WHITE PAPER COMPENDIUM | PART 3 | 2025

RODENSTOCK MYCON™

EFFICACY AND SATISFACTION IN EVERYDAY USE

Myopia and future eye health,
why slowing progression matters



RODENSTOCK

Because every eye is different

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EFFICACY AND SATISFACTION IN EVERYDAY USE

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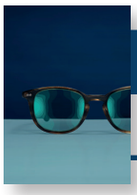
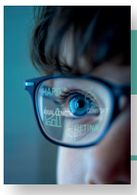
PART 1 – MYOPIA IN SOCIETY

Insights and Background on Myopia and its Treatment Options



PART 2 – DESIGN AND BENEFITS OF LENSES WITH HAPD™ TECHNOLOGY

Rodenstock's Solution for Myopia Control in Children



PART 3 – EFFICACY AND SATISFACTION IN EVERYDAY USE

Studies and Data Supporting Myopia Control Lenses

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1 KEY FINDINGS

The control of myopia in children has become a crucial focus in optometry because of the increasing global prevalence of myopia, particularly among children and young adults. To address the progression of myopia in children, Rodenstock offers specialized lens solutions, MyCon™ and MyCon™ 2 featuring HAPD™ Technology (Horizontal Asymmetrical Peripheral Defocus).

This whitepaper provides an overview of the latest data on HAPD™ lenses, highlighting key results from clinical studies and insights from post-market performance follow-up (PMPF) data. These findings offer valuable information on the effectiveness of the lenses and wearer acceptance, providing practical guidance for eye care professionals and shaping future research in this rapidly evolving field.

This section highlights key results from the underlaying clinical study and recent PMPF data.

A clinical study conducted by Tarutta et al. from 2012 to 2018 encompassed 146 Caucasian children aged 7-14 years. Among these, 94 subjects wore myopia control lenses, and 52 subjects wore single vision lenses as a control for comparison. The results of the study showed that these myopia control lenses demonstrated long-term efficacy in controlling myopia progression (Tarutta et al., 2019).

The progression of myopia was assessed at multiple intervals over a duration of up to 5 years. Baseline evaluations indicated equivalent myopic progression in both the control and treatment cohorts. However, spherical equivalent refraction (SER) measurements indicated that, after 12-18 months, myopia progression decelerated by 49% in the group wearing the study myopia lenses. This deceleration persisted, showing a 40% reduction in myopia progression after 4-5 years. Furthermore, the study also documented a 56% and 35% decrease in axial length growth after 2 years and after 4-5 years respectively.

Rodenstock MyCon™ lenses, based on the same principle as the myopia lens used in the study, are expected to deliver similar effectiveness. In conclusion, MyCon™ lenses from Rodenstock aim to follow the principle of reducing myopia progression in the long term and thus can improve the future eye health of paediatric patients.

To corroborate the findings of the underlying clinical study, Rodenstock invests in Post Market Performance Follow-up (PMPF). As part of this initiative, clinically relevant parameters for myopia progression such as axial length (AL) and spherical equivalent refraction (SER) were collected by two renowned optical institutions in Spain. Myopia control lenses with the same principle as MyCon™ (HAPD™ Technology)

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were fitted to 158 children aged 6-14 years, over a 12-month period. At the 12-month follow-up, there was an average reduction in myopia progression (SER) by 47%-64% and a 55% reduction in axial length growth. These significant results not only confirm the efficacy of the product but also surpass the outcomes of the initial study.

Additionally, as part of the PMPF, a qualitative survey was conducted among opticians regarding myopia control lenses that utilize the same principle as MyCon™ lenses. The survey results indicated excellent ratings for wearer acceptance, adaptation period, ease of handling, and overall satisfaction. Almost all the surveyed opticians expressed their intent to continue using the MyCon™ lenses.

These findings further establish the

MYCON™ LENSES AS AN EFFECTIVE AND USER-FRIENDLY SOLUTION IN MYOPIA MANAGEMENT,

reinforcing their clinical benefits, practitioner approval, and strong wearer comfort.

