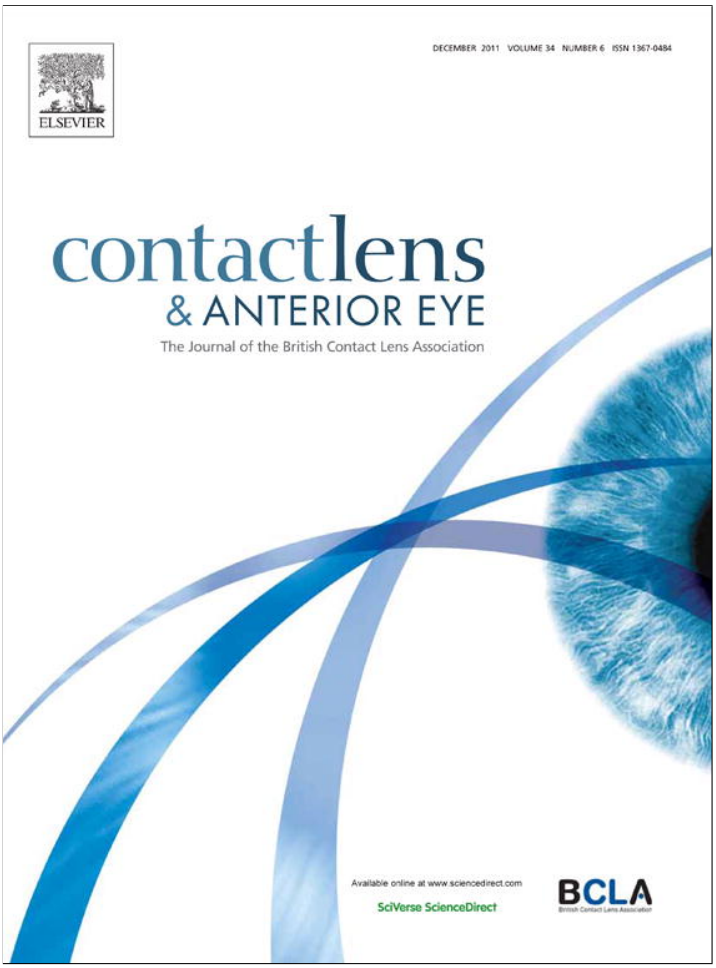

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Letter to the Editor

The European Contact Lens Forum (ECLF) – The results of the CLEER-Project

Keywords:
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1. About the European Contact Lens Forum (ECLF)

For many eye care professionals, the commencement of the CLEER-Project in the spring of 2008 was the first time they became aware of the ECLF, the European umbrella organization for most stakeholders in the contact lens field (Table 1).

ECLF is unique in that it is Eurocentric, its membership encompasses practitioners, academia, and industry, and with a flexible organizational structure, it is able to act and react swiftly in the long-term interests of wearers as well as its members.

ECLF's mission is:

- To facilitate the exchange of information between all CL practitioners, academics, and the CL industry
- To promote CLs to European eye care professionals (ECPs)
- To address issues relevant to the safe use and supply of CLs with European authorities and other professionals

The ECLF's vision is that:

- All CL professionals have a comprehensive understanding of all aspects of CL use
- ECPs see CLs as a core part of their practice and recommend them to all potential wearers
- All efforts are made to ensure the safe use of CLs under all circumstances

Table 1
Members of the European Contact Lens Forum (ECLF) (in alphabetical order).

ECLF (European Contact Lens Forum) membership (in alphabetical order):
ECLSO, European Contact Lens Society of Ophthalmologists
ECOO, European Council of Optometry and Optics
EFCLIN, European Federation of Contact Lens Industry
EUROMCONTACT, European Federation of National Associations and International Manufacturers of Contact Lens Products
IACLE, International Association of Contact Lens Educators

The ECLF's objectives are to:

- Promote CL and CL care education, thereby increasing the number of CL prescribers and wearers
- Maintain high standards of professionalism and cordial relations between the CL-prescribing professions within the European Community
- Conduct activities which are mutually beneficial to all involved in CLs, whilst pursuing the highest level of consumer health and safety
- Support continuing education to all relevant professionals

2. The Contact Lens European Evidence Report Project (CLEER-Project)

The ECLF initiated the CLEER-Project to gather Eurocentric data on significant incidents resulting from CL wear (including the wear of plano cosmetic CLs [pcCL]). The project's purpose was to generate data to support discussions with the EU and EU national authorities about regulating pcCLs (and their supply) as medical devices (currently not the case in the EU) in the interests of minimizing the number and severity of adverse outcomes resulting from the unregulated and unmonitored (no post-market surveillance) use of such CLs.

