mg $\pm 10\%$
Capsulorhexis size	5.5 mm
Incision size	6.7-7.5 mm
Sutures required	3-5
Surgical duration	25 minutes
Manipulation	Low rate

Abbreviations: mg = milligram; mm = millimeter.

Source: SING IMT™ Instructions for Use;³² Borkenstein 2022;²⁵ Gryzbowski 2020.²⁹

The SING IMT™ is surgically implanted into the capsular bag of the eye after removal of the crystalline lens, with implantation facilitated by a preloaded delivery system.^{32; 94} Designed to facilitate easy and safe implantation of the device into the patient's eye, the SING IMT™ delivery system is composed of a single use, sterile and disposable cartridge, along with an injector, including an injector syringe and a loaded injector tip (**Figure 3**).³² The SING IMT™ device cartridge is stored and supplied pre-loaded with the device and injector tip in the proper loading position.³² The cartridge acts to not only store and protect the device, but also lubricates and loads the implant into the injector.³² The pre-loaded system allows the clinician to prepare the device for implantation and injection in under a minute, helping to shorten the procedure time.³⁴ The upper window of the injector also enables clinicians to confirm the device is located in the proper position for deployment.³⁴ Wing tips on the injector include markings to provide visual confirmation of correct alignment.⁹⁴ Overall, the use of the delivery system acts to help streamline the surgical implantation procedure of the SING IMT™ device, in addition to generating a smaller corneal wound, potentially contributing to a safer and less invasive procedure.^{29; 38}

Figure 3: SING IMT™ delivery system



4.3 Visual Rehabilitation

Following implantation of the SING IMT™, post-operative visual rehabilitation is an essential component for patients to attain optimal results with the device.^{34; 94} Visual rehabilitation allows patients to become accustomed to the device for static vision, ambulation, and depth perception, with each eye performing a different function (central vs. peripheral vision).^{29; 34} Between six to eight bi-weekly (every 2 weeks) rehabilitation sessions are recommended following implantation to help patients maximize the results from their device and new vision.⁹⁴ The sessions aim to evaluate the patient's visual function and constraints, enhance the patient's use of their new vision, instruct patients on key visual strategies, and encourage patients to continue to make further progress.⁹⁴

It is important for patients to have realistic goals and expectations regarding the outcomes that can be achieved with the device to help avoid dissatisfaction or disappointment.^{25; 94} While the SING IMT™ in combination with full visual rehabilitation may help patients to see faces of family or friends, read, watch television, or participate in hobbies, unrealistic goals include driving, playing tennis, or never using external magnifying aids.⁹⁴ It is important that patients be fully informed of the importance of visual rehabilitation following implantation, as well as realistic outcomes that can be expected.^{25; 34}

Samsara Vision provides virtual training opportunities and support for clinical teams throughout the entire patient journey.⁹⁴ SING IMT™ 60-minute training sessions are offered which cover:⁹⁴

- SING IMT™ introduction and patient selection criteria to identify the best candidates for treatment.
- Surgical training pearls and recommendation for an optimal surgical outcome
- Post-operative low-vision rehabilitation to maximize the patient's new vision

4.4 Clinical and Humanistic Value

SING IMT™ in combination with visual rehabilitation helps patients with late-stage AMD to improve vision and independence in everyday life.

Clinical data for SING IMT™ support its safety and effectiveness at improving short-term visual acuity (best corrected distant visual acuity [BCDVA], best corrected near visual acuity [BCNVA]), visual function (reading acuity, speed, fixation stability), and QoL in patients with late-stage AMD.³³⁻³⁹ Outcomes are anticipated to persist long-term, through to at least 5-years, based on evidence for the first-generation IMT device.^{96; 97} The currently available clinical evidence for the SING IMT™ (as of January 2025) is summarized in **Table 5**. Three additional ongoing clinical studies will serve to strengthen the clinical evidence base in support of the SING IMT™.⁹⁸⁻¹⁰⁰

Table 5: Summary of available published clinical evidence for the SING IMT™*

Study name	Design	Population	Length of Follow-Up	Outcomes
Toro 2025 ³³	Retrospective study	35 patients aged >55 years with stable central visual acuity loss caused by untreatable bilateral late-stage AMD GA, disciform scar, or both)	6-months	<ul style="list-style-type: none"> • BCNVA and BCDVA • ECD • IOP • ACD • Complications/AEs
Savastano 2024 ³⁵	Case Series	5 pseudophakic patients affected by late-stage dry AMD	3-months	<ul style="list-style-type: none"> • BCNVA and BDCVA • Complications/AEs
Sasso 2024 ³⁷	Retrospective study	11 patients aged >55 years with cataract and bilateral GA or disciform scar	24-weeks	<ul style="list-style-type: none"> • BCDVA distance • Reading acuity • Reading speed • Fixation stability
Savastano 2024 ³⁴	Prospective study	11 patients aged >55 years with GA or disciform scar	3-months	<ul style="list-style-type: none"> • BCNVA and BDCVA • IOP • ACD • ECD • QoL
Toro 2023 ³⁸	Non-comparative retrospective study	24 patients aged >55 years, with stable central visual acuity loss resulting from untreatable bilateral late-stage AMD (GA or disciform scar)	3-months	<ul style="list-style-type: none"> • BCNVA and BDCVA • ECD • Complications/AEs
Mastropasqua 2023 ³⁹	Prospective multicentric observational case series study	6 patients aged >55 years with irreversible, stable, late-stage dry or wet AMD	6-months	<ul style="list-style-type: none"> • BCNVA and BDCVA • IOP • ECD • ACD • Complications/AEs
Savastano 2022 ³⁶	Case Series	3 male patients affected by both cataract and GA	4-weeks	<ul style="list-style-type: none"> • Surgical experience • Complications/AEs

*As of January 2025. Note that 5 case reports have been omitted from this table. Only data from studies on more than one patient have been included and reported in the subsequent sections.

