

BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email info.bmjopen@bmj.com

BMJ Open

Shortened cataract surgery by standardisation of the perioperative protocol according to the Joint Commission International accreditation: observational study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-028656
Article Type:	Research
Date Submitted by the Author:	18-Dec-2018
Complete List of Authors:	Okumura, Yuichi; Juntendo University Graduate School of Medicine, Department of Ophthalmology; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement Inomata, Takenori; Juntendo University Faculty of Medicine, Department of Ophthalmology; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement Iwagami, Masao; London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology Eguchi, Atsuko; Juntendo University Graduate School of Medicine, Department of Hospital Administration Mizuno, Ju; Juntendo University Faculty of Medicine, Department of Anesthesia and Pain Medicine Shiang, Tina; University of Massachusetts Medical School, Department of Radiology Kawasaki, Shiori; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement; Juntendo University Faculty of Medicine, Department of Cardiovascular Surgery Shimada, Akie; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement; Juntendo University Faculty of Medicine, Department of Cardiovascular Surgery Inada, Eiichi; Juntendo University Faculty of Medicine, Department of Anesthesia and Pain Medicine Amano, Atsushi; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement; Juntendo University Faculty of Medicine, Department of Cardiovascular Surgery Murakami, Akira; Juntendo University Faculty of Medicine, Department of Ophthalmology
Keywords:	Cataract and refractive surgery < OPHTHALMOLOGY, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

BMJ Open: first published as 10.1136/bmjopen-2018-028656 on 14 June 2019. Downloaded from <http://bmjopen.bmj.com/> on April 23, 2024 by guest. Protected by copyright.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Title: Shortened cataract surgery by standardisation of the perioperative protocol according to the Joint Commission International accreditation: observational study

Authors: *Yuichi Okumura^{1,2}, Takenori Inomata^{2,3}, Masao Iwagami⁴, Atsuko Eguchi^{2,5}, Ju Mizuno⁶, Tina Shiang⁷, Shiori Kawasaki^{2,8}, Akie Shimada^{1,7}, Eiichi Inada⁶, Atsushi Amano^{2,8} and Akira Murakami³.*

Affiliations:

¹Juntendo University Graduate School of Medicine, Department of Ophthalmology, Tokyo, Japan.

²Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement, Tokyo, Japan.

³Juntendo University Faculty of Medicine, Department of Ophthalmology, Tokyo, Japan.

⁴London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology, London, UK.

⁵Juntendo University Faculty of Medicine, Department of Hospital Administration, Tokyo, Japan.

⁶Juntendo University Faculty of Medicine, Department of Anesthesia and Pain Medicine, Tokyo, Japan.

⁷University of Massachusetts Medical School, Department of Radiology, Worcester, MA, US.

⁸Juntendo University School of Medicine, Department of Cardiovascular Surgery, Tokyo, Japan.

***Corresponding Author:** Takenori Inomata, 3-1-3 Hongo, Juntendo University School of Medicine, Department of Strategic Operation Management Improvement, Tokyo 113-0033, Japan.

Tel: +81-3-5802-1228; Fax: +81-3-5689-0394, E-mail: tinoma@juntendo.ac.jp

Word count: 1932

Key Words. Cataract surgery, external accreditation, joint commission international, patient safety, operating time, time period in operating room.

Synopsis: JCI accreditation initiatives were implemented in December 2015 at Juntendo University Hospital. After implementation, we found that the total procedure/surgery time of cataract surgery decreased by 18.2% while maintaining the same quality of patient care.

ABSTRACT

Objectives: To investigate the impact of standardisation of the perioperative protocol based on the Joint Commission International (JCI) accreditation guidelines for operating time in cataract surgery.

Design: Retrospective observational study.

Setting: Single centre in Japan.

Participants: Between March 2014 and June 2016, 3,127 patients underwent cataract surgery under topical anaesthesia including 2,581 and 546 patients before and after JCI accreditation, respectively.

Primary and secondary outcomes: We compared three time periods, comprising the pre-procedure/surgery time (prePT), procedure/surgery time (PT), and post-procedure/surgery time (postPT), and total procedure/surgery time (TPT) of cataract surgery between patients before and after JCI accreditation, by regression analysis adjusted for age, sex, and cataract-surgery associated confounders.

Results: The main outcomes were prePT, PT, postPT, and TPT. prePT (19.8 ± 10.5 vs. 13.9 ± 8.5 min, $P < .001$) and postPT (3.5 ± 4.6 vs. 2.6 ± 2.1 min, $P < .001$) significantly decreased after JCI accreditation, while PT did not significantly change (16.8 ± 6.7 vs. 16.2 ± 6.3 min, $P = .065$).

Consequently, TPT decreased on average by 7.3 min per person after JCI accreditation (40.1 ± 13.4 vs. 32.8 ± 10.9 min, $P < .001$). After adjusting for confounders, prePT ($\beta = -5.82$ min, 95%CI -6.75 – -4.88), PT ($\beta = -0.76$ min, 95%CI -1.34 – -1.71), postPT ($\beta = -0.847$ min, 95%CI -1.24 – -0.45), and TPT ($\beta = -7.43$ min, 95%CI -8.61 – -6.24) were significantly shortened after JCI accreditation.

Conclusion: Perioperative protocol standardisation, based on JCI accreditation, shortened TPT in cataract surgery under local anaesthesia.

Strengths and limitations of this study

• To our knowledge, this is the first study to investigate the impact of standardisation of the perioperative protocol for cataract surgery on operating room efficiency by comparing relevant time periods in the operating room for patients who underwent cataract surgery before and after Joint Commission International accreditation (JCI).

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- This study examined the three time periods, comprising the pre-procedure/surgery time, procedure/surgery time, and post-procedure/surgery time, and total procedure/surgery time of cataract surgery between patients before and after JCI accreditation.
 - The main limitation is that this study was conducted at a single university hospital; therefore, the generalisability of our findings may be limited.
 - Another limitation inherent to this study was that the impact of surgeon level and/or clinical experience of the surgeons and nurses was not analysed.

For peer review only

INTRODUCTION

Cataract surgery is the most common intraocular surgery [1]; worldwide population aging has resulted in substantial growth of the number of patients eligible for cataract surgery.[2] Cataract surgery is one of the most cost-effective surgical interventions [3, 4] and is important for hospital financial management as a profitable operating theatre.[5] Therefore, it is essential to continuously review surgical techniques and practices regarding efficiency, decreasing costs, and increasing safety in order to produce more reliable results for patients.

Cataract surgery is generally recognised as a safe and highly reproducible surgery. However, the recent focus on healthcare errors and safety supports performing cataract surgery from a patient safety perspective.[6] The Joint Commission International (JCI) advocates for maintenance of patient safety, continuous improvement of the quality of practice, and accrediting healthcare organisations in compliance with standards.[7] The JCI requires continuous quality improvement for international patient safety goals (IPSGs), which are important issues concerning patient safety. The IPSGs help confirm correct patient identification, encourage effective communication between patients and medical staff, improve the safety of high-alert medication administration, and ensure safe surgeries (correct surgical site, procedures, and patient for the surgery).[8] JCI accreditation is expected to improve patient safety associated with surgical operations; however, there is concern that these changes may impair efficiency by prolonging operating room time with an excessive focus on patient safety. Previous studies have reported improved medication management during JCI accreditation [7, 9]; however, there has been no study regarding the impact of IPSG procedures on operating room efficiency under topical anaesthesia with a large number of cases over a short period of time.[10]

In this study, we examined the impact of the standardisation of the perioperative protocol for cataract surgery on operating room efficiency by comparing relevant time periods in the operating room for patients who underwent cataract surgeries before and after JCI accreditation.

METHODS

Study design

We conducted a retrospective observational study between March 2014 and June 2016 at Juntendo University Hospital. This study was approved by the Institutional Review Board and Medical Ethics Committee of Juntendo University Hospital (approval number: 16-153) and was conducted in accordance with the tenets of the Declaration of Helsinki. The requirement for written informed consent was waived due to the retrospective observational nature of the study; patients could exclude themselves by using the opt-out method on our hospital website.

