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Original Article

Economic appraisal of prosthetic replacement of ocular surface ecosystem in Canada

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Objective: To perform an economic appraisal of the Prosthetic Replacement of Ocular Surface Ecosystem (PROSE; BostonSight, Needham Heights, Mass.) lens in patients with a distorted corneal surface or ocular surface disease in Canada.

Design: Retrospective observational cohort study with cost, cost-utility, and benefit-cost analyses.

Participants: Patients who received PROSE from the only PROSE clinic in Canada from 2018 to 2020.

Methods: Visual acuity (VA) outcomes of the participants were assessed. Benefits were defined as VA improvements that were converted into utilities and then quality-adjusted life years. Economic values were derived via government statements, clinic financial statements, and published literature.

Results: Average best-corrected VA (BCVA) improvement was -0.42 ± 0.41 logMAR ($p = 2.68 \times 10^{-13}$) or Snellen 20/53 for the overall cohort, -0.51 ± 0.48 ($p = 5.42 \times 10^{-8}$) or Snellen 20/65 for distorted corneal surface patients, and -0.31 ± 0.30 ($p = 1.30 \times 10^{-7}$) or Snellen 20/41 for ocular surface disease patients. This corresponded to discounted quality-adjusted life year gains of 0.51, 0.65, and 0.42, respectively, over an estimated 5-year PROSE device lifespan. Average cost to fit a patient with PROSE was USD$5 469.85 (CAD$7 087.28), of which USD$4 971.38 (CAD$6 441.42) was clinic cost and USD$498.47 (CAD$645.87) was patient cost. Cost-utility was USD$10 256.47 (CAD$13 289.31) for the overall cohort, USD$8 439.79 (CAD$10 935.44) for distorted corneal surface patients, and US$13 069.90 (CAD$16 934.67) for ocular surface disease patients. The benefit-cost ratio was 34.4 for all, 43.8 for distorted corneal surface patients, and 28.3 for ocular surface disease patients.

Conclusions: Our economic appraisal demonstrated that PROSE treatment provides a significant, cost-effective benefit to Canadian patients with distorted corneal surfaces and ocular surface diseases. This indicates that PROSE clinics are an efficient investment.

Objectif: Réaliser une évaluation économique de la lentille PROSE (*Prosthetic Replacement of Ocular Surface Ecosystem*; BostonSight, Needham Heights, MA) chez des patients présentant une distorsion cornéenne ou une maladie de la surface oculaire au Canada.

Nature: Étude d'observation de cohorte rétrospective comportant 3 analyses (coûts, coût-utilité et coûts-avantages).

Participants: Patients qui ont reçu la lentille PROSE entre 2018 et 2020 à la seule clinique qui offrait ces lentilles au Canada.

Méthodes: On a mesuré l'acuité visuelle (AV) des patients après l'utilisation de la lentille. Les avantages ont été définis en fonction de l'amélioration de l'AV qui, à son tour, a été convertie en utilité et ensuite en années de vie pondérées en fonction de la qualité. Les valeurs économiques ont été tirées des déclarations gouvernementales, des états financiers des cliniques et des articles publiés dans la littérature médicale.

Résultats: L'amélioration moyenne de la meilleure acuité visuelle corrigée (MAVC) se chiffrait à $-0{,}42 \pm 0{,}41$ logMAR ($p = 2{,}68 \times 10^{-13}$), soit 20/53 sur l'échelle Snellen, pour l'ensemble de la cohorte, à $-0{,}51 \pm 0{,}48$ ($p = 5{,}42 \times 10^{-8}$), soit 20/65 sur l'échelle Snellen, pour les patients qui présentaient une distorsion cornéenne et à $-0{,}31 \pm 0{,}30$ ($p = 1{,}30 \times 10^{-7}$), soit 20/41 sur l'échelle Snellen, pour les patients qui présentaient une maladie de la surface oculaire. Cette amélioration se traduisait par un gain actualisé par année de vie pondérée en fonction de la qualité de 0,51, de 0,65 et de 0,42, respectivement, sur la durée de vie fonctionnelle estimée de 5 ans de la lentille PROSE. Le coût moyen par patient de l'ajustement d'une lentille PROSE était de 5 469,85 $US (7 087,28 $CAN), dont 4 971,38 $US (6 441,42 $CAN) en coût pour la clinique et 498,47 $US (645,87 $CAN) en coût pour le patient. Le coût-utilité se chiffrait à 10 256,47 $US (13 289,31 $CAN) pour l'ensemble de la cohorte, à 8 439,79 $US (10 935,44 $CAN) pour la cohorte distorsion cornéenne et à 13 069,90 $US (16 934,67 $CAN) pour la cohorte maladie de la surface oculaire. Le rapport coûts-avantages s'élevait à 34,4 pour tous les patients, à 43,8 pour la cohorte distorsion cornéenne et à 28,3 pour la cohorte maladie de la surface oculaire.