Abbreviations: ACD = anterior chamber depth; AE = adverse event; AMD = age-related macular degeneration; BCDVA = best corrected distant visual acuity; BCNVA = best corrected near visual acuity; ECD = endothelial cell density; GA = geographic atrophy; IOP = intraocular pressure; QoL = quality of life.

4.4.1 Best-Corrected Distance and Near Visual Acuity

SING IMT™ helps to improve visual acuity for patients with late-stage AMD.

BCNVA and BCDVA have been evaluated in 6 studies including a total of 46 patients, with follow-up up to 6-months following implantation of the SING IMT™.^{33-35; 37-39} Across all studies, BCNVA and BCDVA were found to be improved from baseline to final follow-up. A summary of the visual acuity results across studies are included in **Table 6**.

Table 6: Summary of BCVA results for the SING IMT™

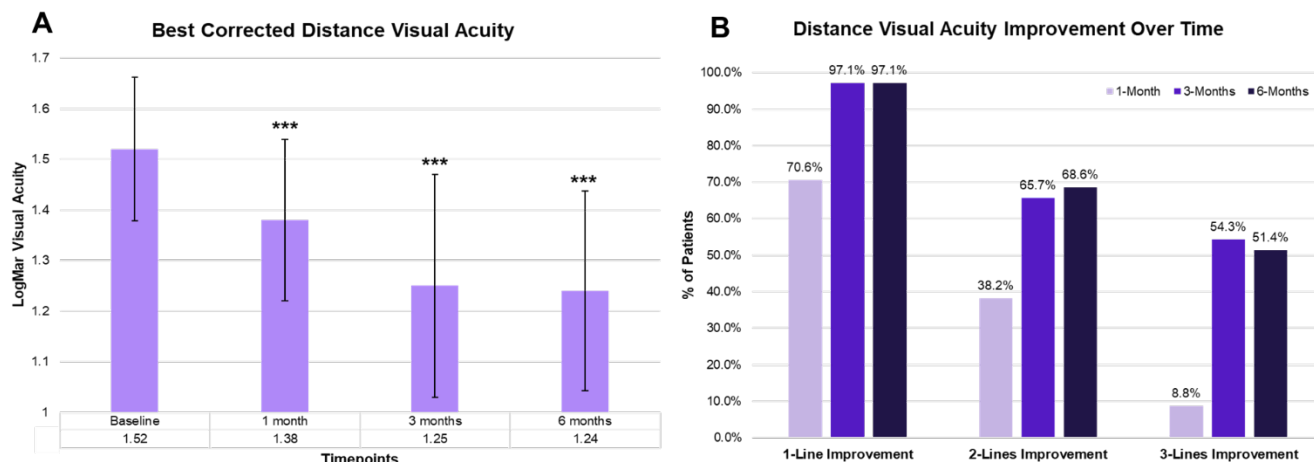
Study	BCVA Results Summary
Toro 2025 ³³	<ul style="list-style-type: none"> Mean BCDVA significantly improved for all patients with a mean change from baseline of -0.29 ± 0.142 (SD) LogMAR ($p < 0.001$) at 6-months post-surgery. At 6-months post-surgery, at least 1-, 2-, and 3-line gains in BCDVA were achieved in 97.1%, 68.6% and 51.4% of operated eyes, respectively. The percentage of patients able to read at near distance increased from 28.6% at baseline to 97.1% at 6-months. Corrected near visual acuity was also significantly improved by ~3 lines at 6 months post-surgery.
Savastano 2024 ³⁵	<ul style="list-style-type: none"> BCDVA improved from baseline to 3-months post-operatively on average by 16.8 ± 10.2 ETDRS letters. BCNVA improved from baseline to 3-months post-operatively on average by 13.8 ± 7.4 ETDRS letters.
Savastano 2024 ³⁴	<ul style="list-style-type: none"> Significant improvement in BCDVA from baseline to 1- and 3-month follow-up ($p < 0.001$), with differences of 11.64 and 10.91 letters respectively. Statistically significant ($p < 0.001$) improvement in BCNVA for reading from baseline (unevaluable) to both 1- (50.91 letters) and 3-month follow-up (59.09 letters).
Toro 2023 ³⁸	<ul style="list-style-type: none"> Mean visual acuity in the study eyes significantly improved by $+14.9 \pm 7.1$ letters for BCNVA and $+7.7 \pm 3.2$ Jaeger levels for BCDVA at three months ($p < 0.0001$). All study eyes also demonstrated an improvement in BCDVA by 3-month follow-up, with 70.83% of patients gaining ≥ 2 lines, 58.33% ≥ 3 lines, and 25.00% ≥ 4 lines.
Mastropasqua 2023 ³⁹	<ul style="list-style-type: none"> From baseline to 6-months, mean BCDVA improved by +10.0 letters (6.25; 13.8) letters and mean BCNVA improved by -0.30 LogMAR (-0.55; -0.20). At 6-months; 5 patients gained at least 1 line on the ETDRS chart, 4 patients gained 2 or more lines, 2 patients gained 3 or more lines, 1 patient gained 6 lines, while only one patient experienced a BCDVA reduction of 5 letters. All patients experienced an improvement in BCNVA.
Sasso 2024 ³⁷	<ul style="list-style-type: none"> BCDVA significantly increased ($p < 0.0001$) from baseline to 24-week follow-up. From baseline to week 24 follow-up, 82% of patients improved by 10 letters, 54.5% improved by 15 letters, and the remaining patient improved by 25 letters.

