# IMI—Instrumentation for Myopia Management

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The rising prevalence of myopia has underscored the importance of early diagnosis and effective management strategies to control its progression and to prevent complications. Advancements in instrumentation enable clinicians to provide individualized evidence-based care for patients. Instrumentation for myopia control encompasses a wide range of technologies designed to assess refractive error, biometric parameters, including axial length, accommodative responses, as well as detailed assessment of ocular health. These tools offer clinicians the ability to move beyond traditional clinical techniques, providing more accurate, detailed, and repeatable measurements critical for the detection and monitoring of myopia progression. This allows for a personalized approach to treatment planning, enabling the selection and optimization of myopia control interventions. Furthermore, advanced imaging and real-time data visualization support patient education by fostering understanding, which may improve adherence to treatment plans. By adopting these technologies, clinicians can address the complexities of myopia management, deliver precise and effective care, and contribute to global efforts to curb the myopia epidemic. The integration of advanced instrumentation into clinical practice encourages early intervention and management strategies for patients at risk of becoming myopic (pre-myopia), as well as improving patient outcomes for myopic patients.

Keywords: myopia, instrumentation, myopia control, myopia management

O phthalmic instruments play a critical role in helping clinicians manage myopia, from assessing at-risk children to diagnosing, monitoring progression, and evaluating treatment efficacy. Furthermore, they are indispensable for monitoring the health and integrity of the posterior segment, given the increased risk of associated disease in myopic eyes. Relevant ophthalmic instrumentation can be broadly categorized based on purpose, to assess the optical, structural, or functional aspects of the eye and vision as illustrated in Figure 1.

The broad definitions of two of the categories are as follows:

- Optical: parameters and metrics directly impacting the light refraction (curvatures, indexes) and their consequences (topography, optical power, refraction, aberrations, accommodation)
- Structural: parameters and metrics defining the intraocular distances and tissue thickness (total and partial intra-ocular distances, thicknesses, intraocular imaging).

For the purposes of this article, discussion is limited to instrumentation for optical and structural assessments. Functional and multimodal instrumentation will not be discussed.

**Optical Assessment:** 

- Ocular refraction: to obtain on-axis and off-axis refraction of the eye using objective or subjective methods.
- Corneal curvature (keratometry/topography/topography): to obtain quantitative information on the anterior and posterior corneal curvature, elevation, asphericity, and thickness parameters of the cornea.
- Aberrometry: to measure the optical imperfections in the visual system
- Pupillometry: to measure the dimensions of, and stimulus driven, as well as spontaneous variations in pupil size

Structural Assessment:

• Dimensional: intraocular measurements used specifically for axial length and peripheral eye length through

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**FIGURE 1.** Classification of the instrumentation utilised in the management of myopia. AC/A, accommodative convergence/accommodation ratio; ACD, anterior chamber depth; AK, autokeratometry; AR, autorefraction; CSF, contrast sensitivity function; ffERG, full-field electroretinography; gf-mfERG, global flash multifocal electroretinography; LT, lens thickness; mfERG, multifocal electroretinogram; MRT, multispectral refraction topography; PERG, pattern electroretinogram; RT, retinal thickness; VA, visual acuity; VCD, vitreous chamber depth; WFWFR, wide-field wavefront refraction. Although shown in this figure, functional and multimodal instrumentation are not covered in this article.

one-dimensional scanning systems such as the low-coherence optical biometers.

- Imaging: technologies to obtain images of the ocular structures
  - Fundus photography: for detailed, largely qualitative analysis of internal posterior segment structures, including wide-field retinal imaging
  - Posterior segment high resolution crosssections: quantitative analysis of two- or three-

dimensional (3D) optical sections of the retina, choroid, and sclera through optical coherence tomography

 Anterior segment: assessment of cornea, anterior chamber and crystalline lens assessment through qualitative methods such as slit-lamp biomicroscope or quantitative analysis through Scheimpflug photo/videography or anterior segment optical coherence tomography (OCT)

## **OPTICAL**

### **Ocular Refraction**

During childhood, the eye elongates alongside concomitant changes in the cornea and lens power. A mismatch between the eye's axial length and the optical power of the cornea or lens results in a refractive error. A myopic refractive error can arise in one of a few ways because of excessive axial length (axial myopia), excessive corneal, or lenticular power (refractive myopia).<sup>1</sup>

Measurement of Refractive Error. Refractive error can be measured using objective methods that assess the eye's optical state, as well as subjective methods that incorporate perceptual aspects of vision. Cycloplegic subjective refraction is considered the gold standard for determining refractive error, particularly in clinical practice, because it incorporates both optics and perception while controlling for accommodation. However, because patient cooperation and comprehension is required, it may not be suitable for younger children.<sup>2–4</sup> For younger children, objective methods such as cycloplegic retinoscopy and cycloplegic autorefraction are the next best methods to accurately determine refractive error. In clinical trials, data obtained by objective methods tend to be favored and considered more repeatable with less potential for subjective variability. Both cycloplegic retinoscopy and cycloplegic autorefraction generally yield comparable refractive results, with mean spherical differences falling within 0.50D of the other.5,6

Cycloplegic Refraction. Control of accommodation during refraction assessment is especially critical for young children, where accommodation can cause measurements to vary by as much as 4D.7 Not using cycloplegia may lead to an overestimation of the magnitude of myopia and possibly misclassifying hyperopia and emmetropia as myopia.<sup>8-14</sup> Although noncycloplegic refractive error may be on average 0.6D-0.8D more myopic than cycloplegic results in myopic children,<sup>11,15,16</sup> this difference is larger and more variable for hyperopic and emmetropic children (1.80D  $\pm$  1.11D and  $1.26D \pm 0.93D$ , respectively).<sup>11</sup> Refraction without cycloplegia can result in misclassification of children aged four to 15 years, with errors most likely to occur in younger children with more hyperopic refractive errors and smaller axial length.<sup>10</sup> There is evidence to suggest that cycloplegia should always be included in the clinical workup for patients up to 20 years old; beyond age 20 the difference between cycloplegic and non-cycloplegic refractive errors falls below 0.25D.<sup>8,11</sup>

In clinical practice the two commonly used cycloplegic agents are 1% cyclopentolate and 1% tropicamide. Cyclopentolate has an overall stronger cycloplegic effect than tropicamide, and also has a different time course with maximal effect taking up to 60 minutes compared to maximal cycloplegia with tropicamide at 30 minutes after installation.<sup>17</sup> Although there are minor differences in cycloplegic effect between the two cycloplegic agents as per a metaanalysis, the difference is neither statistically significant nor clinically meaningful.<sup>18</sup> Tropicamide and cyclopentolate have a similar effect on anterior chamber depth, crystalline lens thickness, crystalline lens power, and vitreous chamber depth.<sup>19</sup> Because tropicamide demonstrates a similar cycloplegic effect without the longer-lasting mydriatic effects, the International Myopia Institute recommends the use of two drops of 1% tropicamide separated by five minutes, with refractive error measurement at 30 minutes after instillation.<sup>4</sup> It should be noted that it is more difficult to achieve complete cycloplegia in children with darker irides because of the sequestering effect of iris pigment.<sup>20,21</sup>

When compared to cycloplegic subjective refraction, both cycloplegic retinoscopy and cycloplegic autorefraction tend to overestimate myopic spherical and cylindrical power and underestimate hyperopic power.<sup>22</sup> Retinoscopy accuracy strongly depends on the skill of the clinician.<sup>22</sup> With skilled clinicians, the repeatability (consistency of measurements by the same clinician) and reproducibility (consistency of measurements by different clinicians) of cycloplegic retinoscopy can be within 0.25D.<sup>23</sup>

Although the use of cycloplegia is preferred to precisely determine refractive error, cycloplegia can be inconvenient for patients due to its impact on vision and the small risk of allergic reaction.<sup>24</sup> Also, not all eye care practitioners have the scope of practice to perform cycloplegic refractions. A practical alternative, if unable to perform a cycloplegic refraction, is to use optical fogging to relax accommodation in young patients. Fogging the contralateral eye by 6.00D, in patients seven to 16 years old during non-cycloplegic retinoscopy achieves refractive results that are on average only 0.3D more myopic when compared to cycloplegic retinoscopy.<sup>25</sup> If myopia has already been determined, the amount of fogging has a negligible effect on the final refractive result, so the conventional 2.00D fogging in retinoscopy may suffice.<sup>26</sup>