Joint Commission International accreditation

1
2
3 The Joint Commission is a United States-based non-profit tax-exempt 501(c) organisation that
4 accredits US health care organisations and programs. Its international branch, named JCI, was
5 established in 1998; JCI accredits medical services worldwide. Juntendo University Hospital was
6 accredited by the JCI on December 12, 2015. For JCI accreditation, inspectors from the JCI visit
7 and evaluate hospitals to observe hospital operations, conduct interviews, and review medical
8 documentation in order to determine whether hospitals meet compliance standards set forth by
9 the JCI. The goal of JCI accreditation is to evaluate care, standardise hospital processes, provide
10 education, and promote quality improvement for the surveyed organisations.
11
12
13
14
15

16 17 **Study period and participants**

18 We identified patients who underwent cataract surgeries (phacoemulsification with intraocular
19 lens implantation) under topical anaesthesia in Juntendo University Hospital between March
20 2014 and June 2016. We excluded combined cases, such as cataract extraction with
21 trabeculectomy or anterior vitrectomy, to fairly compare operation times. Patients were divided
22 into the two groups: a group before and a group after JCI accreditation.
23
24
25
26

27 **Outcome measures**

28 In Juntendo University Hospital, surgeons and nurses are required to computationally record the
29 timing of the following events: the patient entered the surgical room, the surgery started and
30 ended, and the patient was discharged from the surgical room. As performed in our previous
31 studies,[11-15] we first defined total procedure/surgery time (TPT) as the duration between
32 patient entrance to and discharge from the operating room. Then, we divided TPT into three
33 specific time periods (**Figure 1**): pre-procedure/surgery time (prePT), procedure/surgery time
34 (PT), and post-procedure/surgery time (postPT). PrePT was defined as the time elapsed in
35 minutes between patient entry to the operating room (patient in room, PIR) and the attachment of
36 monitors, such as an electrocardiogram and blood pressure gauge, and sign in. PT was defined as
37 the time elapsed in minutes between the start and end of surgery (the procedure/surgery start time
38 to the procedure/surgery finish time; PST and PF, respectively). postPT was defined as the time
39 elapsed in minutes between PF and the time that the patient exited the room (patient out of room,
40 POR).
41
42
43
44
45
46
47
48
49

50 **Analysis**

51 Patient characteristics were compared between patients who underwent cataract surgery before
52 and after JCI accreditation, by using the unpaired *t*-test for age, best-corrected visual acuity
53 (BCVA), and intraocular pressure (IOP) and the chi-squared test for sex and the prevalence of
54 complications associated with cataract surgery.
55
56
57
58
59
60

First, we crudely compared prePT, PT, postPT, and TPT between patients before and after JCI accreditation by using the unpaired *t*-test. Then, we conducted adjusted analyses with multivariable regression models, adjusting for age, sex, BCVA, IOP, and complications associated with cataract surgery.

Finally, as a post hoc descriptive analysis to detect the overall temporal trend during the study period, we plotted the monthly averages of prePT, PT, postPT (**Supplementary Figure 1A-C**), and TPT (**Figure 2**).

All data were analysed with STATA version 14 (Stata Corp, College Station, TX, USA).

Patient and public involvement

No patients were involved in the research design, and no patients were directly involved in this study.

RESULTS

Characteristics of patients

A total of 3,127 patients (mean age, 71.6 years old [interquartile range, 66–79 years]; male sex, 44.1%) underwent cataract surgery under local anaesthesia at Juntendo University Hospital.

Although the age and sex distributions were similar, BCVA and IOP were slightly, but significantly, worse after JCI accreditation (**Table 1**). The complication rate of cataract surgery did not significantly differ between the groups (**Supplementary Table 1**).

Table 1. Patient characteristics

Variables	Before JCI n = 2,581	After JCI n = 546	<i>P</i> value	Total n = 3,127
Age, years (SD)	71.6 (10.3)	71.9 (10.6)	.477	71.6 (10.3)
Sex, number (%)				
Men	1,138 (44.1)	242 (44.3)	.925	1380 (44.1)
Women	1,443 (55.9)	304 (55.7)		1747 (55.9)
BCVA, LogMAR (SD)	0.34 (0.3)	0.37 (0.4)	*.040	0.35 (0.3)
IOP, mmHg (SD)	14.0 (3.1)	14.3 (3.2)	*.015	14.0 (3.1)
Complication, yes (%)	72 (2.8)	18 (3.3)	.483	90 (2.4)

BCVA: best-corrected visual acuity, IOP: Intraocular pressure, JCI: Joint Commission International. *P* values were calculated by using an unpaired *t*-test (* < .05) for age, BCVA, and IOP, and by using the chi-squared test for sex and complications.

Crude analysis

Table 2 compares time periods in the operating room between groups before and after JCI accreditation. The prePT (19.8±10.5 min vs. 13.9±8.3 min, before vs. after JCI, respectively, $P<.001$) and postPT (3.5±4.6 min vs. 2.6±2.1 min, $P<.001$) were significantly reduced after JCI accreditation. However, the PT was not significantly different between before and after JCI accreditation (16.8±6.7 min vs. 16.2±6.3 min, $P=.065$). Consequently, TPT was significantly reduced by an average of 7.3 min per patient after JCI accreditation (40.1±13.4 min vs. 32.8±10.9 min, before vs. after JCI, respectively, $P<.001$).

Table 2. Operation time intervals

	Before JCI	After JCI		Total
Time periods, min (SD)	n = 2,581	n = 546	<i>P</i> value	n = 3,127
Pre-procedure/surgery time	19.8 (10.5)	13.9 (8.3)	*** < .001	18.7 (10.4)
Procedure/surgery time	16.8 (6.7)	16.2 (6.3)	.065	16.7 (6.6)
Post-procedure/surgery time	3.5 (4.6)	2.6 (2.1)	*** < .001	3.4 (4.3)
Total procedure/surgery time	40.1 (13.4)	32.8 (10.9)	*** < .001	38.8 (13.2)

JCI: Joint Commission International. *P* values were calculated by using an unpaired *t*-test (*** < .001).

Adjusted analysis

After adjusting for age, sex, BCVA, IOP, and complications associated with cataract surgery in multivariable regression analysis, prePT ($\beta=-5.82$ min, 95%CI -6.75--4.88, $P<.001$), PT ($\beta=-0.76$ min, 95%CI -1.34--1.71, $P=.011$), postPT ($\beta=-0.847$ min, 95%CI -1.24--0.45, $P<.001$), and TPT ($\beta=-7.43$ min, 95%CI -8.61--6.24, $P<.001$) were significantly shortened after JCI accreditation (**Table 3A–D**).

Table 3. Adjusted operation time intervals

A.

prePT	Coefficient	SE	<i>P</i> value	[95% Conf. Interval]
JCI accreditation, yes	-5.823	0.480	*** < .001	-6.765 -4.882
Sex, women (vs. men)	0.497	0.370	.179	-0.228 1.221

Age, years	-0.026	0.018	.144	-0.061	0.009
BCVA, LogMAR	-0.542	0.579	.349	-1.678	0.593
IOP, mmHg	-0.026	0.058	.659	-0.140	0.089
Complication, yes	-0.338	1.084	.755	-2.463	1.788

B.

PT	Coefficient	SE	<i>P</i> value	[95% Conf.	Interval]
JCI accreditation, yes	-0.756	0.299	*.011	-1.342	-0.171
Sex, women (vs. men)	-0.547	0.230	.017	-0.997	-0.096
Age, years	0.033	0.011	.003	0.011	0.055
BCVA, LogMAR	3.042	0.360	< .001	2.336	3.748
IOP, mmHg	0.004	0.036	.908	-0.067	0.075
Complication, yes	10.278	0.674	< .001	8.956	11.599

C.

postPT	Coefficient	SE	<i>P</i> value	[95% Conf.	Interval]
JCI accreditation, yes	-0.847	0.201	*** < .001	-1.241	-0.454
Sex, women (vs. men)	0.258	0.155	.095	-0.045	0.561
Age, years	-0.005	0.007	.487	-0.020	0.009
BCVA, LogMAR	-0.224	0.242	.355	-0.699	0.251
IOP, mmHg	-0.018	0.024	.473	-0.065	0.030
Complication, yes	0.353	0.453	.437	-0.536	1.242

D.

TPT	Coefficient	SE	<i>P</i> value	[95% Conf.	Interval]
JCI accreditation, yes	-7.427	0.605	*** < .001	-8.613	-6.240
Sex, women (vs. men)	0.208	0.466	.655	-0.705	1.121
Age, years	0.002	0.022	.937	-0.042	0.046
BCVA, LogMAR	2.275	0.730	.002	0.844	3.706
IOP, mmHg	-0.039	0.074	.595	-0.183	0.105
Complication, yes	10.293	1.366	< .001	7.615	12.971

JCI: Joint Commission International, BCVA: best-corrected visual acuity, IOP: Intraocular pressure, PrePT: pre-procedure/surgery time, PT: procedure/surgical time, postPT: post-procedure/surgery time, SE: standard error. *P* values were calculated by using an unpaired *t*-test (* < .05, *** < .001).

Post hoc descriptive analysis of monthly changes in TPT

The monthly average of TPT considerably changed since October 2015, approximately 2 months before the JCI accreditation (December 12, 2015) (**Figure 2**). The results of prePT, PT, and postPT are shown in **Supplementary Figure 1**.

DISCUSSION

Cataract surgery is an established minimally invasive and efficient surgical procedure.[16] However, because of rising medical expenses and lack of healthcare workers caused by the aging society,[10, 17] it is necessary to perform cataract surgery efficiently while maintaining quality of care.[14] Therefore, it is important to analyse the efficiency of services to ensure effective use of finite medical resources.[18] We explored the effect of standardisation of perioperative protocols in cataract surgery by using the transition to JCI accreditation.