Abbreviations: BCDVA = best corrected distant visual acuity; BCNVA = best corrected near visual acuity; ETDRS = Early Treatment Diabetic Retinopathy Study; LogMAR = Logarithm of the Minimum Angle of Resolution.

All 6 studies reported BCVA results for distance,^{34; 35; 37-39} while 5 reported BCVA for near or reading.^{33-35; 38; 39} The improvement in BCVA distance following implantation of the SING IMT™ ranged from 10 to 17 letters, from baseline to 3 and ~6-month follow-up,^{33-35; 37-39} The majority of patients across studies gained approximately 2 or more lines at follow-up with the device.^{34; 37-39} BCNVA with the SING IMT™ was reported to improve by 14 letters, 59 letters, or 7.7 Jaeger levels in three separate studies from baseline at 3-months,^{34; 35; 38} with an improvement of ~3 lines or -0.30 LogMAR observed in two studies at 6-months follow-up.^{33; 39} Visual representations of the significant improvement in both BCVA near and distance from

baseline to 6-month follow-up from Toro and colleagues,³³ are presented in **Figure 4** and Figure 5. In comparison, anti-VEGF agents for patients with wet AMD have been reported to improve visual acuity by 2.3 to 8.9 letters after 1 year of treatment, according to a systematic literature review of 12 RCTs.⁹²

Figure 4: Improvement of distance visual acuity following SING IMT implantation

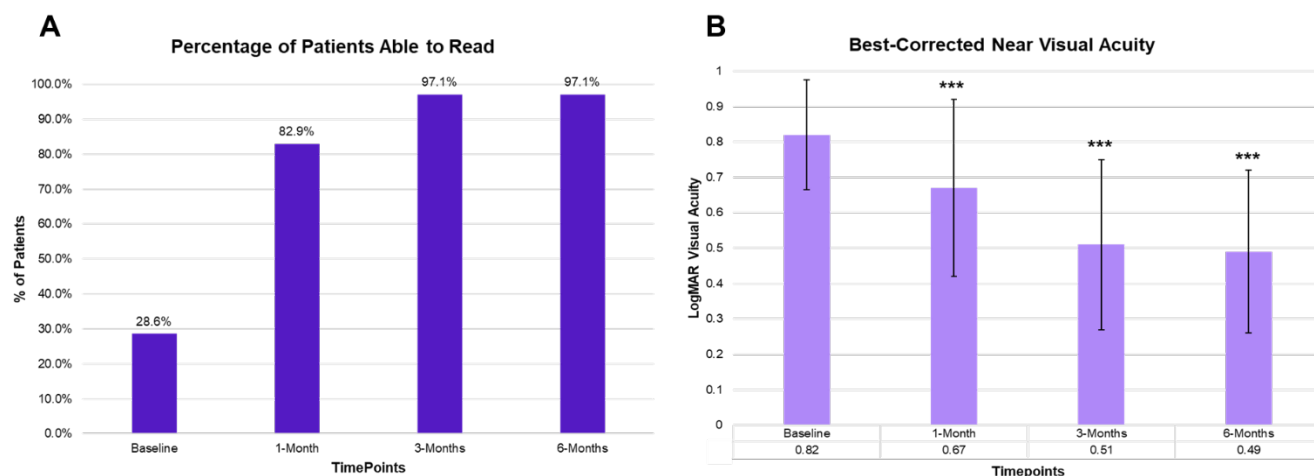


Note: (A) Mean \pm SD LogMAR BCDVA at baseline and at different postoperative follow-up timepoints. (B) Percentage of patients who achieved at least 1-, 2-, or 3-line improvement in LogMAR BCDVA at different timepoints compared to baseline. *** $p < 0.001$.

Abbreviations: BCDVA = best-corrected distance visual acuity; LogMAR = Logarithm of the Minimum Angle of Resolution; SD = standard deviation.

Source: Toro 2024.³³

Figure 5: Improvement of near visual acuity following SING IMT implantation



Note: (A) Percentage of patients who were able to read at near distance at baseline and at different postoperative timepoints, (B) Mean \pm SD LogMAR DCNVA at baseline and at different postoperative timepoints. *** $p < 0.001$.

Abbreviations: DCNVA = distance-corrected near visual acuity; LogMAR = Logarithm of the Minimum Angle of Resolution; SD = standard deviation.