**Autorefraction.** Autorefractors, whether closed-field or open-field, are widely used as an objective method for measuring refractive error and are generally well tolerated by most patients. Closed-field devices use an enclosed target image, whereas open-field models allow patients to view an external target through a beam-splitter, offering a natural viewing experience and minimizing instrument-induced accommodation.<sup>27</sup>

Using fogging as a technique to relax accommodation has proven ineffective for closed-field autorefractors resulting in an overestimation of myopia.<sup>28</sup> With fogging, refractive results with handheld and tabletop autorefractors elicit on average 0.60 to 0.80 D more myopia (less hyperopic) in comparison to subjective refraction.<sup>10,11,16,29-31</sup> Repeatability of measurements with fogged autorefraction is, at best, within 1.00 D.32 The difference between cycloplegic and non-cycloplegic autorefraction is greater in younger and more hyperopic children.<sup>13</sup> However, myopic eyes exhibit the smallest differences across all age groups.<sup>11</sup> Although handheld devices allow for measurements with younger children, they tend to produce more myopic results than tabletop instruments,<sup>29,30</sup> with the overestimation being as much as 2.00 D.33 Non-cycloplegic autorefraction with fogging in closed-field devices lacks the accuracy needed for precise diagnosis and is best suited as a preliminary step prior to subjective refraction. However, with cycloplegia, validated autorefractors provide reliable and accurate measurements regardless of the device type.<sup>33</sup>

Binocular open-field autorefractors minimize proximal accommodation by offering a natural viewing environment with an unobstructed view of a distant target. They can also measure peripheral refraction and generally produce less myopic results compared to closed-field devices.<sup>34</sup> If cycloplegia cannot be used, open-field autorefractors provide the results closest to cycloplegic retinoscopy, especially in children aged six to 11 years.<sup>35</sup> The differences between open-field autorefractor measurements and binocular subjective refraction are clinically insignificant (mean difference <0.25

D), and highly repeatable within 0.25 diopters.<sup>30,36,37</sup> Openfield autorefractors offer more accurate measures of astigmatism, particularly for oblique axes, than closed-field counterparts.<sup>35</sup> Cycloplegia does not appear to significantly affect the accuracy of measurements for the astigmatic components.<sup>35</sup> Axis determination is deemed to be more accurate with autorefraction than with retinoscopy.<sup>38</sup>

Despite the reduced accuracy of non-cycloplegic autorefraction, it can be useful for screening purposes, particularly with binocular open-field instruments, which are more effective at accurately classifying myopia, hyperopia, and high myopia in school-aged children.<sup>6,28</sup> However, the accuracy of these instruments varies among models.<sup>16,30</sup>

Peripheral Refraction. The eye has multiple refractive states surrounding the fovea based on the radially gradient optical powers of the lens and cornea and contour of the retina. This is termed peripheral refraction. Measuring peripheral refraction has been a significant focus in clinical research serving as an indicator of how prolate the eye is subsequent to axial elongation and to determine whether there is a relationship between peripheral refraction, myopia progression and efficacy of myopia control treatments.<sup>39</sup> Peripheral refraction is often most commonly measured with patients viewing fixation targets placed along the horizontal visual field typically at 10°, 20° and 30° nasal and temporal to the fovea.40 Relative peripheral refraction (RPR) is calculated as the difference between peripheral and central refractive states; hyperopic RPR refers to the relative hyperopia along the periphery and is denoted by a positive value (and vice versa for myopic RPR).<sup>41-45</sup> Variations of techniques including subjective refraction, retinoscopy, autorefraction and aberrometry have been used to measure peripheral refraction.<sup>46,47</sup> As with central refraction, peripheral refraction is best measured with cycloplegia.<sup>47</sup> Accuracy is limited with subjective refraction in the periphery because of poorer resolution thresholds with increasing eccentricity.48-50 Because the use of autorefractors for peripheral refraction is beyond the scope of manufacturers' intended use, validation of the instruments is needed to determine accuracy and repeatability of peripheral measurements.<sup>37,51</sup> Specifically, the pupil shape is more elliptical than spherical in off-axis measurements, which challenge the wavefront assumptions in the algorithm used by the autorefractor to determine refractive power.<sup>50</sup> Open-field autorefractors have shown strong repeatability and accuracy for peripheral refraction across different pupil sizes in comparison to their aberrometer counterparts.52

Measuring RPR may have clinical relevance for predicting myopia control treatment effects. Children with hyperopic RPR in the nasal retina have been shown to have a greater treatment effect with myopia control spectacles compared to children with myopic RPR.<sup>53</sup> Naso-temporal asymmetry did not increase as much in the spectacle group compared to the group treated with single-vision spectacles, but more research is needed to ascertain the full relevance and clinical application of this finding.<sup>54</sup>

**Wide-Field Refractive Mapping.** Recently, new technologies have been marketed that allow a quick and continuous refractive characterization across the central 50° to 100° of the visual field.<sup>55–58</sup> Further work is needed, but this technique may have value in predicting patients at risk of developing myopia or perhaps to support algorithms to individualize myopia control management.

#### **Corneal Topography/Tomography**

Corneal topography provides detailed mapping of the corneal front surface curvature/elevation, and in addition, tomography can measure corneal thickness and back surface curvature. These techniques play a crucial role in contact lens fitting, and in the diagnosis and management of a variety of ocular conditions. Corneal topography refers to the measurement and visualization of the anterior corneal surface, primarily focusing on curvature and elevation data. Tomography involves the 3D reconstruction of the entire cornea, including both anterior and posterior surfaces, and corneal thickness. Reflective and projection-based methods are commonly used in corneal imaging.

**Application of Topography/Tomography.** Corneal topography/tomography plays a crucial role in evaluating patients' suitability for contact lens fitting, in particular orthokeratology treatment.<sup>59</sup> Baseline topography/tomography serves as a critical reference point in orthokeratology procedures representing the original shape and condition of the cornea, which will subsequently be altered by treatment. Changes to the corneal shape are measured and analyzed in relation to this baseline and can be used to help quantify treatment success and effectivity.

Some instruments have integrated software for contact lens fitting, allowing practitioners to simulate how specific lens designs will interact with a patient's cornea. This feature supports a tailored approach to lens selection, optimizing comfort and vision. Additionally, the software may include free-form design capabilities, enabling precise customization of lens parameters to align with the unique curvature and characteristics of the individual's cornea, resulting in improved lens fit and visual outcomes.

Contact lens fitting with external software based on corneal mapping information offers an alternative approach with enhanced customization, particularly for challenging cases requiring asymmetric or specialized lens designs. This approach provides significant flexibility in lens design, enabling effective management of even the most challenging cases with tailored, bespoke solutions.

**Topography.** Placido disc-based keratoscopy uses a circular pattern of alternating light and dark rings with a central aperture for observing tear film reflections that conform to the corneal shape.<sup>60</sup> The Placido disc technique does not measure corneal height directly but rather treats the eye as a mirror, with the reflected image's location being highly responsive to corneal slope but less so to corneal height.<sup>61</sup> These topographers depend on reflections, so issues such as tear film instability can cause distorted reflections, leading to data gaps and inaccuracies.<sup>62</sup> Additionally, irregular corneal surfaces can result in skew ray errors when using a reference axis for calculations.<sup>63</sup>

Placido-disc systems come in two variations: small-cone and large-cone. Small-cone units use a shorter working distance and project more rings onto the cornea compared to large-cone systems. Nose and eyebrow shadowing is more significant with larger Placido-disc cones, limiting the analyzed area. Some modern devices combine Placido discs with Scheimpflug imaging and scanning-slit technology to improve accuracy.