3. Background

Currently, the EU's Medical Device Directive (MDD) regulates prescription (corrective, powered) CLs (clear/handling tint, or coloured) and pcCLs. However, the latter is only regulated when the indication for use is 'therapeutic'.

Somewhat paradoxically, most countries regulate the right-to-fit CLs quite closely. Largely, CL fitting is limited to suitably trained ECPs such as ophthalmologists, optometrists, and dispensing opticians. However, in the EU or EEA countries, the right-to-supply/sell CLs is often not regulated at all, whilst the UK exercised its EU rights and chose to regulate the supply of all CLs in its territory [5].

4. The CLEER-Project

The CLEER-Project ran as an Internet-based data collection project (www.cleer-project.eu) (see Fig. 1). ECLF chose this path for rapidity of deployment, brevity of reporting, prevention of data transcription errors, and ease of analysis subsequently.

All ECPs eligible to fit CLs lenses within their country were invited to contribute to the CLEER-Project database. A no-cost, one-time registration was required and the log-in supplied was required when submitting a report. These barriers to open access were included in the interests of data integrity and to protect the report database from 'nonsense' submissions and computer hackers.

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Fig. 1. Screen shot from the CLEER-Project's website Welcome page.

5. Significant incidents only

To keep the results meaningful and concise, the ECLF decided to request reports only of significant incidents. These were defined as:

An asymptomatic or symptomatic, clinician-observed event that necessitated one, or any combination of the following actions:

- Temporary or permanent discontinuation of CL wear
- Treatment, and/or. . .
- Referral to a more appropriate professional

The presence of observed signs and symptoms were recorded, but not their severity. This was done for simplicity and to avoid the need for the project to dictate a single grading scale which may not have been familiar to reporters. It was also possible to enter relevant comments in each report.

6. Regulatory conditions of the CL sale

The CLEER-Project collected information about the category of the source (regulated or unregulated) of the CLs but no other details. The two options were:

Regulated: CLs were acquired **with a valid CL prescription** (in date and from an eligible ECP)
Unregulated: CLs were acquired **without a valid prescription** or without any verification.

Data collection started on 2008 June 1 and ceased on 2009 December 31. All database information will be destroyed two year after data collection ceased.

The following data was included in the questionnaire:

- Type of CLs: GP (also known as RGP) or soft CLs
- Prescription: Powered or plano
- Purpose: Corrective or cosmetic (coloured)
- Source of supply: Regulated or unregulated
- Incident-related information (presence only, multiple entries were possible):
  - Conjunctival hyperaemia
  - Conjunctival staining
  - Corneal neovascularization
  - Corneal staining/corneal erosions
  - Contact lens-induced papillary conjunctivitis (CLPC or CLIPC)
  - Contact lens-induced peripheral ulcer (CLPU) and other non-infectious infiltrative events
  - Infectious keratitis (with or without ulceration)
  - Vision-threatening signs (an overall assessment of the significant incident's morbidity)
  - Other (free text)
- Management: Within own practice/referred to another practice, hospital (name . . .), etc.
- Comments (free text)

7. Analysis

The data were analyzed using SPSS Version 17 (2008) software, employing mostly the Chi-square [χ^2] exact test. Probability was set at $p \leq 0.05$ for statistical significance. The necessary population and contact lens market data were drawn from a number of sources including internal, unpublished resources (market research data) from some of the ECLF members (e.g., EUROMCONTACT market statistics), the US CIA's The World Fact Book data on total country populations and Morgan et al. data [6–9].

8. Results

The CLEER-Project gathered 1276 reports from 65 ECPs and 3 ECP associations, from 13 European countries. This group of reporters represents almost 25% of those who registered (Table 2).

The majority of the reports (1208/94.7%) relate to soft CLs (SCLs). The SCL category includes all conventional, frequent replacement, and disposable SCLs, with or without power and/or colour, made either of hydrogel (Hy) or silicone hydrogel (SiHy) materials.

The remaining (68) reports related to (rigid) gas permeable CLs (RGP, or simply GPs). The representation of 5.3% of the total number of reports mirrors almost exactly the overall market share such CLs enjoy (4.8–5.7%). GP prescribing patterns do, however, vary greatly from country to country [10–12].

836 (65.5%) of all reports relate to purchases through regulated channels. 777 of which were SCLs (64.3% of all 1206 CLs) and 59 were GPs (86.8% of all GPs) (Table 3).

A total of 141 reports (11.05% of the total) were associated with coloured CLs. 138 were SCLs (11.4%) and 3 were GPs (4.4%).

