LABORATORY SCIENCE

Paper waste from instructions for use brochures in cataract surgery implant packaging in Europe and the United States

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Purpose: To assess the extent of paper waste generated per year by instructions for use (IFUs) brochures included in intraocular lens (IOL) packaging in Europe and the U.S.

Setting: Rothschild Foundation Hospital, Paris, France; Royal Free London NHS Foundation Trust; Center for Sight, London, United Kingdom.

Design: Experimental study.

Methods: A sample of IOLs were collected and each IFU was weighed. In addition, the cumulative weight of these brochures used in cataract surgeries performed annually in Europe and the U.S. was estimated, and the potential annual paper conservation that could be achieved if all manufacturers adopted electronic IFUs (e-IFUs) in Europe and the U.S. was determined.

Results: The mean and standard deviation of the weight for overall IFUs, classic IFUs, and e-IFUs were 17.6 ± 13.8 g, 23.5 ± 13.2 g, and 2.9 ± 1.9 g, respectively. The estimated cumulative weight of paper generated from the IFUs accompanying implants used in European and U.S. cataract surgeries is 153 tons. If all manufacturers transition to e-IFUs, the cumulative weight saved would be 128 tons (−84%), equivalent to 120 tons of carbon dioxide equivalent and the preservation of more than 2000 trees annually.

Conclusions: The classic IFUs in IOL packaging result in a significant amount of paper waste annually. Therefore, there is an urgent need for a rapid transition to e-IFU technology. The adoption of e-IFUs has already been authorized in Europe and the U.S., and it is crucial to expedite this process.

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The modern world increasingly recognizes the significance of waste reduction, minimizing carbon footprints, and embracing sustainable practices in various aspects of human activity, including the healthcare sector. While the primary goal of the healthcare industry is to enhance human health and save lives, it is crucial to consider the environmental effect of its operations. The healthcare system accounts for nearly 10% of greenhouse gas emissions in the U.S., and its ecological footprint cannot be overlooked.[1] One area that demands attention is the operating rooms, which account for up to 30% of hospital waste.[2] Considering that ophthalmology has the highest surgical volumes in the medical field, it becomes evident that ophthalmologists have a significant opportunity to contribute to reducing unnecessary waste in operating rooms.[3]

Cataract surgery, the most frequently performed surgical procedure in ophthalmology, plays a significant role in the field, with approximately 20 million surgeries being conducted worldwide annually.[4–6] This includes 5 million surgeries in Europe and 3.7 million in the U.S.[7,8] Given these statistics, cataract surgeons must actively participate in efforts to address this issue.

Intraocular lenses (IOLs), essential medical devices used in cataract surgery, necessitate detailed and comprehensive informational materials to accompany each unit, ensuring proper utilization. These informational materials, instructions for use (IFUs), are typically printed on paper and included in the product packaging. They provide crucial information translated into multiple languages facilitating global distribution of the same product. In fact, most countries mandate translation, with only a handful permitting the use of English. This allowance is usually limited to professional users and established devices. Some researchers have already drawn attention to the excessive waste generated by lengthy IFUs printed in multiple languages.[9,10] However, the environmental implications and cumulative paper waste resulting from this practice in Europe and the U.S., which may appear insignificant, have

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yet to be quantified and could be more significant than previously acknowledged.

Electronic IFUs (e-IFUs) are a relatively new approach that use shorter paper documents with concise instructions provided in multiple languages, accompanied by a link or QR code that allows access to the IFU on the internet (Figure 1). This significantly reduces the need for extensive printed materials. This practice significantly contributes to paper usage savings. However, despite being permitted in both Europe and the U.S., e-IFUs are not universally adopted by all manufacturers.

This study aims to provide insights into the extent of paper waste generated by IFUs in IOL packaging used in cataract surgeries conducted in Europe and the U.S. In addition, we aim to calculate the potential reduction in paper waste that could be achieved if every manufacturer transitioned to e-IFUs.

METHODS

Sample Collection of IOL Models

We collected a representative sample of IOL models used for cataract surgery in 3 ophthalmic surgery centers: Rothschild Foundation Hospital in Paris, Royal Free London NHS Foundation Trust, and Center for Sight in London. IOL models were chosen without any connection to their IFUs from the available options within our region. This unbiased approach was adopted to ensure that the results were not influenced by the packaging practices of any specific company.