An alternative corneal topography approach utilizes color light-emitting diode technology, first introduced in 1997 but only recently made commercially available. This type of topographer uses 670 multicolored pseudorandom points through specular reflection to reconstruct corneal shape<sup>64</sup> Unlike Placido-disc based systems, this method eliminates alignment errors (Placido mismatch), improving accuracy for asymmetric or irregular corneas.<sup>65–67</sup>

An alternative method for comprehensive ocular surface assessment uses the corneo-scleral profilometry system, capturing topographical data across the cornea, limbus, and sclera. The system uses a sequential dual-projector configuration with symmetrical telecentric projectors aligned with a digital camera. This design enables critical noise and bias reduction during image processing through redundant data acquisition, thereby significantly enhancing measurement accuracy.<sup>61</sup>

**Tomography.** There are various methods available to obtain a 3D topographical map of the cornea: The scanning slit system combines a 3D scanning slit beam with a Placido attachment. It uses triangulation to measure the distance between a reference slit beam and its reflection captured by a camera, generating a detailed 3D topographic map including corneal curvature, anterior and posterior elevation, and pachymetry.<sup>68</sup>

Anterior segment OCT utilizes low-coherence interferometry to compare time-delayed infrared light reflections from anterior segment structures against a reference.<sup>69</sup> Time-domain OCT generates cross-sectional images through adjustments in the reference mirror's position, while Fourierdomain OCT utilizes a stationary mirror, with cross-sectional images created through interference between sample and reference reflections.<sup>70</sup> Fourier-domain OCT offers faster acquisition times, reducing motion artifacts and improving resolution to better characterize normal and pathological structures.

The Scheimpflug principle uses a camera perpendicular to a slit-beam, creating an optical section of the cornea and lens when applied to the anterior eye. Multiple images can be used to create a 3D representation of the anterior chamber through lateral raster scanning or by rotating around the visual axis.<sup>71</sup> Scheimpflug imaging addresses poor data capture from the corneal periphery due to its non-planar shape.<sup>72</sup> It ensures accurate focus by aligning the refracting lens and desired image plane. This principle allows for clear imaging of non-parallel objects by manipulating the image and lens planes.<sup>73</sup>

Additional Features of Topography for Dry Eye Assessment. Research links dry eye symptoms to myopic refractive error, with higher prevalence in myopic children significantly affecting their education and wellbeing.<sup>74,75</sup> Long-term use of orthokeratology can reduce meibomian gland integrity and have a detrimental impact on the tear film in children and adolescents.<sup>76,77</sup> Conversely it has been noted that symptoms of discomfort and dryness may be lower in patients using overnight orthokeratology than those wearing contact lenses during the day.<sup>78</sup>

Some corneal topographers offer supplementary functions for evaluating the tear film including measurement of its volume (tear meniscus height) and stability (breakup time or surface quality) using non-invasive videokeratography. There are also instruments with integrated meibography (by eyelid transillumination of infrared light reflection) to image the meibomian glands.<sup>79</sup> The creation of customizable dry eye reports integrating imaging, grading scales, and questionnaires can support patient education and hopefully compliance with treatment recommendations.<sup>80</sup> However, further work is needed to better understand the within-patient repeatability and correlation of many of these objective measures of tear film quality with patient-reported symptoms.

#### Aberrometry

Aberrometry is the measurement of optical imperfections in the visual system, measures can be acquired using various technologies, including:

- Hartmann-Shack Aberrometers
- Tscherning Aberrometers
- Ray-Tracing Aberrometers
- Pyramidal Wavefront Sensing

Each method uses different techniques and offers unique advantages for assessing and correcting optical imperfections in the visual system.

Hartmann-Shack (or Shack-Hartmann) aberrometers are among the most widely used devices and were some of the earliest instruments developed for clinical use.<sup>81–86</sup> These instruments input a small infrared laser source into the eye that after reflection from the retina creates an exiting wavefront that gets subdivided by a lenslet array to create spot images on a sensor. Deviations in location of these spot images yield the wavefront slope.

Tscherning aberrometers project a collimated laser source through a mask containing a matrix of pinholes forming a bundle of thin rays. These rays form a spot pattern on the retina that is distorted according to the aberrations of the eye. This spot pattern is imaged onto a sensor, and the location of the spot patterns from their ideal positions provides the wavefront slope. A limitation of some Tscherning aberrometers is overlapping of the spots in eyes with higher amounts of aberrations.<sup>87,88</sup>

Ray-Tracing aberrometers direct a narrow laser beam into the eye parallel to the line of sight by means of an x-y scanner. The scanner moves the beam to cover the entire pupil area. The direction that the light beams take when entering and leaving allows for a reconstruction of the wavefront error.<sup>87</sup>

Pyramidal wavefront sensing aberrometer technology is based upon the Foucault knife-edge test and uses a fourfaceted pyramid prism in the focal plane to divide the wavefront into four parts.<sup>89</sup> The pyramid prism creates four images of the pupil at the detector plane. Differences in intensity between these images are caused by the differences in slope of the wavefront as it exits the eye.<sup>90–92</sup> The sensor range can be extended by introducing dynamic modulation of either the pyramid itself or the focused beam.

**Application of Aberrometry.** On-eye aberrometry can quantify how myopia control strategies affect the accommodative response.<sup>93–95</sup> Studies have shown that if an eye fails to accommodate properly while wearing a myopia control lens, the lens may not effectively slow down axial elongation as intended.<sup>93–97</sup> However, in general, accommodation is not affected by current myopia control optical designs.<sup>95,96</sup> Measures of accommodative response have been found to be similar between an autorefractor and aberrometer when care is taken to measure through the same pupil and lens position<sup>98</sup> Additionally, because aberrometry provides localized refractive state measurements across the entire pupil, it allows localized defocus within specific zones to be assessed (Fig. 2).<sup>95</sup>

Aberrometry has been used, primarily in clinical research, to analyze the pupil, measuring the percentage exposed to



**FIGURE 2.** Example of zone-wise lens analysis method. Refractive state can be quantified as the average dioptric value within the available lens regions of the central and first annular zone of a dual-focus (*top panel*) lens. Equivalent pupil regions can then be used to analyze the same regions on a single vision contact lens (*bottom panels*). Reproduced from reference 95.

emmetropic, hyperopic and myopic defocused light. In eyes wearing dual-focus lenses, hyperopic defocus decreased while myopic defocus increased, both theoretically aiding in slowing axial elongation.<sup>96,99</sup> Similarly, myopic defocus within the pupil area increased 1.2- to 3.0-fold with a multizoned compared to a single vision contact lens design when measured on eye.<sup>97</sup> On-eye aberrometry also potentially allows for visualization of how a contact lens behaves on the eye, making it possible to detect issues such as lens decentration.<sup>100</sup>

Representation of Aberrations. The optical aberration map of the eye can be presented using color coded wavefront slope measurements, but it is more common to have aberrations expressed using mathematical models such as Zernike polynomials.<sup>101,102</sup> Another method for analyzing aberration maps is to compute the retinal image of a visual object, such as a point of light, resulting in a point-spread function (PSF). This PSF can be mathematically combined with an image to provide an estimated representation of the vision attainable.<sup>103</sup> For easier comparisons, wavefront data or PSF may be reduced to various single metrics that have been shown to correlate well with human vision.<sup>104,105</sup> Some authors have questioned the effectiveness of Zernike polynomials in accurately representing total ocular wave aberrations, particularly in cases with higher-order aberrations, such cases of keratoconus or in eyes wearing zonal contactor spectacle lenses.92,96,106-110

An alternative approach is zonal wavefront reconstruction, which avoids the use of Zernike polynomials.<sup>95,110,111</sup> Unlike the modal method, which tends to smooth out irregularities caused by abrupt local slope changes in wavefront profiles, the zonal wavefront reconstruction may preserve more detailed features of the slope data.<sup>112</sup>

Additionally, although autorefractors provide local refraction at a single point or over a small pupil area, aberrometers can assess the refractive state across the entire pupil (Fig. 3).<sup>98</sup> Sagittal power or wavefront vergence can be calculated as the local slope at each pupil point divided by the local radius at the same point.<sup>113</sup> Local curvature power can be determined as the derivative of sagittal power, offering advantages in describing zonal lenses with non-coaxial optics.<sup>108,114</sup> Aberrometry also enables detailed descriptions of myopia control contact and spectacle lenses.<sup>97,98,107,108,115-118</sup>

## Pupillometry

Pupillometry refers to the measurement of the dimensions and spontaneous variation of the eye's pupil. The pupil responds to three distinct kinds of stimuli: illumination (causing constriction – the pupillary light reflex), near fixation (causing constriction—pupil near response), and emotionally charged stimuli (causing dilation in the psychosensory pupil response). The pupil controls the amount of light entering the eye, and changes in its size and shape impacts the optics of the eye.<sup>119,120</sup> Generally, smaller pupils enhance image quality and depth of field, while larger pupils improve visual sensitivity.<sup>119,121,122</sup> Understanding pupil dimensions under different illumination and task conditions is crucial for comprehending the eye as a complex optical system.