Strategies for improving the utilisation rate of the surgical room are to increase the occupancy of the operating room by increasing the number of surgeries or to increase the economic efficiency by reducing the size of the operating room in accordance with the current number of surgeries. To increase the number of surgeries, it is important to shorten TPT and interval time between individual operations; reducing perioperative time (prePT and postPT) would lead to shortening of TPT. In the case of cataract surgery, because there is a short time between patient entry to and exit from the operating room, it is necessary to perform patient confirmation, prepare for surgery, and record the operation while caring for the patient, all within the short surgical time. Therefore, recording is frequently performed between high-priority tasks, and the recording time must be divided and dispersed. We showed that prePT and postPT were shortened by the standardisation of the perioperative protocol at the point of entry to the operating room; Juntendo University Hospital has implemented surgical record sheets (Invasive procedure safety checklist) in their electronic medical records to ensure adherence to IPSP standards (**Supplementary Table 2**). In surgeries that involve a large number of cases in a short period of time, such as cataract surgeries, standardisation of records and tasks is important for increasing the efficiency of the operating room. A previous study reported that clarification of the group goal was effective for improving efficiency,[19] indicating that the standardisation of perioperative protocols in Juntendo University Hospital has shortened the perioperative time by streamlining the process. Here, we revealed that, for a surgical procedure that cannot be

shortened further, such as cataract surgery, improvement of non-surgical portions, such as preparation of surgery and communication among medical personnel, is important for shortening the utilisation time of the operating room.

Additionally, we revealed that PT itself is shortened after JCI accreditation (**Table 3C**), indicating that the thorough standardisation of the perioperative protocol positively influenced the preparation process for surgery and communication between medical staff, resulting in shortened PT. Our results showed that TPT decreased by an average of 7.3 min per patient. Since the average cataract operation time in our hospital is 16.7 min, shortening of cataract operation time by 7.3 min corresponds to a 43.7% reduction in the average cataract operation time; if we performed three cataract surgeries, the time saved would allow for one additional surgery. In addition, since the number of complications did not change before and after the JCI accreditation, standardisation of the perioperative protocol did not impair patient safety, while improving efficiency in operating room use.

Since IPSPG measures may have affected clinical practice gradually, simply comparing surgical time intervals before and after JCI accreditation cannot accurately determine the effect of introducing JCI standards. Therefore, we conducted a trend analysis, as shown in **Figure 2**; notably, time intervals sharply declined in advance of the accreditation date. This indicates that the continuous standardisation of IPSPG in Juntendo University Hospital was gradually introduced during preparation for the JCI accreditation, implying that the focus of the medical staff changed within a few months. Fostering IPSPG in the effort for the JCI accreditation increased efficiency of cataract operation time and added value to our hospital as a profit centre.

There were several limitations in this study. First, since this study was conducted at a single university hospital, the generalisability of our findings may be limited. Depending on the size of a hospital and its current practice, the impact of standardisation on the perioperative protocol for cataract surgery may differ. Second, we did not assess the influence of the surgeon level and/or clinical experience of the surgeons and nurses. However, based on the number of complications, we suspect that the influence of individual surgeon level and job experience on operation time did not substantially change between before and after the JCI accreditation. In addition, time is required to train surgeons and medical professionals, whereas standardisation of the perioperative protocol can be introduced with little time investment.

In conclusion, we investigated the impact of JCI accreditation and implementation of standardised procedures on time periods in the operating room. PrePT and postPT were significantly shortened; thus, TPT was significantly reduced after implementing IPSPGs. Therefore, we conclude that the improvement of patient safety by standardisation of the preoperative protocols can also improve the efficiency of surgery under topical anaesthesia.

Acknowledgments

The authors thank the colleagues working at Juntendo University Hospital, Department of Surgery and Ophthalmology.

Author Contributions:

Y.O.: Performance of the research, data collection, data analysis, and writing of the paper; T.I.: Performance of the research, research design, data analysis, and writing of the paper; I.M.: Research design, data analysis, and writing of the paper; A.E.: Data collection, data analysis; J.M.: Research design, data analysis; T.S.: Writing of the paper; S.K.: Data collection, data analysis; A.S.: Data collection, writing of the paper; E.I.: Research design, writing of the paper; A.A.: Research design, writing of the paper; A.M.: Research design, writing of the paper; all authors reviewed the manuscript.

Funding

No funding disclosures.

Competing Interest

This study was supported by Hoky Medical, Inc. The sponsor or funding organisation had no role in the design or conduct of this research.

Patient consent

The requirement for written informed consent was waived due to the retrospective observational nature of the study; patients could exclude themselves by using the opt-out method on our hospital website.

Ethics approval

Institutional Review Board of Juntendo University Hospital (approval number: 16-153).

Data Sharing

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

REFERENCES

1. Spalton D, Koch D. The constant evolution of cataract surgery. *BMJ* 2000;321:1304.
2. Hatch WV, Campbell Ede L, Bell CM, et al. Projecting the growth of cataract surgery during the next 25 years. *Arch Ophthalmol* 2012;130:1479-81.
3. Foster A, Gilbert C, Johnson G. Changing patterns in global blindness: 1988-2008. *Community Eye Health* 2008;21:37-9.
4. Eye Care Comparative Effectiveness Research T. Cost-effectiveness of cataract surgery in Japan. *Jpn J Ophthalmol* 2011;55:333-42.
5. Abbott T, White SM, Pandit JJ. Factors affecting the profitability of surgical procedures under 'Payment by Results'. *Anaesthesia* 2011;66:283-92.
6. Kelly SP, Astbury NJ. Patient safety in cataract surgery. *Eye* 2006;20:275-82.
7. Wang HF, Jin JF, Feng XQ, et al. Quality improvements in decreasing medication administration errors made by nursing staff in an academic medical center hospital: a trend analysis during the journey to Joint Commission International accreditation and in the post-accreditation era. *Ther Clin Risk Manag* 2015;11:393-406.
8. Joint Commission International. International Patient Safety Goals 2017 [Available from: <http://www.jointcommissioninternational.org/improve/international-patient-safety-goals/> accessed July, 15th 2017.
9. Fang X, Zhu LL, Pan SD, et al. Safe medication management and use of narcotics in a Joint Commission International-accredited academic medical center hospital in the People's Republic of China. *Ther Clin Risk Manag* 2016;12:535-44.
10. McGinnis SL, Moore J. The impact of the aging population on the health workforce in the United States--summary of key findings. *Cah Sociol Demogr Med* 2006;46:193-220.
11. Inomata T, Mizuno J, Iwagami M, et al. The impact of Joint Commission International accreditation on time periods in the operating room: A retrospective observational study. *PLoS one* 2018;13:e0204301.

12. Glossary of times used for scheduling and monitoring of diagnostic and therapeutic procedures. *AORN J* 1997;66:601-6.
13. Mazzei WJ. Operating room start times and turnover times in a university hospital. *J Clin Anesth* 1994;6:405-8.
14. Overdyk FJ, Harvey SC, Fishman RL, et al. Successful strategies for improving operating room efficiency at academic institutions. *Anesth Analg* 1998;86:896-906.
15. Hsiao KC, Machaidze Z, Pattaras JG. Time management in the operating room: an analysis of the dedicated minimally invasive surgery suite. *JSLS* 2004;8:300-3.
16. Singh K, Misbah A, Saluja P, et al. Review of manual small-incision cataract surgery. *Indian J Ophthalmol* 2017;65:1281-88.
17. Sasaki T, Izawa M, Okada Y. Current trends in health insurance systems: OECD countries vs. Japan. *Neurol Med Chir (Tokyo)* 2015;55:267-75.
18. Denton B, Viapiano J, Vogl A. Optimization of surgery sequencing and scheduling decisions under uncertainty. *Health Care Manag Sci* 2007;10:13-24.
19. Kang JM, Padmanabhan SP, Schallhorn J, et al. Improved utilization of operating room time for trainee cataract surgery in a public hospital setting. *J Cataract Refract Surg* 2018;44:186-89.

1
2
3
4 Figure Legends
5

6 **Figure 1. Glossary of time periods in the operating room under local anaesthesia. Time**
7 **periods were divided into three intervals (A), prePT = pre-procedure/surgery time. (B), PT**
8 **= procedure/surgery time. (C), postPT = post-procedure/surgery time. (D), TPT = total**
9 **procedure/surgery time (A+B+C). PIR = patient in room, PST = procedure/surgery start time,**
10 **PF = procedure/surgery finish, POR = patient out of room.**
11
12
13
14

15 **Figure 2. Post hoc descriptive analysis of the monthly change of TPT.** The monthly average
16 and standard deviation of TPT during the study period (between March 2014 and June 2016).
17 TPT = total procedure/surgery time, JCI = Joint Commission International.
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

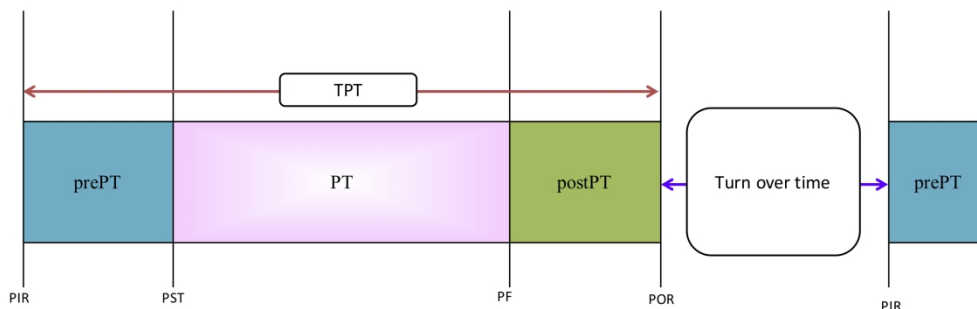


Figure 1

256x83mm (300 x 300 DPI)

