

# CJO RCO

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## RECHERCHE CLINIQUE

Survol des principaux types de lentilles corneennes chez les enfants aphaques ages de moins de 5 ans

## CLINICAL RESEARCH

Life After Areds 2: What Should We Recommend To Patients With or at Risk of Amd?

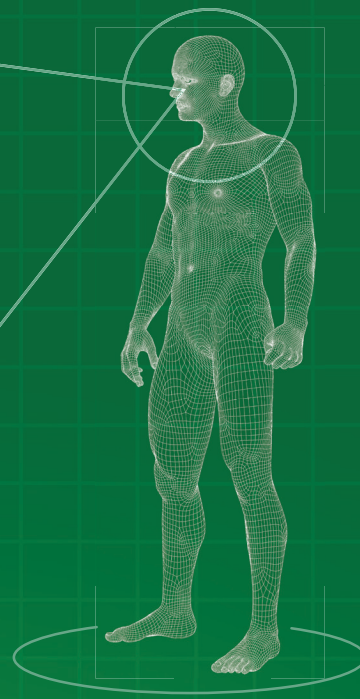
## CLINICAL RESEARCH

Refining Decisions for Identifying Primary Care Patients Who Require a Work-Up for Glaucoma: Intraocular Pressure Changes with Central Corneal Thickness

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On the Cover

*Refining Decisions for Identifying Primary Care Patients Who Require A Work-Up for Glaucoma: Intraocular Pressure Changes with Central Corneal Thickness*

Although I have been on the editorial staff of the *Canadian Journal of Optometry/Revue Canadienne d'Optométrie* since 1985, this is my first editorial! Thanks to the support of the CAO Board, and especially President Dr. Paul Geneau, this issue of *CJO/RCO* will appear very different from what you, our readers, have seen in the past. For as long as I can remember, I and my predecessors as editor-in-chief, the late Drs. Maurice Belanger and Mitch Samek, have aimed to present both basic science and clinical applications that are relevant to Canadian optometric practice. Academic Editor Dr. Claude Gaiisson and I have also tried to show Canadian optometrists what the research community in our two Canadian Schools of Optometry are accomplishing with your support through the Canadian Optometric Education Trust Fund. And we have done this in both official languages.

#### How are we changing the *CJO\*RCO*?

- Individual articles will be accessible to search engines, giving our authors more exposure online.
- Abstracts will appear in both English and French to facilitate online searches.
- We are actively soliciting both Canadian and international authors to submit papers outlining the clinical significance of their work and how it can be applied to your practice.
- As outlined by Dr. Geneau in the accompanying article, we have recruited an editorial board whose members are recognized experts in their respective fields. They will help to identify more authors and provide review articles for the Journal.
- Other than the occasional editorial and some practice management pieces, the content will be exclusively scientific papers with a clinical application or significance.

Over the past few months, with the help of Paula Mucci, our new managing editor at Andrew John Publishing, we have been setting up the new production process. We have also been working with graphic designer, Paul Cavanaugh to establish a new layout for the journal consistent with its new focus. The online instructions to authors have been updated, and Claude Gaiisson and I will continue to work with our authors through the review of their submissions. The new system should greatly speed up the publication process for our authors.

What do you think of the new *CJO\*RCO*? Please send your suggestions and critiques to me at [CJO@opto.ca](mailto:CJO@opto.ca). I look forward to hearing from you.

**B. Ralph Chou, MSc, OD, FAAO**  
**Editor-in-Chief**

**B**ien que j'aie été un membre du personnel de la rédaction de la *Canadian Journal of Optometry/Revue canadienne d'optométrie* depuis 1985, ceci est mon premier éditorial! Grâce à l'appui du conseil d'administration de l'ACO, et notamment du Dr Paul Geneau, son président, ce numéro de la CJO/RCO semblera bien différent de ce que vous, les lecteurs, avez vu dans le passé. D'aussi loin que je me souviens, j'ai, tout comme mes prédécesseurs au poste d'éditeur en chef, les regrettés Drs Maurice Bélanger et Mitch Samek, cherché à présenter des applications scientifiques et cliniques pertinentes pour la pratique canadienne de l'optométrie. Le Dr Claude Giasson, rédacteur académique, et moi avons aussi essayé de montrer ce que les chercheurs de nos deux écoles d'optométrie du Canada accomplissent grâce à votre soutien du Fonds de fiducie des optométristes canadiens pour l'éducation. Et nous l'avons fait dans les deux langues officielles.

#### **De quelle façon allons-nous changer la CJO\*RCO?**

- Les articles individuels seront accessibles via les moteurs de recherche, ce qui donnera plus de visibilité à nos auteurs sur Internet.
- Les résumés seront publiés en français et en anglais pour faciliter les recherches en ligne.
- Nous demandons activement à des auteurs canadiens et étrangers de soumettre des articles expliquant l'importance clinique de leurs travaux et leur application possible dans votre pratique.
- Comme l'indique le Dr Geneau dans l'article d'accompagnement, nous avons recruté un comité de rédaction dont les membres sont des spécialistes reconnus dans leurs domaines respectifs. Ils vont aider à trouver d'autres auteurs et vont fournir des exposés de synthèse pour le Revue.
- Mis à part l'occasionnel éditorial et quelques articles sur la gestion de la pratique, le contenu sera composé exclusivement d'articles scientifiques ayant une application ou une importance clinique.

Au cours des derniers mois, avec l'aide de Paula Mucci, notre nouvelle rédactrice administrative chez Andrew John Publishing, nous avons établi un nouveau processus de production. Nous avons aussi travaillé avec le concepteur graphique, Paul Cavanaugh, à l'établissement d'une nouvelle mise en page pour la revue, qui est adaptée à sa nouvelle orientation. Les instructions en ligne pour les auteurs ont été mises à jour et Claude Giasson et moi allons continuer de travailler avec les auteurs en examinant le matériel qu'ils nous soumettront. Le nouveau système devrait grandement accélérer le processus de publication pour nos auteurs.

Que pensez-vous de la nouvelle CJO/RCO? Je vous invite à envoyer vos suggestions et critiques à CJO@opto.ca. C'est avec plaisir que je les lirai.

**B. Ralph Chou, M. Sc., O.D., F.A.A.O.**  
**Éditeur en chef**

When the CAO Council put the *CJO* on hiatus over the last few months, we did so with the intention of bringing back a stronger and more effective journal. Our long-term objective is to develop the “go to” resource for Canadian optometrists. We have come a long way towards achieving that goal, but we couldn’t have done so without considerable help, most notably from our long standing editors, Editor-in-Chief Dr. Ralph Chou and Academic Editor Dr. Claude Giasson, and with the expertise of CAO’s Director of Marketing and Communications Debra Yearwood.

Dr. Chou and Dr. Giasson have worked hard to produce a stronger and more valuable journal. They have not only focused on bringing our members a better clinical tool, but also on building the strength of the board by including optometrists with a broad array of expertise. I would like to extend my thanks to them for their hard work and dedication. Before I introduce you to our new editorial board, I would like to extend our thanks to Optocase for providing the mini case you’ll find in the journal, not to mention the offer of a free case for CAO members. Also, thanks to Allergan for their work with the *CJO* to bring our members Dry Eye Guidelines.

Quand le Conseil de l’ACO a mis la *RCO* en veilleuse ces quelques derniers mois, il l’a fait avec l’intention de revenir avec une revue plus solide et plus efficace encore. Notre objectif à long terme est de mieux mettre des personnes-ressources à la disposition des optométristes canadiens. Nous avons parcouru un long chemin dans cette direction, mais nous n’aurions pu le faire sans une aide considérable reçue notamment de nos rédacteurs de vieille date, à savoir notre rédacteur en chef, le D<sup>r</sup> Ralph Chou, et notre rédacteur académique, le D<sup>r</sup> Claude Giasson, sans oublier la compétence de notre directrice du marketing et des communications, Debra Yearwood.

Les D<sup>rs</sup> Chou et Giasson ont travaillé fort en ce sens. Ils se sont employés non seulement à offrir à nos membres un meilleur outil clinique, mais aussi à renforcer le comité de rédaction en y affectant des optométristes aux larges compétences. Je les remercie de leur labeur et de leur dévouement. Avant de vous présenter notre nouveau comité de rédaction, j’aimerais remercier Optocase d’avoir fourni le minicas que vous trouverez dans la revue. Je rappelle aussi l’offre d’un cas gratuit aux membres de l’ACO. Merci également à Allergan pour la présentation dans la *RCO* des lignes directrices sur la sécheresse oculaire.

**Dr. Hélène Kergoat**, OD, MSc, PhD, FAAO Professor - Université de Montréal - neurophysiology of vision, clinical optometry / neurophysiologie de la vision, optométrie clinique

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# Survol des principaux types de lentilles cornéennes chez les enfants aphaques âgés de moins de 5 ans

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## Résumé

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L'ajustement en lentille cornéenne est souvent le premier choix pour la correction visuelle des enfants aphaques. Il existe plusieurs types de lentilles qui peuvent être ajustées avec succès pour corriger l'amétropie, stimuler adéquatement le développement visuel, mais également préserver la santé oculaire. Plusieurs facteurs sont déterminants pour le choix du type de lentille. Habituellement, la lentille initialement ajustée est en silicone Élastofilcon A (Silsoft; Bausch & Lomb, Rochester, NY) avec une migration vers une lentille silicone hydrogel sur mesure avec le temps. Bien que l'ajustement chez les jeunes enfants aphaques présente de nombreux défis, les lentilles cornéennes demeurent souvent l'option de choix de la correction des amétropies après une chirurgie de cataracte congénitale. Un survol des principaux types de lentilles cornéennes disponibles pour les enfants aphaques ainsi que leurs caractéristiques sera présenté.

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## Abstract

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Contact lenses are often the first choice for visual correction of aphakic children. There are several types of lenses that can successfully be fitted to correct the ametropia, stimulate visual development, and maintain ocular health. Several factors are important for choosing the type of lens. Usually, the first lens fitted is a silicone Élastofilcon A (Silsoft, Bausch & Lomb, Rochester, NY) with a migration to a custom silicone hydrogel lens over time. Although the fitting in young aphakic children presents many challenges, contact lenses often remain the best option for the correction of refractive errors after congenital cataract surgery. An overview of the main types of contact lenses available for aphakic children and their characteristics will be presented.

Le terme cataracte congénitale ou infantile est utilisé pour décrire une opacification significative du cristallin durant la première année de vie.<sup>1</sup> La cataracte est considérée comme la cause évitable la plus importante de déficit visuel chez l'enfant.<sup>2,3</sup> La prévalence de la cataracte congénitale est estimée à 1 à 15/10 000 enfants selon les critères utilisés pour le diagnostic de la cataracte et de la population étudiée. Si la cataracte est dense, centrale et supérieure à 3 mm de diamètre, si la vue du fond d'œil est impossible, ou si la cataracte est associée au strabisme, un traitement chirurgical s'impose.<sup>4</sup> Il est préférable que la chirurgie s'effectue le plus tôt possible et surtout à l'intérieur de la période critique du système visuel, soit avant 17 semaines.<sup>5</sup>

Entre 2 jours et 2 semaines après l'opération, l'amétropie secondaire à l'aphakie doit être corrigée pour éviter l'amblyopie qui s'installe rapidement en bas âge.<sup>6</sup> Présentement, les deux méthodes les plus employées pour la correction visuelle sont le port de lunettes et de lentilles cornéennes.<sup>3,7</sup> L'insertion d'une lentille intra-oculaire se fait moins fréquemment chez les enfants de moins de 1 an en raison des variations importantes de réfraction qui se produisent durant les premières années de la vie de l'enfant causées par l'élongation axiale de l'œil.<sup>3,8,9</sup>

L'ajustement en lentilles cornéennes est souvent le premier choix pour la correction visuelle des enfants aphaques.<sup>7,10</sup> En effet, non seulement l'aspect esthétique est amélioré, mais aussi le grossissement de l'image, l'anisétropie, les distorsions périphériques, la restriction du champ visuel avec présence d'un scotome mobile (effet *Jack in the box*) et le poids sont réduits.<sup>10,11</sup> Ces aspects sont d'autant plus importants si l'aphakie est unilatérale. De plus, les changements réfractifs secondaires à la croissance sont faciles à modifier en changeant les paramètres des lentilles cornéennes au besoin. Il existe plusieurs types de lentilles qui peuvent être ajustées avec succès chez le jeune enfant. Que ce soit en lentille souple, rigide perméable au gaz, en ou en sclérale, l'objectif sera à la fois de compenser l'amétropie du sujet, afin de stimuler adéquatement le développement visuel, mais également de préserver la santé oculaire par un choix de matériau et de designs permettant une oxygénation adéquate de la cornée. Le présent article sera un survol des principaux types de lentilles cornéennes ajustées chez les enfants aphaques ainsi que de leurs caractéristiques.