**Application of Pupillometry.** It is well established that the pupil diameter influences the type and magnitude of higher-order aberrations experienced by the eye.<sup>123–126</sup> These aberrations impact several factors including the eye's measured refraction,<sup>127</sup> the on-eye effective power of a lens,<sup>128–130</sup> optimal image quality,<sup>131–133</sup> and associated optimal myopic correction.<sup>116</sup> The pupil not only regulates the light entering the eye, but also determines which optical components influence the light, which reaches the retina.<sup>134</sup>



**FIGURE 3.** Color maps of ex-vivo measures wavefront error (*top panels*, micrometers) and power (*bottom panels*, diopters) of a single vision (*left panels*) and dual-focus (*right panels*) contact lens across a 10.0 mm measurement diameter with nominal distance powers of -1.00 and -1.25 D, respectively. Map coordinates are in millimeters. Reproduced from reference 95.

In presbyopic corrections or myopia control methods which aim to introduce myopic defocus, such as dual-focus soft contact lenses with zonal designs, pupil size interacts with lens centration and lens optical zone geometry to influence image quality and the amount of myopic defocus reaching the retina.<sup>96,97,100,135</sup> For example, Figure 4 row 1 shows sample refractive power maps over an 8 mm aperture of a single vision lens (column 1) and two-sample zonal lens designs. If this power map were limited by a 4 mm aperture, the central lens zone would dominate the optics received by the retina (Fig. 4, row 2). However, because contact lenses typically center well on the cornea, although the pupil is not typically centered within the limbus, the lens's zonal geometry may not align perfectly with the pupil.<sup>100</sup> This decentration causes irregularly-shaped zonal portions of the lens to appear in front of the pupil, impacting the distribution of optical zones and the may impact the effectiveness of myopia control (Fig. 4, row 3).

Knowledge of pupil size is crucial in understanding the visual impact of all myopia control treatments, including pharmacological agents and can also be used to monitor compliance.<sup>136,137</sup> The combination of pupil size and optical properties of an optical device, such as orthokeratology lenses, can have an impact on myopia control efficacy.<sup>138</sup>

Pupil dimensions should be measured and considered when managing myopia to better understand visual outcomes and treatment effectiveness.

**Methods of Measurement.** There are various methods available to measure the pupil diameter accurately, although pupil dynamics because of light and accommodative responses do create challenges.<sup>139,140</sup> Most frequently pupil diameter is measured with distance fixation in high or low illumination.<sup>141</sup> However, task-dependent pupil size may have many important advantages for optimizing visual performance for a patient. For example, in young children or presbyopic patients, pupil size may dictate the effectiveness of the treatment approach, knowing a patient's pupil size during their typical tasks may help troubleshoot problems and optimize treatment.<sup>142</sup>

Traditional methods to measure pupil size, such as rulers or low-tech subjective cards (e.g., Rosenbaum Cards<sup>143</sup>) with varying sizes of black circles to compare to the perceived pupil size may be sufficient for some general clinical practice situations. However, these methods have often been replaced by objective methods in many clinical and research settings. Automated objective pupillometry provides more accurate, reliable, and reproducible measurements.<sup>144,145</sup> Objective measures of pupil size have become commonplace



FIGURE 4. Lens-only defocus maps of a Proclear 1 day (left column), MiSight 1 day (middle column), and Biofinity center distance 2.00 D (right column) lens (all CooperVision) for an 8 mm central aperture (top row), 4 mm centered aperture (middle row), and 4 mm aperture with the lens decentered horizontally (bottom row) (courtesy of Clinical Optics Research Lab, Indiana University).

in some multifunction instruments that also provide other important clinical data.

Handheld Pupillometers. Modern handheld pupillometers typically use infrared light to obtain an average pupil diameter over the measurement time (e.g., 3-4 seconds) providing greater accuracy and repeatability, making them reliable for most clinical practices.<sup>146</sup> It should be noted that although pupil diameter is typically quantified with a single number, the shape of the pupil is typically elliptical rather than perfectly round and changes with time.147,144

Mobile Device-Based Pupillometers. As mobile device hardware and software have advanced significantly over the past decade, pupil measurement technology has been integrated into these devices through native technology or specialized applications. Examples include applications in which the device's native camera flash is used to trigger pupil constriction and capture a video of the pupil during the constriction and re-dilation phases.<sup>149</sup>

Additionally, other technologies not only monitor viewing distance but can also acquire pupil size information, further demonstrating the versatility of mobile devices in providing advanced eye care assessments. These developments have

made pupillometry more accessible and convenient, allowing for broader application in both clinical and everyday settings.150

Multifunction Instruments. Instruments designed for other primary purposes, such as autorefractors, aberrometers and corneal topographers can also be used for pupillometry, generally using an infrared light source to minimize their impact on the pupil size measured.<sup>80,151,152</sup> It is important to note that aberrometers and corneal topographers usually acquire measures along various axes. Topographers are typically aligned to the videokeratoscopic axis whereas aberrometers align to the primary line of sight.<sup>153–155</sup> Although this difference is subtle and unlikely to significantly affect pupil size measurements, it may impact the apparent location of the pupil.<sup>151,153,156,157</sup>

Similarly, OCT instruments, which provide highresolution, cross-sectional images of the eve's anterior segment using infrared light, can also provide pupil diameter information. However, the test-retest reliability and accuracy of a binocular prototype was found to be slightly inferior to those of a dedicated infrared pupillometer, perhaps because of a slower measurement of a single B-Scan frame (so no averaging and potential alignment errors).  $^{158}\!$ 

### STRUCTURAL

#### **Axial Dimension Measurement (Biometry)**

Biometry, although infrequently defined in the scientific literature, is generally understood in two contexts. First, it refers to "measurements of human features," which are often used to identify individuals—a field commonly known as biometrics. Second, it encompasses "the application of statistical analysis to biological data," a discipline recognized as biostatistics.<sup>159</sup> In ophthalmology, biometry specifically pertains to the measurement of ocular anatomical features, such as length, curvature, and optical power. These measurements are critical for various clinical applications, including the assessment of eye growth, the planning of refractive surgery and the fitting of contact lenses. Axial dimension biometers are used in the field of myopia to assess principally axial length but have also been used to monitor changes in choroidal thickness.

Application of Biometry. Axial length is a critical biomarker in myopia management, directly correlating with ocular complications and vision loss in myopia.<sup>160</sup> Its measurement provides a reliable and precise method for assessing individual risk profiles and monitoring the effectiveness of myopia control treatments over time.<sup>161-163</sup> There is a direct correlation between axial length and refractive error. However, changes in ocular components, such as the crystalline lens, influences the impact that axial elongation has on refractive error.<sup>164,165</sup> As a general guide, 0.1 mm of axial growth equates to approximately 0.2 D increase in myopic refractive error (or decrease in hyperopic refractive error).<sup>165,166</sup> Biometry is particularly valuable in regions where optometrists and other primary eye care practitioners are restricted from using cycloplegia. Axial length measurements have not been found to be affected by cycloplegia.<sup>167,168</sup> Correlation between choroidal thickness, axial length, and refractive error has been well established.<sup>169</sup>

#### Methods of Measurement.

A-Scan Ultrasonography. Ultrasonography uses moderate to high-frequency, mechanical ultrasound pulses, rather than light, to measure distances from the time taken for the ultrasound waves to reflect from a surface.<sup>170</sup> The ultrasound impedance of the intervening media needs to be accounted for, as it affects the speed of propagation of the waves. Available commercial instruments have a precision of  $\approx 0.1$  mm (equivalent to about 0.25 D) with a moderately high intraobserver and low interobserver reproducibility.<sup>171-174</sup> Because it also requires the contact of a probe (ultrasound source) with the ocular surface corneal anesthesia is required and as such is invasive and less ideal for pediatric assessment.