Conclusions: Notre évaluation économique a révélé que le traitement avec une lentille PROSE procure des avantages significatifs et rentables pour les patients canadiens qui présentent une distorsion cornéenne ou une maladie de la surface oculaire, ce qui permet d'affirmer que les cliniques PROSE représentent un investissement efficace.

The Prosthetic Replacement of Ocular Surface Ecosystem (PROSE; BostonSight, Needham Heights, Mass.) is a fluid-ventilated, gas-permeable scleral lens therapeutic device invented by the Boston Foundation for Sight, now known as BostonSight, and approved by the U.S. Food and Drug Administration (FDA) in 1994. It is used to treat patients with complex corneal disorders, including severe ocular surface diseases and corneal irregularities, by vaulting the cornea and covering the corneal surface in a constant liquid reservoir.[1] Previous studies have demonstrated its benefit for improving symptoms, comfort, and visual function in patients who have failed other medical management options or other methods of optical correction. Specifically, this benefit has been shown in conditions including

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keratoconus, Stevens–Johnson syndrome, post-penetrating keratoplasty, and chronic graft-versus-host disease.[1–7]

PROSE is currently available at clinics in the United States, India, Japan, and as of 2017, Canada. Currently, the only PROSE clinic in Canada is in Toronto at the Kensington Eye Institute (KEI). An economic appraisal of PROSE was conducted in 2009 based on patients within the United States. That study found that the Boston Ocular Surface Prosthesis, the former name for PROSE, had an average cost-effectiveness of US$24 900 per quality-adjusted life year (QALY) and average benefit-cost ratio of 4.0:1.[8]

This study is necessary because it has been over a decade since the economic benefits of PROSE were analyzed, and such an appraisal has never been conducted for PROSE patients in Canada, which has a vastly different health care system with different economic considerations compared with the United States. Furthermore, the burden of corneal disease is associated with significant costs; a 2013 report estimated a volume of more than 4,000 corneal procedures and 1,000 corneal transplants per year in Ontario, with estimated annual direct costs of CAD$5.4 million and CAD$1.7 million, respectively.[9] Here we report cost, cost-utility, and benefit-cost analyses of treating PROSE patients at the KEI clinic. We aim to provide an updated Canadian perspective on the economic benefits of PROSE treatment to clinicians, administrators, and government health officials involved in PROSE clinic funding and operation.

Methods

This study was carried out with approval from the University of Toronto Research Ethics Board and in accordance with the Declaration of Helsinki. Informed consent for the research was obtained from the patients.

Study population

The charts of 92 patients who were seen at the KEI PROSE clinic from 2018 to 2020 were retrospectively reviewed. Fourteen patients (14.9%) were excluded because of a history of PROSE fitting at BostonSight, leaving a total of 78 patients who had all PROSE fitting appointments at KEI and received a PROSE device. An analysis of these patients was published previously.[10] The difference in best-corrected visual acuity (BCVA) between baseline and final was available for 76 patients, who comprised the cohort in this economic appraisal. The other 2 patients were excluded because of lack of BCVA data.

Device fitting

Device fitting was conducted as per the previously published article.[10] Patients completed an intake form regarding their ocular history at their initial fitting visit. An optometrist (S.R. or J.L.) trained in PROSE device fitting examined each patient. The initial assessment included corneal tomography scans with Pentacam (Oculus, Wetzlar, Germany) to assess corneal irregularity and anterior segment optical coherence tomography (OCT) scans with Cirrus HD OCT (Carl Zeiss Meditec Inc, Jena, Germany) to assess lens clearance over the ocular surface and haptic alignment over areas of aberrant conjunctival tissue. The OCT scans also were used to monitor changes in device fit over time.

