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Objective and subjective evaluation of the performance of medical contact lenses fitted using a contact lens selection algorithm

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ABSTRACT

Purpose: To evaluate the performance of medical contact lenses (CLs) for a wide range of clinical indications.
Design: Prospective cross-sectional study.
Methods: A total of 281 eyes were evaluated in 281 consecutive patients (≥18 years of age; CL use ≥3 months) who visited the contact lens service in a tertiary academic clinic for a scheduled follow-up visit. The main outcome measured were clinical indications for CL wear; CL type; change in corrected distance visual acuity (CDVA) with CL use; CL wearing duration; CL wearing time; subjective performance measured using a visual analog scale (VAS) questionnaire (score range: 0–100); and effectiveness of the lens-selection algorithm.
Results: Wearing CLs significantly improved CDVA compared to wearing spectacles (median change: −0.15 logMAR, range: 1.00 to −2.10; $P<.001$). Daily-wear CLs were worn by 77% of patients for a median of 15 h/day (range: 5–18 h/day), median 7 days/week (range: 1–7 days/week). High subjective scores were measured, with similar results obtained between the scleral lens and soft lens groups. The medical CL fitting was found to be generally effective (the overall satisfaction rating was ≥70 for 81% of patients).
Conclusions: Fitting CLs based on the lens-selection algorithm yielded positive clinical results, including improved visual acuity, satisfactory wearing time, and high overall subjective performance. Moreover, subjective performance was similar between users of scleral lenses and users of soft lenses. These results underscore the importance of prescribing scleral lenses and the need for tertiary eye clinics to offer patients a variety of CL types.

To treat a wide range of ocular diseases, modern-day eye-care practitioners have a growing arsenal of medical contact lenses (CLs). The primary optical indication for fitting a patient with medical CLs is to improve visual acuity in cases of high refractive error and/or irregular astigmatism [1]; less common indications include anisometropia, nystagmus, and occlusion [2]. In a clinical setting, another important indication for CL use is for therapeutic purposes (e.g., in the case of a corneal bandage, in which the cornea is physically protected from the environment in order to improve hydration, promote corneal healing, and relieve pain) [3–10]. Often, several effects are desired [4,6]. All of these applications have specific requirements with respect to the lenses' design and material. A wide variety of CL types are currently available, including conventional soft lenses, silicone hydrogel lenses, rigid gas-permeable (RGP) corneal lenses, scleral lenses, hybrid lenses, occlusive lenses, iris print lenses, filter lenses, piggyback systems, and scleral prosthetics. Tailoring a CL to adequately fit the patient's needs requires a trained eye-care practitioner.

Clinical applications for CLs have expanded due to improvements in the materials used (for example, lens materials that are more oxygen-permeable) [3] and recent innovations in lens design, including custom-made specialized lenses [11,12], and toric- and tangential scleral lens designs [13–15]. In turn, these developments have altered the prescription habits of eye-care practitioners. For example, the improved material properties of silicone hydrogels has led to a major shift from conventional soft lenses to silicone hydrogel lenses [5,8]. More interestingly, the increased availability of custom-designed contact lenses for patients with keratoconus

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or keratoplasty [11,16–20] has been accompanied by a large increase in the use of scleral lenses [21–23].

Scleral lenses play an important role in medical CL practice, particularly in cases in which other lens designs have suboptimal results, for example in the case of unstable lens fitting, poor tolerance, unsatisfactory visual improvement, and/or unsatisfactory corneal bandage. However, the ability to fit scleral lenses requires specific skills and training. Another factor that has hampered the popularity of scleral lenses is prejudice with respect to poor handling of scleral lenses and a lack of comfort for the user. Recently, Van der Worp et al. [21] and Schornack [22] reviewed the outcomes of studies using scleral lenses, and several studies have evaluated the fitting of medical CLs in specific settings [1,3,5,7,19,24]. However, no overarching, evidence-based method for fitting the optimal CL type in more challenging clinical cases is currently available. In addition, the patients' subjective experiences based on these various treatment strategies also warrant attention.

Our goal was to evaluate the experiences of CL practitioners and patients in a large, tertiary clinic. Thus, we prospectively evaluated the outcomes of medical CL fitting in which the lens type is based on a practical lens selection algorithm, and we examined the clinical outcomes and patient satisfaction in response to the strategies chosen. Importantly, the comprehensive lens selection algorithm enables practitioners to achieve desirable results.

1. Methods

In this prospective observational study, we included all consecutive patients (in total 281 patients) who visited the Contact Lens service (Visser Contact Lens Practice) at the University Medical Center Utrecht from August 2014 through October 2014 for a follow-up for a medically indicated CL. The inclusion criteria were ≥18 years of age and CL use for ≥3 months prior to enrollment. The exclusion criteria were patients who came for an emergency visit or patients who were unable or unwilling to participate. Our institution's Ethics Review Board (Medisch Ethische Toetsingscommissie) ruled prospectively that approval was not required for this study; however, all participating patients provided written informed consent. All procedures were performed in accordance with the Declaration of Helsinki and with local laws regarding research on human subjects.