2 EFFICACY OF LENS DESIGN

A fundamental requirement for myopia control lenses is their demonstrated efficacy in slowing the progression of myopia in children, aside from wearer acceptance and product variety. In this chapter, we will present and analyse the scientifically validated outcomes derived from a long-term clinical study of myopia control lenses.

Additionally, we will review and interpret the latest market data and post-market performance metrics of myopia control lenses that utilize HAPD™ Technology. This will provide a comprehensive understanding of their real-world effectiveness and wearer acceptance. The following section aims to offer a detailed overview of the clinical and practical benefits of lenses such as MyCon™/MyCon™ 2, substantiated by robust scientific evidence and current usage data.

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2 EFFICACY OF LENS DESIGN

2.1 SCIENTIFIC STUDIES ON THE DEVELOPMENT OF LENS DESIGN

In recent years, numerous scientific studies have been conducted on myopia management and the mechanisms that trigger signals for eye growth. The following study results have influenced the development of MyCon™ lenses with HAPD™ Technology:

- Peripheral refraction and eye length varies in different parts of the retina [(Atchison et al., 2005), (Atchison et al., 2006), (Millodot, 1981), (Seidemann et al., 2002), (Verkicharla et al., 2012)].
- Differences of asymmetries in the peripheral refraction and the eye shape were shown for different refractive groups and progressive and non-progressive myopes [(Faria-Ribeiro et al., 2013), (Radhakrishnan et al., 2013), (Schmid, 2011)].
- There is a link between prolonged near-work and the development of myopia [(Ip et al., 2008), (Mutti et al., 2002), (FAAO & FAAO, 1998), (Saw et al., 2005)].
- There is an anatomical asymmetry in the retina in the nasal and temporal regions (in terms of cone and ganglion cell density) implying a neuro-functional dominance of the nasal retina [(Curcio & Allen, 1990), (Curcio et al., 1990)].
- Long-term results of perifocal defocus spectacle lens correction in children with progressive myopia have demonstrated effectiveness in managing myopia progression (Tarutta et al., 2019).

Based on the above-cited studies and additional insights from research and development, the MyCon™ and MyCon™ 2 lenses are engineered utilizing HAPD™ Technology (Horizontal Asymmetrical Peripheral Defocus) as their mechanism of action. These lenses are crafted to feature a central vision zone that maintains stable refraction, thereby ensuring clear vision around the optical centre. Simultaneously, the asymmetrical peripheral zones (nasal power up to 2.0D, temporal power up to 2.5D) are designed to create a gradient of increasing power along the horizontal meridian. For more comprehensive information on the lens design, please consult Part 2 of the White Paper.

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2.2 THE FOUNDATIONAL CLINICAL STUDY

Rodenstock's evidence-based solution for controlling myopia progression has been evaluated for its effectiveness. The following scientific study underscore the clinical significance of lenses on which MyCon™ Technology is based. An independent study was carried out from 2012-2018 for investigating the efficacy of a lens, which uses a principle of mechanism for slowing down myopia progression on which Rodenstock MyCon™ is based (Tarutta et al., 2019).

The study was conducted by the Helmholtz National Medical Research Centre for Eye Diseases of the Russian Ministry of Health in Moscow and monitored the myopia progression of a group of 146 Caucasian boys and girls, with myopia varying between -1.00 and -6.00 D.

The participants were divided into two groups with the same average age of 10.5 years. The first experimental group comprised 94 participants (aged 7-14 years) who used myopia control lenses, while the second control group included 52 participants (aged 8-14 years) who used standard single vision lenses.

During the study, myopia progression (mean power and axial length) was assessed after 6 months, 12-18 months, 2 years, 3 years, and 4-5 years from the start of lens wear.

The refraction measurements (spherical equivalent) indicated that the progression of myopia slowed by 49% after 12-18 months in the group that wore the study's myopia lenses. After 4-5 years, there was an average reduction in myopia progression of 40% compared to the control group (Figure 1). Furthermore, axial length growth was reduced on average by 56% after 2 years and 35% after 4-5 years.