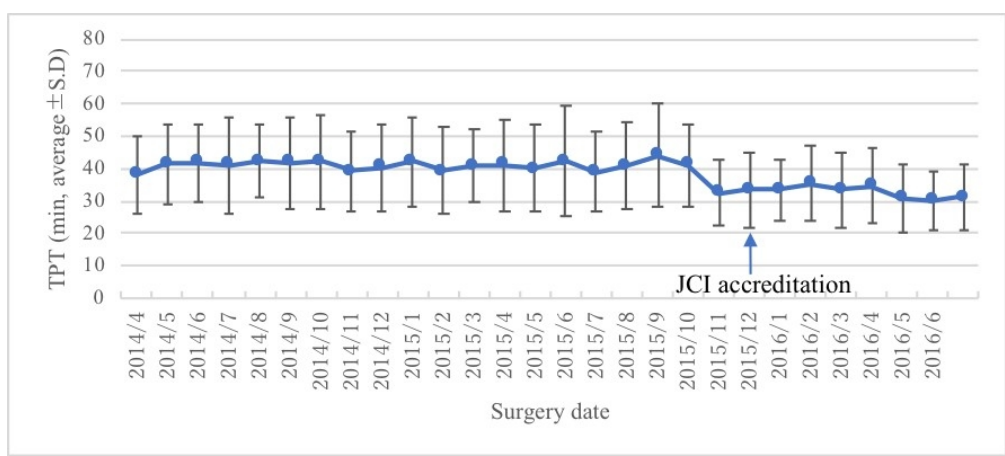


Figure 2

150x66mm (150 x 150 DPI)

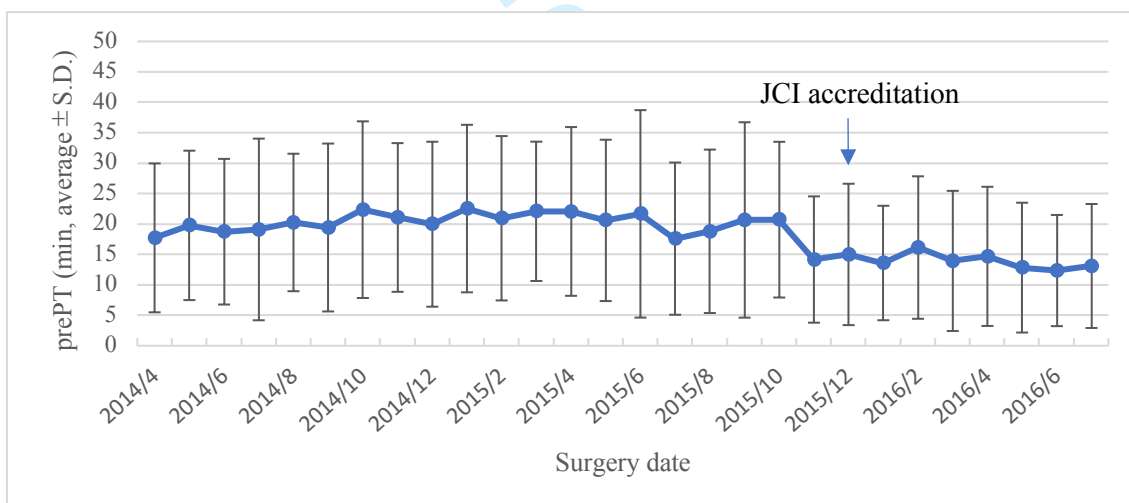
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Title: Shortened cataract surgery by standardisation of the perioperative protocol according to the Joint Commission International accreditation

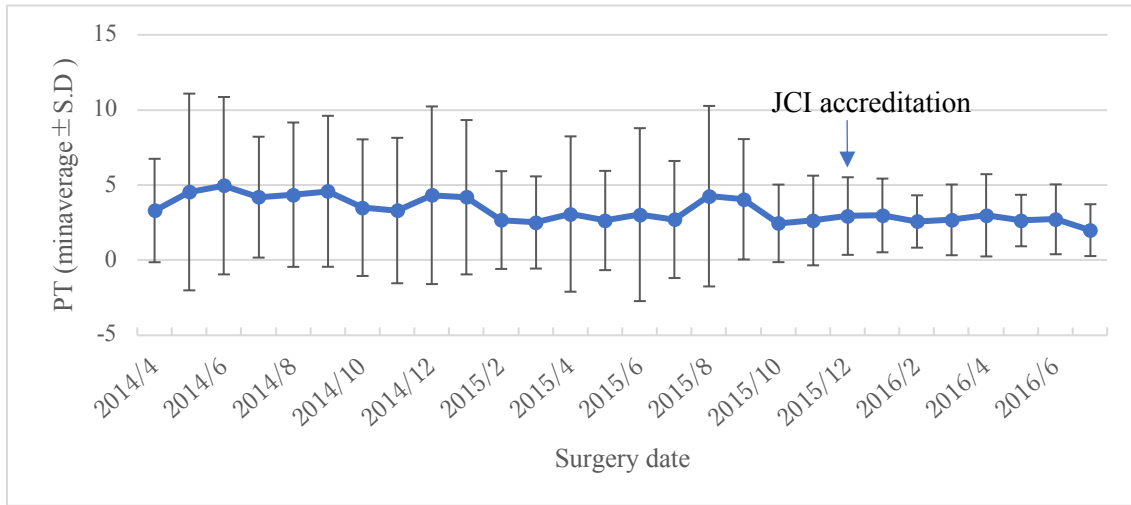
Authors: Yuichi Okumura, Takenori Inomata, Masao Iwagami, Atsuko Eguchi, Ju Mizuno, Tina Shiang, Shiori Kawasaki, Akie Shimada, Eiichi Inada, Atsushi Amano, and Akira Murakami

Supplementary Figure S1. Post hoc descriptive analysis of monthly change in pre-PT, PT, and post-PT. Supplementary Figure 1 A–C shows the monthly average of pre-PT (A), PT (B), and post-PT (C) for the overall temporal trend analysis during the study period (between March 2014 and June 2016). prePT: pre-procedure/surgery time, PT: procedure/surgery time, post-PT: post-procedure/surgery time, JCI: Joint Commission International.

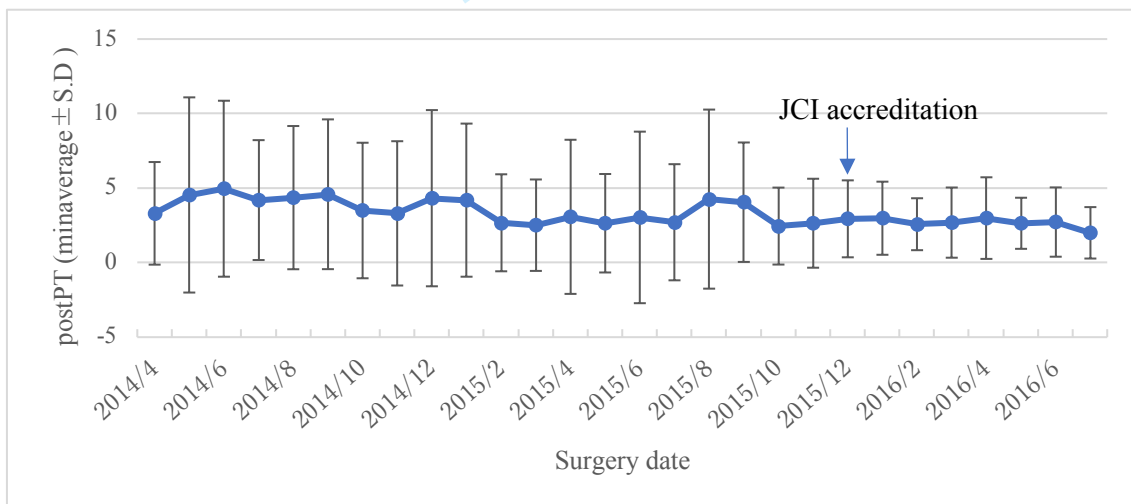
A.



B.



C.



Supplementary Table S1. Complications in cataract surgery

	Before JCI	After JCI		Total
	n = 2,581	n = 546		n = 3,127
Variables	n (%)	n (%)	<i>P</i>	n (%)
Complication (+)	72 (2.8)	18 (3.3)	.483	90 (2.4)
Complication (-)	2509 (97.2)	528 (96.5)		3037 (97.1)
Posterior capsule rupture	9 (0.3)	3 (0.3)		12 (0.4)
Zonule of Zinn rupture	4 (0.2)	0		4 (0.1)
Dropped nucleus	1 (0.0)	0		1 (0.0)
Iris prolapse	27 (1.0)	5 (0.9)		32 (1.0)
CCC incomplete	3 (0.1)	0		3 (0.1)
Capsule tear	28 (1.1)	10 (1.8)		38 (1.2)

CCC; Continuous curvilinear capsulorrhexis, JCI; Joint International Commission, *P* value calculated using the chi-square test.