*Partial Coherence Interferometry.* Partial coherence interferometry (PCI) was introduced clinically in the early 1990s.<sup>175</sup> As light is approximately 930,000 times faster than sound, the time for a reflection to reach a sensor is too fast for it to be accurately quantified. Hence, in its current form, this technique splits the laser beam, both passing through the optics of the eye, taking different paths before they are recombined to produce an interference pattern (because the path difference between the beams is smaller than the coherence length). Measurements of axial dimensions using this approach are more than 10 times higher in resolution than that of ultrasound.<sup>176</sup> Lens thickness measurement

with this technique has only been reported in two prototype devices,<sup>177,178</sup> commercial instruments using partial coherence interferometry typically use imaging instead.<sup>179</sup> In children, the repeatability (standard deviation) of this technique has been found to vary between ~0.02 mm and 0.06 mm dependent on the instrument used.<sup>167,179-184</sup>

*Optical Low Coherence Reflectometry.* Optical low coherence reflectometry (OLCR) was developed in the late 1980s for reflection measurement in telecommunication devices with micrometer resolution and first applied to in vivo biological tissue (the eye).<sup>185</sup> It differs from partial coherence interferometry by using a superluminescent diode of a slightly higher wavelength (typically 820 nm) and a rotating glass cube that alters the path length of the reference beam,<sup>186</sup> allowing for the measurement of corneal and lens thickness as well as axial length. It has a similar resolution to partial coherence interferometry with a repeatability in children of 0.02 to 0.06 mm.<sup>167,183,184,187,188</sup> Attempts have also been made to assess the choroidal reflections, but these are less reproducible.<sup>189,190</sup>

Optical Coherence Tomography. OCT was developed in the late 1990s and its potential to increase the accuracy of axial length measurement was soon recognized.<sup>191</sup> However, it was not until swept light sources with a large coherence length became available that they were able to have the depth of scan needed to measure axial length.<sup>191</sup> The technique is similar to partial coherence interferometry and optical low coherence reflectometry, except that the beam is scanned across the eye to create a B-scan (which can demonstrate whether the beam is accurately targeted on the macula) and the change of path of the reference beam has moved from time domain (a physically moving mirror or cube) to spectral domain (where the point detector is replaced by a spectrometer using a diffractive element to spatially separate the different wavelength contributions into a line image that is recorded by a high-speed line scan camera) or a swept light source (which rapidly sweeps a narrow line-width over a broad range of wavelengths, detected sequentially by a high-speed photodetector). Repeatability of axial length measurement in children has been reported to be 0.01 to 0.05 mm.<sup>167,180,183,192</sup>

Enhanced depth imaging has been achieved by viewing the inverted image when the instrument head is moved closer to the eye,<sup>193</sup> effectively moving the instruments focal point or using a longer wavelength,<sup>194</sup> allowing imaging of choroidal thickness. However, this still has its challenges (see the International Myopia Institute–The Dynamic Choroid report).<sup>195</sup> Repeatability in children between two sessions has not been reported.

**Image Analysis.** The Scheimpflug principle is achieved with a camera perpendicular to a slit beam, allowing it to image an optical section of the cornea and lens with quantification of parameters using image analysis. As with all optical and acoustic techniques, the refractive index of the intervening tissues needs to be corrected for.<sup>196</sup> Some instruments can rotate around the visual axis to allow a 3D image of the anterior eye to be rendered and corneal thickness and anterior chamber depth to be measured; however, the pupil size "aperture" prevents its ability to measure axial length.<sup>197</sup>

**Multifunction Instruments.** Multifunction instruments have revolutionized clinical practice by integrating multiple diagnostic capabilities into a single device. These instruments, which combine axial length measurement, typically via PCI or OLCR as previously described, with assessments such as autorefraction, pupillometry, keratometry, and corneal topography, streamline patient care. This integration helps in gathering comprehensive data efficiently, saving time and reducing costs for both practitioners and patients.

In addition to their primary functions related to myopia management, such instruments often come equipped with features for contact lens fitting and dry eye assessment. They are also supported by software that track changes over time and include normative data for axial length, helping practitioners compare individual patient data to established benchmarks. The generated reports are valuable tools for tracking patient progress and making informed decisions about myopia management.

**Algorithms to Estimate Axial Length.** Measuring axial length should be regarded as the benchmark for myopia management, but lack of access to a biometer should not delay implementation.<sup>162</sup> In the absence of direct measurements, algorithms for estimating axial length, endorsed by professional bodies including the College of Optometrists in the United Kingdom,<sup>198</sup> serve as interim tools for risk assessment alongside refraction.

Although these models help to differentiate between normal and high-risk ocular profiles, biological variability limits their accuracy.<sup>199</sup> Axial length estimation should be viewed as a transitional approach to guide clinical decision making and encourage future adoption of direct biometry.

Despite its clear benefits, axial length measurement remains underused in primary care settings, ranking behind refraction, age, and family history in clinical decision making for myopia control.<sup>200</sup> Financial constraints appear to be a significant barrier to biometry adoption, with cost of adding new technology frequently cited as a barrier.<sup>201–204</sup> Clinicians have also expressed concerns about the interpretation of axial length data and its role in distinguishing normal from myopic eye growth.<sup>203</sup> Addressing these challenges through improved estimation models and cost-effective solutions can facilitate winder integration of biometry into myopia management.

Early axial length estimation models, were based on the linear relationship between refractive error and axial length,<sup>205–208</sup> deriving estimates from spherical equivalent refractive error alone or combined with corneal curvature.<sup>209–213</sup> However, these models performed poorly in clinical settings, showing wide limits of agreement (0.70 mm to -1.56 mm),<sup>199,213,214</sup> and a 30% misclassification rate for vision impairment risk.<sup>214</sup>

Their limitations stem from their failure to account for key factors such as age and sex. Age, significantly influences eye growth, with rapid elongation in the first two years, nearing adult size by age five, and elongating slightly thereafter.<sup>215</sup> Myopic eyes exhibit abnormal growth patterns, potentially continuing into adulthood, especially in highly myopic eyes at risk of complications.<sup>216-222</sup> Biological sex also affect axial length with males typically having longer eyes than females.<sup>223-226</sup> Although age-adjusted models show improved accuracy, their limits of agreement (±0.23 mm) are still too wide for treatment monitoring.<sup>213</sup>

Machine learning techniques, including multiple linear regression, symbolic regression, gradient boosting and multilayer perceptrons have enhanced estimation models by incorporating non-linear relationships between age, sex, refraction and corneal.<sup>199,210,227-229</sup> Among these, multiple linear regression demonstrated superior performance across diverse populations, accurately identifying high-risk myopic eyes and approaching the physiological limits of estima-

tion accuracy without including lens power, demonstrating the effectiveness of a comprehensive approach.<sup>199</sup> These advancements highlight the potential for improved screening but reinforce the need for direct biometry in long-term management.

## **Posterior Segment Imaging**

**Application of Posterior Segment Imaging.** Posterior eye imaging has a role to play in monitoring the safety of myopia control treatments, which are generally used in children and young adults, and also in the monitoring of older adults to detect and monitor pathology caused by myopia.<sup>230,231</sup> Short-term choroidal thickness changes imaged with OCT have also been suggested to aid in predicting the effectiveness of myopia treatments in an individual, refractive development in young adults and myopia maculopathy.<sup>232–237</sup>

**Fundus Cameras.** Retinal cameras use digital imaging chips for instant image capture and viewing. Many devices include an autofocus function while others allow the initial working distance to be more accurately determined using a split pupil presentation. A second anterior eye-focused camera can also be used to aid positioning. A high positive-powered lens is then dropped into place to neutralize the optical power of the crystalline lens and cornea, allowing an inverted aerial view of the fundus to be seen.<sup>238</sup> Near-infra-red sensitive light is typically used to facilitate positioning such that the retina is in focus and the camera centered on the features of interest.<sup>239</sup> This feature minimizes the impact on pupil size prior before the synchronized white light flash captures the image to optimize retinal imaging.<sup>238</sup>

The quality of the images captured depends on both the camera optics and the optics of the patient being imaged. Factors such as cataracts and corneal anomalies can affect image quality, as will small pupils unless a mydriatic is used for dilation. The image size varies based on the refractive error of the patient and the camera used with a magnification difference of approximately 5% to 30%,<sup>240,241</sup> impacting the accuracy of calliper measurements. Consistent monitoring of the size of a lesion over time should use the same camera for reliability. Recording flash intensity helps streamline follow-up images and ensures more consistent results. Extracting color planes can aid in highlighting important features, such as viewing just the green pixels to enhance blood vessels and hemorrhages (Fig. 5).