During the study visit, the primary and secondary clinical indication for CL use, CL type, and CL history were recorded; in addition, the following data were obtained from the patients' medical history: the presence of allergies and/or eczema, the use of topical eye drops (e.g., lubricants, prophylactic antibiotics, steroids, glaucoma eye drops, anti-allergy eye drops, or other eye drops), and average CL wearing time. Best corrected distance visual acuity (CDVA) was measured as Snellen visual acuity both with (CL CDVA) and without (spectacle CDVA) CLs.

All patients were also instructed to complete a questionnaire covering the following four specific topics: lens comfort, visual quality, lens handling, and overall satisfaction with their lenses. Scores were obtained on a visual analog scale (VAS); the scores ranged from 0 (unacceptable performance) to 100 (excellent performance). This questionnaire was used in our previous studies, and approval for using it here was granted by the Research and Ethics Committee of the City University, London, United Kingdom

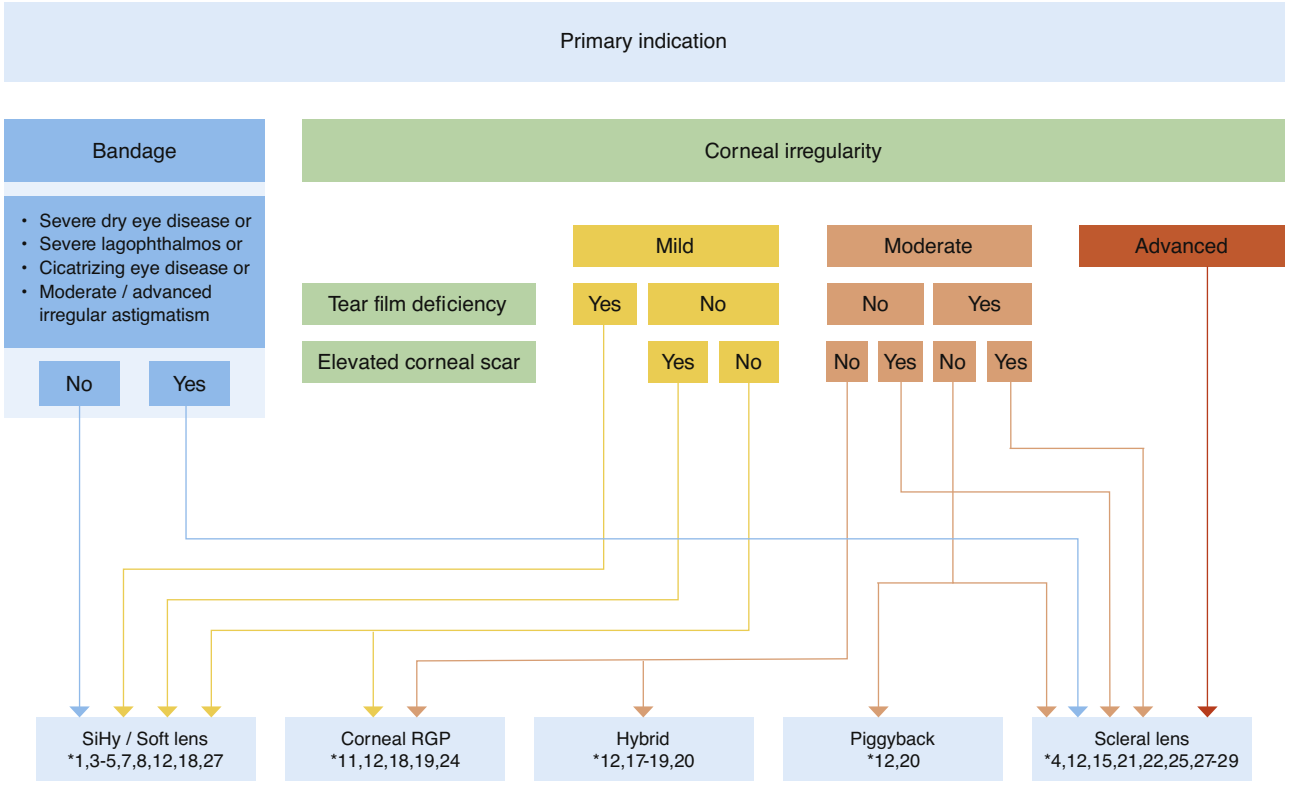

Fig. 1. Contact lens selection algorithm.
Description: A selection algorithm for selecting contact lenses for two principal medical uses: irregular astigmatism and bandage.
SiHy = silicone hydrogel; RGP = rigid gas-permeable.
* = references listed in the main reference list.
Mild corneal irregularity = acceptable subjective visual quality with SiHy; Moderate corneal irregularity = unacceptable subjective visual quality with SiHy, acceptable lens fit with RGP corneal; Advanced corneal irregularity = unacceptable subjective visual quality with SiHy, no acceptable lens fit with RGP corneal.
Note: The grading of severe dry eye included grade IV and V based on the Oxford Index for staining and tear film break-up time [30]. SiHy or RGP corneal trial lenses were used to determine the grade of "mild", "moderate", or "advanced" corneal irregularity.

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[25,26]. Patients with a visual acuity score of <1/300 (i.e., <distinguish hand motion) did not complete the questions regarding visual quality; CVDA was also not evaluated in these patients. Patients with continuous-wear bandage lenses were omitted from the lens handling section of the questionnaire, as their lenses were replaced by our contact lens service; lens wearing time was also not determined in these patients.