Supplementary Table S2. Invasive procedure safety checklist in Juntendo University Hospital Surgery Room

A. Confirmation steps at the time when a patient enters the operation room (Sign in)

- 1 Identify the patient by his / her name (full name) and date of birth
- 2 Surgical site and operative site of the patient
- 3 Marking of surgical site
- 4 Allergies
- 5 Moving teeth, false teeth, a tooth under treatment
- 6 Restricted limbs, range of joint motion
- 7 A biological monitor is worn by the patient and is operating normally
- 8 Significant changes in vital signs before surgery

B. Confirmation steps at the time when the procedure/ surgery starts (Time out)

- 1 All team members introduce their names and roles by themselves
- Confirmation by physician
- 2 Patient name, date of birth
 - 3 Surgical method and surgical procedure

1
2
3
4
5
6 4 Confirmation of skin incision location and site

7 5 Important points of surgery

8
9 6 Scheduled operation time

10
11 7 Expected bleeding volume

12
13 8 Confirm installation of neutral zone

14 Confirmation by nursing team

15 9 Sterilisation of equipment and materials used for surgery

16
17 10 Problems to be shared within the team regarding allergies and equipment

18
19 11 Display necessary images

20
21 12 Operation of intermittent pneumatic device

22 23 C. Confirmation steps at the time when patient leaves the operation room (Sign out)

24
25 Confirmation by nursing team

26 1 Surgical method and surgical procedure

27 2 Equipment, gauzes, and needles used for surgery

28 3 Confirmation of the number and name of (pathological) specimens

29 4 Confirmation of return of unused blood products

30 5 Problems with equipment that must be addressed

31 6 Major problems with postoperative recovery and management

32 7 Postoperative equipment

33
34
35
36
37
38 Proof that the confirmation checklist was used by the physician and nursing team

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4, 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4, 5, 6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4, 5, 6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3, 4, 5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4, 5, 6
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4,5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	4,5,6
		(b) Describe any methods used to examine subgroups and interactions	4,5,6
		(c) Explain how missing data were addressed	4,5,6
		(d) If applicable, describe analytical methods taking account of sampling strategy	4,5,6
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A

1				
2	Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
3				
4				
5				
6			(b) Indicate number of participants with missing data for each variable of interest	N/A
7				
8	Outcome data	15*	Report numbers of outcome events or summary measures	6,7,8
9	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
10				
11				
12				
13				
14				
15			(b) Report category boundaries when continuous variables were categorized	6
16				
17				
18			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
19				
20	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Supplementary Figure S1
21				
22				
23	Discussion			
24	Key results	18	Summarise key results with reference to study objectives	9
25	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
26				
27				
28				
29	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9,10
30				
31				
32				
33	Generalisability	21	Discuss the generalisability (external validity) of the study results	10
34				
35				
36	Other information			
37	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11
38				
39				
40				

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Shortened cataract surgery by standardisation of the perioperative protocol according to the Joint Commission International accreditation: A retrospective observational study

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-028656.R1
Article Type:	Research
Date Submitted by the Author:	26-Feb-2019
Complete List of Authors:	Okumura, Yuichi; Juntendo University Graduate School of Medicine, Department of Ophthalmology; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement Inomata, Takenori; Juntendo University Faculty of Medicine, Department of Ophthalmology; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement Iwagami, Masao; London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology Eguchi, Atsuko; Juntendo University Graduate School of Medicine, Department of Hospital Administration Mizuno, Ju; Juntendo University Faculty of Medicine, Department of Anesthesia and Pain Medicine Shiang, Tina; University of Massachusetts Medical School, Department of Radiology Kawasaki, Shiori; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement; Juntendo University Faculty of Medicine, Department of Cardiovascular Surgery Shimada, Akie; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement; Juntendo University Faculty of Medicine, Department of Cardiovascular Surgery Inada, Eiichi; Juntendo University Faculty of Medicine, Department of Anesthesia and Pain Medicine Amano, Atsushi; Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement; Juntendo University Faculty of Medicine, Department of Cardiovascular Surgery Murakami, Akira; Juntendo University Faculty of Medicine, Department of Ophthalmology
Primary Subject Heading:	Ophthalmology
Secondary Subject Heading:	Evidence based practice, Health economics, Health services research, Medical education and training, Medical management
Keywords:	Cataract and refractive surgery < OPTHALMOLOGY, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisational development < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION &

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

	MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™
Manuscripts

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

Title: Shortened cataract surgery by standardisation of the perioperative protocol according to the Joint Commission International accreditation: A retrospective observational study

Authors: *Yuichi Okumura^{1,2}, Takenori Inomata^{2,3}, Masao Iwagami⁴, Atsuko Eguchi^{2,5}, Ju Mizuno⁶, Tina Shiang⁷, Shiori Kawasaki^{2,8}, Akie Shimada^{1,7}, Eiichi Inada⁶, Atsushi Amano^{2,8} and Akira Murakami³*

Affiliations:

¹Juntendo University Graduate School of Medicine, Department of Ophthalmology, Tokyo, Japan.

²Juntendo University Faculty of Medicine, Department of Strategic Operating Room Management and Improvement, Tokyo, Japan.

³Juntendo University Faculty of Medicine, Department of Ophthalmology, Tokyo, Japan.

⁴London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology, London, UK.

⁵Juntendo University Faculty of Medicine, Department of Hospital Administration, Tokyo, Japan.

⁶Juntendo University Faculty of Medicine, Department of Anesthesia and Pain Medicine, Tokyo, Japan.

⁷University of Massachusetts Medical School, Department of Radiology, Worcester, MA, US.

⁸Juntendo University School of Medicine, Department of Cardiovascular Surgery, Tokyo, Japan.

***Corresponding Author:** Takenori Inomata, 3-1-3 Hongo, Juntendo University School of Medicine, Department of Strategic Operation Management Improvement, Tokyo 113-0033, Japan.

Tel: +81-3-5802-1228; Fax: +81-3-5689-0394, E-mail: tinoma@juntendo.ac.jp

Word count: 1932

Key Words. Cataract surgery, external accreditation, joint commission international, patient safety, operating time, time period in operating room.

Synopsis: JCI accreditation initiatives were implemented in December 2015 at Juntendo University Hospital. After implementation, we found that the total procedure/surgery time of cataract surgery decreased by 18.2% while maintaining the same quality of patient care.

ABSTRACT

Objectives: To investigate the impact of standardisation of the perioperative protocol based on the Joint Commission International (JCI) accreditation guidelines for operating time in cataract surgery.

Design: Retrospective observational study.

Setting: Single centre in Japan.

Participants: Between March 2014 and June 2016, 3,127 patients underwent cataract surgery under topical anaesthesia including 2,581 and 546 patients before and after JCI accreditation, respectively.

Primary and secondary outcomes: We compared three time periods, comprising the pre-procedure/surgery time (prePT), procedure/surgery time (PT), and post-procedure/surgery time (postPT), and total procedure/surgery time (TPT) of cataract surgery between patients before and after JCI accreditation, by regression analysis adjusted for age, sex, and cataract-surgery associated confounders.

Results: The main outcomes were prePT, PT, postPT, and TPT. prePT (19.8 ± 10.5 vs. 13.9 ± 8.5 min, $P < .001$) and postPT (3.5 ± 4.6 vs. 2.6 ± 2.1 min, $P < .001$) significantly decreased after JCI accreditation, while PT did not significantly change (16.8 ± 6.7 vs. 16.2 ± 6.3 min, $P = .065$).

Consequently, TPT decreased on average by 7.3 min per person after JCI accreditation (40.1 ± 13.4 vs. 32.8 ± 10.9 min, $P < .001$). After adjusting for confounders, prePT ($\beta = -5.82$ min, 95%CI -6.75 – -4.88), PT ($\beta = -0.76$ min, 95%CI -1.34 – -1.71), postPT ($\beta = -0.85$ min, 95%CI -1.24 – -0.45), and TPT ($\beta = -7.43$ min, 95%CI -8.61 – -6.24) were significantly shortened after JCI accreditation.

Conclusion: Perioperative protocol standardisation, based on JCI accreditation, shortened TPT in cataract surgery under local anaesthesia.

Strengths and limitations of this study

• To our knowledge, this is the first study to investigate the impact of standardisation of the perioperative protocol for cataract surgery on operating room efficiency by comparing relevant time periods in the operating room for patients who underwent cataract surgery before and after Joint Commission International accreditation (JCI).

- 1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60
- This is the only study to have investigated the pre-procedure/surgery time, procedure/surgery time, post-procedure/surgery time, and total procedure/surgery time of cataract surgery between patients before and after JCI accreditation.
 - The main limitation is that this study was conducted at a single university hospital; therefore, the generalisability of our findings may be limited.
 - Another limitation inherent to this study was that the impact of surgeon level and/or clinical experience of the surgeons and nurses was not analysed.