Source: Toro 2024.³³

Although the impacts of the SING IMT™ device on visual acuity in the long-term have not yet been investigated, these observed improvements are anticipated to be largely maintained over time, in alignment with the long-term visual acuity results observed for the first-generation IMT device.⁹⁶ A prospective open-label multi-centre clinical trial of 217 patients with late-stage AMD (GA and/or disciform scar) investigating the long-term outcomes of patients who received the IMT device, reported that improvements in visual acuity could still be seen through 5 years post-implantation.⁹⁶ At 5-year follow-up, mean BCDVA was found to be improved from baseline by 2.4 ± 2.69 lines in all remaining patients ($n=76$).⁹⁶ Approximately 62% of patients maintained a clinically significant 2-line improvement in BCDVA through 5 years post-implantation with the IMT device.⁹⁶ Retention of BCDVA improvements were found to be higher in patients aged 65 to <75 years, compared to those 75 years of age or older.⁹⁶ Similar persistence in visual acuity gains in the long-term are expected with the SING IMT™ device, given the same mechanism of action.

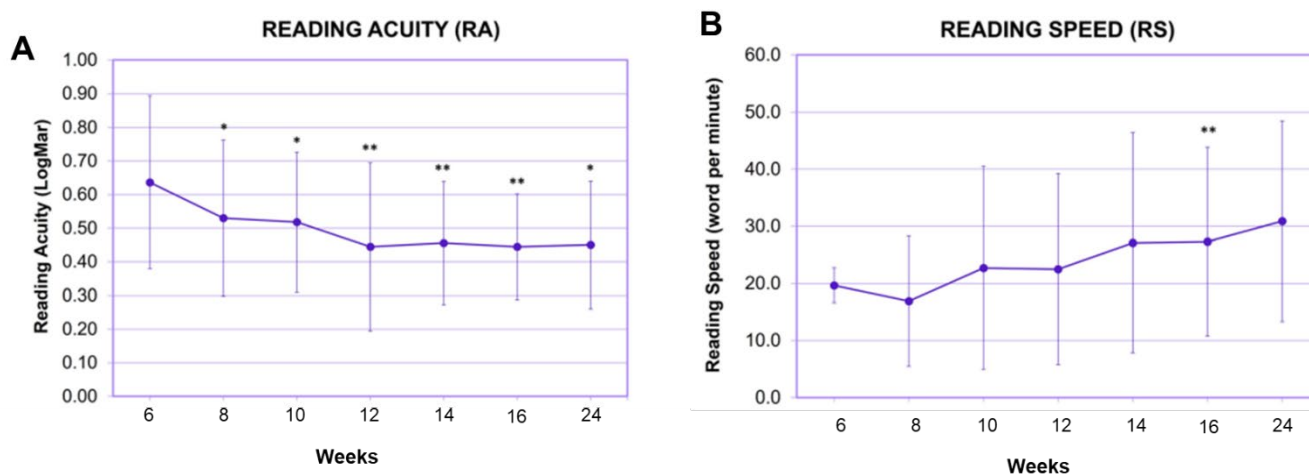
4.4.2 Functional Outcomes (Reading Acuity, Reading Speed, Fixation Stability)

SING IMT™ improves key functional visual outcomes, such as reading acuity, reading speed, and fixation stability in patients with late-stage AMD.

Functional visual outcomes such as reading acuity, reading speed, and fixation stability, for patients that received the SING IMT™ were evaluated in a retrospective study of 11 patients with bilateral GA or disciform scar.³⁷ Reading performance indicators, such as reading speed and accuracy are considered key contributors and indicators of a patient's visual ability and vision-related QoL.³⁷

Average reading acuity was found to significantly improve ($p=0.0181$) by approximately 0.2 LogMAR from 6 weeks (0.64 ± 0.26 LogMAR) to 24 weeks (0.45 ± 0.19 LogMAR) post-operatively, with the SING IMT™.³⁷ Reading speed similarly improved from 6- to 24-week follow-up, with an average improvement of 14 words per minute.³⁷ Statistical significance could not be estimated between weeks 6 and 24 for reading speed due to patients lost to follow-up; however, the observed improvement between week 6 and week 16 was statistically significant ($p=0.0057$).³⁷ All 11 patients achieved a fixation stability of at least 15 seconds, by the final 24-week follow-up.³⁷ Overall, the SING IMT™ has demonstrated ability in improving functional visual outcomes in patients with late-stage AMD.

Figure 6: Reading acuity (A) and reading speed (B) from week 6 to week 24 following SING IMT™ implantation



*p<0.05, **p<0.005

Abbreviations: LogMAR = Logarithm of the Minimum Angle of Resolution; RA = reading acuity; RS = reading speed.

Source: Sasso 2023.³⁷

4.4.3 Patient-Reported Outcomes and Quality of Life

Clinical visual benefits of the SING IMT™ translate into improved quality of life for patients with late-stage AMD.