## AJUSTEMENT DES LENTILLES

Durant les 18 premiers mois suivant la naissance, une croissance rapide de l'œil se produit. Elle entraîne généralement une réduction de l'hypermétropie, une augmentation du diamètre cornéen et une diminution de la courbure cornéenne. Des changements fréquents tant au niveau de la courbure de la lentille, du diamètre ainsi que de la puissance de la lentille devront suivre cette évolution et ce, surtout durant les 2 premières années de vie.<sup>10</sup>

Les mesures de puissance cornéenne au kératomètre sont parfois impossibles à obtenir, surtout pour les moins de 2 ans, donc l'évaluation de base peut devoir être faite sous anesthésie générale.<sup>5,10,12</sup> Les valeurs moyennes d'études antérieures sont plus fréquemment utilisées comme point de départ.<sup>10,12,13</sup> Russell et al. ont rapporté une puissance cornéenne au kératomètre à la naissance entre 47,00 D. à 48,50 D. et un aplatissement plus rapide chez les patients aphaques. Le bébé a une puissance cornéenne moyenne à l'ajustement initial de 46,3 D.  $\pm$  2,8 D., et à 1 an de 44,6 D.  $\pm$  2,3 avec une diminution moyenne de 0,2 D.  $\pm$  0,2 D./mois.<sup>12</sup>

Les puissances dioptriques varient aussi durant les premières années.<sup>5,10</sup> La puissance moyenne requise en bas âge est plus élevée (+25,5 D.  $\pm$  4 D. à 3 mois) et devient moins convexe avec le temps (+17,94  $\pm$  3,8 D. à 3 ans d'âge) en raison de la croissance de l'œil. Ceci représente une variation de 0,23 D. par mois.<sup>5</sup> Le diamètre cornéen mesure à la naissance en moyenne 10 mm et atteint sa taille adulte vers l'âge de 2 ans avec un diamètre de 11,7 mm.<sup>10</sup>

De plus, le monde visuel d'un nourrisson se situe en vision rapprochée.<sup>10</sup> Puisque les enfants ayant subi une extraction du cristallin n'ont plus la possibilité d'accommoder, une compensation pour la distance rapprochée doit être faite. Une correction de +2,50 à +3,00 D. est généralement ajoutée à la prescription en vision de loin pour permettre une vision nette au près.<sup>8,13</sup> Cette correction devrait être réduite à +1,00 ou +1,50 entre l'âge de 18 à 24 mois, puisque l'enfant



s'intéresse davantage à des objets éloignés. Vers l'âge de 3-4 ans, la lentille cornéenne devrait être ajustée pour la vision éloignée et des lunettes avec foyer devraient être prescrites pour corriger la vision de près.<sup>10</sup>

Les rayons ultra-violet (UV) sont associés à une variété de maladies oculaires.<sup>14,15</sup> L'œil aphaque est potentiellement plus vulnérable aux rayons UV dû à l'absence du cristallin qui les filtre partiellement. Certains types de lentilles offrent la possibilité d'ajouter un filtre UV, mais aucune étude clinique ne confirme qu'il soit requis.<sup>12</sup>

D'autres aspects influencent la réussite du port de lentilles cornéennes.<sup>11</sup> Tout d'abord, ce sont les parents qui sont responsables de l'insertion et du retrait. Donc l'habileté et la motivation de ceux-ci sont déterminantes. De plus, de nombreuses visites sont requises et viennent s'ajouter aux nombreux rendez-vous en pré et post opération de cataracte. Il arrive aussi que les lentilles se déplacent ou même se perdent puisque les enfants se frottent beaucoup les yeux. En effet, les enfants de moins de 8 ans perdraient en moyenne une lentille tous les 9,2 mois.<sup>3</sup> Ceci occasionne des coûts supplémentaires qui s'ajoutent au prix initial souvent élevé de ce type de lentille.<sup>12</sup> Dès que l'enfant est en âge de comprendre, il faut lui expliquer que ceci est un bénéfice pour lui et non une punition.<sup>3,11</sup> Lorsque la correction est unilatérale, l'avantage de la lentille n'est pas toujours évident pour l'enfant qui s'est habitué à utiliser seulement son meilleur œil.

#### AJUSTEMENT DES LENTILLES SOUPLES

Les lentilles souples sont les plus fréquemment utilisées chez les enfants puisqu'elles sont les plus faciles à ajuster et à manipuler.<sup>10</sup> La courbure cornéenne moyenne du nouveau-né se situe entre 48,50 D. (6,96 mm) et 47,00 D. (7,18 mm) et s'approche de celle de l'adulte vers l'âge de 3 ans avec 43,25 D. (7,8 mm).<sup>10,12</sup> L'ajustement initial s'effectue généralement 0,5 mm plus plat que la courbure cornéenne moyenne.<sup>10</sup> Ainsi, pour le nouveau-né, la courbure de départ serait idéalement de 7,4 mm. Des modifications régulières de la courbure des lentilles seront nécessaires dû un aplatissement rapide de la cornée durant les 18 premiers mois de vie.<sup>10</sup> Le diamètre de la lentille souple est habituellement 2,5-3,0 mm plus large que le diamètre horizontal de l'iris. Chez le nouveau-né, puisque le diamètre cornéen est en moyenne de 10 mm, le diamètre choisi initialement est généralement 12,5-13,0 mm et sera modifié avec la croissance.<sup>10</sup> Une lentille offrant un mouvement trop ample sera considérée trop plate et devra être resserrée. A contrario, une lentille offrant un mouvement limité devra être aplatie afin de favoriser un échange lacrymal adéquat sous sa surface. Finalement, la relation courbure/diamètre peut être influencée par le design spécifique de la lentille et sa puissance. Un diamètre plus grand permet un meilleur centrage et une meilleure stabilité de la lentille cornéenne. Toutefois, il devient parfois difficile pour les parents d'effectuer les manipulations si le diamètre de la lentille est trop grand.<sup>10</sup>

#### LENTILLES SOUPLES EN SILICONE

Les enfants aphaques devraient porter leur lentille en port prolongé afin de minimiser les problèmes reliés à la manipulation et de stimuler constamment la vision. Actuellement, il existe une seule lentille approuvée pour le port prolongé 30 jours pour le traitement de l'aphakie pédiatrique. Il s'agit de la lentille en silicone Élastofilcon A (Silsoft; Bausch& Lomb, Rochester, NY).<sup>16</sup> Elle est la lentille de choix, puisque la perméabilité à l'oxygène (DK) est de 340 X10<sup>-11</sup> cm<sup>2</sup> mL O<sub>2</sub>/sec mL mm Hg avec une transmissibilité à l'oxygène (DK/t) de 58 à 0,61 mm.<sup>12</sup> Elle est disponible en version pédiatrique entre les puissances de +23,00 D. à +32,00 D. avec des sauts de 3 D. Le diamètre est de 11,3 mm et 3 courbures sont disponibles : 7,5 mm (45,00 D.), 7,7 mm. (43,75 D.) et 7,9 mm (42,75 D.).<sup>16</sup> La lentille ayant une courbure de 7,5 mm est généralement la première ajustée puisqu'elle se rapproche le plus des valeurs théoriquement obtenues avant l'âge de 18 mois.<sup>5,10</sup> Une courbure plus plate est nécessaire lorsque l'enfant vieillit : ainsi les courbures de 7,7 mm et 7,9 mm seront généralement utilisées après l'âge de deux ans. À l'âge de 4 ans, presque tous les patients requièrent la courbure de 7,9 mm.<sup>5,10,12</sup> La lentille en Elastofilcon A ne comporte pas que des avantages : son coût élevé d'acquisition et de remplacement peut en limiter l'usage. De plus, le diamètre de la lentille s'avère rapidement trop petit en raison de la croissance de l'œil. Elle ne contient aucun filtre UV. Finalement, le silicone est un composé qui attire beaucoup les lipides des larmes nécessitant un remplacement fréquent, de 2 à 4 fois par année selon les patients.<sup>10</sup>

### LENTILLES SOUPLES HYDROGEL CONVENTIONNELLES

Les lentilles cornéennes hydrogel conventionnelles en port quotidien sont disponibles en plusieurs paramètres, ce qui facilite l'ajustement. Le matériau est beaucoup plus résistant aux dépôts lipidiques bien qu'il ait une grande affinité envers les protéines. Ces lentilles peuvent être remplacées sur une base annuelle et il est possible d'ajouter un filtre UV. Le coût des lentilles hydrogel, ainsi que leur remplacement, représente une économie substantielle pour les parents. Par contre, ces lentilles offrent une oxygénation médiocre, à haute puissance convexe, ce qui limite énormément leur attrait.<sup>10,17,18</sup> En effet, elles peuvent entraîner une néovascularisation, un œdème du stroma et même une dysfonction chronique de l'endothélium.<sup>19</sup>

### LENTILLES SOUPLES HYDROGEL À REMPLACEMENT FRÉQUENT

Il existe peu de lentilles souples hydrogel jetables disponibles dans les corrections fortement convexes. La lentille en Benz G offre des paramètres sur mesure pour cette catégorie de patients.<sup>20</sup> La lentille en omafilcon A offerte jusqu'à +20 D. avec une courbure de 8,6 mm et un diamètre de 14,2 mm. requiert un remplacement mensuel.<sup>21</sup> Le fait de remplacer régulièrement les lentilles minimise les risques d'infection et l'accumulation de dépôt. Le problème de la perméabilité à l'oxygène demeure, mais le mouvement plus élevé optimise la libre circulation des larmes sous la surface de la lentille. Ce mouvement permet de compenser, en partie, les risques inhérents d'infections reliés aux débris accumulés sous la surface de la lentille.<sup>22</sup> Leur courbure de base plus plate et un diamètre plus grand font que l'on réserve ces lentilles aux patients plus âgés, soit souvent à partir de 3 ans.