Weight Measurements

The IFUs in the packaging of each IOL were meticulously extracted and weighed individually using high-precision balances. At the Rothschild Foundation Hospital, the AccuWeight IC255 300 g balance was used with an accuracy of ±0.05%. The Royal Free London NHS Foundation Trust and the Center for Sight used the Digi DS-502 6 kg × 1 g IP65 Bench Scale. Before each measurement, the balance was calibrated to ensure utmost accuracy. The weight of each IFU was recorded in grams. This process was repeated for all IFUs within the sampled IOL units.

Data Analysis

The recorded weights of the IFUs were then entered into Microsoft Excel software (v. 2305 build 16.0.16501.20074) for the calculation of descriptive statistics. The IFUs were divided into 2 groups: the classic IFUs and the e-IFUs.

To understand the typical weight and variability of IFUs, both classic and e-IFUs, we computed the mean weight and standard deviation for each group and the overall total. These metrics provided insights into the central tendency and dispersion of the IFUs' weights, enabling us to assess the typical weight of an IFU, an e-IFU, and the variations across different IOL models.

Paper Waste Assessment

Using the calculated mean weight of the IFUs and the estimated number of cataract surgeries performed in Europe and the U.S. (8.7 million), we estimated the global production of IFUs and the annual paper waste generated from printing these brochures for surgeries in both regions.[7,8] We also determined the carbon dioxide equivalent (CO_2eq) emissions, taking into account that 1 ton of paper production results in 942 kg of CO_2eq as well as the equivalent number of copier paper reams, considering that 1 ton of paper is equivalent to 400 reams.[11,12] In addition, we assessed the number of trees necessary to produce this nonrecycled quantity of paper, noting that approximately 17 trees are needed to produce 1 ton of paper.[12] Although we did not account for the portion of paper that is recycled because of the difficulty in determining the percentage of recycled paper, it is important to acknowledge that the IFUs are typically discarded in biological waste bins and not recycled, resulting in a genuine loss of paper and wood resources.

Figure 1. The recto-verso image of the lightest electronic Instructions for Use, integrated into all Zeiss IOLs, weighs only 1.4 grams. The QR code is visible in the bottom right corner. The following pages provide instructions informing users that a physical copy can be requested at no cost, in compliance with the regulatory obligation in the European Union. Reprinted with permission from Zeiss.

Furthermore, we evaluated the potential reduction in paper usage that could be achieved if all manufacturers transitioned to e-IFUs in Europe and the U.S., along with the number of trees that could be saved annually.

Moreover, we conducted a qualitative assessment of the user-friendliness of each available e-IFU in the market. In addition, we provided information regarding the manufacturing site of each examined IOL. Through this qualitative analysis, we aimed to gain insights into the distance covered by the IFUs from the manufacturing site to the surgical site. By presenting this information, we aim to enhance our understanding of the avoidable carbon emissions and environmental degradation that arise from transporting bulky and unnecessary IFU brochures.

RESULTS

The IFUs were classified into 3 primary groups: classic paper IFUs, which contained all the necessary information printed on paper; hybrid IFUs, consisting of partial information on paper with an additional link to internet-based resources within the same leaflet; and fully electronic IFUs. Table 1 presents a summary of the results for all IFU weights.

The mean weight of all IFUs combined was 17.6 g while the mean weight of e-IFUs alone was significantly lower at 2.9 g (more than 6 times less). We found that only 2 manufacturers have fully transitioned to e-IFUs.

Based on our estimations, the cumulative weight of IFUs for the 8.7 million cataract surgeries performed annually in Europe and the U.S. amounts to 153 tons. This quantity of nonrecycled paper corresponds to approximately 2700 trees required for annual production and results in 149 tons of CO_2eq gas emissions during production.

If e-IFUs were exclusively used, the theoretical cumulative weight would be approximately 25 tons (calculated as