A PROSE device from a fitting set was applied and allowed to settle on the patient's eye for between 30 minutes and 2 hours. The device was then customized based on the lens fit over the patient's eye and over-refraction over the lens. The personalized device was ordered and then fitted on the patient to ensure proper fit, comfort, and vision. The device was dispensed after patients were educated on its care, handling, application, and removal. Each patient returned for follow-up within a few months and then as needed to monitor for issues with lens wear and to make further adjustments.

Clinical outcomes

The BCVA was measured at baseline and all subsequent follow-up appointments via Snellen charts and then converted to logMARs for analysis. The BCVA measured at the most recent follow-up appointment was considered the final BCVA. Based on the previous economic appraisal in the literature and KEI clinician experience, the full benefit of a PROSE device was projected to last for 5 years on average.[8] In our cohort of 76 eyes, beginning in 2018, only 1 eye (1.3%) had documented discontinuation of PROSE over 277.6 ± 172.5 days of follow-up. The combination of previous literature and a very low dropout rate over almost a year of follow-up in our cohort indicates that 5 years of use appears to be a realistic estimate.

Economic costs

All values for analysis were converted from Canadian dollars to US dollars according to the annual average exchange rate for 2018 published by the Bank of Canada, which was 1.2957.[11] KEI clinicians and financial statements were consulted to determine the economic costs of purchasing and fitting PROSE. Cost per patient was calculated by dividing the annual costs by the number of patients. On average, each patient was scheduled to return to the KEI clinic for follow-up every 12 months. In accordance with the previous economic appraisal, follow-up costs were included in our calculations, and we assumed that follow-up costs at the KEI clinic did not change over time.[8]

We also incorporated personal patient costs associated with treatment. Our patients required a mode of 2 appointments for fitting. Furthermore, according to KEI clinicians, almost all patients were accompanied by a caregiver. We assumed that each patient and his or her caregiver had to take a full day off work for each appointment, leading to an estimate of 4 total days off work for 2 appointments. We

valued this time at 4/365 of the 2018 median income in Canada, which was US$28 093 ($36 400) according to Statistics Canada.[12] We assumed that most patients used an automobile to travel to and from the clinic and returned home after each visit rather than paying for additional accommodations because they were all from within Ontario and all but 3 patients (3.9%) lived fewer than 4.5 hours away from KEI according to the time taken for the shortest route from their home address to KEI. According to KEI clinicians, only 1 patient, who lived in Kapuskasing, used air travel. Furthermore, according to Google Maps, the average patient travelled 113.45 km one way for each visit, resulting in an average total travel distance of 453.80 km per patient to be fitted with PROSE. This is likely a slight underestimate of the true distance travelled because all patients likely did not travel according to the shortest possible distance. Travel was valued at US$0.42/km (CAD$0.54/km)—the 2018 automobile allowance rate published by the government of Canada.[13] Based on these assumptions, average personal patient cost was US$307.87 (CAD$398.91) for time taken off work and US$190.60 (CAD$246.96) for travel, resulting in an overall average of US$498.47 (CAD$645.87).

We also compared the cost incurred by the patient attending the KEI clinic with the patient cost for attending the BostonSight clinic based in Boston, Mass., which was the only alternative prior to the KEI clinic's opening. The previous economic appraisal used a modal fitting time of 5 consecutive days.[8] Thus, we valued patient and caregiver time at 10/365 of the 2018 median income in Canada, resulting in an average cost of US$769.68 (CAD$997.27) for time taken off work.[12] The previous appraisal estimated travel costs at US$300 round trip for airfare or train fare in 2006, which corresponded to US$367.61 (CAD$476.31) in 2018 according to the Bank of Canada's inflation calculator.[8,14] Also, in concordance with the previous appraisal, we used the 2018 federal per diem in Norfolk County, Mass., to estimate costs for lodging (USD$161 or $208.61 per day) and meals and incidental expenses (USD$59 or CAD$76.45 per day, but USD$44.25 or CAD$57.59 on the first and last days of travel).[8,15] Based on a 5-day visit, this cost was USD$1 070.50 (CAD$1 387.05). Therefore, the overall average personal patient cost for attending the BostonSight clinic was USD$2 207.79 (CAD$2 860.63).