### LES LENTILLES SOUPLES EN SILICONE HYDROGEL

Des lentilles à remplacement fréquent existent également en silicone hydrogel. Il s'agit à la base d'un matériau hydrophile permettant une augmentation de perméabilité par l'ajout de silicone dans la matrice. Le modulus, soit la rigidité relative de la lentille, est ainsi augmenté, de même que son angle de mouillage, ce qui peut induire une sensation d'inconfort. De plus, cette lentille entraîne parfois de l'irritation et le développement de conjonctivite à papilles géantes suite à l'érosion mécanique de la surface oculaire. Les lentilles sont disponibles dans plusieurs paramètres et permettent même la correction de l'astigmatisme. Toutefois due à l'épaisseur importante de la lentille associée à la prescription élevée, la correction demeure plus précise et facilitée avec l'utilisation d'une lentille sphérique combinée avec le port de lunettes pour corriger l'astigmatisme résiduel.<sup>10</sup> Elles n'ont pas de filtre UV pour les prescriptions requises pour les enfants aphaques.<sup>20</sup>

### LES LENTILLES PERMÉABLES AU GAZ

Les lentilles perméables au gaz (PAG) peuvent aussi être prescrites chez les enfants de tout âge, à condition que les parents collaborent bien à la pose, au retrait et à leur entretien. Les lentilles PAG offrent de nombreux avantages. En effet, elles ont une perméabilité à l'oxygène nettement supérieure et peuvent être fabriquées dans presque n'importe quels paramètres. Il est possible d'ajouter un filtre UV. L'astigmatisme cornéen, même irrégulier, peut être corrigé ce qui aide grandement lors de cataractes traumatiques impliquant la cornée.<sup>10</sup> Avec ce type de lentilles les infections et la néovascularisation cornéenne sont beaucoup moins fréquentes.<sup>5,6,10,19</sup> Par contre l'adaptation initiale au confort peut être plus difficile. De plus, si l'enfant frotte beaucoup ses yeux, il peut causer de l'irritation, des abrasions cornéennes et même l'éjection des lentilles.<sup>10</sup>

### LENTILLES SCLÉRALES

De nos jours, les lentilles mini-sclérales et les lentilles sclérales peuvent être considérées à tout âge. Leur adaptation est plus complexe mais ceci est largement compensé par la qualité supérieure de la vision obtenue, surtout en présence d'astigmatisme. Les lentilles ne touchent pas la cornée, mais s'appuient plutôt sur une couche de fluide et la conjonctive. Elles procurent un confort comparable aux lentilles souples, tout en offrant les qualités des semi-rigides. La perméabilité à l'oxygène est supérieure aux hydrogels et comparable aux silicones hydrogels si le dégagement est optimal. Le matériau contient un filtre UV. Les dépôts adhèrent rarement au point de nuire à la vision ou au confort du patient. Il s'agit d'une excellente alternative à considérer.<sup>23</sup> Elles sont toutefois peu utilisées actuellement en pédiatrie dû au coût initial qui est environ 10 fois plus élevé qu'une PAG, ainsi qu'en raison du diamètre plus grand de la lentille qui peut être plus difficile pour les parents au départ à manipuler.<sup>10</sup>

## SUIVI

Régulièrement il est nécessaire de modifier l'ajustement du type de lentille cornéenne en fonction de la croissance de l'enfant. Ainsi, l'ajustement avec la lentille en Élastofilcon A généralement utilisée comme essai de départ deviendra une lentille silicone hydrogel sur mesure avec le temps. Le passage se fait habituellement en raison des limites apportées par le diamètre de la lentille en silicone et la présence de dépôts nécessitant un remplacement très fréquent, deux facteurs pouvant contribuer à l'inconfort du patient. Le coût de remplacement du produit justifie aussi le choix des lentilles adoptées.<sup>5,10,12</sup>

Les jeunes patients porteurs de lentilles cornéennes doivent être suivis régulièrement afin d'éviter les effets secondaires. Chez les enfants d'âge scolaire, les études ont prouvé que l'adaptation de lentilles cornéennes était faisable, de façon sécuritaire, et ce, de façon comparable aux patients plus âgés.<sup>11</sup> L'impact psychologique du port de lentille n'est pas à négliger : meilleure acceptation sociale, plus grande estime de soi, activités physique et sports favorisés, vision globale et qualité de vie améliorées.<sup>9,24,25</sup> Même les enfants qui adorent leurs lunettes perçoivent les bénéfices de porter des lentilles cornéennes surtout lorsque les erreurs de réfraction sont telles que celles rencontrées chez les enfants aphaques.

## CONCLUSION

Bien que l'ajustement de lentilles cornéennes chez les jeunes enfants aphaques présente de nombreux défis, elles demeurent souvent l'option de choix de la correction des amétropies après une chirurgie de cataracte congénitale. Le choix des lentilles cornéennes souples pour les enfants aphaques est limité par la disponibilité des paramètres et par la perméabilité à l'oxygène. L'évolution de la disponibilité des matériaux facilite la sélection d'une lentille répondant aux besoins du patient. Il est maintenant possible de stimuler adéquatement le développement visuel tout en préservant la santé oculaire.

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# Life After AREDS 2: What Should We Recommend to Patients With or at Risk of AMD?

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## Abstract

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### PURPOSE

To establish a consensus on clinical recommendation of oral supplementation for patients with or at risk of developing age-related macular degeneration (AMD), from the perspective of the Age-Related Eye Disease Study 2 (AREDS 2) and other studies.

### METHODS

Panel discussion based on a literature review of pertinent articles related to the prevention of AMD with oral supplementation.

### RESULTS

On the basis of the findings, patients must first be encouraged to modify their diet and to eliminate modifiable risk factors before being recommended any type of oral supplementation. Then, recommendations must be customized on the basis of a patient's individual risk profile (i.e., age, gender, heredity, etc.) and severity of disease (i.e., category 1 to 4). Essential fatty acids (omega-3s) and vitamins may play a role, in a given clinical population, to prevent the occurrence or the progression of AMD disease. However, there is no single formula that can be applied to all patients with or at risk of AMD.

### CONCLUSIONS

This group concluded that the full body of literature must be taken into consideration in order to justify clinical recommendations for patients. A single study such as AREDS 2 cannot, by itself, guide clinical practice. In all cases, recommendations must be individualized and patients should be monitored regularly.

### KEY WORDS:

age-related macular degeneration, poly-unsaturated fatty acids, vitamins, AREDS 2

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## Sommaire

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### BUT

Établir des recommandations cliniques consensuelles quant à la gestion clinique des patients atteints ou à risque de développer une dégénérescence maculaire liée à l'âge (DMLA).

### MÉTHODES

Discussion d'un panel d'experts basée sur l'analyse de divers articles scientifiques relatifs à la prise de suppléments vitaminiques et nutritionnels chez des patients atteints ou à risque de DMLA.

### RÉSULTATS

Selon le panel, suite à l'analyse des articles, la première intervention devrait être d'inciter le patient à améliorer son hygiène de vie avant de recourir à des suppléments oraux.

Par la suite, les recommandations cliniques doivent tenir compte du profil de risque du patient, de sa nutrition, de sa condition systémique ainsi que de l'état de sa santé oculaire. Les omégas 3s et les vitamines peuvent jouer un rôle bénéfique auprès de populations cibles afin de prévenir l'apparition ou l'évolution de la DMLA. Comme il n'existe pas de recettes uniques, le tout doit être personnalisé selon les besoins du patient.

### CONCLUSION

Le groupe conclut que l'ensemble de la littérature doit être prise en compte afin de justifier le recours à des suppléments oraux (omégas et vitamines) et que les recommandations doivent être personnalisées. Une seule étude, comme AREDS 2, bien que très importante, ne peut déterminer à elle-seule le comportement clinique des professionnels de la vue. L'importance du suivi régulier du patient doit également être comprise par tous.

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**A**ge-related macular degeneration (AMD) is the leading cause of irreversible vision loss in developed countries.<sup>1,2</sup> It is estimated that there are 17,000 new cases of neovascular (NV) AMD and 180,000 new cases of geographic atrophy (GA) AMD in Canada every year.<sup>3</sup> The disease has a substantial negative impact on patient quality of life and imposes a considerable burden on the economy.<sup>3</sup> Early and intermediate stages of AMD are prevalent in people older than 65 years of age,<sup>4</sup> and without intervention, the condition can evolve to advanced AMD<sup>5</sup> and result in significant loss of visual function.

Published 12 years ago, the Age-Related Eye Disease Study (AREDS) demonstrated that in persons with intermediate to severe AMD, a daily oral supplement containing vitamins and antioxidants reduced the risk of progression to advanced AMD by 25% versus placebo over a period of 5 years.<sup>6</sup> This "AREDS formula" consisted of 500 milligrams (mg) vitamin C, 400 international units (IU) of vitamin E, 15 mg beta-carotene, 80 mg zinc oxide, and 2 mg cupric oxide. Since then, observational studies have suggested that dietary intake of other carotenoids, particularly lutein and zeaxanthin, might play a role in protecting against AMD.<sup>7,8</sup> Moreover, the authors of AREDS<sup>9,10</sup> and others<sup>8,11-13</sup> highlighted the important role of dietary or supplemental forms of omega-3s, for preventing the development of AMD or its progression.

This is the context in which the AREDS 2 was published in May 2013.<sup>14</sup> This study, which was initiated in 2006, demonstrated that the addition of lutein, zeaxanthin, and omega-3s to the original AREDS formula, did not further reduce the risk of progression to advanced AMD

relative to the original formula.<sup>14</sup> However, several secondary and subgroup analyses in this study suggested a benefit to replacing beta-carotene, which is associated with an increased risk of lung cancer in current and former smokers, with other carotenoids such as lutein and zeaxanthin. These conflicting results, notably with regard to omega-3s, have led to confusion among health care professionals about how to counsel patients and their caregivers about dietary strategies to prevent the development and progression of AMD.

On November 1, 2013, a group of Quebec experts, consisting of eight optometrists and one ophthalmologist, gathered in Montreal to discuss the outcomes of the AREDS 2 from a clinical perspective, with the goal of guiding the optimal management of this disease. In order to consider the AREDS 2 in a more global context, a general critique was undertaken. Then, each participant was assigned to review and present the key findings of a published article related to the use of dietary supplements or dietary factors associated with AMD (see **Table 1** for a brief synopsis of the studies and key findings). A facilitated group discussion that ensued focused on synthesizing the data with the eventual goal of developing a clear and practical set of consensus-based, nonbinding clinical recommendations for patients with AMD.

### GENERAL CRITIQUE OF THE AREDS 2

First, it is important to recognize that the AREDS 2 was founded on the original AREDS. A socioeconomic analysis of the patients enrolled in this latter study showed that they were, on average, more educated and better nourished at baseline than the average American<sup>14</sup> as well as those attending optometry practices in Canada. Moreover, a substantial proportion of patients were already taking vitamin and antioxidant supplements,<sup>6,14</sup> which suggested that their overall nutrition status was already supported by an external source of these nutrients. In this regard, there was no real placebo group in the AREDS 2. Moreover, 14% of patients were additionally taking “nonauthorized” supplements, which further increased their antioxidant intake.<sup>14</sup> Furthermore, the dosage and formulation of omega-3 supplements that were used in this study (eicosapentaenoic acid greater than docosahexaenoic acid [EPA>DHA] 1000 mg/day versus 2000 mg/day, as esters or triglycerides) were not optimal, considering the results of earlier studies on this subject. Finally, the AREDS 2 evaluated progression of AMD from moderate to advanced disease (NV and GA forms) without considering the effects of supplementation on the risk of development of the disease or its progression from mild to moderate disease.

The conclusions of the AREDS 2 can be applied to patients who were similar to those who were evaluated in the study, that is, patients with moderate to advanced AMD who are well nourished and well educated. Before extrapolating the study results to other patients, evidence derived from other studies must first be considered in order to appreciate the general context from which clinical recommendations can be formulated.

### GENERAL RECOMMENDATIONS

After considering the outcomes of several studies that were presented and keeping a general context in mind, a consensus was reached by this group of experts—that recommendations should be based on the individual patient and their particular risk profile. Health care professionals should assess a patient’s modifiable risk factors at the earliest opportunity to better counsel and categorize their risk of developing AMD or its progression to advanced AMD and to tailor advice about lifestyle, diet, and supplements. Tools are available to assist health care professionals in this regard. The results of the Macular Assessment Program (MAP), which aimed at evaluating the perceptions versus the realities of 290 Canadian optometrists, were recently reported and reviewed at this meeting.<sup>15</sup> This tool enables optometrists to categorize patients as having low, moderate, or high risk of AMD, on the basis of an evaluation of their modifiable and nonmodifiable risk factors. The literature suggests that the most important modifiable risk factors are smoking, alcohol consumption (>3 standard drinks/day), sun exposure (photostress), poor-quality diet, obesity, cardiovascular risk factors, and adherence to medication, whereas the most important nonmodifiable risk factors include age, gender, family history, ethnicity (Caucasians), and socioeconomic and educational status.

Therefore, all patients should be strongly encouraged to act on their modifiable risk factors

including smoking, diet, exercise, weight control, cholesterol, sun protection, and cardiovascular risk factors. This should constitute the foundation of counselling for all patients at risk of AMD or with AMD of any severity. Dietary advice should include information on food sources of lutein and zeaxanthin (e.g., green leafy vegetables and canned corn) and omega-3 fatty acids (e.g., wild fatty fish such as salmon, herring, and mackerel).