The impact of SING IMT™ on patient-reported outcomes and QoL was assessed in a prospective study of 11 patients with GA or disciform scar.³⁴ Patients' QoL was assessed using the "Low Vision Quality of Life" (LVQoL) questionnaire, which is designed for the assessment of low vision rehabilitation.³⁴ At 3-months follow-up following implantation of the SING IMT™, all patients exhibited an improvement in QoL.³⁴ Overall QoL scores significantly (p<0.001) increased from a mean baseline score of 60.5±12.1, to 71.0±13.5 at 3-months follow-up.³⁴

Established QoL evidence for the first-generation IMT¹⁰¹ lends credence to these findings, suggesting that the improvements are likely to persist long-term. The prospective, open-label, multicentre clinical trial of 217 patients with late-stage AMD, also assessed the impact of the IMT device on QoL outcomes at 1 year.¹⁰¹ In this trial, QoL was evaluated using the National Eye Institute 25-item Visual Function Questionnaire (NEI VFQ-25) and the Activities of Daily Life scale.¹⁰¹ At 1-year post IMT implantation, statistically and clinically significant mean improvement was found across 7 of the 8 relevant NEI VFQ-25 scales from baseline.¹⁰¹ The overall mean composite NEI VFQ-25 score significantly (p<0.0001) improved from baseline by 6.1±14.4 points.¹⁰¹ The improvement in QoL via NEI VFQ-25 scores was also found to directly correlate with improvement in BCVA, with patients improving by at least 2 BCVA lines experiencing a significantly greater increase in NEI VFQ-25, compared to those who did not.¹⁰¹ Activities of Daily Life subscales were also found to improve significantly at 1-year follow-up from baseline for distance, intermediate, and near activities.¹⁰¹ In summary, the SING IMT™ is anticipated to result in long-lasting patient QoL benefits through improvement in visual acuity.

4.4.4 Safety

SING IMT™ is safe and well-tolerated by patients, with no unexpected safety signals.

Key safety outcomes such as complications and adverse events following SING IMT™ implantation have been assessed in 6 studies including 46 patients, with follow-up to 4-weeks, 3-months or 6-months.^{33-36; 38; 39} The SING IMT™ was generally found to be safe and well-tolerated by patients, with no unexpected safety signals observed. Notably, the observed endothelial cell density (ECD) loss was comparable to that observed with standard cataract surgery.^{33; 38} A summary of the safety findings for SING IMT™ is included in **Table 7**.

Table 7: Summary of safety findings for the SING IMT™

Study	Safety Results Summary
Toro 2025 ³³	<ul style="list-style-type: none"> The mean (SD) change from baseline in corneal ECD at 6-months in operated eyes was -280.7 (315.9) cells/mm² (-11.4 %). This is a result similar to that seen with standard cataract surgery. The most frequent adverse event was corneal edema, and all cases were resolved with topical medications. No clinically meaningful change from baseline was observed in terms of IOP or ACD.
Savastano 2024 ³⁵	<ul style="list-style-type: none"> No corneal edema or endothelia failure observed during 3-month follow-up. No patient experienced an elevation of IOP. One patient experienced a dislocation of the device into the vitreous chamber, which was corrected without further complications.
Savastano 2022 ³⁶	<ul style="list-style-type: none"> At 4-weeks follow-up, no significant complications or side effects were observed.
Savastano 2024 ³⁴	<ul style="list-style-type: none"> The rate of ECD loss was approximately 8.3% from baseline to 3-months. ACD and IOP were not statistically different from baseline to 1- and 3-months. No patients were lost to follow-up. One patient developed anterior uveitis, and another patient developed acute angle closure with pupillary block; both cases were treated and resolved.
Toro 2023 ³⁸	<ul style="list-style-type: none"> Mean ACD was not significantly different from baseline at 1- and 3-months. A significant decrease in IOP was observed in the study eye from baseline to 3-months ($p < 0.05$) ECD loss was $10.4 \pm 13.3\%$ at 3 months ($p = 0.0025$). ECD was comparable between the implant and fellow eyes at all time points. The most common complication was corneal edema, reported in over a quarter of cases. No aborted surgeries, conversions or device malfunctions occurred. The majority of patients (almost 70%) did not report any AEs; 14 ocular AEs were reported in 7 patients (29.17%).
Mastropasqua 2023 ³⁹	<ul style="list-style-type: none"> At 6-month follow-up ACD was unchanged from baseline. ECD loss from baseline to 6-months was 12.6%. Mean IOP decreased by 4.50 mmHg (-5.75; -0.25) from baseline to 6-months. 83.3% of patients had increased IOP measurement in the short term post-operatively Intraoperative surgical iridectomy was performed in 3 patients. The remaining 3 patients required YAG laser iridotomy treatment for IOP management. No intraoperative complications were reported. The most reported AE was corneal edema in 2 patients.

Abbreviations: ACD = anterior chamber depth; AE = adverse event; ECD = endothelial cell density; IOP = intraocular pressure; SD = standard deviation; YAG = Yttrium-Aluminum-Garnet.