Composite images, where a range of images (usually about seven) can be taken with the patient looking in set locations, which are subsequently "stitched" together using software to give a larger field of view of up to 85° (Fig. 6).<sup>242</sup> Some software is capable of displaying stereo image-pairs to appropriate goggles from fundus images captured from different locations or angles.<sup>243</sup> Overlay or comparison functions enable enhanced monitoring of change between visits. Deep learning artificial intelligence has been applied to fundus images of children to predict the development of high myopia<sup>244</sup> and to grade lesions.<sup>245</sup>

**Scanning Laser Ophthalmoscopes.** Rather than using a pixel matrix to image the fundus, scanning laser ophthalmoscopes scan a laser in a raster pattern, with the reflectance of light at individual successive points across the fundus used to form an image.<sup>246</sup> This approach allows the use of brighter light than conventional photography, producing clearer images. Incorporating adaptive optics

#### Myopia Management Instrumentation



FIGURE 5. Fundus image (top left) split into its red (top right), green (bottom left), and blue (bottom right) components (courtesy James Wolffsohn).



**FIGURE 6.** Fundus mosaic made up of nine 45° standard images "stitched" together using registration software (courtesy James Wolffsohn).

corrects higher-order aberrations to enhance lateral and axial resolution, enabling detailed visualization of retinal structures such as photoreceptors, nerve fibers and retinal blood flow as well as axial sectioning of retinal tissue.<sup>247</sup>

A widescreen confocal scanning laser ophthalmoscope provides up to a 200° view of the retina, covering approximately 82% of the surface area.<sup>248</sup> This is achieved using two ellipsoidal mirrors with focal points that are conjugate (one at the pupillary plane to minimize wavefront aberrations and facilitate the wide field of view). The system focuses light through a confocal aperture and various filters onto the light sensor to capture images of the retinal periphery without the need for high illumination, largely without pupil dilation.<sup>248</sup> The collimated, low powered green laser (532 nm) image contains information from the sensory retina through to the pigment epithelium layers of the retina. The red channel (633 nm laser) image contains information from the deeper structures of the retina, from the pigment epithelium through to the choroid. Fluorescein angiography can be achieved with the blue (488 nm) and indocyanine green angiography with the infrared (805 nm) laser. Because of the combination of red and green images of different retinal layers,



FIGURE 7. Widefield scanning laser ophthalmoscope fundus image (courtesy James Wolffsohn).

the fundus pictures look very different compared to those conventionally seen from standard fundus cameras, which capture red, green, and blue light from the retinal surface (Fig. 7).

**Optical Coherence Tomography.** OCT uses lowcoherence interferometry to generate high-resolution, crosssectional (B-scan) images of the retina and choroid. It captures two-dimensional slices, displaying distinct retinal layers. Analysis of these layers aids in detecting pathological changes and monitoring of ocular disease. Its noninvasive nature makes it ideal for repeated clinical evaluations. Enhanced depth imaging and swept-source OCT improve visualization of deeper structures such as the choroid to reveal thickness and vascular patterns (Fig. 8). The measurement of choroidal thickness provides insights into structural changes associated with myopia, including changes with myopia progression. OCT can also be valuable in diagnosing, evaluating, and monitoring retinal changes associated with myopia such as myopic maculopathy and staphyloma.<sup>249–251</sup>

Studies have shown that myopia is associated with a thinner choroid, and a thinner choroid is linked to faster axial elongation, making it a potential biomarker for myopia progression.<sup>252–254</sup> Because of the natural distribution of thickness across the choroid, measurement variations can occur between visits and across different instruments.<sup>255</sup> Studies have highlighted the limitations in the reliability and reproducibility of choroidal thickness measurements, suggesting that changes of less than 10 µm may not represent a true physiological change.<sup>189,256</sup>

Interventions such as orthokeratology and atropine have been associated with choroidal thickening, suggesting a protective mechanism against myopia progression.<sup>257,258</sup> Although choroidal thickness may be a valuable indicator for monitoring myopia, it is primarily used in research, and its direct role in the clinical management of patients has yet to be established.

## General Application of Instrumentation for Myopia Management

The use of instrumentation varies according to the stage in the natural history of myopia from assessment of the at-risk patients who are not myopic, through the initial onset and progression of myopia to its active management through optical, pharmacological, or combined treatments. This approach spans across the individual's lifetime, beginning in childhood or adolescence, through the active progression phase, and into the stabilization and long-term management of myopia in adulthood and old age.

**Pre-Myopia.** Before the onset of myopia, assessing a child's risk of becoming myopic involves evaluating various factors, including family history, near vision activities and outdoor exposure. Quantifiable parameters such as axial length and refractive error offer valuable insights. Refractive



FIGURE 8. OCT image (courtesy Deborah Jones).

error at the age of 6 years (1st grade) has been indicated to be a strong predictor of future myopia.<sup>259</sup> Researchers have found that only 10% of third graders with a refractive error of at least 1.00 D developed myopia, compared to 75% of those with emmetropia.<sup>260</sup> Also, children at high risk of developing myopia (refraction less than 0.75 D at age six) had a greater likelihood of becoming myopic by age 13. Using such predictors does depend on the availability of cycloplegic refractive error data, which may not be the case in all situations. Noninvasive quantitative methods are now preferred for estimating myopia risk. New algorithms and nomograms based on optical biometry have been developed to assess the likelihood of developing myopia in adulthood by analyzing axial length measurements taken during childhood, adolescence, and young adulthood.<sup>163</sup> Normative axial length data have been incorporated into multifunction instruments to aid in the prediction and progression monitoring of myopia. There are also a variety of online myopia risk assessment tools available to support clinicians in their management of patients.

The use of peripheral and wide-field refraction as predictors of myopia progression remains controversial. Although a study identified significant changes in relative peripheral refraction before the onset of myopia and until stabilization, other research found no causal link between peripheral refraction patterns and one-year myopia progression.<sup>261,262</sup> Emerging technologies such as wide-field wavefront refraction and multispectral refraction topography have shown a potential connection between retinal refraction patterns across a wide field (50° to 100°) and myopia trends, but evidence remains limited.<sup>263-265</sup>

Myopia Onset and Progression. Frequent comprehensive assessments of visual function (distance visual acuity) and refraction (with relaxed accommodation) are essential for early diagnosis of myopia. Studies have shown that on average, myopia is first diagnosed in a patient when the spherical equivalent value is -1.00 D or worse suggesting that myopia has been progressing and those eyes have been uncorrected for some time.<sup>200,266</sup> For patients at risk of developing myopia, frequent visits, at least every six months, can support initiation of a myopia control treatment at the earliest onset of myopia.<sup>162,164</sup> Early detection of myopia is also possible through measuring changes in axial length as it is known that the peak rate of axial elongation occurs in the two to three years before the onset of a myopic refractive error.<sup>163,267</sup> Biometry changes (axial growth) are crucial to understand the rate of ocular growth whereas binocular vision, accommodation, and AC/A ratio might also identify functional changes that apparently accompany the process of myopization.<sup>26</sup>

A study conducted in Taiwan examined changes in corneal curvature, anterior chamber depth and crystalline lens thickness in myopic, emmetropic and hyperopic eyes. The study found notable differences in ocular growth among these three refractive groups. Between the ages of eight and 14 years, a significant change in lens thickness was observed, coinciding with a period of rapid eye growth. During this time, myopic eyes consistently demonstrated a trend towards having thinner crystalline lenses compared to emmetropic and hyperopic eyes.<sup>268</sup> Another study investigated the change in the crystalline lens before and after the onset of myopia and discovered that although axial length and refractive error changed significantly in the one year before the onset of myopia, the lens thick-

ness remained largely stable with age associated changes observed before and after the onset of myopia.<sup>269</sup> Similar to using nomograms to estimate the risk of developing myopia before its onset, these same nomograms remain useful for individuals who are already myopic and help assess the risk of further progression toward high myopia in adulthood.<sup>270</sup>

**Myopia Control Treatment.** Myopia control today primarily focuses on monitoring ocular growth by measuring changes in refraction and axial length with an optical biometer. Comprehensive evaluations of myopic patients should also include assessments of binocular vision, accommodation and corneal curvature/topographical changes. In cases of rapid myopia progression or when high or very high myopia occurs during childhood and adolescence, visual function may deteriorate and retinal changes can often be detected through fundus photography and OCT imaging.