Patients with continuous-wear CLs visited the practice every 4–6 weeks to either replace or clean their lenses, and they were prescribed prophylactic antibiotic eye drops (chloramphenicol 0.5%, minims BID; Bausch & Lomb). All other patients were monitored at an interval that met their specific clinical needs.

1.1. Contact lens selection

The selection of a specific CL type was based on the severity of the disorder and the presence of additional indications and/or other complicating factors.

Our CL selection algorithm was developed for two principal uses for medical CLs: irregular astigmatism and bandage (Fig. 1). The grading of severe dry eye included grade IV and V based on the Oxford Index for staining and tear film break-up time [30]. A grade of mild, moderate, or advanced corneal irregularity was determined based on CL performance and acceptable visual quality: SiHy or RGP corneal trial lenses, which were fitted in accordance with the manufacturer's guidelines, were used to assess the effects of corneal irregularity. The grade "mild" refers to acceptable subjective visual quality with a SiHy lens; the grade "moderate" refers to unacceptable subjective visual quality with a SiHy lens and an acceptable lens fit with a RGP corneal lens; and the grade "advanced" refers to unacceptable subjective visual quality with a SiHy lens and an unacceptable lens fit with a RGP corneal lens. A grading system for irregular astigmatism (based on absolute values measured using corneal topography) was not applicable in this study, as the actual location of the corneal irregularity or cone (i.e., central or peripheral) can have a significant influence on CL fitting. For example, an advanced centrally located keratoconus might benefit from a RGP corneal lens, whereas a less advanced inferiorly located protrusion might impede the fitting of an RGP corneal lens, thus requiring a scleral lens.

Our approach to select the appropriate type of soft lens (including conventional soft lenses or silicone hydrogel lenses) is summarized in Fig. 2. Indications beyond this scope (e.g., occlusion lenses, filter lenses, or cosmetic lenses) were not included in the lens selection algorithm, as these types of lenses are directly related to their specific indications. Medical refractive indications, including high refractive error (i.e., refractive error that exceeded ±10 diopters [D]), aphakia, and anisometropia, were tailored to the individual patient's needs. The best-fitting CL material and design was prescribed to each individual patient based on the practitioner's judgment using trial lenses.

A detailed description of the scleral lens fitting protocol has been described previously [13,15,25]. In brief, fitting was based on the landing of the scleral lens on the sclera and vaulting of the lens over the cornea and limbus. Ideal scleral lens fitting has a well-balanced haptic bearing, gentle movement of the lens with the push-up test, and adequate corneal and limbal clearance. All other lenses were fitted in accordance with the applicable manufacturers' protocols.

1.2. Statistics

One eye in each subject was selected at random using an autonomous software tool (nQuery Advisor, version 7.0, Statistical