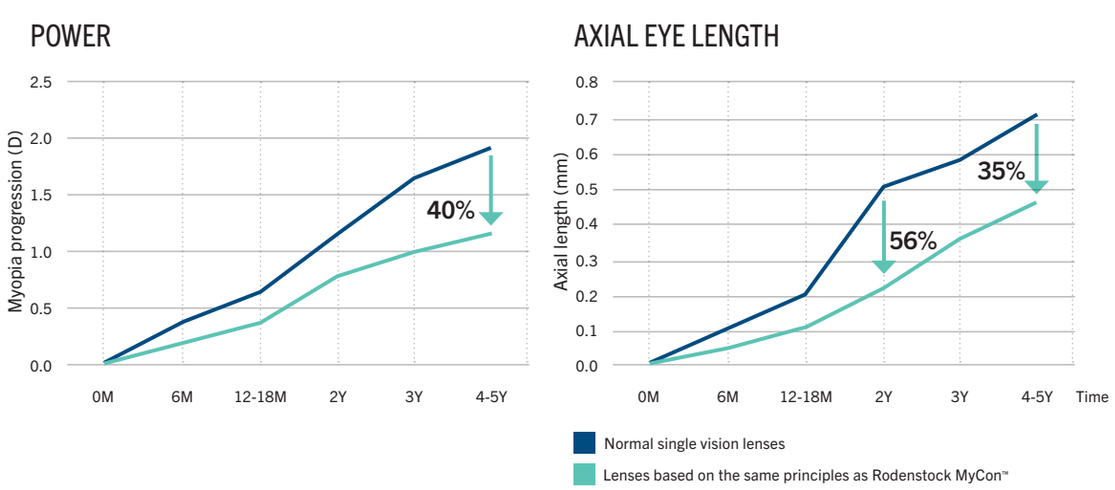

Figure 1 . Results of the clinical study carried out with lenses upon the principles of MyCon™ is based. In blue, the control group's development; in mint, the experimental group's development (adapted from Tarutta et al., 2019)

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2 EFFICACY OF LENS DESIGN

2.3 POST-MARKETING INVESTIGATIONS: DATA COLLECTION AMONG OPTICIANS IN SPAIN

Rodenstock engages in a proactive and systematic process of continuous post-market surveillance. As part of these ongoing monitoring efforts, a post-market performance follow-up (PMPF) process was implemented to assess the wearer acceptance and efficacy of Rodenstock's myopia lens solutions in practical settings.

2.3.1 METHODOLOGY

To conduct the investigation, a collaborative framework was established in 2023 involving two types of optical institutions, implementing a comprehensive data collection process to evaluate the efficacy of the HAPD™ principle.

The framework included two key participants: an optical retail chain with several stores and an independent optician, each with experience in myopia management and established patient follow-up procedures. The primary objective was to gather longitudinal data on patients using the myopia control lens, focusing on refractive changes and, in some cases, additional axial length measurements. This collaboration provided access to a paediatric population spanning the entire Spanish territory.

All participating opticians had extensive expertise in eye care services and maintained detailed patient records. Their participation ensured a diverse patient sample and a rigorous data collection process, which included:



PATIENT ENROLMENT

Patients who met the inclusion criteria, such as age range (6 to 14 years) and initial refractive error, were included in the data analysis. Informed consent was obtained from all participants prior to enrolment.

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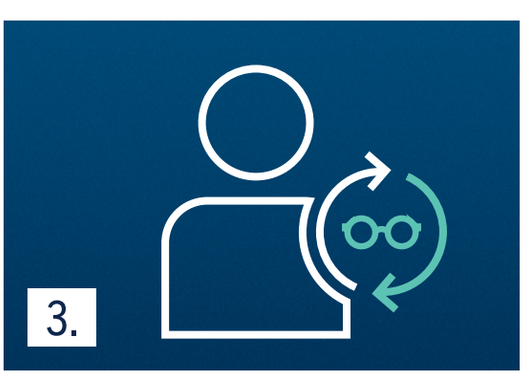
BASELINE DATA COLLECTION

A thorough anamnesis was conducted to collect information on the patient's ocular history, systemic health, and lifestyle factors. Comprehensive refractive measurements were performed using standardized phoropter procedures and, at one collaborating optical institution, an optical biometer (AI-Scan, Nidek Corporation).