For peer review only

INTRODUCTION

Cataract surgery is the most common intraocular surgery [1]; worldwide population aging has resulted in substantial growth of the number of patients eligible for cataract surgery.[2] Cataract surgery is one of the most cost-effective surgical interventions [3, 4] and is important for hospital financial management as a profitable operating theatre.[5] Therefore, it is essential to continuously review surgical techniques and practices regarding efficiency, decreasing costs, and increasing safety in order to produce more reliable results for patients.

Cataract surgery is generally recognised as a safe and highly reproducible surgery. However, the recent focus on healthcare errors and safety supports performing cataract surgery from a patient safety perspective.[6] The Joint Commission International (JCI) advocates for maintenance of patient safety, continuous improvement of the quality of practice, and accrediting healthcare organisations in compliance with standards.[7] The JCI requires continuous quality improvement for international patient safety goals (IPSGs), which are important issues concerning patient safety. The IPSGs help confirm correct patient identification, encourage effective communication between patients and medical staff, improve the safety of high-alert medication administration, and ensure safe surgeries (correct surgical site, procedures, and patient for the surgery).[8] JCI accreditation is expected to improve patient safety associated with surgical operations; however, there is concern that these changes may impair efficiency by prolonging operating room time with an excessive focus on patient safety. Previous studies have reported improved medication management during JCI accreditation [7, 9]; however, there has been no study regarding the impact of IPSG procedures on operating room efficiency under topical anaesthesia with a large number of cases over a short period of time.[10]

In this study, we examined the impact of the standardisation of the perioperative protocol for cataract surgery on operating room efficiency by comparing relevant time periods, while maintaining the quality of patient care.

METHODS

Study design

We conducted a retrospective observational study between March 2014 and June 2016 at Juntendo University Hospital. This study was approved by the Institutional Review Board and Medical Ethics Committee of Juntendo University Hospital (approval number: 16-153) and was conducted in accordance with the tenets of the Declaration of Helsinki. The requirement for written informed consent was waived due to the retrospective observational nature of the study; patients could exclude themselves by using the opt-out method on our hospital website.

Joint Commission International accreditation

1
2
3 The Joint Commission is a United States-based non-profit tax-exempt 501(c) organisation that
4 accredits US health care organisations and programmes. Its international branch, named JCI, was
5 established in 1998; JCI accredits medical services worldwide. Juntendo University Hospital was
6 accredited by the JCI on December 12, 2015. For JCI accreditation, inspectors from the JCI visit
7 and evaluate hospitals to observe hospital operations, conduct interviews, and review medical
8 documentation in order to determine whether hospitals meet compliance standards set forth by
9 the JCI. The goal of JCI accreditation is to evaluate care, standardise hospital processes, provide
10 education, and promote quality improvement for the surveyed organisations.
11
12
13
14
15

16 17 **Study period and participants**

18 We identified patients who underwent cataract surgeries (phacoemulsification with intraocular
19 lens implantation) under topical anaesthesia in Juntendo University Hospital between March
20 2014 and June 2016. We excluded combined cases, such as cataract extraction with
21 trabeculectomy or anterior vitrectomy, to fairly compare operation times. Patients were divided
22 into the two groups: a group before and a group after JCI accreditation.
23
24
25
26

27 **Outcome measures**

28 In Juntendo University Hospital, surgeons and nurses are required to computationally record the
29 timing of the following events: the patient entered the surgical room, the surgery started and
30 ended, and the patient was discharged from the surgical room. As performed in our previous
31 studies,[11-15] we first defined total procedure/surgery time (TPT) as the duration between
32 patient entrance to and discharge from the operating room. Then, we divided TPT into three
33 specific time periods (**Figure 1**): pre-procedure/surgery time (prePT), procedure/surgery time
34 (PT), and post-procedure/surgery time (postPT). PrePT was defined as the time elapsed in
35 minutes between patient entry to the operating room (patient in room) and the attachment of
36 monitors, such as an electrocardiogram and blood pressure gauge, and sign in. PT was defined as
37 the time elapsed in minutes between the start and end of surgery (the procedure/surgery start time
38 to the procedure/surgery finish time; PST and PF, respectively). postPT was defined as the time
39 elapsed in minutes between PF and the time that the patient exited the room (patient out of room).
40
41
42
43
44
45
46
47

48 **Analysis**

49 Patient characteristics were compared between patients who underwent cataract surgery before
50 and after JCI accreditation, by using the unpaired *t*-test for age, best-corrected visual acuity
51 (BCVA), and intraocular pressure (IOP) and the chi-squared test for sex and the prevalence of
52 complications associated with cataract surgery. We collected information on the complications
53 associated with cataract surgery including posterior capsule rupture, Zonule of Zinn rupture,
54
55
56
57
58
59
60

dropped nucleus, iris prolapse, continuous curvilinear capsulorrhexis incomplete, and capsule tear.

First, we crudely compared prePT, PT, postPT, and TPT between patients before and after JCI accreditation by using the unpaired *t*-test. Then, we conducted adjusted analyses with multivariable regression models, adjusting for age, sex, BCVA, IOP, and complications associated with cataract surgery. Multicollinearity was investigated to determine which variables were to be included in the adjusted analyses. This was achieved by examining the bivariate correlations between all variables and calculating the variance inflation factors (VIF). VIF values greater than 2.5 are often considered to indicate multicollinearity.[16] Sensitivity analysis was conducted using only the right eye of each patient.

Finally, as a post hoc descriptive analysis to detect the overall temporal trend during the study period, we plotted the monthly averages of prePT, PT, postPT (**Supplementary Figure 1A-C**), and TPT (**Figure 2**).

All data were analysed with STATA version 15 (Stata Corp, College Station, TX, USA).

Patient and public involvement

No patients were involved in the research design and conception of this research study.

RESULTS

Characteristics of patients

A total of 3,127 patients (mean age, 71.6 years old [interquartile range, 66–79 years]; male sex, 44.1%) underwent cataract surgery under local anaesthesia at Juntendo University Hospital. Although the age and sex distributions were similar, BCVA and IOP were slightly, but significantly, worse after JCI accreditation (**Table 1**). The complication rate of cataract surgery did not significantly differ between the groups (**Supplementary Table 1**).

Table 1. Patient characteristics

Variables	Before JCI n = 2,581	After JCI n = 546	<i>P</i> value	Total n = 3,127
Age, years (SD)	71.6 (10.3)	71.9 (10.6)	.477	71.6 (10.3)
Sex, number (%)				
Men	1,138 (44.1)	242 (44.3)	.925	1380 (44.1)
Women	1,443 (55.9)	304 (55.7)		1747 (55.9)
BCVA, LogMAR (SD)	0.34 (0.3)	0.37 (0.4)	*.040	0.35 (0.3)

IOP, mmHg (SD)	14.0 (3.1)	14.3 (3.2)	*.015	14.0 (3.1)
Complication, yes (%)	72 (2.8)	18 (3.3)	.483	90 (2.4)

BCVA: best-corrected visual acuity, IOP: intraocular pressure, JCI: Joint Commission International. *P* values were calculated by using an unpaired *t*-test (* < .05) for age, BCVA, and IOP, and by using the chi-squared test for sex and complications.

Crude analysis

Table 2 compares time periods in the operating room between groups before and after JCI accreditation. The prePT (19.8±10.5 min vs. 13.9±8.3 min, before vs. after JCI, respectively, *P*<.001) and postPT (3.5±4.6 min vs. 2.6±2.1 min, *P*<.001) were significantly reduced after JCI accreditation. However, the PT was not significantly different between before and after JCI accreditation (16.8±6.7 min vs. 16.2±6.3 min, *P*=.065). Consequently, TPT was significantly reduced by an average of 7.3 min per patient after JCI accreditation (40.1±13.4 min vs. 32.8±10.9 min, before vs. after JCI, respectively, *P*<.001).

Table 2. Operation time intervals

	Before JCI	After JCI	<i>P</i> value	Total
Time periods, min (SD)	n = 2,581	n = 546		n = 3,127
Pre-procedure/surgery time	19.8 (10.5)	13.9 (8.3)	*** < .001	18.7 (10.4)
Procedure/surgery time	16.8 (6.7)	16.2 (6.3)	.065	16.7 (6.6)
Post-procedure/surgery time	3.5 (4.6)	2.6 (2.1)	*** < .001	3.4 (4.3)
Total procedure/surgery time	40.1 (13.4)	32.8 (10.9)	*** < .001	38.8 (13.2)

JCI: Joint Commission International. *P* values were calculated by using an unpaired *t*-test (*** < .001).

Adjusted analysis

After adjusting for age, sex, BCVA, IOP, and complications associated with cataract surgery in multivariable regression analysis, prePT (β =-5.82 min, 95%CI -6.75--4.88, *P*<.001), PT (β =-0.76 min, 95%CI -1.34--1.71, *P*=.011), postPT (β =-0.847 min, 95%CI -1.24--0.45, *P*<.001), and TPT (β =-7.43 min, 95%CI -8.61--6.24, *P*<.001) were significantly shortened after JCI accreditation (**Table 3A–D**). No severe multicollinearity was observed in the adjusted analysis

(Supplementary Table 2). Sensitivity analysis using only the right eye of each patient showed similar results with those presented in Table 3 (Supplementary Table 3).