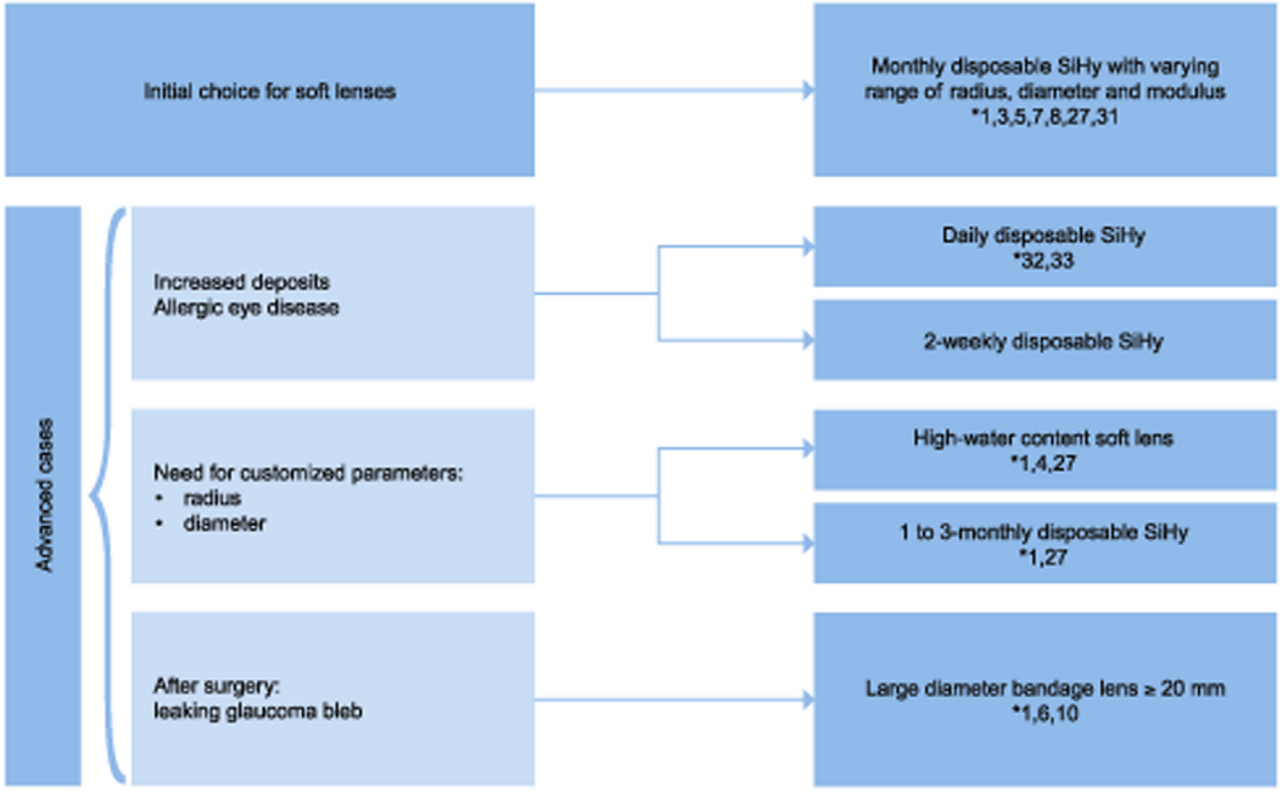

Fig. 2. Initial and advanced selection of soft lenses for medical use [32,33].
Description: Flowchart for the initial and advanced selection of soft lenses (conventional soft or SiHy lenses) for medical use.
SiHy = silicone hydrogel.
* = references listed in the main reference list.

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Table 1
Clinical indications and contact lens type.

Indication	No. of eyes, n (%)	Contact lens type						
		Scleral	Soft	RGP Corneal	Occlusive	Iris	Filter	Other[a]
Keratoconus	**71 (25)**	**60**	**4**	**6**	**0**	**0**	**0**	**1**
Dry eye disease	**66 (23)**	**14**	**52**	**0**	**0**	**0**	**0**	**0**
Keratitis sicca	60	10	50	–	–	–	–	–
Keratitis lagophthalmos	6	4	2	–	–	–	–	–
Keratoplasty	**55 (20)**	**51**	**1**	**2**	**0**	**0**	**0**	**1**
Corneal scar	**25 (9)**	**17**	**2**	**4**	**1**	**0**	**0**	**1**
After herpes simplex keratitis	9	6	2	1	–	–	–	–
After other infectious keratitis	13	9	–	3	1	–	–	–
After trauma	3	2	–	–	–	–	–	1
Refractive	**19 (7)**	**3**	**11**	**2**	**0**	**1**	**2**	**0**
High refractive error >+/−10 D	9	3	4	1	–	1	–	–
Aphakia	6	–	4	–	–	–	2	–
Anisometropia	4	–	3	1	–	–		–
Cornea decompensation	**17 (6)**	**0**	**14**	**0**	**0**	**1**	**2**	**0**
Corneal erosions	**12 (4)**	**0**	**12**	**0**	**0**	**0**	**0**	**0**
Other irregular astigmatism	**5 (2)**	**3**	**0**	**2**	**0**	**0**	**0**	**0**
After surgery (other than keratoplasty)	4	3	–	1	–	–	–	–
Unknown cause	1	–	–	1	–	–	–	–
Miscellaneous indications	**11 (4)**	**0**	**3**	**1**	**4**	**2**	**0**	**1**
Binocular diplopia	3	–	–	–	3	–	–	–
Trichiasis	2	–	2	–	–	–	–	–
Aniridia	1	–	–	–	–	1	–	–
Entropion	1	–	1	–	–	–	–	–
Bulbus atrophy	1	–	–	–	–	–	–	1
Iris atrophy	1	–	–	–	–	1	–	–
Nystagmus	1	–	–	1	–	–	–	–
White pupil	1	–	–	–	1	–	–	–
Total no. of eyes, n (%)	**281 (100)**	**148 (53)**	**99 (35)**	**17 (6)**	**5 (2)**	**4 (1)**	**4 (1)**	**4 (1)**

D = Diopter; RGP = rigid gas-permeable.
[a] Other = a piggyback system for keratoconus (n = 1), a hybrid lens for keratoplasty (n = 1), a tinted soft keratoconus lens for a corneal scar after trauma (n = 1), and a prosthetic scleral lens for bulbous atrophy (n = 1).

Solutions, Cork, Ireland). All Snellen visual acuity values were converted to logMAR values for statistical calculations.

All variables were tested for normal distribution using the Kolmogorov-Smirnov test. The only variable that was found to be distributed normally was patient age. For non-normally distributed paired data, the Wilcoxon signed rank test was used. Differences between groups were analyzed using the non-parametric Kruskal-Wallis test (for continuous outcomes), the Fisher's exact test (for categorical outcomes), or ANOVA (age). With the exception of patient age (which is reported as the mean and standard deviation), all summary data are reported as the median and range. Subgroup analyses were performed on the following stratified data: primary clinical indication (keratoconus, dry eye disease, or post-keratoplasty) and primary CL type (scleral lens or soft lens). Differences with a *P*-value <0.05 were considered statistically significant. All statistical analyses were performed using SPSS version 20.0 (IBM Corp., Armonk, NY,US).

2. Results

This study included 281 eyes from 281 patients; 160 patients were female (57%), and 142 eyes were right eyes (51%). The mean age of the patient cohort was 55 ± 17 years (range: 18–93 years). Slightly more than half of the patients (n = 158) wore CLs in both eyes, whereas 63 and 60 patients wore a single lens in the right or left eye, respectively.