### RECOMMENDATIONS STEMMING FROM THE AREDS 2

When a health care professional decides to recommend a vitamin supplement to a patient, the general consensus is that lutein and zeaxanthin should be preferred over beta-carotene. There is a growing body of evidence suggesting that high-dose beta-carotene supplementation (20–30 mg/day) is associated with a higher risk of lung cancer in smokers.<sup>14,16</sup> The AREDS 2 confirmed that any patient who actively smoked in the past must be considered a smoker, regardless of the duration since cessation. This is an important point because the prevalence of current and ex-smokers is higher in Quebec compared with the national average. According to the Canadian Tobacco Use Monitoring Survey, in 2012, 14.9% of the Quebec population aged 45 years and older identified themselves as current smokers and a further 44.7% were former smokers.<sup>17</sup>

### RECOMMENDATIONS BASED ON CATEGORY OF AMD

#### Primary Prevention of AMD

Among the group of experts of the AREDS 2, it was felt that unaffected people with risk factors for the disease (e.g., family history or genetic risk) had been less well studied in randomized controlled trials and that the potential benefits of supplementation with antioxidants remains unclear for them. However, strong evidence from observational studies suggests that diets rich in omega-3 fats and fish intake are associated with protection against the development of AMD.<sup>8,9,12,18</sup> Consequently, eye health professionals may consider recommending omega-3 supplements or a diet rich in omega-3 sources in patients with risk factors for AMD (e.g., genetics), especially those who are poorly nourished, rather than recommending antioxidant supplements. Most of the experts also agreed that the safety and tolerability profile for omega-3 supplements was favourable and that supplementation did not appear to introduce unacceptable risks. There was stronger consensus among this group of experts that with regard to other modifiable risk factors, counselling that includes recommendation of regular exercise, sun protection, weight control, control of cardiovascular risk factors, and cessation of smoking, is very important and should not be neglected as a first step to prevent AMD occurrence.

#### Progression from Early AMD to Advanced AMD

The AREDS failed to demonstrate any significant benefit of supplementation in patients with less severe AMD (i.e., Category 1 or 2).<sup>6</sup> In this study, very few patients with Category 2 disease at baseline (i.e., patients with extensive small drusen, pigment abnormalities, or a few intermediate drusen) developed advanced AMD over the study period. On the basis of the available data, some clinicians therefore would not explicitly recommend antioxidant supplements to individuals with early AMD unless there was clear evidence of poor diet quality or dietary intake of carotenoids and omega-3s was insufficient. Dietary interventions may be of value in reducing the risk of progression in these patients.

#### Intermediate or Advanced AMD

For those patients who already have advanced AMD (i.e., defined by AREDS category), there may be some benefit in taking an antioxidant supplement with or without omega-3s, given that both the AREDS and the AREDS 2 showed a 25 to 30% reduction in the risk of progression from moderate to advanced AMD in the affected eye, as well as progression in the other eye.<sup>6,14</sup> Patients who are most likely to benefit from supplements are those who fit the profile of the patients studied in the AREDS and AREDS 2, that is, those with category 3 (many intermediate drusen or at least one large druse with abnormal pigmentation) or category 4 AMD (GA affecting the fovea or wet AMD with retinal fibrosis).<sup>14</sup>

Some experts still believe that patients with intermediate or advanced AMD could also benefit from omega-3 fatty acid supplementation despite the negative findings of the AREDS.<sup>2,14</sup>



particularly older patients who often have comorbid conditions (cardiovascular disease, diabetes, etc.), in whom the beneficial effects of fatty acid supplementation have been more clearly demonstrated. However, at this time, given the available evidence from randomized controlled trials, the optimal dose of omega-3 supplements, duration of treatment, and the magnitude of potential benefit remain unclear. There is consistent evidence from observational studies that people who consume the highest amount of omega-3s, particularly in the form of triglycerides or fatty fish in their diet have a lower incidence of AMD or progression to advanced AMD compared with those with the lowest intake.<sup>9,12,18</sup> Moreover, supplementing the diet with omega-3s, through either diet or supplements, could offer ancillary benefits, notably in patients presenting with symptoms of dry eyes, which is often the case in patients with AMD.

It was acknowledged that many patients with AMD want to do something to try to improve their health and prevent the progression of their disease. Taking a supplement that offers a potential 25% reduction in the risk of progression<sup>6</sup> may offer them hope and a sense of control over their disease. Notably, evidence suggests that people with the lowest dietary intakes of antioxidants<sup>14</sup> and those under 75 years of age<sup>7</sup> may derive the greatest benefits from supplementation. These patients might therefore constitute the best group to target in terms of clinical recommendations around diet and supplements. This further underscores the importance of classifying patients according to their risk of advanced AMD in the clinical setting.

#### **SHOULD WE RECOMMEND SUPPLEMENTS VERSUS DIETARY INTERVENTIONS?**

This group of experts acknowledged that patients must first be counselled to modify their diet to include green vegetables (source of lutein and zeaxanthin), and carotenoids and vitamins (fruits and vegetables), as well as fatty fish, if possible from wild sources, several times a week. For example, some studies reported benefits of consuming four or more portions of fish weekly.<sup>18</sup> In addition to the quantity of fish, the type of fish may also be influential with respect to outcomes.<sup>12</sup> Moreover, clinicians should be cognizant of the tendency of patients to over-report or overstate adherence to dietary recommendations. The populations studied tended to be better nourished and more highly educated than the general population, particularly in the AREDS<sup>6</sup> and the AREDS 2.<sup>14</sup> This might have biased the results of studies. Consequently, it seems logical to recommend supplements to people with nutritional deficiencies and risk factors for AMD, as well as for people living alone (who are often less well nourished) in the hope that outcomes will be superior to those expected in well-nourished patients.

Once supplementation is recommended, it is essential to assess adherence during follow-up visits. One should not assume that patients are always adherent to their prescribed regimen. Factors that may limit patient adherence to dietary supplementation include lack of perceived benefit (e.g., no effects on vision), cost of supplements, size of pills, frequency of dosing, and potential problems with tolerability (e.g., gastrointestinal discomfort). Eye care professionals should be prepared to discuss the reasons for recommending supplements and help their patients set reasonable goals. From the start, it should be made clear to patients that supplements do not improve vision but that they are meant to reduce the risk of progression to more advanced disease. The AREDS suggested that in patients with category 3 or 4 AMD who are generally well nourished, the risk of progression to advanced disease may be reduced by 25 to 30% with antioxidant supplementation.<sup>6</sup>

#### **INFORMATION FOR OTHER HEALTH CARE PROFESSIONALS**

Vitamin and nutritional supplements can have an impact on a patient's medication regimen. When in doubt, eye care professionals should seek advice from the pharmacist to better evaluate the risk of potential drug–nutrient interactions. Although there have been some concerns about the use of supplements in patients with existing renal dysfunction, in the clinical experience of this group of advisors, such problems have been uncommon. Patients should also be reminded to inform their family physician about any intake of vitamins or omega-3s, notably when taking other medications such as warfarin or antidiabetic drugs, since the dosage of these might need to be adjusted based on the patient's response to omega-3s.

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## RECOMMENDATIONS FOR OPTIMAL FREQUENCY OF FOLLOW-UP

Timing of follow-up is an important consideration because the optometrist needs to see the intermediate AMD patient at the right time to see progression of the disease. Like recommendations for supplements and diet, the frequency of follow-up should ideally be individualized to the patient's risk profile and needs. It was generally agreed that patients with milder cases of AMD (i.e., category 2 or lower) should be seen at least annually. The majority of patients with category 3 AMD should be monitored every 6 months and, in some cases, more often. Patients with NV AMD should be seen more frequently by their ophthalmologist (i.e., three or four times annually). Self-report of symptoms using the Amsler grid does not substitute for clinic visits, although it can complement the tools used for assessing the progression of disease. Finally, clinical visits represent an opportunity for optometrists to educate patients about modifiable risk factors, the importance of following clinical recommendations, and to modify the treatment and follow-up plan as needed.

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## EXAMINATION OF THE PATIENT WITH AMD

In a perfect world, optical coherence tomography (OCT) would be used to test all patients with AMD to monitor for progression to neovascular disease. However, given the limited resources, judicious use of this technology is necessary. It was suggested that a baseline OCT followed by annual testing might be appropriate in Category 3 or 4 patients with no new symptoms or complaints and without evidence of hemorrhage or exudate on clinical examination. OCT is not mandatory but is recommended in patients with dry AMD, especially if a visual acuity change occurs. Fundus photography is a good tool to document a patient's status and allow for easy evaluation of a patient's disease progression. In addition, it can be beneficial to show patients pictures of their eye examination, results of OCT, or both to help them understand their disease and its eventual progression and thereby promote greater adherence to the proposed treatment regimen.

For patients with category 1 or 2 AMD, use of the Amsler grid remains appropriate despite suboptimal sensitivity and specificity. This at-home test is particularly helpful for patients to self-evaluate the progression of their eye disease. Optometrists must remember to instruct patients to test one eye at a time.

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## CONCLUSION

The first step in the management of a patient with AMD is to identify the disease and determine its severity. Recommendations must be customized based on a patient's individual risk profile (i.e., age, gender, heredity, etc.) and severity of disease (i.e., category 1 to 4). There is no single formula that can be applied to all patients with or at risk of AMD.

Patients must, first and foremost, be encouraged to modify their diet and to eliminate modifiable risk factors such as smoking, sedentary lifestyle, excessive alcohol intake, and so on. The patient should be encouraged to exercise regularly. Medication adherence (for hypertension, hypercholesterolemia, diabetes, etc.) must be reinforced. Taking a supplement must not be a substitute for making healthy lifestyle changes.

Next, the optometrist should ensure that the patient's eyewear provides adequate protection against ultraviolet rays. Evidence to date supports the use of a daily high-dose antioxidant supplement consisting of vitamins C and E, carotenoids, and zinc (i.e., the AREDS 2 formula), to reduce the risk of progression from intermediate to advanced AMD. Optometrists should recommend this type of supplement to patients with category 3 or 4 AMD to mitigate the risk of disease progression. The benefits in patients with milder forms of AMD or in those who are at risk of developing the disease is less clear. In such cases, it could be beneficial to recommend an omega-3 supplement, and eventually vitamin supplements, based on the patient's diet quality. The results of observational studies, including those derived from the original AREDS study, suggest that omega-3 supplementation may help to prevent or slow the progression of disease in its early stage. This approach has biological plausibility, since omega-3 fatty acids are concentrated in the retina and have been shown to modulate retinal function.

On the basis of the recently reported AREDS 2 study, substitution of beta-carotene by lutein plus zeaxanthin seems reasonable, since these carotenoids have been shown to protect against AMD without the associated risk of lung cancer in smokers. Consequently, any patient who has previously been a smoker or been exposed to second-hand smoke should consider taking supplements that do not contain beta-carotene.

This group concluded that the full body of literature must be taken into consideration in order to justify clinical recommendations for patients. A single study cannot, by itself, guide clinical practice. In all cases, recommendations must be individualized and patients should be monitored regularly.