Quality-adjusted life years

We determined change in QALYs via BCVA before and after receiving treatment. Previous studies have shown that quality of life is directly proportional to BCVA in the better-seeing eye independent of the disease, disease duration, age, race, sex, and socioeconomic status.[16–20] In our cohort, the better-seeing eye was not always the one receiving PROSE. Consequently, we used the better-seeing eye before PROSE for patients with bilateral PROSE and used only the eye receiving PROSE in unilateral cases. A similar assumption was made in previous studies.[8,21,22] The BCVA values before and after PROSE were converted into utilities via a polynomial equation developed by Lansingh and Carter[23]: $y = -0.0479x^3 + 0.191x^2 - 0.4233x + 0.9128$, where y is utility and x is BCVA in logMAR. The QALY gain was calculated as the utility gain, which was the difference between pre-PROSE and post-PROSE utility multiplied by the life expectancy of PROSE, which was estimated to be 5 years.

Cost-utility analysis

The cost-utility ratio was calculated using the following equation by Lansingh and Carter[23]: $CU = C_D/[U_2(1 - e^{-rL})/r - U_1(1 - e^{-rL})/r]$, where CU is cost-utility, C_D is discounted cost, U_2 is post-PROSE utility, U_1 is pre-PROSE utility, L is life expectancy of PROSE in years, and r is discount rate. The standard real discount rate recommended in cost-utility analyses, 3% per year, was applied to account for the time value of outcomes.[24] This described the relationship between the cost per patient and the benefit in QALYs.

Benefit-cost analysis

A benefit-cost ratio was calculated by converting the average discounted benefit in QALYs into an economic value. As performed in the previous economic appraisal, we used FDA guidelines to assign a value to a healthy life year to provide a comprehensive estimate.[8] Recently, the FDA used a value of USD$369 000 (CAD$478 113).[25] This value was then divided by the cost per patient. This ratio described the relationship between the cost per patient and the societal economic value provided by PROSE.

Results

Patient characteristics

All patient characteristics are summarized in Table 1. The 76 patients had an average age of 52.4 ± 18.4 years (range, 15–86 years). Thirty-seven patients (48.7%) were female and 39 (51.3%) were male. The average baseline BCVA in the better eye receiving PROSE was 0.56 ± 0.46 logMAR (range, 0.00–2.00 logMAR) or Snellen 20/73. In the better PROSE-receiving eye, 38 patients (50%) had a primary diagnosis involving a distorted corneal surface and 38 (50%) had an ocular surface disease. The most common diagnosis was keratoconus in 24 patients (31.6%), followed by graft-versus-host disease in 8 (10.5%). The most common presenting symptoms were blurry vision in 66 patients (86.8%), photophobia in 54 (71.1%), and eye pain in 41 (53.9%). Among the patients with a distorted corneal surface, average age was 49.9 ± 17.8 years, 17 (44.7%) were female, 21 (55.3%) were male, and average baseline BCVA

Table 1—Summary of key patient characteristics with *p* values comparing the distorted corneal surface and ocular surface disease groups

Characteristic	Overall (n = 76)	Distorted Corneal Surface (n = 38)	Ocular Surface Disease (n = 38)	*p* Value
Age, y (mean ± SD)	52.4 ± 18.4	49.9 ± 17.8	54.9 ± 18.9	0.24
Sex				0.82
Male	39 (51.3%)	21 (55.3%)	18 (47.4%)	
Female	37 (48.7%)	17 (44.7%)	20 (52.6%)	
Baseline BCVA, logMAR (mean ± SD) and Snellen	0.56 ± 0.46 20/73	0.65 ± 0.19 20/89	0.46 ± 0.41 20/58	0.08

was 0.65 ± 0.19 logMAR (range, 0−2 logMAR) or Snellen 20/89. The patients with ocular surface disease had an average age of 54.9 ± 18.9 years, 20 (52.6%) were female, 18 (47.4%) were male, and average baseline BCVA was 0.46 ± 0.41 logMAR (range, 0−1.3 logMAR) or Snellen 20/58. The 2 groups were not significantly different in terms of age ($p = 0.24$), sex ($p = 0.82$), or baseline BCVA ($p = 0.08$).

Visual acuity changes

All BCVA data are summarized in Table 2. The average final BCVA of the entire cohort was 0.14 ± 0.21 logMAR (range, −0.12 to 0.88 logMAR) or Snellen 20/28. The average improvement was −0.42 ± 0.41 logMAR (range, −1.60 to 0.18 logMAR) or Snellen 20/53; BCVA improved significantly ($p = 2.68 \times 10^{-13}$). Sixty-two of the patients (81.6%) had better BCVA, 11 (14.5%) had no change in BCVA, and 3 (3.9%) had worse BCVA. At baseline, 15 of 76 patients (19.7%) were legally blind, defined as Snellen BCVA of 20/200 or worse. After treatment, no patients were legally blind.