Table 1. Weights of IFU brochures for selected IOL sample

Manufacturer	Name	Lens type	Weight	No. of languages	Manufacturing site
Classic IFUs					
B&L	Akreos (P)	Monofocal	53.7	25	U.S.
B&L	Envista	Monofocal	18.9	24	U.S.
B&L	Luxgood (P)	Monofocal	24.4	20	France
B&L	Luxsmart (P)	EDOF	24.0	20	France
Cristalens	Artis T PL E (P)	Monofocal T	8.2	6	France
Cristalens	Artis PL M (P)	Multifocal	8.4	6	France
Cristalens	Artis symbiose (P)	Multifocal	8.6	7	France
J&J	TECNIS monofocal (P)	Monofocal	21.5	14	U.S.
J&J	Eyhance (P)	Monofocal +	21.0	14	U.S.
J&J	Symfony (P)	EDOF	21.0	14	U.S.
J&J	TECNIS synergy (P)	Multifocal	21.5	14	The Netherlands
Physiol	Isopure	EDOF	11.4	25	Belgium
Physiol	Finevision HP	Multifocal	13.0	23	Belgium
Physiol	MicroF	Multifocal	12.5	25	Belgium
Rayner	RayOne aspheric	Monofocal	43.0	24	UK
Rayner	Rayone EMV (P)	Monofocal +	42.7	23	UK
Rayner	Rayone Trifocal (P)	Multifocal	42.7	23	UK
Rayner	Sulcoflex	Add-on	26.5	23	UK
		Mean weight:	**23.5 g**		
Hybrid IFUs					
Hoya	Vivinex (P)	Monofocal	18.6	4	Singapore
Hoya	Vivinex impress (P)	EDOF	18.4	4	Singapore
Physiol	Micropure	Monofocal	12.8	32	Belgium
		Mean weight:	**16.6 g**		
Electronic IFUs					
Alcon	Clareon	Monofocal	2.9	32	U.S.
Alcon	Vivity	EDOF	5.8	33	U.S.
Alcon	Panoptix	Multifocal	5.6	33	U.S.
Zeiss	CT Asphina 509	Monofocal	1.4	24	China
Zeiss	CT Lucia 621	Monofocal	1.5	24	China
Zeiss	AT Lara	EDOF	1.4	24	France
Zeiss	AT Lisa	Multifocal	1.4	24	France
		Mean weight:	**2.9 g**		
		Total mean weight:	**17.6 g**		
		Estimated cumulative weight:	**153 tons**		

B&L = Bausch & Lomb; IFU = instruction for use; J&J = Johnson & Johnson; (P) = preloaded; T = torric

8.7 million multiplied by the mean weight of e-IFUs). This implies a potential reduction in paper usage of 128 tons if all manufacturers transition to e-IFUs (calculated as the current estimated cumulative weight minus the theoretical weight if only e-IFUs were used, which is 25 tons). The adoption of e-IFUs offers the opportunity to conserve 128 tons of paper, equivalent to more than 50 000 reams of copier paper, and approximately 2200 trees annually. In addition, this switch can reduce 120 tons of CO_2eq greenhouse gas emissions per year.

All except one e-IFU in our sample used QR code technology instead of a simple internet link. The authors conducted tests on each e-IFU and found them user-friendly and functional. QR codes are easier and faster to use with the widespread use of smart devices in healthcare.

Table 1 also provides information on the manufacturing sites of the IOLs, revealing their global distribution, spanning from China to the U.S.

DISCUSSION

The cataract surgery community strongly agrees that the waste generated in operating rooms is excessive and should be reduced. Two surveys were conducted on 1500 cataract surgeons, one in the U.S. and the other in Europe, by the Ophthalmic Instrument Cleaning and Sterilization Task Force and the ESCRS, respectively.[13,14] These surveys revealed that over 90 percent of cataract surgeons agree on the excessive waste generated in operating rooms and the need for its reduction. Furthermore, sustainability has emerged as a focal point in numerous conferences where dedicated sessions involving surgeons and representatives from ophthalmic companies have been conducted. An illustrative instance occurred at the American-European Congress of Ophthalmic Surgery held in Florence in June 2023. This study used a systematic approach to provide a precise and comprehensive assessment of the actual paper waste

associated with including IFUs in the packaging of cataract surgery implants in Europe and the U.S. While the weight of individual paper IFUs in IOL packaging may seem insignificant, the cumulative weight becomes substantial when considering the 8.7 million cataract surgeries performed yearly. This accumulated weight results in significant environmental costs related to paper production, waste disposal, and the energy consumed during these processes and transportation of the IFUs. Our findings indicate that including lengthy IOL IFU brochures translated into multiple languages is excessive and contributes to an estimated 153 tons of paper waste annually.

In the present digital era, where surgeons worldwide have easy access to the internet through their smartphones, transitioning to the provision of crucial informational materials digitally emerges as a potential solution. This transition would reduce the reliance on paper and minimize the environmental footprint. Embracing digitalization aligns with the wider global trend toward sustainability. E-IFUs serve as a viable alternative, and our study demonstrates that their adoption could result in a significant reduction of 128 tons (−84%) of paper waste and a concurrent decrease of 120 tons of CO_2eq greenhouse gas emissions per year if this technology was to be universally embraced by manufacturers in both Europe and the U.S.