FOLLOW-UP EXAMINATIONS

Follow-up examinations were scheduled every 6 months to monitor the progression of myopia. At each follow-up visit, the anamnesis was updated, and refractive and axial length measurements were repeated.



DATA STORAGE AND ANONYMIZATION

Both participating optical institutions utilized their proprietary electronic health record (EHR) systems to store patient data. To protect patient privacy, all identifiable information not needed for the study was removed from the data before sharing it with the research team.

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2 EFFICACY OF LENS DESIGN

ENSURING ACCURATE AND RELEVANT STATISTICAL OUTCOMES THROUGH CAREFUL CONTROL GROUP SELECTION

To compare the data obtained from myopic children wearing the myopia lenses with HAPD™ Technology during the PMPF initiative, we collected control group data from various published clinical trials investigating the efficacy of myopia spectacle solutions. When selecting the control groups, we prioritized studies with populations that matched our PMPF data in terms of degree of myopia progression, ethnicity, age range, baseline SER (Spherical Equivalent Refraction), and AL (Axial Length).

Table 1 summarizes the studies we evaluated for constructing the control group for PMPF data. The average change in SER and AL for the control group after a 12-month follow-up are −0.59 D and 0.265 mm, respectively.

STUDY	CONTROL GROUP	AGE [YEARS]	BASELINE SER [D]	BASELINE AL [MM]	GENDER (M/F)	12-MONTH PROGRESSION SER [D]	12-MONTH PROGRESSION AL [MM]
Sanchez-Tena et al., 2024	SV	10.49 [8.76–11.32]	−2.01 ± 1.03	23.98 ± 0.82	47.6/52.4	−0.25 ± 0.32	0.23 ± 0.15
Yuval et al., 2024	SV	9.97 ±1.72	−2.74 ±1.37	24.39 ±0.78	54.1/45.9	-0.644	0.32
Nucci et al., 2023	SV	11.34 ± 3.96	-1.54 ± 0.74	24.64 ± 0.79		-0.8828	0.22
Santodomingo-Rubido et al., 2012	SV	9.9 ± 1.9	-2.08 ± 1.23	24.26 6 1.01	15/15	0.62	0.37
Garcia-del Valle et al., 2021	SV	11.90 ± 2.13	−3.31 ± 1.76	24.48 ± 0.78	8/18	−0.57 ± 0.52	0.22
Chamberlain et al. 2019	SV	10.1 ± 1.4	−2.19 ± 0.81	24.46 ± 0.66	37/ 37	−0.58	0.23 ± 0.03

Table 1: The data of control groups from various published clinical studies investigating the efficacy of myopia spectacle solutions. SV- Singl Vision Lens, SER- Spherical Equivalent Refraction, Al- Axial Length, M- Male, F- Female, D- Dioptre, mm- millimetre (Chamberlain et al., 2019a; Garcia-del Valle et al., 2021; Nucci et al., 2023a; Sanchez-Tena et al., 2023; Santodomingo-Rubido et al., 2012a; Yuval et al., 2024).

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2.3.2 RESULTS

Figure 2 depicts the average change in spherical equivalent refraction (SER) and axial lengths (AL) collected during the PMPF initiative. The data is presented for two Spanish data collection centres (Optician-1 and Optician-2).

Optician-1 evaluated 119 children {Age range: 6-14 years; Age (mean ± SD): 10.9 ± 2.08 years; SE (mean ± SD): -2.66 ± 1.58 D}, while Optician-2 evaluated 39 children {Age range: 6-14 years; Age (mean ± SD): 11.5 ± 2.20 years; SE (mean ± SD): -2.29 ± 1.47 D; AL (mean ± SD): 24.3 ± 0.80 mm} during the follow-up period of one year.