Various myopia control treatments have been shown to increase choroidal thickness, which may influence the assessment of their actual effectiveness. Because these increases in choroidal thickness may be transient and may return to baseline after stopping treatment, this effect should be considered when evaluating axial elongation control and potential rebound effects.<sup>271–274</sup>

In both clinical practice and research settings, the assessment of potentially myopic or newly myopic eyes often involves a standard comprehensive ophthalmic examination. Researchers utilize various additional technologies to explore the effects of myopia control treatments on ocular structure, optical properties and the functional status of the myopic eye. Although refractive error change and axial length are primary outcomes in myopia control trials, other parameters such as corneal thickness, anterior chamber depth, crystalline lens thickness, retinal changes, choroidal thickness and electroretinal activity have also been studied to provide a more detailed understanding of the impact of these treatments.<sup>232,275–278</sup>

Adult and Elderly Myopic Eye Follow-Up. Given the risks associated with high myopia,<sup>279</sup> frequent follow-up is crucial, particularly starting at age 50 for patients with very high myopia ( $\leq$ -10 D, or  $\geq$ 28 mm) and after 60 years for high myopia (-6.00 to -10.00 D, or 26-28 mm).<sup>163</sup> Alongside the standard clinical techniques of fundus biomicrosopy and binocular indirect ophthalmoscopy for assessing the anterior segment and the fundus, the use of fundus photography and OCT are preferred for identifying and monitoring myopic maculopathy and other retinal changes.<sup>250,280</sup> Peripheral changes that can increase the risk of retinal detachment can be more easily identified with wide-field fundus photography. A study conducted in China demonstrated that the use of an ultrawide field imaging fundus camera was superior to mydriatic standard examination for the detection of lesions in superior and inferior quadrants.<sup>281</sup> Individuals with myopia, particularly those with high myopia, have an increased risk of developing glaucoma<sup>282-285</sup> As a result, tonometry should be performed. Various methods are available to measure IOP; however Goldmann tonometry is still considered to be the gold standard.<sup>286</sup> Non-contact tonometry methods tend to overestimate IOP in comparison to Goldmann applanation tonometry.<sup>287,288</sup> Along with careful monitoring of intraocular pressure, changes in the retinal ganglion cell layer and optic head nerve structure should be carefully investigated and followed up with posterior segment OCT and visual field assessment Myopia Management Instrumentation

# Communication and Clinical Decision Support Software

Despite increasing awareness and engagement in myopia control, many eve care professionals (ECP) continue to prioritize vision correction only with single vision spectacles or contact lenses. Although the perceived effectiveness of myopia control methods is high, their adoption remains inconsistent.<sup>200</sup> This hesitancy to fully engage in myopia management can be attributed to a range of clinical, communication and commercial factors. The additional chair time and continuity of care requirements to best serve the needs of individual patients raise significant concerns. Despite high levels of training, eye care professionals also report a lack of confidence in personalized decision making and communication of essential information for myopia management.<sup>201,203</sup> Clinical decision support and communication tools that alleviate or resolve residual barriers to the use of myopia control treatments by ECPs, and their uptake by patients and parents, will be instrumental in supporting ECPs to manage their patients in accordance with the widely accepted standard of care

Communication Challenges. Raising parental awareness about myopia's causes, risks, and treatment benefits is crucial, because parents play a pivotal role in healthcare decisions and lifestyle choices affecting their children.<sup>290,291</sup> Effective treatment uptake relies on parents recognizing the importance of interventions for their child's eye health. Many parents see myopia as a minor inconvenience rather than a serious health issue,<sup>292</sup> often unaware of the risks of eve disease and vision loss. Educating parents about the potential consequences of progressive myopia and the practicalities, costs, risks, and benefits of various treatment options is essential.<sup>292</sup> It's also important to set realistic expectations, as the benefits of myopia management may take years to become evident, unlike the benefits of simple vision correction which are immediately evident. Simplifying this complex information into relatable terms within consultation time constraints is a significant challenge, but worth addressing as most parents will respond positively to the clear message that action can be taken to prevent or slow their child's anticipated vision changes. Standardized communication tools that simplify and clarify myopia management can enhance parents' understanding, foster trust in ECP recommendations and ultimately improve treatment implementation and outcomes.

**Clinical Challenges.** Myopia management presents complex clinical challenges that go beyond the straightforward task of updating vision prescriptions. The field demands nuanced decision-making, with evolving treatments and guidelines often providing conflicting evidence about efficacy and safety.<sup>293,294</sup> Clinicians frequently face uncertainties in identifying suitable candidates, managing pre-myopic children, and addressing progressive myopia in adults.<sup>201</sup> The absence of clear protocols for discontinuing treatment and the need for ongoing monitoring, particularly as eye growth and myopia progression continues, further complicates care. Clinical decision support software could support clinical decision making and

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offer the personalized, evidence-based care necessary for myopia management.

**Rationale for the Introduction of Communication and Decision Support Software.** The persistent challenges and uncertainties in myopia management highlight the need for decision-support tools that enhance clinician confidence, improve communication and provide evidence-based insights for informed clinical decision making. An ideal software solution would make myopia management accessible to clinicians, patients and parents, delivering several key benefits including:

- 1. Enhanced Clinical Guidance: Up-to-date, evidencebased tools tailored to individual patients would help clinicians navigate complex myopia management cases, reducing uncertainty and boosting confidence. Incorporating current clinical guidelines would also aid compliance and governance.
- 2. Efficient Patient Communication: Automated tools that deliver personalized, easy-to-understand information on myopia risks and treatment options would bridge communication gaps between ECPs and parents. These tools could simplify the conversation, emphasizing treatment benefits while encouraging early intervention and management, ultimately increasing treatment uptake.
- 3. Streamlined Workflow: Integration with existing electronic health record systems would reduce administrative burdens, freeing up clinician time for patient care by streamlining the clinical workflow.
- 4. Improved Clinical Outcomes: By supporting better decision-making, early risk identification, and comprehensive treatment monitoring, such tools would contribute to more consistent and effective myopia management, optimizing outcomes for each child.

**Essential Characteristics of Communication and Decision Support Software.** Effective decision-support software should be robust, offering precise, individualized, and evidence-based insights to ECPs. The key characteristics that such software must possess to be effective in myopia management include:

• Evidence-Based

The software should be grounded in the latest clinical research and use robust, multinational datasets to provide reliable and representative guidance. The computational models behind its recommendations must reflect the most up-to-date scientific knowledge.

• Clinically Validated

Rigorous testing against clinic data is essential to ensure that the software's recommendations are both theoretically sound and practically effective. Clinically validated tools build ECP trust and confidence in the robustness of the software.

Individual Patient Application

The software must provide personalized guidance by considering key predictive factors, such as baseline refraction, axial length, age, sex, and ethnicity,<sup>295</sup> offering tailored insights for each patient's unique progression and treatment response.

- Dual Applicability: Refractive Error and Axial Length The software should integrate data from both spherical equivalent refractive error and axial length monitoring, because both are critical for evaluating treatment outcomes. By addressing both parameters, the software enables a comprehensive approach to myopia management. It should accommodate situations where cycloplegic refraction is not available by making suitable adjustments for noncycloplegic data and when axial length data is unavailable, it should use keratometry values to estimate axial length.
- Direct Comparison Capabilities Tools should allow for direct comparison between refractive error and axial length changes, using metrics and visualizations that help ECPs track the overall effectiveness of treatments across both dimensions.
- Meaningful Age-Specific Projections

The software must offer age-specific projections of myopia progression, helping ECPs anticipate changes and adjust treatment plans accordingly. These projections provide an essential benchmark for long-term management.