For the 38 patients with distorted corneal surface disease as the primary diagnosis, final BCVA was 0.14 ± 0.19 logMAR (range, −0.12 to 0.6 logMAR) or Snellen 20/28, and improvement was −0.51 ± 0.48 logMAR (range, −1.6 to 0.12 logMAR) or Snellen 20/65 ($p = 5.42 \times 10^{-8}$). Ten patients (26.3%) were legally blind at baseline, and none were legally blind after receiving PROSE. Thirty-two patients (84.2%) had better BCVA, 5 (13.2%) had no change, and 1 (2.6%) had worse BCVA.

For the 38 patients with ocular surface disease as the primary diagnosis, final BCVA was 0.15 ± 0.24 logMAR (range, −0.12 to 0.88 logMAR) or Snellen 20/28, and improvement was −0.31 ± 0.30 logMAR (range, −1.12 to 0.18 logMAR) or Snellen 20/41 ($p = 1.30 \times 10^{-7}$). Five patients (13.2%) were legally blind at baseline, and none were legally blind after receiving PROSE. Thirty patients (78.9%) had better BCVA, 6 (15.8%) had no change, and 2 (5.3%) had worse BCVA.

There was no significant difference in the final BCVA between the distorted corneal surface and ocular surface disease groups ($p = 0.74$). However, the distorted corneal surface group had a significantly better improvement in BCVA ($p = 0.04$).

Costs

The total KEI cost for running the PROSE clinic, including clinical services and device purchase, was USD$183 941 (CAD$238 332) from April 2019 to April 2020. We used this fiscal year because it provided the most accurate cost evaluation according to the KEI finance team. During this period, 37 patients received a PROSE device, resulting in an average KEI cost of USD$4 971.38 (CAD$6 441.42) per patient. This, combined with the average patient cost of USD$498.47 ($645.87), provides a total average cost of USD$5 469.85 (CAD$7 087.28) to provide a patient with a PROSE device.

Quality-adjusted life years

For all 76 patients, the average pre-PROSE utility was 0.75 ± 0.11 (range, 0.45−0.91), and the average post-PROSE utility was 0.86 ± 0.07 (range, 0.66−0.97), resulting in an average utility gain of 0.11 ± 0.10 QALY per year (range, −0.07 to 0.39 QALY) and a relative 14.7% improvement in utility owing to PROSE. This resulted in an overall gain of 0.55 QALY over the 5-year lifespan of the PROSE device.

For the 38 patients with distorted corneal surface disease, the average pre-PROSE utility was 0.72 ± 0.11 (range,

Table 2—Summary of best-corrected visual acuity (BCVA) data

Group	Baseline BCVA, logMAR (mean ± SD) and Snellen	Final BCVA, logMAR (mean ± SD) and Snellen	*p* Value	Change in BCVA, logMAR (mean ± SD) and Snellen
Overall (n = 76)	0.56 ± 0.46 20/73	0.14 ± 0.21 20/28	*2.68×10^{-13}*	−0.42 ± 0.41 20/53
Distorted corneal surface (n = 38)	0.65 ± 0.19 20/89	0.14 ± 0.19 20/28	*5.42×10^{-8}*	−0.51 ± 0.48 20/65
Ocular surface disease (n = 38)	0.46 ± 0.41 20/58	0.15 ± 0.24 20/28	*1.30×10^{-7}*	−0.31 ± 0.30 20/41
p Value	0.08	0.74		*0.04*

Note: Significant *p* values ($p < 0.05$) are italicized.

0.45−0.91) and the average post-PROSE utility was 0.86 ± 0.07 (range, 0.72−0.97), resulting in an average gain of 0.14 ± 0.12 QALY per year (range, −0.04 to 0.39 QALY) and a relative 19.4% improvement. The overall QALY gain was 0.70.

For the 38 patients with ocular surface disease, the average pre-PROSE utility was 0.77 ± 0.11 (range, 0.58−0.91) and the average post-PROSE utility was 0.86 ± 0.08 (range, 0.66−0.97), resulting in an average gain of 0.09 ± 0.08 QALY per year (range, −0.07 to 0.31 QALY) and a relative 11.7% improvement. The overall QALY gain was 0.45.