Key safety outcomes, including anterior chamber depth (ACD), intraocular pressure (IOP), and ECD were measured in five studies.^{33; 34; 38; 39} ACD was found to be unchanged from baseline in eyes implanted with the SING IMT™, to 3- and 6-month follow-up, across the four studies that reported it.^{33; 34; 38; 39} Intraocular pressure, while reported to be largely unchanged from baseline in three studies at 3- and 6-months follow-up,³³⁻³⁵ some changes in IOP were observed in the remaining 2 studies at 3- and 6-month follow-up.^{38; 39} Despite a short term increase in IOP observed in 83.3% of patients,³⁹ the IOP was significantly reduced at 6-months follow-up in the same study, while a second study³⁸ confirmed this result with reduced IOP at 3-month follow-up, relative to baseline. Intraoperative surgical iridectomy or Yttrium-Aluminum-Garnet (YAG) laser iridotomy treatment was performed in all patients for IOP management.³⁹ The authors therefore recommend intraoperative mechanical iridectomy be performed to help manage acute increases in IOP that may occur following implantation.³⁹ Endothelial cell density is a key marker of corneal health, and while all studies reported a decrease in ECD at follow-up with the SING IMT™, the reported percentages were comparable to that observed with standard cataract surgery.^{33; 38} ECD loss ranged from 8.3% to 12.6% across studies.^{33; 34; 38; 39} One study also reported that ECD loss was comparable between the implant and fellow eye at all time points up to 3-month follow-up.³⁸

Implantation of the SING IMT™ was generally well-tolerated, and the majority of patients did not experience any major complications or AEs. The AEs that did occur were not unexpected given the nature of the device, and all such AEs were resolved with medical or surgical solutions.³⁸ The most common complication reported across all four studies was corneal edema, the majority (~88%) of which were quickly resolved with topical therapy.^{33; 34; 38; 39}

Overall, the safety data associated with implantation of the SING IMT™ are expected to be similar to or improve upon safety data achieved with the use of the predicate IMT device.⁹⁷ A safety analysis of the IMT over 2-years in 217 patients reported the device was well-tolerated with a relatively low occurrence of AEs.⁹⁷ The most frequent complications observed were not considered significant safety concerns; however, ECD loss with IMT was 20% at 3-months and 27% at two years follow-up.⁹⁷ In comparison, studies on the SING-IMT have measured ECD loss at only 8.3 and 10.4% at 3-months,^{34; 38} and between 11.4 and 12.6% at 6-months.^{33; 39} This reduced initial ECD loss, in addition to the smaller incision size associated with SING IMT™ relative to the original IMT is expected to result in relative reductions in ECD loss long-term.^{29; 97}

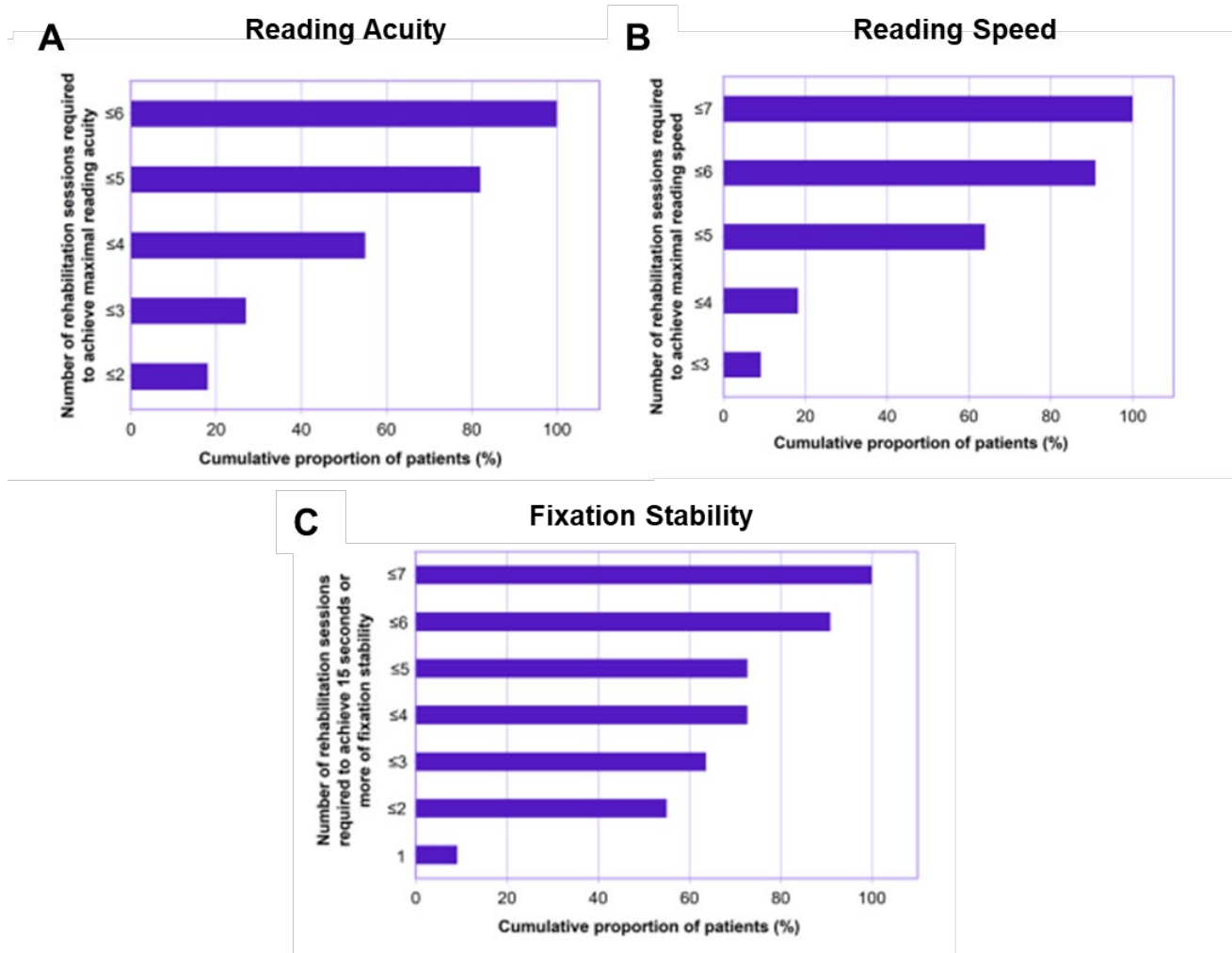
Taken together, data from 6 clinical studies spanning 4-weeks to 6-months follow-up have reported that the SING IMT™ is safe and well-tolerated by patients, with no unexpected safety signals observed.