Thirty-four percent of patients presented with some form of allergy, and 15% had eczema. Sixty-one percent of patients used topical eye drops; among the patients who used eye drops, 47% used a lubricant, 24% used prophylactic antibiotics, 15% used steroids, 7% used glaucoma eye drops, 5% used anti-allergy eye drops, and 2% did not specify the type of eye drops used.

2.1. Clinical indications

The three most common clinical indications in our study cohort were keratoconus (in 25% of cases), dry eye disease (23%), and keratoplasty (20%). The primary clinical indications and the CLs applied are summarized in Table 1. The results of these three main indication groups were further analyzed, and the demographic data are summarized in Table 2.

In total, 26 of the 281 eyes (9%) had a secondary clinical indication for CL fitting; these indications included dry eye disease (n = 5), aniridia (n = 4), decompensated cornea (n = 3), corneal scarring after trauma (n = 3), anisometropia (n = 2), aphakia (n = 2), high refractive error (exceeding +/−10 D; n = 1), corneal scarring after infection (n = 1), keratoplasty (n = 1), corneal dystrophy (n = 1), recurrent erosions (n = 1), trichiasis (n = 1), and white pupil secondary to cataract (n = 1).

All corneal transplants, with the exception of one anterior lamellar keratoplasty, were perforating/penetrating grafting procedures. Indications for transplant surgery included keratoconus

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Table 2
Main groups of clinical indications: general data.

Indication group	No. of eyes	Mean age, years (range)	Gender, % male/female	Allergy, n (%)	Eczema, n (%)
Keratoconus	71	47 (21–74)	47/54	33 (46)	19 (27)
Dry eye disease	66	59 (20–87)	24/76	20 (30)	10 (15)
Keratoplasty	55	63 (27–90)	51/49	19 (35)	5 (9)
Difference between the three indication groups, *P*-value		<0.001[a]	=0.004[b]	=.13[b]	=0.03[b]

[a] Analysis of variance (ANOVA) test.
[b] Fisher's exact test.

(n = 24), Fuchs endothelial dystrophy (n = 18, all of which were performed in the pre-endothelial keratoplasty era), post-infectious keratitis scar (n = 8), cornea decompensation (n = 4), and unspecified corneal dystrophy (n = 1).

The most common primary clinical reasons for applying CLs were to improve visual acuity (in 63% of cases) and as a bandage (34%). A small number of patients were fitted with CLs for cosmetic purposes (n = 4), occlusion (n = 3), or for improved contrast vision (n = 1).

2.2. Contact lens types

The types of CLs used by the study cohort are summarized in Table 1. The most commonly used CLs were scleral lenses (in 53% of cases) and soft lenses (either conventional soft lenses or silicone hydrogel lenses; 35%); the results of these two groups were analyzed further.

The scleral lens group contained patients who used mini-scleral lenses (15–18 mm in diameter; n = 20 patients) or regular scleral lenses (18–22 mm in diameter, n = 128 patients).

The most popular soft lenses were monthly disposable silicone hydrogels (n = 65); the remaining soft lenses were 3-month disposable silicone hydrogels (n = 13), daily disposable silicone hydrogels (n = 7), daily disposable soft lenses (n = 4), large-diameter soft lenses (n = 4), 2-week disposable silicone hydrogels (n = 2), 3-month disposable soft lenses (n = 2), monthly disposable soft lenses (n = 1), and aphakia soft lenses (n = 1).

The RGP corneal lens designs included a standard corneal design (n = 8), a keratoconus design (n = 6), and a keratoplasty design (n = 3).

2.3. Visual acuity outcomes

There was a significant improvement in median logMAR CL CDVA (−0.15; range: 1.00 to −2.10) compared to the median log MAR spectacle CDVA ($P < 0.001$). The visual outcomes for the total cohort, the major clinical indication subgroups, and the lens subgroups are summarized in Table 3. CDVA improvement by CL wear differed significantly between the major indication groups ($P < 0.001$, Kruskal-Wallis test); specifically, CL CDVA improved significantly more in the patients with keratoconus and keratoplasty compared with the patients with dry eye disease. Furthermore, users of scleral lenses had significantly more CDVA improvement than users of soft lenses ($P < 0.001$, Kruskal-Wallis test).

Eighteen of the 281 eyes (6%) had visual acuity that was <1/300 (i.e., <distinguish hand motion).

Table 3
Spectacle and contact lens CDVA.

Indication or lens group	No. of eyes CDVA ≥1/300,[a] n (%)	Spectacle CDVA	Contact lens CDVA	CDVA difference	*P*-value[b]
Total group	263 (94)				
LogMAR		0.30 (2.52 to −0.10)	0.10 (2.52 to −0.20)	−0.15 (1.00 to −2.10)	<0.001
Snellen equivalent		20/40	20/25	N/A	N/A
Keratoconus	71 (100)				
LogMAR		0.40 (2.52 to −0.10)	0.10 (1.00 to −0.10)	−0.30 (0.12 to −1.70)	<0.001
Snellen equivalent		20/50	20/25	N/A	N/A
Dry eye disease	64 (97)				
LogMAR		0.10 (1.30 to −0.10)	0.07 (0.80 to −0.20)	0.00 (0.14 to −1.13)	=0.007
Snellen equivalent		20/25	20/24	N/A	N/A
Keratoplasty	55 (100)				
LogMAR		0.42 (2.52–0.00)	0.05 (2.22 to −0.10)	−0.32 (0.15 to −2.10)	<0.001
Snellen equivalent		20/53	20/22	N/A	N/A
Scleral lenses	148 (100)				
LogMAR		0.40 (2.52 to −0.10)	0.05 (1.30 to −0.20)	−0.30 (0.15 to −2.10)	<0.001
Snellen equivalent		20/50	20/22	N/A	N/A
Soft lenses	88 (89)				
LogMAR		0.19 (2.52 to −0.10)	0.12 (2.52 to −0.10)	0.00 (0.14 to −1.40)	=0.032
Snellen equivalent		20/31	20/27	N/A	N/A