Using a 3% discount rate and 5-year lifespan for the PROSE device, the discounted QALY gain was 0.51 for the entire cohort, 0.65 for the patients with a distorted corneal surface, and 0.42 for the patients with ocular surface disease. There was a significant difference in the QALY gain between the distorted corneal surface and ocular surface disease groups ($p = 0.04$).

Cost-utility

For all 76 patients, the average cost-utility was USD$10 256.47 (CAD$13 289.31) per QALY gained. For the 38 patients with distorted corneal surface disease, the average cost utility was USD$8 439.79 (CAD$10 935.44) per QALY gained. For the 38 patients with ocular surface disease, the average cost utility was USD$13 069.90 (CAD$16 934.67) per QALY gained.

Benefit-cost ratio

The economic value provided by PROSE was calculated using the discounted QALY gains of 0.51, 0.65, and 0.42 for all patients, distorted corneal surface patients, and ocular surface disease patients, respectively, and the FDA valuation of USD$369 000 (CAD$478 113) per life year. The results were USD$188 190 (CAD$243 838) in all patients, USD$239 850 (CAD$310 774) in distorted corneal surface patients, and USD$154 980 (CAD$200 808) in ocular surface disease patients. Because the average cost per patient was USD$5 469.85 (CAD$7 087.28), the benefit-cost ratio was 34.4 in all patients, 43.8 in distorted corneal surface patients, and 28.3 in ocular surface disease patients. These ratios far exceeded a neutral benefit-cost ratio of 1.0, indicating that the benefits greatly outweighed the costs. Table 3 provides a summary of discounted QALY gains, cost utilities, and benefit-cost ratios.

Table 3—Summary of discounted quality-adjusted life year (QALY) gains, cost utilities, and benefit-cost ratios

Group	QALY Gain	Cost Utility ($/QALY)	Benefit-Cost Ratio
Overall (n = 76)	0.51	US$10 256.47 (CAD$13 289.31)	34.4
Distorted corneal surface (n = 38)	0.65	US$8 439.79 (CAD$10 935.44)	43.8
Ocular surface disease (n = 38)	0.42	US$13 069.90 (CAD$16 934.67)	28.3

Discussion

Our economic appraisal determined that PROSE provides a significant improvement in BCVA in patients with distorted corneal surfaces and ocular surface diseases, consistent with previous studies.[1−7] Most patients in our cohort, whether they had a distorted corneal surface or ocular surface disease, had improved vision with PROSE. None of the legally blind patients remained blind with PROSE. This indicates that it is an effective treatment for patients with complex corneal diseases after other corrective methods have failed. We found that patients with distorted corneal surfaces experienced a more significant improvement in BCVA than patients with ocular surface disease. Although the difference in baseline BCVA was not significantly different, the worse baseline BCVA in the distorted corneal surface patients likely contributed to them having a more drastic improvement. The 2 groups had a similar final BCVA, demonstrating that PROSE may provide a similar visual acuity outcome regardless of the nature of the corneal disorder. The only discontinuation in this cohort during follow-up was owing to discomfort, demonstrating that disease progression does not appear to be a main contributing factor leading to discontinuation over time.

The establishment of a PROSE clinic in Ontario was recommended by the Provincial Vision Strategy Task Force in 2013, because the Ministry of Health and Long-Term Care in Ontario was funding patients to go out of country via the Ontario Health Insurance Plan to the BostonSight clinic in Needham Heights, Mass. for PROSE.[9] The KEI PROSE clinic made it possible for these patients to receive treatment at an estimated 22.6% of the work- and travel-related costs of visiting the BostonSight clinic, providing estimated savings of USD$1 709.32 (CAD$2 214.77) per patient in the context of patient costs. We also accounted for the costs associated with these patients requiring a caregiver to accompany them, which made our estimate more comprehensive and was not considered in the previous PROSE appraisal.[8] Thus, the KEI clinic makes PROSE more affordable from an Ontario patient perspective. The KEI clinic orders PROSE devices from Boston, necessitating a longer time to fit patients—an average of 81 days (range, 12−282 days) from the initial visit to the first dispense in this cohort in comparison with a 5-day visit at BostonSight—but this is associated with substantial cost savings for patients. However, in August 2019, the Special Access Program (SAP) requirement for clinicians to order PROSE devices, which were not yet approved for sale in Canada, was removed. The SAP requirement substantially lengthened the time of care for earlier patients because approval took more than 1.5 months according to KEI clinicians. Therefore, removal of the SAP requirement should make the fit time for patients substantially shorter in future studies.