The baseline values (measurements taken before wearing the myopia lenses) were collected during each participant's first visit, and the data from subsequent visits at 0.5 years (between > 3 and ≤ 9 months), 1 year (between > 9 and ≤ 15 months), and 1.5 years (between > 15 and ≤ 21 months) were adjusted relative to the baseline.

AT THE 1-YEAR FOLLOW-UP, LENSES WITH HAPD™ TECHNOLOGY AS MYCON™/MYCON™ 2 SIGNIFICANTLY DECREASED THE PROGRESSION OF SER BY 47% TO 64% AND AXIAL LENGTH BY 55% COMPARED TO THE VIRTUAL CONTROL GROUP

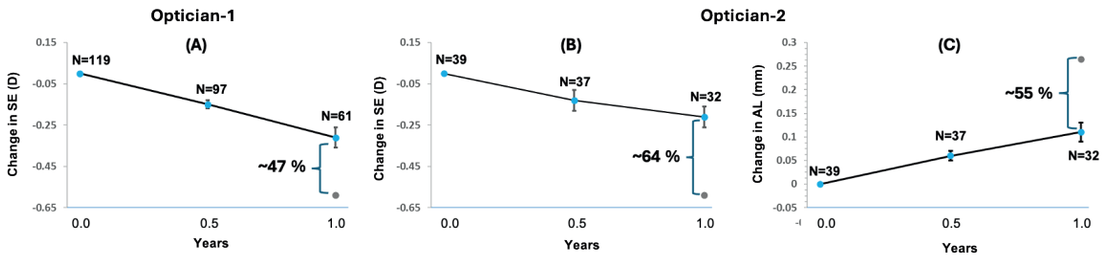

Figure 2 . (A)- Average (± 1 SD) of spherical equivalent refraction (SER) obtained by Optician-1. (B) and (C) are the spherical equivalent refraction (SER) and axial length (AL) obtained by Optician-2. The grey dots in panel (A), (B), and (C) represents the reference data for age matched myopic children's wearing single vision lenses obtained from different published clinical studies for different myopia spectacle solutions (Refer the Methods section for further details;(Chamberlain et al., 2019b; Garcia-Del Valle et al., 2021; Nucci et al., 2023b; Sanchez-Tena et al., 2023; Santodomingo-Rubido et al., 2012b; Yuval et al., 2024).

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2.3.3 DISCUSSION

The aim of this white paper is to highlight the key findings of studies evaluating the clinically significant effects of myopia control lenses based on the HAPD™ Technology.

An independently conducted study by Tarutta et al., using myopia control lenses which HAPD™ Technology is based on, concluded that these lenses can effectively control myopia progression by an average of 40% compared to the control group. Furthermore, axial length growth was reduced by an average of 56% after 2 years and 35% after 4-5 years.

The data collected through Rodenstock's post market performance follow-up (PMPF) supports the findings of Tarutta et al. The PMPF data showed that myopia control lenses based on the HAPD™ Technology can effectively control myopia progression by 47-64% after 12 months in comparison to a virtual control group. The axial length growth also slowed down by 55% after 12 months compared to the virtual control group. Possible reasons for the higher efficiency of Optician 2 compared to Optician 1 are that the participants were on average older (i.e. 11.5 ± 2.20 years vs. 10.9 ± 2.08 years) and had on average a lower baseline SE (i.e. -2.29 ± 1.47 D vs. -2.66 ± 1.58 D). Previous research could show that myopia progression decreases with age (Donovan et al., 2012; Naduvilath et al., 2025) and increases with baseline SE. This may have resulted in a slower progression of myopia in Optician 2 compared to Optician 1, and thus a greater difference from the virtual control group and higher efficiency.

The significant effects of lenses based on the HAPD™ Technology in controlling myopia progression make them an ideal candidate for myopia management.

2.4 POST-MARKETING INVESTIGATIONS: SURVEY AMONG OPTICIANS IN SPAIN

As part of the PMPF data collection, another qualitative survey was conducted among opticians regarding myopia lenses with HAPD™ Technology. This survey involved 74 opticians in Spain from 2022 to 2023.