CDVA = corrected distance visual acuity; Log MAR = logarithm of the minimal angle of resolution; CDVA outcomes are presented as median (range); N/A = not applicable.
[a] ≥Distinguish hand motion.
[b] Wilcoxon signed ranks test.

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Table 4
Wearing time per day and per week.

Indication or lens group	No. of eyes daily wear, n (%)	Median wearing time per day, hours (range)	Median wearing time per week, days (range)
Total group	216 (77)	15 (5–18)	7 (1–7)
Keratoconus	71 (100)	15 (5–18)	7 (4–7)
Dry eye disease	29 (44)	16 (6–16)	7 (2–7)
Keratoplasty	54 (98)	15 (6–18)	7 (2–7)
Scleral	148 (100)	15 (5–18)	7 (2–7)
Soft	34 (34)	16 (7–17)	7 (4–7)

2.4. Wearing time and duration of CL use

Daily-wear contact lenses were worn by 77% of patients, with a median of 15 h per day (range: 5–18 h) and a median of 7 days per week (range: 1–7 days). The remaining 23% of patients wore their lenses continuously; these lenses were either silicone hydrogels (n = 59) or soft lenses (n = 6). The wearing time data in the clinical indication and lens type subgroups are summarized in Table 4.

In our cohort, 96% of patients wore their CLs ≥8 h per day. Among the patients who wore their CLs <8 h per day, 5 used scleral lenses, 2 used occlusive lenses, 1 used a soft lens, 1 used a tinted soft keratoconus lens, 1 used a filter lens, and 1 used a prosthetic scleral lens.

The median duration of wearing the current CL type was 6 years (range: 3 months to 39 years), and median CL wear duration in general was 11 years (range: 4 months to 53 years). Fifty-eight percent of patients had used a different CL type prior to the study.

2.5. Subjective performance

Median VAS outcome for the entire cohort was 84 for the topic of comfort (range: 14–100), 76 for visual quality (range: 4–100), 86 for lens handling (range: 15–100), and 85 for overall satisfaction (range: 7–100). The outcome of the patient questionnaire for all patient subgroups is summarized in Table 5.

The three clinical indication groups did not differ significantly with respect to comfort ($P = 0.16$), visual quality ($P = 0.14$), lens handling ($P = 0.15$), or overall satisfaction ($P = 0.43$; Kruskal-Wallis test).

Scleral lens users did not differ significantly from soft lens users with respect to comfort ($P = 0.29$), lens handling ($P = 0.21$), or overall satisfaction ($P = 0.21$, Kruskal-Wallis test). However, with respect to subjective visual quality, scleral lens users differed significantly from soft lens users (median VAS scores were 77.5 and 75, respectively; $P = 0.009$, Kruskal-Wallis test).

Five percent of patients scored <50 in the comfort topic; 3 used scleral lenses, 6 used soft lenses, 2 used corneal lenses, 2 used iris lenses, and 1 used a filter lens. Fifteen percent of patients scored <50 for visual quality; 14 used scleral lenses, 18 used soft lenses, 2 used filter lenses, 2 used iris lenses, 2 used corneal lenses, and 1 used a tinted soft keratoconus lens. Five percent of patients scored <50 in for lens handling; 9 used scleral lenses, and 1 used a tinted soft keratoconus lens. Lastly, 5% of patients scored <50 for overall satisfaction; 5 used scleral lenses, 6 used soft lenses, and 2 used iris lenses.

2.6. Effectiveness of medical CL fitting

We defined good performance of medical CL fitting as an overall satisfaction VAS score ≥70 (out of 100); this criterion was achieved in 81% of patients. Moreover, 90% of patients reported an overall satisfaction score ≥60. Importantly, 33% of patients reported an overall satisfaction score ≥90.

3. Discussion

The primary goal of this study was to evaluate the objective and subjective performance of various contact lens types that were fitted based on a lens selection algorithm and were used for a broad range of clinical indications. Our results show that similar outcomes can be achieved with both soft lenses and scleral lenses when fitting medical contact lenses. Importantly, subjective comfort, handling, and overall satisfaction were similar between scleral lens users and soft lens users. In addition to underscoring the clinical value of scleral lenses, our results also highlight the need for practitioners to be familiar with a wide range of lens types and tailored lens selection.