Table 3. Adjusted operation time intervals

A.

prePT	Coefficient	SE	<i>P</i> value	[95% Conf.	Interval]
JCI accreditation, yes	-5.823	0.480	*** < .001	-6.765	-4.882
Sex, women (vs. men)	0.497	0.370	.179	-0.228	1.221
Age, years	-0.026	0.018	.144	-0.061	0.009
BCVA, LogMAR	-0.542	0.579	.349	-1.678	0.593
IOP, mmHg	-0.026	0.058	.659	-0.140	0.089
Complication, yes	-0.338	1.084	.755	-2.463	1.788

B.

PT	Coefficient	SE	<i>P</i> value	[95% Conf.	Interval]
JCI accreditation, yes	-0.756	0.299	*.011	-1.342	-0.171
Sex, women (vs. men)	-0.547	0.230	.017	-0.997	-0.096
Age, years	0.033	0.011	.003	0.011	0.055
BCVA, LogMAR	3.042	0.360	***< .001	2.336	3.748
IOP, mmHg	0.004	0.036	.908	-0.067	0.075
Complication, yes	10.278	0.674	***< .001	8.956	11.599

C.

postPT	Coefficient	SE	<i>P</i> value	[95% Conf.	Interval]
JCI accreditation, yes	-0.847	0.201	*** < .001	-1.241	-0.454
Sex, women (vs. men)	0.258	0.155	.095	-0.045	0.561
Age, years	-0.005	0.007	.487	-0.020	0.009
BCVA, LogMAR	-0.224	0.242	.355	-0.699	0.251
IOP, mmHg	-0.018	0.024	.473	-0.065	0.030
Complication, yes	0.353	0.453	.437	-0.536	1.242

D.

TPT	Coefficient	SE	<i>P</i> value	[95% Conf. Interval]
JCI accreditation, yes	-7.427	0.605	*** < .001	-8.613 -6.240
Sex, women (vs. men)	0.208	0.466	.655	-0.705 1.121
Age, years	0.002	0.022	.937	-0.042 0.046
BCVA, LogMAR	2.275	0.730	.002	0.844 3.706
IOP, mmHg	-0.039	0.074	.595	-0.183 0.105
Complication, yes	10.293	1.366	***< .001	7.615 12.971

Conf.: confidence, JCI: Joint Commission International, BCVA: best-corrected visual acuity, IOP: intraocular pressure, PrePT: pre-procedure/surgery time, PT: procedure/surgical time, postPT: post-procedure/surgery time, SE: standard error. Complications associated with cataract surgery included posterior capsule rupture, Zonule of Zinn rupture, dropped nucleus, iris prolapse, continuous curvilinear capsulorrhexis incomplete, and capsule tear. *P* values were calculated by using an unpaired *t*-test (* < .05, *** < .001).

Post hoc descriptive analysis of monthly changes in TPT

The monthly average of TPT considerably changed since October 2015, approximately 2 months before the JCI accreditation (December 12, 2015) (**Figure 2**). The results of prePT, PT, and postPT are shown in **Supplementary Figure 1**.

DISCUSSION

Cataract surgery is an established minimally invasive and efficient surgical procedure.[17] However, because of rising medical expenses and lack of healthcare workers caused by the aging society,[10, 18] it is necessary to perform cataract surgery efficiently while maintaining quality of care.[14] Therefore, it is important to analyse the efficiency of services to ensure effective use of finite medical resources.[19] We explored the effect of standardisation of perioperative protocols in cataract surgery by using the transition to JCI accreditation.

Strategies for improving the utilisation rate of the surgical room are to increase the occupancy of the operating room by increasing the number of surgeries or to increase the economic efficiency by reducing the size of the operating room in accordance with the current number of surgeries. To increase the number of surgeries, it is important to shorten TPT and interval time between individual operations; reducing perioperative time (prePT and postPT) would lead to shortening of TPT. In our previous study, [11] we investigated the impact of JCI accreditation with patients who underwent surgery under general anaesthesia in all departments and showed that patient safety and operating room efficiency can be compatible. In the case of

1
2
3 cataract surgery, because there is a short time between patient entry to and exit from the operating
4 room, it is necessary to perform patient confirmation, prepare for surgery, and record the
5 operation while caring for the patient, all within the short surgical time. Therefore, recording is
6 frequently performed between high-priority tasks, and the recording time must be divided and
7 dispersed. We showed that prePT and postPT were shortened by the standardisation of the
8 perioperative protocol at the point of entry to the operating room; Juntendo University Hospital
9 has implemented surgical record sheets (Invasive procedure safety checklist) in their electronic
10 medical records to ensure adherence to IPSP standards (**Supplementary Table 4**). In surgeries
11 that involve a large number of cases in a short period of time, such as cataract surgeries,
12 standardisation of records and tasks is important for increasing the efficiency of the operating
13 room. A previous study reported that clarification of the group goal was effective for improving
14 efficiency,[20] indicating that the standardisation of perioperative protocols in Juntendo
15 University Hospital has shortened the perioperative time by streamlining the process. Here, we
16 revealed that, for a surgical procedure that cannot be shortened further, such as cataract surgery,
17 improvement of non-surgical portions, such as preparation of surgery and communication among
18 medical personnel, is important for shortening the utilisation time of the operating room.

19
20 Additionally, we revealed that PT itself is shortened after JCI accreditation (**Table 3C**),
21 indicating that the thorough standardisation of the perioperative protocol positively influenced
22 the preparation process for surgery and communication among medical staff, resulting in
23 shortened PT. Our results showed that TPT decreased by an average of 7.3 min per patient. Since
24 the average cataract operation time in our hospital is 16.7 min, shortening of cataract operation
25 time by 7.3 min corresponds to a 43.7% reduction in the average cataract operation time; if we
26 performed three cataract surgeries, the time saved would allow for one additional surgery. In
27 addition, since the number of complications did not change before and after the JCI accreditation,
28 standardisation of the perioperative protocol did not impair patient safety, while improving
29 efficiency in operating room use. In this study, cataract surgery was selected to eliminate to the
30 greatest possible extent the effect of different types of surgery, but it is probable that improving
31 the preparation process and the communication among medical staff by standardization of the
32 preoperative protocol would also be effective for shortening the operation time in other types of
33 ophthalmic surgery including vitreous and glaucoma surgeries.

34
35 Since IPSP measures may have affected clinical practice gradually, simply comparing
36 surgical time intervals before and after JCI accreditation cannot accurately determine the effect of
37 introducing JCI standards. Therefore, we conducted a trend analysis, as shown in **Figure 2**;
38 notably, time intervals sharply declined in advance of the accreditation date. This indicates that
39 the continuous standardisation of IPSPs in Juntendo University Hospital was gradually
40 introduced during preparation for the JCI accreditation, implying that the focus of the medical
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3 staff changed within a few months. Fostering IPSGs in the effort for the JCI accreditation
4 increased efficiency of cataract operation time and added value to our hospital as a profit centre.
5

6 There were several limitations in this study. First, since this study was conducted at a single
7 university hospital, the generalisability of our findings may be limited. Depending on the size of
8 a hospital and its current practice, the impact of standardisation on the perioperative protocol for
9 cataract surgery may differ. Second, we did not assess the influence of the surgeon level and/or
10 clinical experience of the surgeons and nurses. However, based on the number of complications,
11 we suspect that the influence of individual surgeon level and job experience on operation time did
12 not substantially change between before and after the JCI accreditation. In addition, time is
13 required to train surgeons and medical professionals, whereas standardisation of the perioperative
14 protocol can be introduced with little time investment.
15

16 In conclusion, we investigated the impact of JCI accreditation and implementation of
17 standardised procedures on time periods in the operating room. PrePT and postPT were
18 significantly shortened; thus, TPT was significantly reduced after implementing IPSGs.
19 Therefore, we conclude that the improvement of patient safety by standardisation of the
20 preoperative protocols can also improve the efficiency of surgery under topical anaesthesia.
21

22 **Acknowledgments**

23 The authors thank the colleagues working at Juntendo University Hospital, Department of
24 Surgery and Ophthalmology.
25

26 **Author Contributions:**

27 Y.O.: Performance of the research, data collection, data analysis, and writing of the paper; T.I.:
28 Performance of the research, research design, data analysis, and writing of the paper; I.M.:
29 Research design, data analysis, and writing of the paper; A.E.: Data collection, data analysis;
30 J.M.: Research design, data analysis; T.S.: Writing of the paper; S.K.: Data collection, data
31 analysis; A.S.: Data collection, writing of the paper; E.I.: Research design, writing of the paper;
32 A.A.: Research design, writing of the paper; A.M.: Research design, writing of the paper; all
33 authors reviewed the manuscript.
34

35 **Funding**

36 No funding disclosures.
37

38 **Competing Interest**

1
2
3 This study was supported by Hoky Medical, Inc. The sponsor or funding organisation had no role
4 in the design or conduct of this research.
5
6

7 **Patient consent**

8 The requirement for written informed consent was waived due to the retrospective observational
9 nature of the study; patients could exclude themselves by using the opt-out method on our
10 hospital website.
11
12
13