## ACKNOWLEDGEMENTS

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**Table 1.** Description of the Clinical Studies Discussed During the Round Table Meeting That Formed the Basis of Clinical Recommendations for Patients with AMD

Study	Trial Design	Participants	Primary Objective	Results	Potential Biases	Conclusions
Dietary Intake Studies						
<b>CAREDS: lutein and zeaxanthin</b> <sup>7</sup>	Observational study; sub-study of the Women's Health Initiative (WHI)	1787 women aged 50 to 79 years with intake of lutein plus zeaxanthin above the 78th (high) and below the 28th (low) percentile at baseline	To evaluate the relationship between dietary lutein plus zeaxanthin and intermediate AMD during a 7-year follow-up	No significant association in the total group (odds ratio [OR] 0.96; 95% confidence interval [CI] 0.75–1.23). Protective effects in women aged <75 years (OR 0.57; 95% CI 0.34–0.95)	Food frequency questionnaire subject to recall bias 36% of eligible participants declined Unknown effects of intake of other nutrients Numerous confounders	A diet rich in lutein plus zeaxanthin may protect against intermediate AMD in healthy women younger than 75 years
<b>CAREDS: dietary fats</b> <sup>11</sup>	Observational study; sub-study of the Women's Health Initiative (WHI)	1787 women aged 50 to 79 years with high and low lutein intake at baseline	To evaluate the relationships between the amount and type of dietary fat and intermediate AMD	Intakes of omega-6 and omega-3 fatty acids were associated with a two-fold higher prevalence of intermediate AMD in high versus low quintiles Intake of monounsaturated fats was associated with a lower prevalence	Food frequency questionnaire subject to recall bias 36% of eligible participants declined Unknown effects of intake of other nutrients Numerous confounders	These results support a growing body of evidence suggesting that diets high in several types of fat may contribute to the risk of intermediate AMD Diets high in monounsaturated fats may be protective
<b>Nurses' Health Study: dietary fat</b> <sup>18</sup>	Prospective follow-up study of participants in the Nurses' Health Study and the Health Professionals Follow-up Study	42,743 women and 29,746 men aged ≥50 years with no diagnosis of AMD at baseline	To prospectively examine the association between fat intake and AMD	567 developed AMD during a follow-up of 10 to 12 years The relative risk for the highest versus the lowest quintile of total fat intake was 1.54 (95% CI 1.17–2.01) Other dietary fats: omega-6 (relative risk [RR] 1.49; 95% CI 1.15–1.94) DHA (RR 0.70; 95% CI 0.52–0.93) >4 servings of fish/wk (RR 0.65; 95% CI 0.46–0.91)	Food frequency questionnaire subject to recall bias Inaccurate classification of types of dietary fats	Total fat intake was positively associated with risk of AMD, which may have been caused by intakes of individual fatty acids such as omega-6, rather than to total fat intakes per se A high intake of fish may reduce the risk of AMD
<b>Rotterdam Study: antioxidants</b> <sup>8</sup>	Prospective cohort study	4120 adults aged 55 years or older in a middle-class suburb of Rotterdam at risk of AMD	To investigate whether regular dietary intake of antioxidants is associated with a lower risk of incident AMD	560 participants (13.4%) developed incident AMD after a mean follow-up of 8 years Dietary intake of both vitamin E and zinc was inversely associated with incident AMD An above-median intake of beta-carotene, vitamins C and E, and zinc, was associated with a 35% reduced risk of AMD Exclusion of supplement users did not affect the results	Food frequency questionnaire subject to recall bias Questionnaire evaluated "typical" intake of nutrients only during the previous year	A high dietary intake of beta-carotene, vitamins C and E, and zinc was associated with a substantially reduced risk of AMD in older adults

Study	Trial Design	Participants	Primary Objective	Results	Potential Biases	Conclusions
<b>Rotterdam Study: antioxidants, zinc and omega-3s<sup>8</sup></b>	Prospective, nested case-control study from the population-based Rotterdam Study	2,167 individuals aged 55 years and older with genetic risk factors for AMD.	To investigate whether dietary nutrients can reduce the genetic risk of early AMD conferred by the genetic variants CFHY402H and LOC387715 A69S	517 participants developed early AMD during a median follow-up of 8.6 years High dietary intakes of zinc, beta-carotene, lutein/zeaxanthin, and EPA/DHA significantly reduced the risk of early AMD by 25% in carriers of genetic variants	Relatively fewer cases of incident AMD (fewer than expected) Only two genetic variants were studied—were they the right ones? Unknown effects of other environmental risk factors	High dietary intake of nutrients with antioxidant properties reduces the risk of early AMD in those at high genetic risk Clinicians should provide dietary advice to young susceptible individuals to postpone or prevent AMD
<b>Christen Study: omega-3s and fish<sup>2</sup></b>	Large, prospective cohort study	38,022 female health care professionals with a mean age of 54.6 years without AMD at baseline	To examine whether intake of omega-3 fatty acids and fish affects the incidence of AMD in women	235 cases of AMD were confirmed during an average of 10 years of follow-up Women with the highest tertile of intake for DHA, compared with those in the lowest (RR 0.62; 95% CI 0.44–0.87) For EPA (RR 0.66; 95% CI 0.48–0.92) Intake of $\geq 1$ fish servings/wk versus $< 1$ (RR 0.58; 95% CI 0.38–0.87) Higher ratio of DHA to EPA offers protection against the negative effects of high dietary intake of omega-6 fatty acids	Low number of early stage AMD cases Women with a history of cardiovascular or cerebrovascular disease, cancer, or other major chronic diseases were excluded Generalizability? Numerous confounders	Regular consumption of DHA and EPA and fish was associated with a significantly decreased risk of incidence AMD and may be of benefit in primary prevention of AMD
Dietary Supplement Studies: The AREDS Studies						
<b>AREDS 8: antioxidants<sup>6</sup></b>	Multicentre, double-masked, randomized clinical trial with four treatment groups: vitamins C (500 mg), E (400 IU) and beta-carotene (15 mg); zinc (80 mg)/copper (2 mg); antioxidants plus zinc / copper; placebo	3640 participants aged 55 to 80 years with AMD of Categories 1 to 4	To evaluate the effect of high-dose vitamins C and E, beta-carotene and zinc supplements on AMD progression and visual acuity	Significant odds reduction for the development of advanced AMD over an average follow-up of 6.3 years for antioxidants + zinc (OR 0.72; 99% CI 0.52–0.98) Participants with Category 3 or 4 AMD had a 25% relative risk reduction for the progression to advanced AMD	Mortality rate was 50% lower in the population studied versus the general population—generalizability to other populations? Colour fundus photography underestimates the true incidence of advanced AMD compared to fluorescein angiography 67% of participants took a multivitamin supplement (e.g., Centrum) during the study Relatively well-nourished population	Persons older than 55 years with Category 3 or 4 AMD and without contraindications such as smoking should consider taking a supplement of antioxidants plus zinc such as that used in this study

Study	Trial Design	Participants	Primary Objective	Results	Potential Biases	Conclusions
<b>AREDS 20: dietary lipid intake<sup>9</sup></b>	Prospective case control study; part of the AREDS randomized controlled trial	4519 participants in the AREDS study aged 60 to 80 years at enrollment provided estimates of habitual nutrient intake through a self-administered semiquantitative food frequency questionnaire.	To evaluate the association of lipid intake with baseline severity of AMD in the AREDS	Dietary omega-3 fatty acid intake was inversely associated with neovascular (NV) AMD (OR 0.61; 95% CI 0.41–0.90) Higher fish consumption was also inversely associated with NV AMD Dietary omega-6 was directly associated with NV AMD prevalence (OR 1.54; 95% CI 1.04–2.29) No statistically significant relationships existed for incidence of geographic atrophy (GA) AMD.	Potential selection of non-nutritional factors associated with risk of NV AMD Food frequency questionnaire subject to recall bias Participant selection bias Dietary intakes could be influenced by other socioeconomic and demographic factors	Higher intake of omega-3 fatty acids and fish was associated with decreased likelihood of having NV AMD The ratio of dietary omega-3/omega-5 intakes may be important
<b>AREDS 30: dietary intake of omega-3s during 12 years of follow-up<sup>10</sup></b>	Nested cohort study within the AREDS multicentre phase 3 clinical trial	1,837 participants at moderate to high risk of AMD.	To investigate whether omega-3 fatty acid intake was associated with a reduced likelihood of developing central GA AMD and NV AMD	364 cases of GA and NV AMD were reported during 12 years of follow-up (19.8 %). Participants who reported the highest omega-3 intake were 30% less likely to develop GA AMD (OR 0.65; 95% CI 0.45–0.92) and NV AMD (OR 0.68; 95% CI 0.49–0.94)	Observational study therefore effects of other risk factors unknown High intakes of omega-3 rich foods could be linked with a generally healthier lifestyle Dietary intake of omega-3s was reported relative to total caloric intake rather than total quantity in grams	The 12-year incidence of GA and NV AMD in participants at moderate-to-high risk of these outcomes was lowest for those reporting the highest consumption of omega-3 fatty acids
<b>AREDS 2: lutein + zeaxanthin and omega-3s<sup>4</sup></b>	Phase 3 multicentre, randomized, double-masked, placebo-controlled study with a 2 × 2 factorial design. Treatment groups (primary randomization): lutein (10 mg) + zeaxanthin (2 mg), DHA (350 mg) + EPA (650 mg), both, or placebo. Secondary randomization: elimination of beta-carotene, reduction of zinc dose, both, or placebo (AREDS formula)	4,203 participants aged 50 to 85 years (mean age 73.1 years) at risk of progression to advanced AMD	To determine whether adding lutein + zeaxanthin, DHA + EPA, or both to the AREDS formulation decreases the risk of developing advanced AMD and to evaluate the effect of eliminating beta-carotene, lowering zinc doses, or both in the AREDS formulation	1608 participants progressed to advanced AMD during a median follow-up of 5 years There was no significant difference between treatment groups in the primary analyses and no apparent effect of beta-carotene elimination or lower-dose zinc on progression to advanced AMD Secondary analysis: 10% risk reduction in participants receiving lutein + zeaxanthin versus no lutein + zeaxanthin ( $p = 0.05$ ). Subgroup analysis: participants with the lowest quintile of dietary lutein + zeaxanthin had a 26% lower risk of progression with lutein + zeaxanthin supplementation vs no lutein + zeaxanthin ( $p = 0.01$ ). Lutein + zeaxanthin reduced the risk of NV AMD by 10% ( $p = 0.05$ ) There was a higher rate of lung cancer in former smokers receiving beta-carotene versus no beta-carotene	The dose of omega-3s was based on cardiovascular studies—is this the optimal dose to prevent progression to advanced AMD? Was the study duration adequate to observe protective effects? 44% of participants were taking a statin—could this interfere with absorption of DHA + EPA?	Addition of lutein + zeaxanthin, DHA + EPA, or both to the AREDS formulation in primary analyses did not further reduce risk of progression to advanced AMD However, because of potential increased incidence of lung cancer in former smokers, lutein + zeaxanthin could be an appropriate carotenoid substitute in the AREDS formulation

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# Refining Decisions for Identifying Primary Care Patients Who Require A Work-Up for Glaucoma: Intraocular Pressure Changes with Central Corneal Thickness

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## Abstract

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### PURPOSE

The factors associated with the increased risk of glaucoma include intraocular pressure (IOP), central corneal thickness (CCT), vertical cup-to-disc ratio, visual field index, age, and diabetes mellitus. We have investigated the relation of IOP with CCT in normal, healthy pre-presbyopic persons.

### METHODS

A total population of 698 normal patients (1396 eyes), aged 4 to 40 years, were evaluated in two separate clinics, one in Houston, Texas, USA and the second in Oakville, Ontario, Canada. IOP was measured using a noncontact tonometry (NCT 20 Topcon). In Houston, CCT was determined by using the Pentacam (Oculus Pentacam – Belinea) and an optical pachymetry that utilized optical low-coherence reflectometry (OLCR) technology, and in Oakville, a Hagg-Streit slit lamp-mounted pachymeter was used.

### RESULTS

Of the total number of eyes tested, 1226 eyes had IOP of 21 millimetres of mercury (mm Hg) or lower and 134 eyes had IOP greater than 21 mm Hg. For the normal IOP group ( $n = 1226$  eyes), the overall IOP mean was 15.63  $\pm$  2.87 mm Hg; the overall CCT mean was 550.21  $\pm$  39.64 micrometres ( $\mu\text{m}$ ). In the normal IOP group, for every 10  $\mu\text{m}$  change in CCT, IOP changed a statistically significant amount of 2.49 mm Hg ( $p < 0.05$  to  $< 0.001$ ), except for the 10 nm CCT bins above and below the 550  $\mu\text{m}$  mean.