A large number of studies have been published recently regarding the indications for—and the application of—medical CLs. In our study, the most common indications were keratoconus, dry eye disease, and keratoplasty; moreover, the most commonly used lens types were scleral lenses and soft lenses (including conventional soft lenses or silicone hydrogel lenses). The objective performance of scleral lenses in our study cohort is consistent with previous reports by our group [15,25,26] and others [21,22]. Specifically, we observed high outcome with respect to median visual acuity. The improvement in CL CDVA compared to spectacle CDVA was the most pronounced in the patient subgroups with optical indications (i.e., the keratoconus and keratoplasty subgroups). This finding supports the putative optical benefit of CLs and is consistent with other studies that report on the use of lenses (including scleral lenses) for medical indications with irregular astigmatism [11,21,22]. With respect to therapeutic lenses, CL CDVA improved as well, even though the primary objective of the lenses was to protect or promote healing of the compromised cornea [6]. The optical advantage of lenses (including scleral lenses) in dry eye disease due to compensation of optical disturbances that arise from tear instability, punctate epithelial erosions, and/or corneal scars have been described previously [28,34,35]. Thus, scleral lenses may be preferred when soft lenses fail, and scleral lenses may even surpass soft lenses in terms of hydrating the cornea, protecting the cornea, and/or correcting an irregular corneal surface [28,29].

Subjective lens performance has also been reported previously. Interestingly, although scleral lenses are often considered to be cumbersome to handle, our study cohort reported remarkably high overall satisfaction, regardless of lens type. Studies of CL performance in which different lens types were evaluated simultaneously in a clinical setting and with various indications have not been reported previously. This paucity of comprehensive studies prevents a comparison of either objective or subjective outcomes, as study design, patient selection, and the types of

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Table 5
Subjective outcomes measured using **a** VAS questionnaire with scores ranging from 0 to 100.

Indication or lens group	No. of eyes, n (%)	Comfort	Visual Quality	Lens Handling	Overall Satisfaction
Total group	281 (100)	84 (14–100)	N/A	N/A	85 (7–100)
Eyes CDVA ≥1/300[a,b]	259 (92)	N/A	76 (4–100)	N/A	N/A
Eyes daily wear	216 (77)	N/A	N/A	86 (15–100)	N/A
Keratoconus	71 (100)	85 (24–97)	N/A	N/A	86 (34–98)
Eyes CDVA ≥1/300[a]	71 (100)	N/A	74 (27–97)	N/A	N/A
Eyes daily wear	71 (100)	N/A	N/A	94 (34–79)	N/A
Dry eye disease	66 (100)	78 (14–100)	N/A	N/A	85 (28–100)
Eyes CDVA ≥1/300[a]	64 (97)	N/A	75 (15–100)	N/A	N/A
Eyes daily wear	29 (44)	N/A	N/A	85 (15–100)	N/A
Keratoplasty:	55 (100)	84 (14–97)	N/A	N/A	85 (15–97)
Eyes CDVA ≥1/300[a]	55 (100)	N/A	84 (14–96)	N/A	N/A
Eyes daily wear	54 (98)	N/A	N/A	85 (44–96)	N/A
Scleral lenses	148 (100)	84 (14–100)	N/A	N/A	85 (15–100)
Eyes CDVA ≥1/300[a]	148 (100)	N/A	77.5 (14–100)	N/A	N/A
Eyes daily wear	148 (100)	N/A	N/A	86 (15–100)	N/A
Soft lenses	99 (100)	84 (14–97)	N/A	N/A	85 (26–98)
Eyes CDVA ≥1/300[a,c]	85 (86)	N/A	75 (4–97)	N/A	N/A
Eyes daily wear	34 (34)	N/A	N/A	91 (55–97)	N/A

CDVA = corrected distance visual acuity; VAS = visual analogue scale; VAS outcomes are presented as the median (range); N/A = not applicable.
[a] ≥Distinguish hand motion.
[b] 4 patients did not complete this question.
[c] 3 patients did not complete this question.

lenses vary widely. Moreover, the indications for CLs are continuously changing due to developments in ophthalmology [1]. Thus, our study is the first to provide an overarching perspective, and our lens fitting algorithm can support the practitioner in selecting the most appropriate lens type.

Our study has several notable strengths. First, the CL practitioners in this study participate in continuing education, with an emphasis on the specific skills needed to advise patients in a tertiary academic clinical setting. Thus, our standardized protocols for lens selection, lens fitting, and patient instruction are the result of many years of experience with a wide range of CLs. Furthermore, all of the major steps and decisions in the lens selection algorithm are based on peer-reviewed literature. In addition, it is important to fit CLs individually when applying bandage CLs to complicated eyes [10,27], which is reflected in our flow chart for soft lenses and silicone hydrogel lenses. Thus, the appropriate material, parameters [10], modulus [31], and replacement strategy are all essential for achieving an optimal lens fit. Importantly, our contact lens service is not affiliated with any CL manufacturer, and health insurance companies reimburse patients for CLs prescribed due to medical indications. Therefore, lens selection was not guided by any factors other than the individual patients' needs and preferences. Another strength of this study was our random selection of unilateral eyes; this step was important, given the high degree of correlation between eyes with respect to lens performance. Lastly, subjective performance was analyzed solely in the eye under study, thus further avoiding any possible undue effects due to the performance of the other eye.