These figures underscore the significant environmental effect of using paper IFUs in IOL packaging, emphasizing the urgent need for the healthcare industry to explore more sustainable alternatives and rapidly transition to e-IFUs. Two different technologies exist: a standard internet link and a QR code, with the latter being more convenient and user-friendly in our assessment (Figure 1).

It is worth noting that e-IFUs offer several advantages over printed IFUs, including the ability to include more information without space limitations and add interactive content and videos that can enhance understanding of lens implantation and the use of injectors. Furthermore, e-IFUs are easier to update, and any errors can be corrected without requiring a product recall, which may be necessary in the case of traditional IFUs. While some argue that e-IFUs may be time-consuming, scanning QR codes is significantly faster than finding the desired language in a printed IFU written in over 20 different languages.

Furthermore, in practical scenarios, IFUs are seldom used by surgeons or paramedical staff, except during transitions to new brands of IOLs or when new ophthalmic assistants join the team. This preparatory training can be readily accomplished preoperatively by engaging in relevant audio-visual instruction. Moreover, during the surgical procedure, because of sterility concerns, the surgical assistant typically opens the lens box rather than the surgeon. Consequently, the surgeon is unable to access the printed IFU. Conversely, an e-IFU displayed on a screen before the surgeon can allow for consultation of the IFU in a sterile and comfortable manner.

Manufacturers' delayed transition to e-IFUs in both Europe and the U.S., despite being authorized in both regions, can be attributed to the substantial regulatory demands placed on manufacturers by the European and U.S. regulatory bodies. These stringent regulations encompass various aspects, such as ensuring universal access to the e-IFUs for individuals using any device as well as guaranteeing that surgeons can effectively use a PC or smartphone to access the e-IFUs.

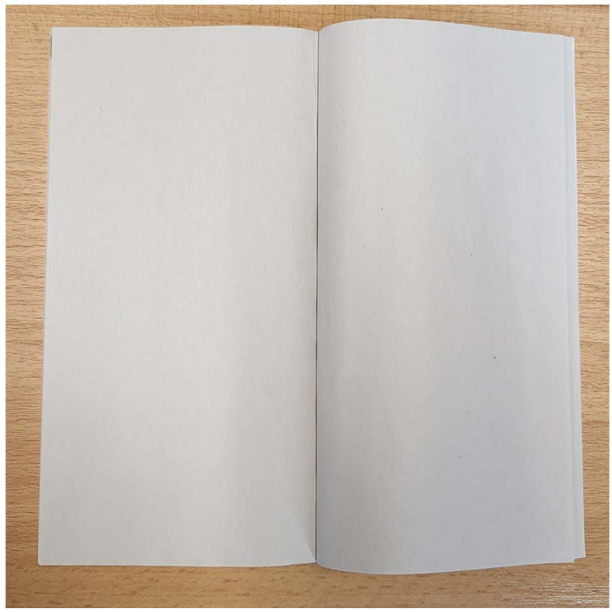

Figure 2. A printed Instructions for Use manual with 24 blank pages at the end of the booklet.

E-IFUs have also received authorization in many other countries. However, they are still prohibited in 60 countries, primarily consisting of smaller low and middle-income nations. Notably, South Africa, Russia, and China are among the countries included in this list. Consequently, for products intended for global markets, including e-IFUs may require using two production lines to package a product—one with a paper IFU and the other without.[9] This is the primary reason why not all manufacturers have transitioned to e-IFUs yet and continue to distribute classic paper IFUs in countries where regulations permit it. Some manufacturers do not seem to be fully aware of the environmental effect of paper IFUs and are not taking the issue of paper waste and environmental concerns seriously. This study identified instances of blank pages in IFUs, highlighting this lack of environmental consciousness (Figures 2 and 3).

Europe and the U.S. have a crucial role in promoting the adoption of e-IFUs in other countries. It is important to establish global harmonization to facilitate the effective implementation of e-IFUs, even within their territories. Regulatory bodies in different nations should make concerted efforts to phase out the reliance on paper IFUs gradually. This endeavor should target inefficient practices, such as including blank pages and providing translations in more than 30 languages, contributing to unnecessary waste.