### CONCLUSIONS

Although many investigators have described a positive correlation between IOP and CCT, this relationship has not been demonstrated in normal, healthy pre-presbyopic persons. There is a significant change of IOP with CCT (2.49 mm Hg IOP change per 100  $\mu\text{m}$  of CCT). These normative data allow primary eye care clinicians to accurately determine normal and abnormal IOP and refine the index of suspicion for identifying patients who need to be worked up for glaucoma.

### KEY WORDS:

central cornea thickness, intraocular pressure, noncontact tonometry, glaucoma

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## Sommaire

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**BUT**

Les facteurs associés à un risque accru de glaucome comprennent la pression intraoculaire (PIO), l'épaisseur cornéenne centrale (ECC), le rapport cup/disc vertical, le relevé de champ visuel, l'âge et le diabète sucré. On a étudié la relation entre la PIO et l'ECC chez des personnes normales et en bonne santé ayant une prépresbytie.

**MÉTHODES**

On a évalué un nombre total de 698 patients normaux (1 396 yeux), âgés de 4 à 40 ans, dans deux cliniques distinctes : l'une à Houston, au Texas, aux États Unis, l'autre à Oakville, en Ontario, au Canada. On a mesuré la PIO à l'aide d'un tonomètre sans contact (NCT 20 de Topcon). À Houston, on a déterminé l'ECC au moyen d'une Pentacam (Pentacam d'Occulus – Belinea) et d'un pachymètre optique ayant recours à la technologie de la réflectométrie à faible cohérence optique (RFCO); à Oakville, on a utilisé un pachymètre avec lampe à fente de Hagg Streit.

**RÉSULTATS**

Parmi tous les yeux examinés, 1 226 yeux présentaient une PIO de 21 millimètres de mercure (mm Hg) ou moins, et 134 yeux avaient une PIO supérieure à 21 mm Hg. Pour le groupe ayant une PIO normale ( $n = 1\ 226$  yeux), la moyenne de la PIO globale était de 15,63 mm Hg,  $\pm 2,87$  mm Hg. La moyenne de l'ECC globale était de 550,21 micromètres ( $\mu\text{m}$ ),  $\pm 39,64 \times\text{m}$ . Dans le groupe ayant une PIO normale, pour chaque variation de 10 nanomètres (nm) de l'ECC, la PIO changeait d'une quantité statistiquement significative, à savoir 0,249  $\mu\text{m}$  ( $p < 0,05$  à  $< 0,001$ ), sauf pour les compartiments de l'ECC de 10 nm inférieurs ou supérieurs à la moyenne de 550  $\mu\text{m}$ .

**CONCLUSION**

De nombreux chercheurs ont décrit une corrélation positive entre la PIO et l'ECC, mais cette relation n'a pas été démontrée chez des personnes normales en bonne santé ayant une prépresbytie. Il existe une variation significative de la PIO en fonction de l'ECC (variation de la PIO de 2,49 mm Hg par 100  $\mu\text{m}$  d'ECC). Ces données normatives permettent aux techniciens en soins oculovisuels primaires de déterminer une PIO normale et anormale et d'affiner l'indice de suspicion servant à identifier les patients devant faire l'objet d'analyses concernant un glaucome. être personnalisées. Une seule étude, comme AREDS 2, bien que très importante, ne peut déterminer à elle-seule le comportement clinique des professionnels de la vue. L'importance du suivi régulier du patient doit également être comprise par tous.

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**M**any investigators have described a positive correlation between IOP and CCT.<sup>1-23</sup> Others have provided a CCT-correction factor for IOP; taking all of the data of these studies together, the average correction factor for IOP is 2.6 mm Hg per 100  $\times\text{m}$  CCT with a range of 0.0 to 6.3 mm Hg.<sup>4,9,24-34</sup> See **Table 1**.

Although the relationship between IOP and CCT has been studied in various populations, a wide range of IOP cases have not been investigated in large numbers of normal healthy pre-presbyopic subjects in North America (USA and Canada) using standard clinical screening measures of IOP (non-contact tonometry or NCT). What is not well delineated is an answer to a general research question: Can the index of suspicion for identifying primary care patients who require a workup for glaucoma be refined by determining a CCT-corrected IOP measured by NCT?

**Table 1.** Studies Quantifying the Relationship between Intraocular Pressure (IOP) and Central Corneal Thickness (CCT)

STUDY		SUBJECTS		METHODOLOGY and RESULTS						CLINICAL GUIDELINE
Year	Author(s)	Eyes	Other	Tonometry (mm Hg)			Pachymetry - Central Corneal Thickness (µm)			IOP change per 100 nm change in CCT
		(n)		Type	(mean)	(sd)	Type	(mean)	(sd)	(mm Hg per 100 nm)
1975	Elhers et al <sup>32</sup>	29	Normal cornea; no edema; intraocular cataract or glaucoma surgery	Goldmann applanation	n/a	n/a	Optical: Hagg-Streit slit lamp-mounted	n/a	n/a	6.3
1978	Johnson et al <sup>33</sup>	2	One (1) 17-year-old female; normal cornea	Cannulated <sup>†</sup>	11.0	n/a	n/a	900	n/a	5.0
				Perkins applanation	35.0					
				Schiotz applanation	34.0					
1993	Whitacre et al <sup>34</sup>	15	Normal cornea; intraocular cataract, glaucoma or vitrectomy surgeries	Perkins applanation simultaneous with manometry controlled IOP's of 10, 20 & 30 mm Hg	n/a	n/a	Optical: Hagg-Streit slit lamp-mounted or ultrasound: Topcon	n/a	n/a	2.5
1997	Wolfs et al <sup>12</sup>	Age 55 yr. or older	>55 yr; normal cornea; eye surgery >12 months ago	Goldmann applanation (assumed)			Ultrasound			1.9
		352	Control		14.6	n/a		537.4	n/a	
		13	Ocular hypertensive		18.7	n/a		553.4	n/a	
		30	Primary open angle glaucoma		14.3	n/a		515.9	n/a	
1998	Foster et al <sup>17</sup>	2456	Ages 10 to 87 yr.; East Asian Mongolian population	Goldmann applanation	12.7	3.4	Optical: Hagg-Streit slit lamp-mounted	504.5	32	2.1

Table 1 continued

Studies Quantifying the Relationship Between Intraocular Pressure and Central Corneal Thickness

STUDY		SUBJECTS		METHODOLOGY and RESULTS						CLINICAL GUIDELINE
Year	Author(s)	Eyes	Other	Tonometry (mm Hg)			Pachymetry - Central Corneal Thickness (µm)			IOP change per 100 nm change in CCT
		(n)		Type	(mean)	(sd)	Type	(mean)	(sd)	(mm Hg per 100 nm)
2001	Feltgen et al <sup>35</sup>	73	Intraocular glaucoma or retinal surgery; ages 13 to 88 yrs., mean = 40.7	Intracameral cannula	19.5	6.5	Ultrasound	580	54	0.0
				Perkins applanation	17.5	6.5				
				Tono-Pen	18.7	7.2				
2001	Singh et al <sup>36</sup>	23	Control	Goldmann applanation/ pneumotonometry	15.7 / 14.1	1.8/ 2.3	Ultrasound	554	32	2.0
		41	Ocular hypertensive		24.6/ 20.5	2.1/2.9				
		10	Normal pressure glaucoma		15.7/ 14.9	2.9/2.7				
		13	Primary open angle glaucoma		27.5/ 22.8	5.1/5.0				
2002	Bhan et al <sup>37</sup>	181	Normal cornea	Tono-pen	14.7	5.0	Ultrasound	551	49	1.0
				Goldmann applanation	14.4	4.9				2.3
				Ocular Blood Flow (OBF) pneumotonometry	16.4	6.4				2.8
2002	Doughty et al <sup>38</sup>	104	Normal cornea; European; ages 5 to 15 yr.	Noncontact	16.7	2.9	Ultrasound & specular microscopy	529	34	2.5
		75	Normal cornea; European; ages 32 to 60 yr.	Perkins applanation	13.0	3.5				
		91	Normal cornea; European; ages 61 to 82 yr.	Perkins applanation	13.6	2.5	Ultrasound	527	34	4.9

Table 1 continued

Studies Quantifying the Relationship Between Intraocular Pressure and Central Corneal Thickness										
STUDY		SUBJECTS		METHODOLOGY and RESULTS						CLINICAL GUIDELINE
Year	Author(s)	Eyes	Other	Tonometry (mm Hg)			Pachymetry - Central Corneal Thickness ( $\mu\text{m}$ )			IOP change per 100 nm change in CCT
		(n)		Type	(mean)	(sd)	Type	(mean)	(sd)	(mm Hg per 100 nm)
2006	Kohlhaas et al <sup>39</sup>	125	Normal cornea; ages 18 to 91 yr, mean = 72.9 + 13.2; cataract surgery; masked, prospective clinical trial	Perkins applanation simultaneous with manometry controlled IOPs of 20, 35 and 50 mm Hg	n/a	n/a	Ultrasound	569	44	4.0
2011	Heidary et al <sup>40</sup>	180	Normal cornea; ages 8 to 16 yr.; Malay population	Noncontact	15.7	3.1	Specular microscope	530.9	31	3.5
2012	Sakalar et al <sup>41</sup>	30,320	Normal cornea; ages 8 to 16 yr.; Turkish population	Noncontact	14.2	2.9	Ultrasound	558.3	34	0.2
2012	Fern et al <sup>42</sup>	670	Normal cornea; ages 17 to 22 yr.; The COMET Study Group	Goldmann applanation	15.1	0.1 SE	Ultrasound	562.4	1.8 SE	2.0
Average = 2.6										

\*Cannulated tonometry means cannulation of anterior chamber of eye and manometric determination of intraocular pressure (IOP).  
 OHT - ocular hypertensive subject  
 POAG - primary open-angle glaucoma  
 SE- standard error

This question is important because in general, the most commonly used screening measure of IOP is the NCT. In a population-based prevalence survey of more than 5000 individuals aged 40 years and over, participants who had a screening IOP greater than 30 mm Hg were over 38 times more likely to have glaucoma (as defined in the study) compared with individuals with an IOP below 15 mm Hg.<sup>35</sup> In the Blue Mountains Eye Study, the odds of developing glaucoma were four to seven times higher when the screening IOP was greater than 21 mm Hg than in those with lower IOP.<sup>36</sup> Further, the chances of developing glaucoma is two to eight times higher in patients with IOP asymmetry between eyes greater than 3 mm Hg than in patients with smaller or no intraocular pressure asymmetry.<sup>37</sup> Thus, although the level of IOP is directly related to the probability of glaucomatous visual field loss, it is not currently known how the use of the screening NCT relates to CCT.