This study also had some considerations that merit mention, the most important of which is patient selection. Our contact lens service is in a tertiary academic center, and this may have resulted in a disproportionate selection of more severe clinical indications. Because of its excellent cornea unit, our ophthalmology department has a relatively large population of patients with severe dry eye and—at the other end of the clinical spectrum—a relatively large proportion of post-graft and keratoconus patients. Thus, our clinic is an interregional referral center for patients with keratoconus, and the most severe cases are referred to our contact lens service for evaluation and—if needed—revision of their current CLs. The stage of the disease limited the available lens types to more advanced solutions; thus, a relatively higher proportion of scleral lenses were prescribed, whereas other lens types (for example, RGP corneal lenses) were underreported. Wu et al. [24] illustrated this phenomenon by reporting that RGP corneal lenses do not ensure improved quality of life for patients with severe keratoconus; thus, Wu et al. stressed the importance of prescribing the appropriate CL type for each grade of keratoconus. Moreover, patients may require refitting as their disease stages change [6], and the optimal CL type for an irregular cornea should not be determined solely by the degree of irregularity. Secondary features such as tear film deficiency and elevated corneal scars can also play an important role, as summarized in our lens selection algorithm.

Interestingly, we found that 58% of patients previously wore different lenses, and the new lens type yielded a high level of overall satisfaction. This result suggests that the majority of patients wore lenses that were not optimally fitting prior to changing their lens type. This suboptimal fitting might have been due to a change in the clinical situation (for example, the progression of pathology, additional complicating factors, and/or postsurgical factors) or after being referred to our clinic for poor CL performance. Expanding this prospective study to include a more general population will likely reveal important information regarding various CL types in patients in earlier stages of disease.

A limitation of our study was the fact that the cross-sectional observational design did not allow us to study complications associated with the lenses. Thus, we were unable to evaluate the safety, durability, or refractive stability of the lenses. Interestingly, however, four of the 281 patients in our study cohort needed (relatively minor) revision in their lenses (all four of which were scleral lenses); these revisions were based on either suboptimal fitting or altered corneal refraction. This finding is consistent with our previous finding that updating scleral lenses with relatively

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minor changes every 1.5–2 years is common practice and is recommended in order to ensure the lens material's quality and oxygen permeability [26]. A detailed analysis of these four cases did not provide additional insight (data not shown). In their recent review of scleral lenses, Van der Worp et al. [21] concluded that adverse events are rare in these modalities. In addition, other studies found that the therapeutic use of CLs does not appear to affect the incidence of CL-related complications [3–6,9]. The availability of silicone hydrogel materials with high oxygen permeability has opened new opportunities for patients with hypoxia-related corneal complications. Indeed, several studies reported that silicone hydrogels are both safe and efficacious when worn continuously for therapeutic purposes [3,7,8]. Nevertheless, it is obvious that the wearing of CLs involves some risk, and care should be exercised when fitting a compromised eye. Patients must be educated regarding proper lens care and to identify signs of potential complications before they begin using medical CLs.

The high subjective performance of all CL types was reflected by the fact that patients reported wearing their CLs many hours per day and many days per week; likewise, the VAS scores were relatively high with respect to comfort, visual quality, lens handling, and overall satisfaction. Thus, medical contact lens fitting was found to be effective in terms of subjective overall satisfaction. On the other hand, relatively low subjective performance was reported by a small group of patients, which was expressed by lower VAS scores (i.e., <50) and shorter daily use (<8 h per day). The lack of longitudinal follow-up in these lower-performing patients precludes our ability to draw any conclusions regarding whether the lower scores are related to CL performance and/or the underlying disease. In general, good wearing time results [21–23,35] and good general subjective outcomes have been reported among patients who use scleral lenses [15,25], although poor outcome has been reported for some patients [21]. Wu et al. [24] reported good vision-related quality of life among patients with a non-severe stage of keratoconus who used appropriate corneal CLs. Interestingly, the results of the Collaborative Longitudinal Evaluation of Keratoconus (CLEK) studies [36,37] support this finding, although the CLEK study found slightly more ocular discomfort among RGP corneal lens wearers [36], and patients with keratoconus generally grow increasingly less tolerant to wearing rigid contact lenses [37]. Lastly, Erdurmus et al. [18] reported that patients with keratoconus experience similar CL impact on quality of life, regardless of whether they use RGP corneal lenses, hybrid lenses, or soft toric CLs.

With respect to subjective performance and lens handling, scleral lenses were similar to soft lenses. This finding is somewhat remarkable, given the initial psychological resistance that patients often express in response to scleral lenses. Nevertheless, other studies have reported similar patient satisfaction results among patients who use scleral lenses [14,15,29].

In conclusion, we comprehensively evaluated the objective and subjective performance of a broad range of contact lens types used for a variety of clinical indications. Our results revealed that high outcome can be achieved with medical CLs in terms of visual acuity and overall patient satisfaction. Our results also underscore the role of scleral lenses in modern contact lens practice, and they emphasize the need for the availability of several CL types in order to fit the CL to each patient's needs and preferences. Thus, medical CL fitting was effective, and the lens-selection algorithm can help practitioners choose the appropriate CL type.

Conflict of interest

E.S. Visser is co-owner of Visser Contact Lens Practice, Nijmegen, the Netherlands. No other conflicting relationships exist for any authors.

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