4.4.5 Visual Rehabilitation

Post-operative visual rehabilitation is important to optimize patient benefit from the SING IMT™.

Visual rehabilitation is a crucial step following implantation of the SING IMT™ for patients to become accustomed to their new vision and to achieve optimal results.³⁴ To evaluate the impact of rehabilitation training following SING IMT™ implantation, Sasso 2023 assessed visual acuity and key functional outcomes (i.e., reading acuity, reading speed, fixation stability) following seven rehabilitation sessions, comparing results between the first and last session post-implantation.³⁷ Distance visual acuity (BCDVA) was found to be significantly improved ($p=0.0125$) from the first to the last rehabilitation session.³⁷ Reading acuity also significantly improved from 0.64 ± 0.26 LogMAR at the first session to 0.45 ± 0.19 LogMAR by the final session.³⁷ The majority of patients (55%) achieved the highest reading acuity after four rehabilitation sessions (**Figure 7A**).³⁷ Reading speed also improved (numerically but not statistically) from the second session (16.9 ± 11.4 words per minute) to the final session (30.9 ± 17.6 words per minute), although was not statistically significant ($P=0.0057$).³⁷ Most patients (64%) were found to have achieved maximum reading speed following 5 rehabilitation sessions (**Figure 7B**).³⁷ For fixation stability, the majority of patients (55%) required only 2 rehabilitation sessions to achieve 15 seconds or more, with all patients achieving this following the final session (**Figure 7C**).³⁷ Overall, the SING IMT™ when paired with rehabilitation training sessions can improve visual acuity and function, with the majority of patients achieving significant benefits within 4-5 rehabilitation sessions.

Figure 7: Cumulative proportion of patients achieving maximum A) reading acuity B) reading speed and C) fixation stability by rehabilitation session



Source: Sasso 2023.³⁷

4.5 The Economic Value of SING-IMT

4.5.1 Offsetting the cost of blindness

The SING IMT™ is anticipated to reduce the economic burden associated with profound vision loss in late-stage AMD, generating economic benefits for both patients and society.

As described in **Section 2.2.3**, late-stage AMD is associated with substantial economic burden. With healthcare costs continually rising, the economic impact and the value for money of new interventions is an important consideration for the healthcare system in general and specifically in relation to AMD.^{16; 92; 102} SING IMT™ provides a means of improving vision in late-stage AMD by compensating for the central vision loss. As such, patients are less impacted by visual impairment and central vision blindness from GA. A variety of published evidence emphasizes the staggering cost of vision loss and the immense value that restoring vision can bring to the healthcare system and society.^{17; 92; 103-105}

A retrospective cohort study of 22,120 patients with GA and 72,476 controls was conducted to understand the cost burden of GA alone, and GA with visual impairment or blindness in elderly patients in the US (aged 65 or older).¹⁰³ The analysis considered hospitalization, emergency room visits, outpatient visits, and homecare services. Patients with GA had significantly higher all-cause HCRU relative to patients without GA, even without presence of visual impairment. Similarly, patients with GA and visual impairment incurred significantly higher HCRU than GA-only counterparts, driven by hospitalization costs (net difference \$5,096). Patients with GA and blindness also incurred statistically significant differences in costs versus the GA-only cohort (additional \$9,952 per year), driven by hospitalization and emergency room visits.¹⁰³

A recent cost analysis estimated the economic impact of vision loss and irreversible legal blindness in Spain over a 10-year time horizon (2021 to 2030).¹⁷ Direct healthcare, direct non-healthcare and lost productivity costs were considered, with costs extrapolated to 2030.¹⁷ Vision loss or blindness associated with AMD in Spain was estimated to cost €10,634 per patient per year in 2021, with this expected to grow to €11,432 by 2030.¹⁷ Total cumulative societal costs of over €7.5 million were attributed to AMD, increasing to close to €11 million by 2030.¹⁷

A European cost-effectiveness analysis comparing treatment for nAMD reported cost estimates for low vision aids and nonmedical costs (including costs for caregivers, transportation and residence), by level of vision impairment.⁹² As can be seen in **Table 8**, typical one-time costs for low vision aids are nearly five times higher for patients with less than 20/200 vision compared to those with normal vision, while nonmedical costs were 37 times higher.⁹²

Table 8: Costs associated with low vision aids and nonmedical costs, by level of vision impairment

Visual acuity	Low vision aids (Cost, SE)	Nonmedical costs (Costs, SE)
20/20 to 20/25 (normal)	\$218.24 (\$85.95)	\$1,141.69 (\$327.09)
20/30 to 20/40	\$451.69 (\$74.97)	\$6,165.32 (\$1,947.80)
20/50 to 20/100	\$1,020.00 (\$53.74)	\$19,477.18 (\$2,599.00)
Less than 20/200	\$1,065.87 (\$73.76)	\$42,318.61 (\$3,822.44)

Abbreviations: SE = Standard error.