Further, research indicates that CCT-corrected IOP formula seems to oversimplify the relationship of a “true” IOP based on pachymetry measurement. Currently, CCT results are commonly classified as thin, average, or thick.<sup>38</sup> The Ocular Hypertensive Treatment Study (OHTS) showed that CCT was a significant predictor of which patients with ocular hypertension are at higher risk for converting to glaucoma (eyes with CCT of 555  $\mu\text{m}$  or less had a threefold greater risk of developing glaucoma compared with eyes that had CCT of more than 588  $\mu\text{m}$ ).<sup>18</sup>

In a study using CCT-corrected IOP, the OHTS prediction model did not perform better than the original model (without the CCT-corrected IOP), and analysis showed that CCT continued to be a statistically significant predictor in the multivariate model (**Table 2**).<sup>39</sup> CCT is a predictor of ocular hypertension converting to glaucoma, which is not fully explained by a CCT-corrected IOP adjustment. CCT is not to be considered a true independent risk factor for glaucoma.<sup>40</sup>

The validity of CCT-corrected IOP is based on the accuracy and precision of these measurements. Accuracy is the degree of closeness of a measured quantity to its true value. Precision (reproducibility or repeatability), which is closely related to accuracy, is the degree to which repeated measurements show similar results.<sup>41</sup>

The cornea, which is the most anterior tissue of the eye, is a transparent curved tissue, which vaults over the iris, pupil, and anterior chamber.<sup>42</sup> The cornea refracts light with the crystalline lens to focus images on the retina; the cornea accounts for approximately two-thirds of the eye's

**Table 2.** Central Corneal Thickness (CCT) Groups with Mean IOP and Statistical Analysis for the Normal IOP Group (7 – 20 mm Hg)

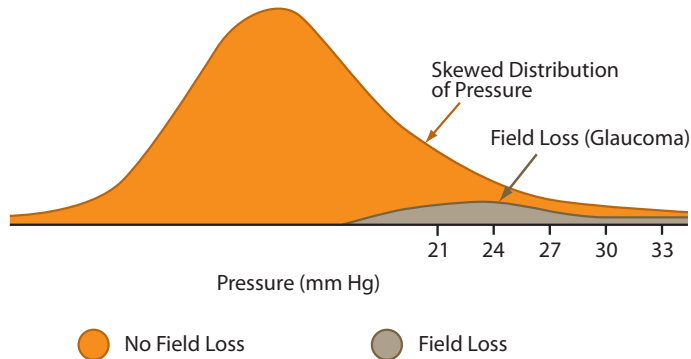
Row	Number of Eyes	Range CCT (µm)	CCT Group	Mean IOP (mm Hg)	SD	Standard Error of the Mean	t-value	Significance (p)	Degrees of Freedom (df)
1 <sup>c</sup>	9	359–454	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2 <sup>b</sup>	8	455–464	460	12.75	3.01	1.06	2.56	<0.01	113
3 <sup>b</sup>	8	465–474	470	13.13	3.72	1.32	1.81	<0.05	113
4	23	475–484	480	14.15	2.17	0.45	2.71	<0.01	128
5	34	485–494	490	12.68	2.73	0.47	5.41	<0.001	139
6	62	495–504	500	14.77	2.77	0.35	1.81	<0.05	167
7	62	505–514	510	14.44	2.77	0.35	2.57	<0.02	167
8	116	515–524	520	14.42	2.24	0.21	3.48	<0.001	221
9	114	525–534	530	14.84	3.13	0.29	1.84	<0.05	219
10	112	535–544	540	15.43	2.94	0.28	0.32	>0.5	217
11 <sup>a</sup>	107	545–554	550	15.55	2.58	0.25	0.00	>0.5	212
12	136	555–564	560	16.07	2.69	0.23	-1.53	>0.05	241
13	109	565–574	570	16.23	2.38	0.23	-2.01	<0.05	214
14	103	575–584	580	16.85	2.48	0.24	-3.72	<0.001	208
15	77	585–594	590	17.04	2.46	0.28	-3.97	<0.001	182
16	45	595–604	600	16.43	2.71	0.40	-1.85	<0.05	150
17	29	605–614	610	16.83	2.88	0.53	-2.17	<0.05	134
18	26	615–624	620	17.63	2.26	0.44	-4.09	<0.001	131
19 <sup>b</sup>	17	625–634	630	18.00	2.32	0.56	-3.98	<0.001	122
20 <sup>b</sup>	13	635–644	640	18.36	1.84	0.51	-4.95	<0.001	118
21 <sup>b</sup>	7	645–654	650	17.21	2.38	0.90	-1.78	<0.05	112
22 <sup>c</sup>	9	655–701	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Total = 1226									

<sup>a</sup>Mean CCT group

<sup>b</sup>CCT groups with less than 20 eyes

<sup>c</sup>CCT groups with less than 7 or no eyes

**Figure 1.** In this diagram of intraocular pressure distribution there is a visible skew toward higher pressures (exaggerated slightly compared to the actual distribution). The average pressure among those with glaucomatous visual field loss is in the low 20s, even though glaucoma is not present in most individuals with similar pressures. And, although it is not common, some individuals with pressures in the upper teens have glaucomatous visual field loss.



total optical power.<sup>43</sup> The adult CCT of approximately 540  $\mu\text{m}$  is reached by the age of 3 years<sup>1,2</sup> and remains stable throughout life.<sup>3,44</sup> The accuracy and precision of CCT measurement vary slightly with different instruments.<sup>45-52</sup>

IOP is the fluid pressure in the eye measured in millimetres of mercury. IOP is mainly determined by the coupling of the production of aqueous humour from the eye's ciliary body and its drainage through the anterior chamber angle, specifically the trabecular meshwork and Schlemm's canal. The normal range for IOP is 10 to 21 mm Hg, with a mean of 15.5 mm Hg.<sup>53</sup> Clinically, IOP is measured with a Goldmann applanation tonometer or, more commonly, its derived successor, the noncontact (air-puff) tonometer (NCT). Corneal thickness and rigidity influence IOP, according to the Imbert-Fick law. This law states that the force to applanate the anterior corneal surface is equal to the true IOP times the applanated area at the posterior corneal surface, assuming the cornea is 520  $\mu\text{m}$  thick.<sup>54,55</sup> Corneal indentation produced by a fixed force depends on many factors, including CCT, elasticity, and viscoelasticity, as well as other structural and physiological properties of the cornea. IOP is maintained throughout life. It is similar between the genders, and diurnal and some seasonal variations may exist.<sup>56</sup> The IOP distribution in the general population is not a normal Gaussian distribution but is skewed toward higher pressures, where an associated increase in visual field loss is often present (**Figure 1**).<sup>57</sup> IOP measurement has been shown to be accurate and precise with a number of instruments, including NCT, which may be used as a screening device for IOP measurement.<sup>58-64</sup>

The challenge is investigating IOP with the use of screening devices available in a primary eye care setting (NCT) and determining the relationship between IOP and CCT in normal healthy pre-presbyopic persons.

Taken together, answers to our specific research question—is there a difference in intraocular pressure, as measured with a screening NCT, with varying central corneal thickness in a normal healthy pre-presbyopic population?—and our research objective—to provide data for young normal patients, gathered using screening IOP measuring devices available in a primary eye care setting (NCT), which delineate the relationship between IOP and CCT—will allow routine clinical measures to refine the index of suspicion for identifying primary care patients who require a workup for glaucoma.

## METHODS

In the Houston–Oakville study, a total of 698 normal healthy pre-presbyopic patients (1396 eyes) were evaluated in two separate clinics located in Houston, Texas (USA) and Oakville,

Ontario (Canada). After written informed consent was obtained, data collected included each patient's age, race (by self-report), gender, date of birth, IOP, and CCT.

In Houston, consecutive patients were included from the date of study onset. In Oakville, patients were selected on the basis of willingness to undergo the Optos examination. Young normal subjects aged 4 to 40 years were included. Patients aged 4 years or less (due to lack of cooperation) and those over age 41 years (who were more at risk for glaucoma due to their age) were excluded. Data from a few patients were not included due to inability to procure accurate anterior segment assessment with the Pentacam. Patients with glaucoma (visual field defects, visible optic disc damage, or nerve fiber layer thinning) and those who had undergone Lasik or corneal transplant surgeries were also excluded.

### Intraocular Pressure

NCT, with the Topcon CT-20 auto-NCT, was performed on all patients, at both clinics in the United States and Canada. NCT utilizes an applanation tonometer, which works on the principle of a time interval. It determines IOP by measuring the time in milliseconds from the initial generation of the puff of air to the time when the cornea is flattened exactly to the point where the timing device stops. Patients with all IOP levels were included. NCT use allowed the findings of this study to be generalized to routine clinical vision care.

### Central Corneal Thickness

In Houston, the Pentacam (Oculus Pentacam – Belinea) was used for every patient to determine CCT. The Pentacam is an instrument that uses a rotating Scheimpflug camera to take multiple images of the anterior segment. The centre of the cornea is precisely measured with this rotational imaging process. Measurements take less than 2-seconds apart, and minute eye movements are captured and simultaneously corrected. Images are analyzed by a computer to generate three-dimensional images and calculate the measurements of the eye, including corneal topography, corneal thickness, AC depth, volume, angle, and pupil diameter. In Oakville, a Hagg-Streit slit-lamp mounted optical-pachymeter was used to determine corneal thickness; the Hagg-Streit optical-pachymeter utilizes OLCR (optical low-coherence reflectometry) technology.

## RESULTS

From the Houston–Oakville study capture of 698 patients (1396 eyes), complete data were obtained to evaluate 1360 eyes. Of those 1360 eyes, 1226 eyes had normal IOP (range 7–21 mm Hg), with 514 eyes of male subjects ( $n = 257$ , average age 17.01  $\pm$  16.3, range 5–40) and 712 eyes of female subjects ( $n = 356$ ; average age 20.61  $\pm$  9.65, range 4–39).

Of the 1360 eyes with complete data:

- Average IOP equalled 16.05  $\pm$  3.31 mm Hg
- Average CCT equalled 551.75  $\pm$  40.26  $\mu$ m

Of the 1226 eyes with normal IOP (range 7–21 mm Hg):

- Average IOP equalled 15.63  $\pm$  2.87 mm Hg
- Average CCT equalled 550.21  $\pm$  39.64  $\mu$ m

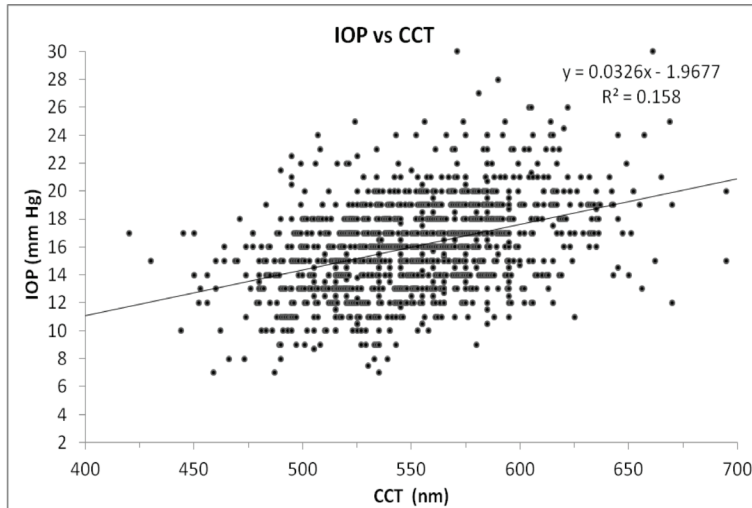
Of the 134 eyes with high IOP ( $>21$  mm Hg):

- Average IOP equalled 22.48  $\pm$  3.13 mm Hg
- Average CCT equalled 583.75  $\pm$  43.49  $\mu$ m.

For the 1360 eyes with complete data, IOP increased with increased CCT as seen in the scatter plot of **Figure 2**. The R-squared value is 0.158, which indicates that about 16% of the variance in measured IOP is associated with changes in CCT and that the other 84% of the variance is attributable to other factors (race, age, idiopathic, etc.). The slope of the scatter plot in **Figure 2** is the correlation coefficient R, which is 0.397; this indicates that measured IOP and CCT are mildly correlated.



**Figure 2.** For our young normal pre-presbyopic population (n = 1360 eyes) this figure shows the scatter plot of intraocular pressure (IOP) versus central corneal thickness (CCT) measurements. The slope of the scatter plot is the correlation coefficient r which is 0.397; this indicates that the measured IOP and CCT are mildly correlated. The square of the correlation coefficient ( $r^2=0.158$ ) indicates the percentage of variance in IOP that can be accounted for by knowing the CCT; that is, about 16% of the variance in measured IOP is associated with changes in CCT and the other 84% of the variance is attributable to the other factors (race, age, idiopathic, etc).



**Table 3.** Intraocular Pressure Increases with an Increase in Central Corneal Thickness

CCT Group	Rows from Table 2	CCT Range	Change in IOP	Change in IOP per 100 nm change in CCT
480 to 620	4 to 18	140	3.48	2.49
460 to 650	2 to 21	190	4.46	2.35

**Figure 3.** For our young normal pre-presbyopic population (n = 1360 eyes), 1226 eyes had normal intraocular pressure (IOP equal or less than 21 mm Hg) which are included in this plot. The graph shows the average IOP (mm Hg) for each of the CCT-groups and corresponding standard deviation (SD) bars (+/-1 SD). See Table 2 for supporting data.