83 of the 138 coloured SCLs (60.1%) were plano, 58 (39.9%) were powered (Table 4).

Of the 83 plano coloured SCLs, 69 (83.1%) were from unregulated sources, only 14 (16.9%) were from regulated ones (Table 5).

Compared with normal (clear or handling tinted) powered SCLs, coloured SCLs (powered and plano combined) resulted in statistically significantly more:

Table 2
Number of reporters and reports by country.

Country[b]	Active reporters[a]	Reports
AT (Austria)	3[a]	333
BE (Belgium)	3	9
CH (Switzerland)	13	66
DE (Germany)	7[a]	645
ES (Spain)	1	1
FR (France)	5	72
GR (Greece)	1	8
LT (Lithuania)	1	1
NL (The Netherlands)	1[a]	15
NO (Norway)	13	37
PL (Poland)	3	45
SE (Sweden)	12	26
UK (United Kingdom)	5[a]	18
	68	1276

[a] Existing databases included.
[b] Listed by internet domain ending.

Table 3
Data overview by type of contact lens, power, colour, etc.

Type	Application	Source	#s
RGP	Powered	Regulated	56
RGP	Powered/cosmetic	Regulated	3
RGP	Powered	Unregulated	9
RGP	Powered/cosmetic	Unregulated	0
RGP		Regulated	59
RGP		Unregulated	9
RGP		Total	68
Soft	Plano/cosmetic	Regulated	14
Soft	Powered	Regulated	724
Soft	Powered/cosmetic	Regulated	28
Soft	Not stated	Regulated	11
Soft	Plano/cosmetic	Unregulated	69
Soft	Powered	Unregulated	329
Soft	Powered/cosmetic	Unregulated	27
Soft	Not stated	Unregulated	6
Soft		Regulated	777
Soft		Unregulated	431
Soft		Total	1208
All CLs		Total	1276

Table 4
Data overview for coloured CLs by power, source, and country.

Country	Cosmetic CLs (plano and powered)				$\sum$
	Plano Cos reg	Plano Cos unreg	Pwr Cos reg	Pwr Cos unreg	
AT		1	10	3	14
BE					
CH	1	1			2
DE	12	58	16	19	105
ES					
FR	1	5	4	3	13
GR					
LT					
NL					
NO				1	1
PL		4		1	5
SE			1		1
UK					
Totals	14	69	31	27	141

- Conjunctival hyperaemia ($p < 0.001$)
- Corneal staining ($p = 0.013$)
- Contact lens induced peripheral ulcers (CLPUs) ($p = 0.004$)
- Contact lens induced papillary conjunctivitis (CLPC) ($p = 0.005$)
- Corneal neovascularisation ($p < 0.001$)
- Infectious keratitis ($p < 0.001$)

Table 5
Summary of regulated *vs.* unregulated sources by country.

Country	Country totals	% of total	Reg.	% of reg.	Unreg.	% of unreg.	Unregulated as % country total
AT	333	26.1	220	26.3	113	25.7	33.9
BE	9	0.7	7	0.8	2	0.5	22.2
CH	66	5.2	48	5.7	18	4.1	27.3
DE	645	50.5	429	51.3	216	49.1	33.5
ES	1	0.1	1	0.1	0	0.0	0.0
FR	72	5.6	47	5.6	25	5.7	34.7
GR	8	0.6	4	0.5	4	0.9	50.0
LT	1	0.1	1	0.1	0	0.0	0.0
NL	15	1.2	14	1.7	1	0.2	6.7
NO	37	2.9	30	3.6	7	1.6	18.9
PO	45	3.5	5	0.6	40	9.1	88.9
SE	26	2.0	13	1.6	13	3.0	50.0
UK	18	1.4	17	2.0	1	0.2	5.6
Total	1276		836		440		34.5

Table 6
Scenarios for regulated *vs.* unregulated sales of plano coloured CLs.

Plano cosmetic contact lenses				
CLEER reports	Reg.	Unreg.	*p*	Unreg. over represented in adverses
	14	69		
	Market shares (%) possible scenarios			
	>45	<55		Yes
	45	55	<0.001	Yes
	30	70	<0.009	Yes
	25	75	<0.087	No
	20	80	<0.476	No
	<20	>80		No

- Corneal erosions ($p = 0.034$)
- Vision-threatening signs ($p = 0.03$)