- Monitoring and Treatment Efficacy Metrics To track myopia progression and treatment efficacy, various metrics are currently available.<sup>161</sup> These include:
  - Absolute Change and Centile Chart Comparisons: Track changes in refraction and axial length and compare them against standardized centile growth charts.
  - Progression Rate and Axial Growth Rate: Calculates rates of myopia progression and axial length growth, tailored to patient-specific factors like age, sex and ethnicity

Although useful, these existing metrics for monitoring myopia progression and treatment are primarily derived from clinical trial analyses. Decision-support software should prioritize development of enhanced metrics tailored for use in individual patients in a clinical setting rather than clinical trials. This will help streamline the complex process of delivering personalized care, enabling clinicians to make evidence-based decisions, communicate effectively with parents and thereby foster greater treatment adoption and long-term adherence without sacrificing valuable chair time.

## Artificial Intelligence in Myopia Control

The interest in applications of artificial intelligence (AI) in ophthalmology and vision science has grown dramatically in recent years, with over 1000 papers on this topic in PubMed in 2023 alone. The majority of these publications relate to the detection of disease, such as diabetic retinopathy,<sup>296</sup> agerelated macular degeneration,<sup>297</sup> anterior segment diseases, and glaucoma.<sup>298</sup>

Generally, AI functions by applying mathematical models or algorithms to large datasets to identify patterns and make predictions. These algorithms often go through initial training phases and improve in performance over time when exposed to increasing amounts of data. In myopia detection and monitoring, the approach depends on the available data that can be used to train AI models.<sup>299</sup> For example, machine learning can use statistical techniques to analyze baseline demographics and clinical measurements, such as spherical equivalent refractive error, axial length, keratometry, and visual acuity. Meanwhile, deep learning, a subset of machine learning, excels in recognizing intricate patterns in medical images, such as those produced by corneal topographers or fundus cameras.<sup>244</sup>

**AI's Role in the Prediction of Myopic Progression.** A random forest machine learning model based on 10-year refraction data from electronic medical records in China demonstrated high prediction accuracy for up to eight years, with limits of agreement of 0.5 D to 0.8 D of the actual value at eight years.<sup>57</sup> Other models have included behavioral factors, such as amount of indoor and outdoor activities, diet, reading habits and cell phone use, have shown high predictive accuracy.<sup>300</sup> Additionally, various machine learning algorithms, including linear regression and logistic regression, have been tested to predict aspects such as axial length elongation<sup>301</sup> and visual acuity in eyes with high myopia.<sup>302</sup>

AI's Role in Detecting Myopic Pathology. The detection of pathological changes associated with high myopia, such as staphyloma, myopic maculopathy, optic disc tilting, and chorioretinal atrophy,<sup>303</sup> can also be challenging, especially in the early stages of myopic disease. Deep learning methods, such as convolutional neural networks, have shown high accuracy in their ability to detect fundus lesions in high myopic patients.<sup>304-306</sup> AI has also been used to explore the genetic components of myopia. For example, machine learning algorithms identified 23 differentially expressed genes associated with myopia, four of which were highly effective diagnostic biomarkers.<sup>304–306</sup> In addition to the detection of pathological myopia and its associated fundus changes, deep learning AI has also been used in the classification of myopia-related fundus lesions, including choroidal neovascularization, peripapillary atrophy, and fundus tessellation.<sup>307-314</sup>

Although the classification of myopia-related fundus changes can be applied clinically, AI's deep learning algorithms can also help in the understanding of the eye's structures. This process has led to the ability to study underlying choroidal changes in myopic patients<sup>254</sup> to train ophthalmology residents in the identification of pathologic myopia through the interpretation of fundus images,<sup>315</sup> and to the ability to label the choroid and retinal layers in high myopia patients.<sup>316</sup>

**AI's Role in Myopia Treatment.** Possible applications of AI have also been explored for use within some of available treatments for myopia, including orthokeratology<sup>317,318</sup> and topical atropine.<sup>319</sup> A retrospective study found machine learning to better estimate the return zone depth and landing zone angle of the four quadrants of an orthokeratology contact lens that three other methods, including the traditional sliding card method provided by the manufacturer.<sup>317</sup> Multiple machine learning models have been applied to retrospectively study the effect of 19 factors on intraocular pressure in myopic children being treated with topical atropine.<sup>319</sup>

As with any technology, AI is not without important considerations of proper use. Two major considerations for AI that must always be considered include the generalizability and bias of the outcomes.<sup>320</sup> The datasets used in AI algorithm development might carry biases related to ethnicity, gender, techniques/equipment used, or other

#### Myopia Management Instrumentation

TABLE.	Instrumentation	for Clini	cal Practice	e and Rese	arch in	Myopia	a Management
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Clinical Technique	Methodology	<b>Clinical Practice</b>	<b>Clinical Research</b>
Cycloplegic refraction	<ul><li> 1 drop of 1% Cycloplentolate OR</li><li> 2 drops of 1% Tropicamide</li></ul>	Essential <sup>*</sup> —at initial visit and appropriate intervals thereafter	Essential for primary outcome measures
Objective refraction	<ul> <li>Retinoscopy</li> <li>Open-Field Autorefraction</li> <li>Closed Field Autorefraction</li> </ul>	Essential – at initial and subsequent visits	Essential—typically open-field used
Subjective Refraction	Subjective refraction	Preferred by clinicians Suitable for older children—confirmation of objective findings	Non-essential Typically not a primary outcome measure
Axial Length (Biometry)	<ul><li>PCI</li><li>OLCR</li><li>OCT</li></ul>	Preferred	Essential—a primary outcome measure for clinical trials
Topography/Tomography (Corneal Curvature)	<ul><li> Reflection</li><li> Projection</li></ul>	Essential for OrthoK patients	Clinical trial dependent
Objective Pupillometry	<ul><li>Infrared light</li><li>Mobile device software</li></ul>	Preferred for OrthoK patients	Clinical trial dependent
Dry Eye Assessment	<ul> <li>Slit lamp microscopy</li> <li>Videokeratography</li> <li>Meibography</li> </ul>	Preferred	Clinical trial dependent
Aberrometry	<ul> <li>Hartmann-Shack</li> <li>Tscherning</li> <li>Ray-Tracing</li> <li>Puremidal Wavefront Songing</li> </ul>	Non-essential	Clinical trial dependent
Posterior segment imaging	<ul><li>Fundus camera</li><li>Scanning laser ophthalmoscope</li><li>OCT</li></ul>	Preferred—for monitoring patients	Clinical trial dependent

\* Where scope of practice permits.

factors, potentially leading to biased algorithms, or at least algorithms with limited heterogeneity or applicability.<sup>321</sup> The opacity of machine learning models, often referred to as "black box" systems, poses challenges in understanding their inner workings and accordingly, the appropriateness of the assumptions these algorithms have made. Similar to much of advancing technology in healthcare, ethical concerns also arise regarding unequal access, exacerbating disparities in patient care. Other ethical considerations with AI include data security, informed consent, privacy, accountability, and trustworthiness for decisions made by AI systems.<sup>322</sup> The ideal clinical situation likely uses AI to augment clinical decision-making rather than supplanting it and requires AI models to be built on large, diverse datasets. Addressing these challenges, however, is paramount for the effective and ethical application of AI in healthcare.

#### **SUMMARY**

The rising prevalence of myopia has driven the development of advanced diagnostic and management tools. Clinical instrumentation plays a crucial role in myopia control, enabling practitioners to measure refractive error, axial length, accommodative responses, and ocular health. Although wavefront aberrometers provide valuable insights into higher-order aberrations and ocular optics, their use remains largely confined to research settings rather than routine clinical practice. In contrast, axial length measurement is a cornerstone of myopia management, with technologies such as PCI, OLCR, and swept-source OCT providing highly precise and repeatable data. Modern instrumentation provides precise and repeatable measurements critical for monitoring progression and evaluating effectiveness of myopia control treatments. The Table summarizes the instrumentation available and its relevance to clinical practice and research. By leveraging the appropriate technologies, clinicians can optimize patient care, effectively monitor myopia progression, and enhance treatment outcomes in the fight against the global myopia epidemic.

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