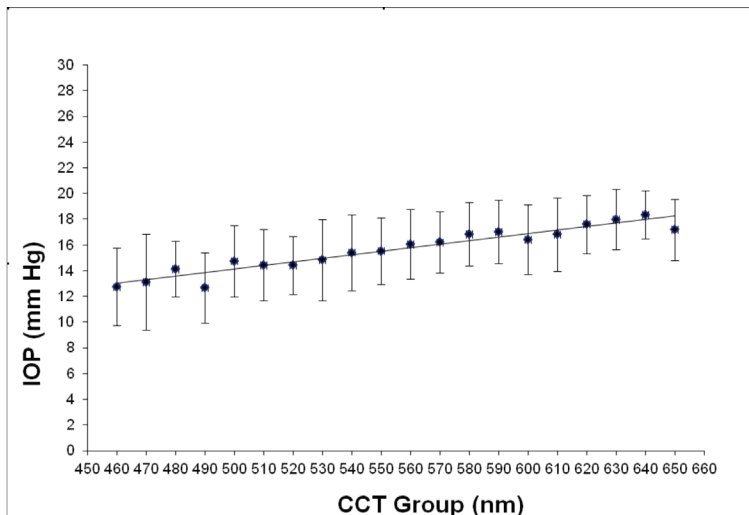


Table 4a. Young Adult Data

Young Normal (IOP ≤21)			High IOP* (IOP >21)		Asian (IOP ≤21)		Black (IOP ≤21)		Hispanic (IOP ≤21)		Other (Pakistani and Indian Descent) (IOP ≤21)		Caucasian (IOP ≤21)	
N =	Total	613	Total	81	Total	36	Total	178	Total	151	Total	82	Total	166
	Male	257	Male	31	Male	19	Male	62	Male	71	Male	34	Male	71
	Female	356	Female	50	Female	17	Female	116	Female	80	Female	48	Female	96
Eyes N =		1226		134		72		356		302		164		332
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Age	18.81	12.98	13.63	5.52	21.28	9.96	19.03	9.56	17.59	8.90	16.82	8.33	21.18	9.62
Intraocular pressure (IOP)	15.63	2.87	22.48	3.13	15.09	2.61	15.66	2.93	16.23	2.81	15.99	2.99	15.13	2.98
Central Corneal thickness (CCT)	550.21	39.64	583.75	42.49	550.64	34.59	537.36	37.81	560.61	39.85	553.25	37.45	553.51	39.20

\*Included in the high IOP group are 1 Asian, 18 Black, 20 Hispanic, 35 Other, and 7 Caucasian who are not included in the respective Ethnicity columns.

Table 4b. t-Test Comparison

Race	IOP	CCT
CxO	0.02	
CxH	0.001	
CxB		0.001
CxA		
CxOverAll		
OxH		
OxB		0.001
OxA		
HxB		0.001
HxA	0.02	
BxA		0.05

High IOP versus Normal IOP

IOP	CCT
	0.01
	Thicker

High IOP thicker cornea

Figure 3 was derived by selecting those eyes (n = 1226) with normal IOP (7–21 mm Hg) and then averaging the IOP for various CCT ranges or CCT groups. For example, the CCT group of 510 µm, IOP values of eyes (n = 62) with corneal thickness ranges from 505 to 514 µm were averaged; for the CCT group of 520 µm, IOP values of eyes (n = 116) with corneal thickness ranges from 515 to 524 µm were averaged. The mean IOP of each CCT group above or below the mean CCT group of 550 µm was significantly different at the 0.05 level. Table 3 summarizes the change in IOP over a range of CCT measurements from the data in Table 2. For rows 4 to 18, which correspond to CCT groups 480 to 620 µm with 20 or more eyes, the change in IOP over the 140-µm CCT range was 3.48 mm Hg, hence a 2.49-mm Hg change per 100 µm of CCT. For rows 2 to 21, which correspond to CCT groups 440 to 650 µm with seven or more eyes, the change in IOP over the 190-µm CCT range was 4.46 mm Hg, hence a 2.35 mm Hg change in IOP per 100 µm of CCT.

Several parameters were different in the comparison of the various groups (see **Table 4**).

At the 0.02 level or higher:

- Asian (15.09  $\pm$  2.61 mm Hg) patients had lower measured IOP than Caucasian (15.13  $\pm$  2.98 mm Hg) or Hispanic patients (16.23  $\pm$  2.81 mm Hg).
- Caucasian (15.13  $\pm$  2.98 mm Hg) patients had lower measured IOP than Hispanic (16.23  $\pm$  2.81 mm Hg) patients.

At the 0.01 level or higher:

- Female (546.92  $\pm$  38.26  $\mu$ m) patients had thinner CCT than male (555.01  $\pm$  40.55  $\mu$ m) patients.
- The high IOP (>21 mm Hg) group had thicker CCT (583.75  $\pm$  42.49  $\mu$ m) than the normal IOP group (555.21  $\pm$  39.64  $\mu$ m).

At the 0.001 level or higher:

- Black patients had thinner CCT (537.36  $\pm$  37.81  $\mu$ m) than other groups (except Asians  $p = 0.05$ ). The overall average of central corneal thickness was 550.21  $\pm$  39.64  $\mu$ m.

Between-site measures were generally not significantly different. Although IOP was lower overall in Canada (14.81  $\pm$  3.09 versus 15.85  $\pm$  2.85 mm Hg), this difference was not statistically significant when comparing Caucasian patients from Canada and the United States (14.81  $\pm$  3.09 versus 15.13  $\pm$  2.98 mm Hg).

## DISCUSSION

The clinical dilemma is that accurate assessment of IOP is important for patients who might have glaucoma (assessing the index of suspicion) and is very important for those who are being treated for glaucoma. How then, is the clinician to judge the IOP accurately in the presence of varying ranges of corneal thickness? In the Houston–Oakville study, the average:

- IOP equalled 15.63  $\pm$  2.87 mm Hg
- CCT equalled 550.21  $\pm$  39.64  $\mu$ m.

Each of these findings has been related to glaucoma incidence, progression, or both, but it is difficult to determine how important a given IOP finding is without knowing the CCT for a given patient.<sup>5,12,18</sup>

Accepting this premise makes it important to know how IOP and CCT are related. The answer to the specific research question helps identify the correction factor that might be used. The influence of CCT on measured IOP<sup>24,25</sup> was reported as early as the 1970s; however, it is only now coming into mainstream clinical care, facilitated by new technology. Using routinely available clinical equipment (CCT measures) allows the general clinician to implement corrections and bring research into clinical care immediately.

## Study Limitations

The Houston–Oakville study limitations include the method of tonometry used. Further, the study was limited to persons living at just two sites, and it may not be possible to generalize the findings to persons of similar reported ancestry living elsewhere.

The gold standard for glaucoma care is Goldmann applanation tonometry. To facilitate gathering of data, the Houston–Oakville study group elected to use a Topcon CT-20 auto-NCT. NCT is a frequently used clinical test for routine IOP examination in primary eye care offices. It is possible that there will be clinical differences in IOP measurements when NCT, rather than Goldmann tonometry, is used. However, Tonnu et al.<sup>65</sup> found moderate agreement between NCT (Topcon CT-80) and Goldmann applanation tonometry (mean difference of 0.7 mm Hg), and there was no significant difference between NCT (Canon TX-10) and Goldmann applanation tonometry, in either intrasession or intersession repeatability testing (two-tail  $t$ -test,  $p > 0.075$ ; degree of freedom (df) = 119).<sup>66</sup> Furthermore, the relation between IOP and CCT is the important factor, not the absolute IOP reading.

The IOP assessment in the Houston–Oakville study was based on a single-average measure (average of two measurements taken consecutively within a 10-second time-frame) at various times throughout the day (9:00 a.m. to 7:00 p.m.). On the surface, this could be a concern, as there can be significant diurnal variations in IOP. Indeed, diurnal IOP fluctuation has been identified as an important risk factor for visual field deterioration in glaucoma.<sup>56</sup> A single IOP measure will seldom be used to establish a diagnosis or alter treatment for any form of glaucoma. However, the result of the Houston–Oakville study compares CCT and IOP, and possible fluctuation would not influence the structural interrelations identified; and the study averages IOP measured at different times of the day. So, the IOP measured in the study is a daylight average, which moderates the extreme readings of the diurnal range of IOP measured. That said, the diurnal variation in IOP (not observed in CCT except for post-sleep corneal edema secondary to hypoxia) adds measurement noise, reduces the relationship between IOP and CCT, and lowers the R-squared value. If all measurements were taken at the same time of the day, then a higher R-squared value might have been found.

### Corneal Thickness

In the Houston–Oakville study, the female subjects had thinner corneas compared with the male subjects by 8.1  $\mu\text{m}$  (546.92  $\pm$  38.26  $\mu\text{m}$  versus 555.00  $\pm$  40.55  $\mu\text{m}$ , respectively;  $t = 2.503$ ,  $p = 0.02$ ). This differs from the OHTS results, which showed that the male subjects had thinner corneas by 4.7  $\mu\text{m}$  (575  $\pm$  38.6  $\mu\text{m}$  versus 570.3  $\pm$  39.4  $\mu\text{m}$ ).<sup>18</sup> The etiology of this difference is unclear. The OHTS investigators suggested that the cornea thins slightly with age, and the subjects of the Houston–Oakville study were substantially younger compared with the subjects of the OHTS. Perhaps the corneal thickness difference of the Houston–Oakville subjects would ultimately “cross over” so that the males would have thinner corneas, as the OHTS investigators found. In any event, the OHTS investigators did not feel that these small differences were clinically significant for glaucoma management or for accurate determination of IOP and the data from the Houston–Oakville study suggest this as well.

### Clinical Application

The results of the Houston–Oakville study shed further light on how measured IOP might be “corrected” on the basis of the measures of CCT. **Figure 3** was derived by averaging the IOP of 1226 eyes, with normal IOP (7–21 mm Hg) for 10  $\mu\text{m}$  CCT groups between 460  $\mu\text{m}$  and 650  $\mu\text{m}$ . From **Table 3**, the CCT groups between 480 and 620  $\mu\text{m}$  had 20 or more IOP measurements, and the average change of IOP per 100  $\mu\text{m}$  of CCT was 2.49 mm Hg. For the CCT groups with CCT between 460 and 650  $\mu\text{m}$ , which had seven or more IOP measurements, the average change of IOP per 100  $\mu\text{m}$  of CCT was 2.35 mm Hg. The “correction” of 2.49 mm Hg for every 100- $\mu\text{m}$  increase in corneal thickness corresponded well with previous results (2.6 mm Hg per 100  $\mu\text{m}$  of CCT; average correction from Table 1). The best “correction” factor to be used is still debated, as is whether a linear factor is even appropriate (although in Figures 2 and 3, it appears that the factor is linear for the 460–650  $\mu\text{m}$  CCT range studied). Nonetheless, correction factors derived from patient samples, such as in the Houston–Oakville study, provide clinicians with a useful estimate of the effects that corneal thickness variations from a normal range may have on the IOP measurement of a given patient.

### CONCLUSION

Data from the Houston–Oakville study provide new insight into the relation between CCT and IOP in young, normal persons. Evaluating and relating IOP to CCT will help improve clinical care. Identification of patients with abnormal CCT will allow the clinician to more closely estimate the accuracy of IOP readings for these patients.

### ACKNOWLEDGEMENTS

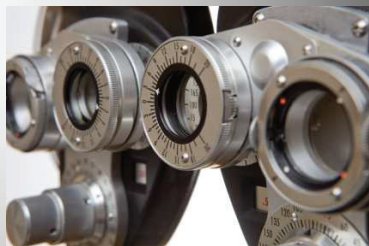
Presented, in part, as a poster at the American Academy of Optometry meeting in December 2005. Thanks to Jumah Absy, Susan Che, and Bonnie Cameron, who participated in data gathering and analysis for the poster; and to Harold Bedell, Susan Che, and Heather Johns-Anderson for comments on the various versions of this manuscript.

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