Source: van Asten et al. 2018.⁹²

Taken together, these analyses demonstrate the potential economic value of moving patients with severe blindness into a health state of less severe vision impairment. Through reduction of visual impairment from GA in late-stage AMD, SING IMT™ is anticipated to ameliorate some of the economic burden associated with GA, providing benefits for patients and society alike.

4.5.2 Cost-utility of an Intraocular Miniature Telescope

Intraocular miniature telescopes are cost-effective, conferring substantial benefit through improvements in vision-related quality of life.

In general, the economic value of a therapy can be assessed over a lifetime using economic modelling approaches such as a cost-utility analysis. According to a published cost-effectiveness analysis on the predecessor device, the IMT conferred substantial improvement in QoL relative to no therapy, all fellow eyes,ⁱ and fellow eyes that underwent cataract surgeryⁱⁱ, with a mean daily QoL gain of 12.5% during the study period.⁴⁰ The mean cost-utility ratios (i.e., costs per quality-adjust life-years [QALY]) ranged from \$16,045/QALY (versus fellow eyes with cataract surgery) to \$19,302/QALY (versus all fellow eyes).⁴⁰ In reference to conventional cost-effectiveness standards in the US and other countries, these results suggest that implantation of the IMT device is highly cost-effective when compared to no therapy, all fellow eyes, and fellow eyes with cataract surgery.⁴⁰ To date, a cost-effectiveness analysis has not been completed for the SING IMT™; however, with the same mechanism of action to the IMT and the favourable shorter-term improvements in QoL observed for the SING IMT™,³⁴ cost-effective relative to no therapy, all fellow eyes, and fellow eyes with cataract surgery is also anticipated. Collectively, the improvement in visual acuity with SING IMT™ and the anticipated maintenance of these gains over time is expected to contribute substantial economic benefits to patients and society.

Relative to the predicate IMT device, the SING IMT™ improves on key design aspects that may contribute to reducing the economic burden of late-stage AMD. For example, the smaller overall diameter, foldable haptics and preloaded delivery system help to reduce the implantation procedure time from 60 minutes with IMT to 25 minutes with the SING IMT™.^{25; 29} Furthermore, the shortened procedure time with the SING IMT™ (relative to IMT), may also afford clinicians the ability to perform additional IMT insertion procedures per day, thereby better serving the patient population with the potential to generate additional revenue for the physician and/or facility.

4.5.3 Pricing Rationale and Patient Accessibility

Central vision loss from GA interferes with critical everyday activities and severely impacts patient quality of life (QoL) and independence,^{1; 12; 13} with progression from late-stage AMD to loss of central vision occurring in just 1.4 to 2.5 years.¹⁴ Patients with dry or wet subtypes can progress to late-stage AMD characterized by GA.⁸ Although there are a dearth of treatment options for patients with GA,^{18; 21; 68; 69} costs are established for anti-VEGF treatments, which help to slow progression in early and intermediate wet AMD. Although regional variability exists, anti-VEGF treatments are estimated to cost as much as €33,137 annually per European patient with nAMD after factoring direct medical and indirect costs.^{92; 106} However,

ⁱ Combined group of the contralateral (fellow) eyes that did not undergo IMT device implantation.

ⁱⁱ Combined group of the contralateral (fellow) eyes that did not undergo IMT device implantation and underwent cataract surgery during the 2-year course of the trial. Note: as standard IOLs implanted during cataract surgery are not designed to improve central vision loss for patients with AMD, cataract surgery is not a direct comparator to the IMT device.

when a patient inevitably progresses to late-stage disease with central vision impairment, these therapies cannot compensate for the central scotoma, meaning patients no longer receive vision-improving benefit, and the vision-impairment related costs incurred by the patient and payer will continue to increase.

SING IMT™ is an elegant solution to address vision loss from late-stage AMD, improve near and distance vision, and maintain these visual benefits in the long-term as the disease continues to progress. Implantation of the SING IMT™ with visual rehabilitation involves a front-loaded, one-time cost comparable to the holistic annual costs of anti-VEGF therapies, but with visual benefits expected to continue over the long-term (as supported by the 5-year data for the predicate IMT device) even as patient disease stage progresses.^{32; 94; 96} As such, SING IMT™ represents considerable value for money given the demonstrated improvements in near and distance vision for patients with GA in late-stage AMD.

SING IMT™ is readily available in Germany, meaning patients from other countries in the European Union can use the S2 form to access this vision-changing therapy as a planned medical treatment. Visit the link to learn more: [Organising planned medical treatment abroad - Your Europe](#).

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