The average overall cost of providing PROSE to a patient was USD$5 469.85 (CAD$7 087.28), of which USD$4 971.38 (CAD$6 441.42) was cost to the KEI clinic. This

comprehensive estimate included all KEI PROSE clinic costs and patient costs. This was a much cheaper cost than estimated for the BostonSight clinic in the previous economic appraisal, USD$11 841 (CAD$15 342), of which USD$10 772 (CAD$13 975) was the cost to the clinic and USD$1 069 (CAD$1 385) was the cost to the patient.[9] The lower clinic cost in our study was likely owing to advances in PROSE production based on materials and equipment significantly reducing device costs since the previous study was published. Additionally, BostonSight clinic patients likely had more fitting appointments based on their modal time of 5 days in comparison with our modal value of 2 appointments, resulting in higher costs for clinic staff. Furthermore, based on KEI clinician knowledge, professional fees are higher at BostonSight than at KEI.

According to the previous appraisal, cutoff values of USD$50 000–USD$100 000 (CAD$64 785–CAD$129 570) are used to determine cost-effectiveness in health care technologies. That study found PROSE to be a cost-effective treatment with a cost-effectiveness ratio of USD$24 900 (CAD$32 262) in their overall cohort, USD$24 800 (CAD$32 133) in patients with distorted corneal surfaces, and USD$25 000 (CAD$32 392) in patients with ocular surface disease.[9] Our study found that PROSE has a more favourable cost-effectiveness than reported in the previous study. We found exceedingly favourable cost utilities of USD$10 256.47 (CAD$13 289.31), USD$8 439.79 (CAD$10 935.44), and USD$13 069.90 (CAD$16 934.67) for the entire cohort, patients with distorted corneal surfaces, and patients with ocular surface disease, respectively. The difference in cost-effectiveness between these studies was driven primarily by reduced clinic costs. As seen in BCVA improvement, the patients with distorted corneal surfaces had a more favourable cost-utility owing to worse baseline utility allowing for greater utility improvement and thus a higher QALY gain from PROSE.

The previous appraisal found benefit-cost ratios of 4.0, 4.1, and 4.0 in the overall cohort, distorted corneal surface group, and ocular surface disease group, respectively. This indicated a highly favourable benefit-cost ratio.[9] Because of reduced clinic costs and an increase in the FDA valuation of a life year from USD$100 000 to USD$369 000 (CAD$129 570 to CAD$478 113), we found even more favourable corresponding benefit-cost ratios of 34.4, 43.8, and 28.3.[9,25] Furthermore, the difference in benefit-cost ratio between the distorted corneal surface and ocular surface disease groups was owing to the aforementioned difference in cost utility, which was driven by the initial BCVA difference.

Our study had some limitations. Because of its retrospective nature, we were limited to using BCVA rather than the more comprehensive Visual Function Questionnaire (VFQ-25) to estimate value provided by PROSE given that VFQ-25 data were not available in the patient charts. Because the previous economic appraisal used the VFQ-25, this also limited our ability to draw more reliable conclusions regarding the comparisons with our appraisal. Furthermore, because our mean follow-up period was less than 1 year, it is possible that our estimation of the lifespan of a PROSE device is inaccurate. It is possible that more patients may begin to fail PROSE over a longer follow-up period because of disease progression, but patients also may receive the full benefits of PROSE for longer than the estimated 5-year lifespan. Consequently, studies with longer observation periods are recommended to elucidate the time length for which patients are expected to receive benefit from PROSE. A long-term prospective study in which VFQ-25 data are collected over several years is recommended.

In conclusion, our economic appraisal of the only PROSE clinic in Canada demonstrated that PROSE treatment provided a significant, cost-effective benefit to patients with distorted corneal surfaces and ocular surface diseases. This indicates that PROSE clinics are an efficient investment of health care funding. This benefit was more pronounced than observed in a previous economic appraisal published in 2009 because of increased FDA valuation of a life, reduced device costs, and lower clinical service costs.

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