The IFU of the Hoya Vivinex IOL offers an interesting compromise between e-IFUs and classic paper IFUs, providing a link for European countries and the U.S. on the one hand and written instructions in a few other languages for

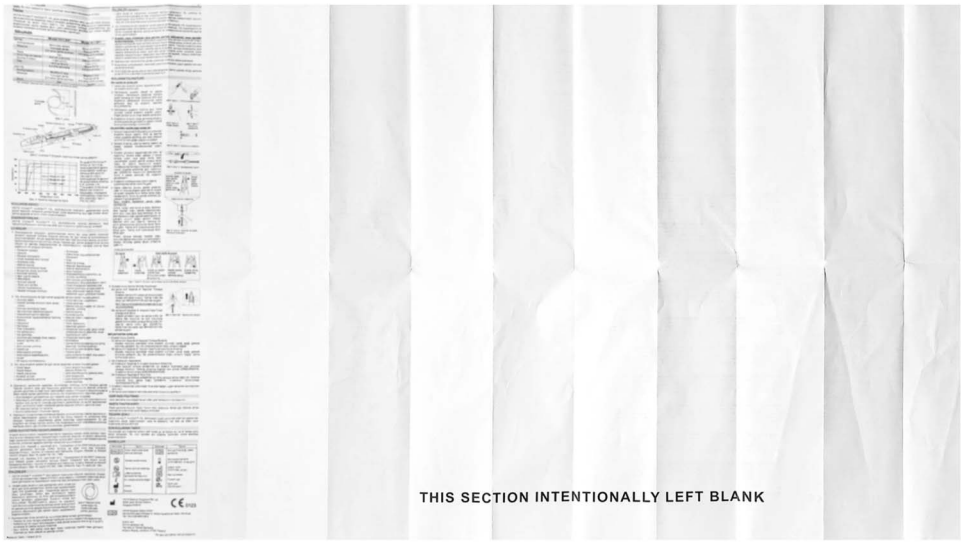

Figure 3. An Instructions for Use pamphlet with a white area of 59 cm × 42 cm with the mention "This section intentionally left blank."

countries that do not accept e-IFUs. This approach can act as an interim measure for manufacturers until global regulators universally accept e-IFUs in all countries.

The significant global waste generated by small documents like IFUs emphasizes the need to implement sustainable practices across the entire cataract surgery process, ranging from manufacturing design to the recycling process. Even seemingly insignificant components such as IFU brochures can significantly contribute to this endeavor. It should be noted, however, that IFU brochures represent only a fraction of the waste and environmental effect produced by cataract surgery. A previous study revealed that cataract surgery generates 827 g of waste (669 g excluding recyclable material) and that the paper packaging of IOL (box and IFU together) accounted for approximately 7.4% of the total waste of cataract surgery, with a mean weight of 63 g per IOL.[10] Considering the weight of the average IFU that we measured, it appears that IFUs are responsible for only 28% of the paper packaging of the IOL and approximately 2% of the total cataract waste.

Regarding the size of IOL boxes, there are significant variations among manufacturers, often driven by marketing considerations. We strongly recommend that cataract surgeons not rely solely on the superficial and aesthetic effect of the packaging but instead opt for the most compact and environment-friendly alternative.

The widespread use of preloaded IOL models with single-use injectors has a notable ecological consequence. This effect stems from the plastic waste produced by the disposable injector and the increased packaging size and weight, particularly for hydrophilic preloaded lenses that necessitate a significant amount of water for lens preservation within the injector.

Although the waste generated by IFUs may seem relatively insignificant compared with other packaging-related issues, it is crucial to address the IFU problem as an important initial measure. We can take a significant step forward by eliminating the requirement for IFUs and embracing electronic alternatives, such as e-IFUs. Furthermore, since this approach has no negative effect on marketing branding, there is no reason to delay its implementation. This step is relevant not only for IOLs but also for other medical devices such as ophthalmic viscoelastic devices that are commonly used in cataract surgery.

Table 1 also indicates the manufacturing sites of each IOL and summarizes how globalization has led to the relocation of industries across the globe. The IOL boxes and IFUs traverse various countries, and the carbon footprint associated with this transportation, which varies from country to country where surgeries are performed, must also be considered.

Our study is the first to quantify the paper waste generated by IFUs. However, it is crucial to acknowledge the limitations of our research. First, our calculations are based on estimated values for the annual number of cataract surgeries conducted in Europe and the U.S., based on the tree-to-paper production ratio, and do not account for recycling. These estimations introduce a certain level of uncertainty to our findings. Second, our sample predominantly consists of major cataract centers in our cities and select European centers, potentially limiting its representativeness for the broader European and US markets. Finally, we did not consider variations in the frequency of usage for specific lenses or manufacturers, nor the market share of each lens or manufacturer, as these data are private.