In a related 3-variable analysis (powered CLs, plano coloured CLs, and powered coloured CLs), the results were the same as for the 2-way analysis, i.e., the combination of the coloured CL types were statistically significantly different from normal powered CLs (for the same variables). However, neither plano nor powered coloured CLs were statistically significantly different from each other or from powered CLs. Plano coloured CLs are thus no different from powered coloured CLs as far as statistically significant incident rates are concerned. The coloured CL category (all variations) however, resulted in statistically significantly more incidents than normal prescription CLs.Unregulated sourcing resulted in statistically significantly more:

- Corneal staining ($p = 0.01$)
- Corneal neovascularisation ($p = 0.004$)
- Vision-threatening signs ($p = 0.016$)

This agrees with other published [1–4] and anecdotal reports. The ratio of unregulated to regulated sales for cosmetic CLs was the reverse of that for the non-coloured CLs. More than four out of five of the plano coloured CLs were acquired from unregulated sources.

An analysis was made of whether plano cosmetic CLs sourced via unregulated channels caused statistically significantly more incidents. Unfortunately, the very nature of unregulated channels makes it impossible to ascertain its market share accurately. However, it is certain that the market shares (regulated *vs.* unregulated) of plano cosmetic CLs are quite different from those of normal CLs (app. 65% *vs.* 35%) with unregulated sources dominating.

Some possible scenarios related to the sourcing of plano cosmetic CLs were canvassed. If only one in four (25%) or more plano cosmetic CLs are sourced via regulated sources then there is no statistically significant difference between the sources of plano cosmetic CLs. If regulated sources have a market share of 30% or more of the plano cosmetic CLs this would result in statistically significantly more incidents via unregulated channels. With too many unknowns no concrete conclusions could be reached (Tables 6 and 7).

9. Discussion

9.1. Unregulated vs. regulated sales

The higher risk to eye health from wearing CLs sourced via unregulated channels is underlined by the results. The proportionally higher ratio of unregulated sourcing of plano cosmetic CLs is even more concerning.

Table 7
Comparisons with other studies.

Country	The CL market		Infectious keratitis (18 months)	Wearers % of pop	CLEER reports	CLEER reporters	Stapleton et al. [13] at 7.2/10,000	Morgan et al. [14] at 9.6/10,000	CLEER
	Population (age: 15–64)	CL wearers (age: 15–64)							
AT	5,541,493	195,515		3.5	333	3[a]	141	188	96
BE	6,899,279	313,805		4.5	9	3	226	301	6
CH	5,176,918	402,442		7.8	66	13	290	386	19
DE	54,384,520	1,611,033		3.0	645	7[a]	1,160	1,547	278
ES	27,306,506	1,090,629		4.0	1	1	785	1,047	0
FR	41,892,404	1,787,595		4.3	72	5	1,287	1,716	37
GR	7,147,004	203,501		2.8	8	1	147	195	1
LT	No comparable data available				1	1	0	0	0
NL	11,324,401	754,050		6.7	15	1[a]	543	724	7
NO	3,141,693	304,274		9.7	37	13	219	292	13
PL	27,558,329	297,441		1.1	45	3	214	286	6
SE	5,929,946	575,205		9.7	26	12	414	552	7
UK	42,604,126	3,026,783		7.1	18	5[a]	2,179	2,906	6
Totals	238,906,619	10,562,271		4.4	1,276	68	7,605	10,140	476

[a] Existing databases included.

10. Conclusions

The results confirm that the wearing of CLs is not always statistical 'significant incident' free but given the number of CL wearers in Europe, the incident rate reported in the CLEER-Project is lower than in comparable previous studies. This is probably due to the low and variable participation rate.

The finding that coloured CLs (plano and powered) resulted in statistically significantly more events than normal powered CLs is noteworthy. The additional findings that plano coloured CLs were not different statistically from powered coloured CLs or normal powered CLs sends a clear message that 'a CL is a CL, regardless of its Rx'. If it is a coloured CL, especially a plano coloured CL, its usage should be even more closely monitored because the rate of statically significant incidents with these CLs is higher.

Given the data for statically significant incidents with plano coloured CLs sourced from unregulated suppliers in particular, there is every reason to believe that they should be at least as tightly regulated as any other CL, i.e., as a medical device.

The CLEER-Project's data shows that unregulated sourcing of CLs is associated with higher rates of statically significant incidents. The proportionally high ratio of unregulated sourcing of plano cosmetic CLs is even more concerning.

The wearing of any type of CL regardless of power (Rx) or intended application can have unexpected consequences. Therefore, all CLs regardless of type should be regulated similarly. The loop-hole regarding the unregulated status of plano cosmetic CLs in many European countries should be closed in the interests of the eye health of wearers. The selection and sourcing of any type of CL without the involvement of an ECP is an on-going cause for concern.

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