The survey results indicated high ratings for wearer comfort and overall satisfaction. Specifically, 97% of opticians reported their intention to continue using the lenses, and 97% noted the ease of use. Additionally, 95% stated



that children adapted well to the lenses, with only 1% not adapting, and 92% of children reported feeling comfortable wearing the lenses.

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2.5 COMPETITIVE ASSESSMENT OF MYOPIA CONTROL LENS EFFICACY

The efficacy of spectacle lenses in slowing myopia progression is a critical factor influencing the purchase decisions of these products. Spectacle lens manufacturers often provide values for their effectiveness in slowing myopia progression, measured as changes in spherical equivalent or axial length compared to a control group wearing single vision lenses or to a literature-based control group. These values are frequently used as marketing tools and are based on studies validating the product's efficacy in myopia control. However, the assumption that the efficacy values promoted by different manufacturers can be compared directly can be misleading.

The efficacy values are influenced by various conditions. The ethnicity of the subjects seems to play a role, with certain populations having higher prevalence rates of myopia. Age is another key factor; younger individuals tend to experience more rapid progression of myopia, and interventions in these populations tend to show greater efficacy. The duration of clinical trials is also of paramount importance. Treatments often show particularly high efficacy in the first to second year, after which the effectiveness tends to level off at a lower rate for some products. The daily wear time of the myopia control lenses profoundly impacts their therapeutic efficacy, with extended wear times correlating with superior outcomes.

A more detailed examination of efficacy values frequently uncovers that these figures are derived from specific subgroups within the overall study cohort, where the product demonstrates enhanced effectiveness. For instance, these subgroups may be selectively chosen based on particular age ranges or daily wearing durations of the spectacles. Furthermore, results are often selectively reported from 12 or 24-month follow-up periods, while the efficacy observed in the ensuing years typically shows a decline.

EFFICACY VALUES
ENVIRONMENT | AGE | DURATION



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3 SUMMARY

In recent years, numerous scientific studies have been conducted on myopia management and the mechanisms influencing eye growth. The insights gained from these studies have contributed to the development of MyCon™ lenses with HAPD™ Technology. These lenses provide clear vision in the central visual area and feature a horizontal, asymmetrical peripheral power progression. The resulting retinal defocus is intended to slow the progression of myopia.

An independent study conducted from 2012 to 2018 (Tarutta et al., 2019) demonstrated the efficacy of myopia lenses, upon which the HAPD™ Technology is based, in slowing the progression of myopia in children.

Rodenstock continually monitors the market following product launches (PMPF) to track the acceptance and effectiveness of MyCon® lenses in practical use. The latest data from Spain confirmed that these lenses with HAPD™ Technology effectively slow the progression of myopia in children over a period of 12 months. This not only supports the existing study results but even surpasses them in certain aspects. Additionally, a qualitative survey among numerous opticians in Spain in 2023 reported high satisfaction regarding wearer comfort, adaptation period, and handling of the lenses. Various market feedback from eye care professionals confirms the advantages of a wide product range, aesthetic appeal, and the positive reception of MyCon™/MyCon™ 2 lenses among young patients and their parents.

The clinical effectiveness of the myopia lenses with HAPD™ Technology described in this white paper aligns with findings from studies on other established myopia lens principles. For instance, clinical data from another study investigating such an established principle showed a similar slowing of myopia progression after 12 months compared to the control group. This study also involved European children in a similar age range (8-13 years) (McCullough et al., 2023).

THE RESULTS OF THESE INVESTIGATIONS AND SURVEYS CONFIRM THE HIGH EFFECTIVENESS AND USER-FRIENDLINESS OF LENSES WITH HAPD™ TECHNOLOGY. IT CAN THUS BE CONCLUDED THAT MYCON™ LENSES REPRESENT AN EFFECTIVE AND COMFORTABLE SOLUTION FOR MYOPIA MANAGEMENT.

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