Further research, in the form of a survey study, could be undertaken to evaluate the receptiveness of surgeons toward embracing e-IFUs and the frequency with which they consult them. Such inquiries might provide valuable perspectives on practical necessities, potentially resulting in the easing of regulatory constraints. This, consequently, could aid manufacturers in reducing waste generation. A potential approach could involve providing the IFU initially when the surgeon receives instructions from the medical device consultants or on the initial delivery of the medical device. Subsequent revisions to the IFU could be provided solely in instances of modifications.

In conclusion, this study has shed light on the environmental effect of IFU brochures used in packaging cataract surgery implants, highlighting a frequently overlooked aspect. It is an illustrative example of the many healthcare products that rely on IFUs. Implementing e-IFUs in the healthcare sector signifies a small but crucial step toward improving overall environmental sustainability. Considering the mounting environmental challenges, every effort to promote sustainability carries immense significance. It is imperative for the healthcare industry and regulatory bodies worldwide to swiftly transition to e-IFUs.

WHAT WAS KNOWN

- According to surveys conducted among cataract surgeons in Europe and the U.S., more than 90% of respondents expressed concerns about excessive waste in the operating room.
- Instructions for use (IFUs) brochures, included in every IOL box, are rarely read and often discarded without consideration, leading to an unknown global environmental effect.

WHAT THIS PAPER ADDS

- The estimated global paper waste from IFUs of implants used in cataract surgeries performed annually in Europe and the U.S. amounts to 153 tons.
- Electronic IFUs that solely feature a QR code to access the IFUs online are authorized in Europe and the U.S. If all manufacturers in Europe and the U.S. adopt this approach, it could potentially lead to an 84% reduction (123 tons) in paper waste and the preservation of approximately 2200 trees annually.

REFERENCES

1. Eckelman MJ, Huang K, Lagasse R, Senay E, Dubrow R, Sherman JD. Health care pollution and public health damage in the United States: an update. Health Aff (Millwood) 2020;39:2071–2079
2. Wu S, Cerceo E. Sustainability initiatives in the operating room. Jt Comm J Qual Patient Saf 2021;47:663–672
3. Chang DF. Needless waste and the sustainability of cataract surgery. Ophthalmology 2020;127:1600–1602
4. Chuang J, Shih KC, Chan TC, Wan KH, Jhanji V, Tong L. Preoperative optimization of ocular surface disease before cataract surgery. J Cataract Refract Surg 2017;43:1596–1607
5. Rossi T, Romano MR, Iannetta D, Romano V, Gualdi L, D'Agostino I, Ripandelli G. Cataract surgery practice patterns worldwide: a survey. BMJ Open Ophthalmol. 2021;6:e000464
6. Grzybowski A, Kanclerz P. Recent developments in cataract surgery. In: Grzybowski A, ed. *Current Concepts in Ophthalmology*. Vol 124. Cham: Springer International Publishing; 2020: 55–97.
7. Press Release European partnership on cataracts between PromTime & the European Society of Cataract & Refractive Surgeons (ESCRS), London, Paris, June 21, 2022
8. Ianchulev T, Litoff D, Ellinger D, Stiverson K, Packer M. Office-based cataract surgery: population health outcomes study of more than 21 000 cases in the United States. Ophthalmology 2016;123:723–728
9. Chang DF. Tackling the challenge of needless surgical waste in ophthalmology. J Cataract Refract Surg 2023;49:333–338
10. Khor HG, Cho I, Lee KRCK, Chieng LL. Waste production from phacoemulsification surgery. J Cataract Refract Surg 2020;46:215–221
11. Tomberlin KE, Venditti R, Yao Y. Life cycle carbon footprint analysis of pulp and paper grades in the United States using production-line-based data and integration. BioResources 2020;15:3899–3914
12. Cushman-Roisin B, Cremonini BT. Data, Statistics, and Useful Numbers for Environmental Sustainability. Amsterdam, the Netherlands: Elsevier Science; 2021
13. Chang DF, Thiel CL. Survey of cataract surgeons' and nurses' attitudes toward operating room waste. J Cataract Refract Surg 2020;46:933–940
14. Chang DF, Elferink S, Nuijts RMMA. Survey of ESCRS members' attitudes toward operating room waste. J Cataract Refract Surg 2023;49:341–347

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