14 **Ethics approval**

15 Institutional Review Board of Juntendo University Hospital (approval number: 16-153).
16
17
18

19 **Data Sharing**

20 The datasets generated during and/or analysed during the current study are available from the
21 corresponding author on reasonable request.
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

REFERENCES

1. Spalton D, Koch D. The constant evolution of cataract surgery. *BMJ* 2000;321:1304.
2. Hatch WV, Campbell Ede L, Bell CM, et al. Projecting the growth of cataract surgery during the next 25 years. *Arch Ophthalmol* 2012;130:1479-81.
3. Foster A, Gilbert C, Johnson G. Changing patterns in global blindness: 1988-2008. *Community Eye Health* 2008;21:37-9.
4. Eye Care Comparative Effectiveness Research T. Cost-effectiveness of cataract surgery in Japan. *Jpn J Ophthalmol* 2011;55:333-42.
5. Abbott T, White SM, Pandit JJ. Factors affecting the profitability of surgical procedures under 'Payment by Results'. *Anaesthesia* 2011;66:283-92.
6. Kelly SP, Astbury NJ. Patient safety in cataract surgery. *Eye* 2006;20:275-82.
7. Wang HF, Jin JF, Feng XQ, et al. Quality improvements in decreasing medication administration errors made by nursing staff in an academic medical center hospital: a trend analysis during the journey to Joint Commission International accreditation and in the post-accreditation era. *Ther Clin Risk Manag* 2015;11:393-406.
8. Joint Commission International. International Patient Safety Goals 2017 [Available from: <http://www.jointcommissioninternational.org/improve/international-patient-safety-goals/> accessed July, 15th 2017.
9. Fang X, Zhu LL, Pan SD, et al. Safe medication management and use of narcotics in a Joint Commission International-accredited academic medical center hospital in the People's Republic of China. *Ther Clin Risk Manag* 2016;12:535-44.
10. McGinnis SL, Moore J. The impact of the aging population on the health workforce in the United States--summary of key findings. *Cah Sociol Demogr Med* 2006;46:193-220.
11. Inomata T, Mizuno J, Iwagami M, et al. The impact of Joint Commission International accreditation on time periods in the operating room: A retrospective observational study. *PloS one* 2018;13:e0204301.

12. Glossary of times used for scheduling and monitoring of diagnostic and therapeutic procedures. *AORN J* 1997;66:601-6.
13. Mazzei WJ. Operating room start times and turnover times in a university hospital. *J Clin Anesth* 1994;6:405-8.
14. Overdyk FJ, Harvey SC, Fishman RL, et al. Successful strategies for improving operating room efficiency at academic institutions. *Anesth Analg* 1998;86:896-906.
15. Hsiao KC, Machaidze Z, Pattaras JG. Time management in the operating room: an analysis of the dedicated minimally invasive surgery suite. *JSLs* 2004;8:300-3.
16. Allison PD. *Multiple Regression: A Primer*. Thousand Oaks, CA: Pine Forge Press 1999.
17. Singh K, Misbah A, Saluja P, et al. Review of manual small-incision cataract surgery. *Indian J Ophthalmol* 2017;65:1281-88.
18. Sasaki T, Izawa M, Okada Y. Current trends in health insurance systems: OECD countries vs. Japan. *Neurol Med Chir (Tokyo)* 2015;55:267-75.
19. Denton B, Viapiano J, Vogl A. Optimization of surgery sequencing and scheduling decisions under uncertainty. *Health Care Manag Sci* 2007;10:13-24.
20. Kang JM, Padmanabhan SP, Schallhorn J, et al. Improved utilization of operating room time for trainee cataract surgery in a public hospital setting. *J Cataract Refract Surg* 2018;44:186-89.

1
2
3
4 Figure Legends
5

6 **Figure 1. Glossary of time periods in the operating room under local anaesthesia. Time**
7 **periods were divided into three intervals (A), prePT = pre-procedure/surgery time. (B), PT**
8 **= procedure/surgery time. (C), postPT = post-procedure/surgery time. (D), TPT = total**
9 **procedure/surgery time (A+B+C). PIR = patient in room, PST = procedure/surgery start time,**
10 **PF = procedure/surgery finish, POR = patient out of room.**
11
12
13
14

15 **Figure 2. Post hoc descriptive analysis of the monthly change in TPT.** The monthly average
16 and standard deviation of TPT during the study period (between March 2014 and June 2016).
17 TPT = total procedure/surgery time, JCI = Joint Commission International.
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

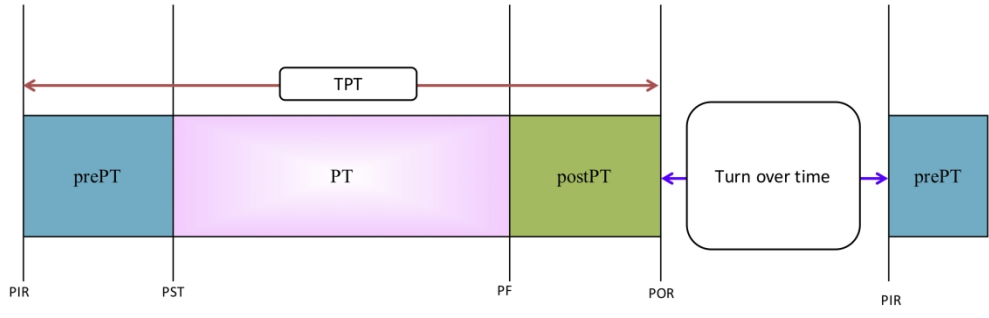


Figure 1

256x83mm (300 x 300 DPI)

BMJ Open: first published as 10.1136/bmjopen-2018-028656 on 14 June 2019. Downloaded from <http://bmjopen.bmj.com/> on April 23, 2024 by guest. Protected by copyright.

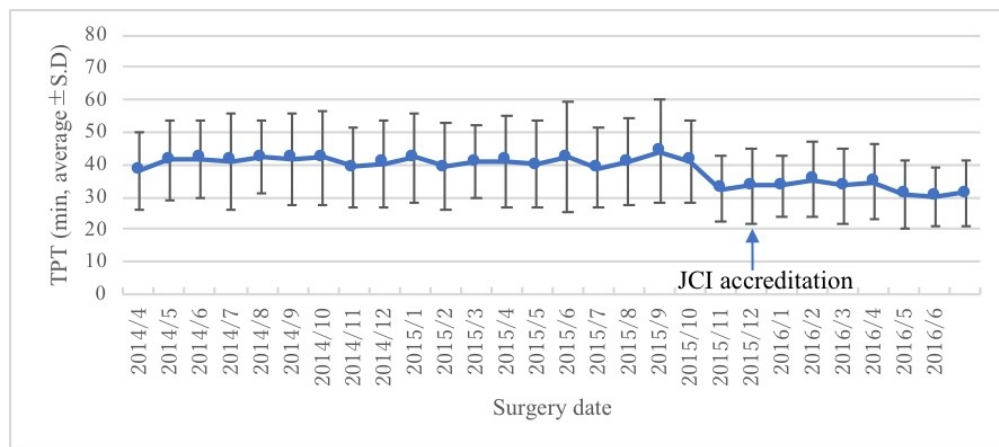


Figure 2

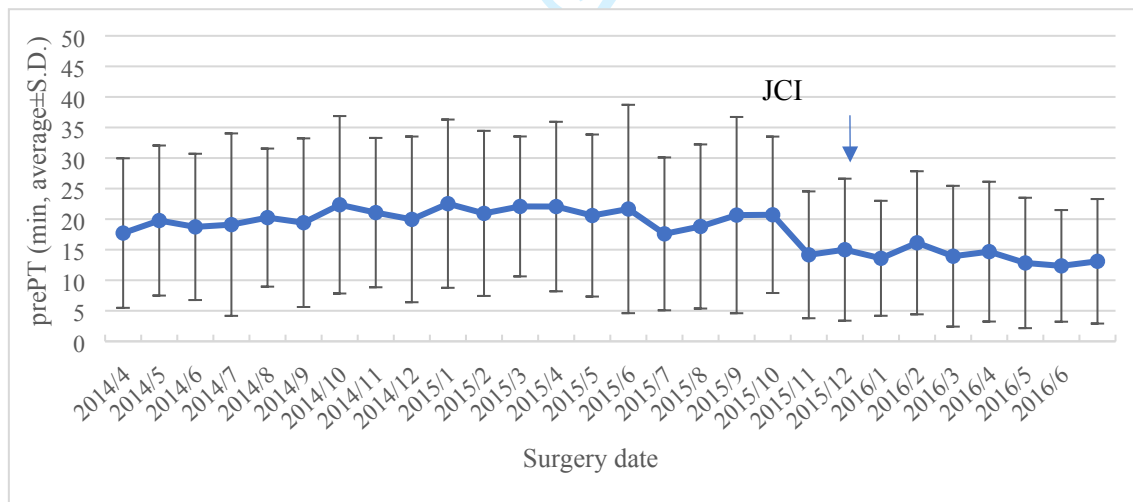
150x66mm (150 x 150 DPI)

Title: Shortened cataract surgery by standardisation of the perioperative protocol according to the Joint Commission International accreditation: A retrospective observational study

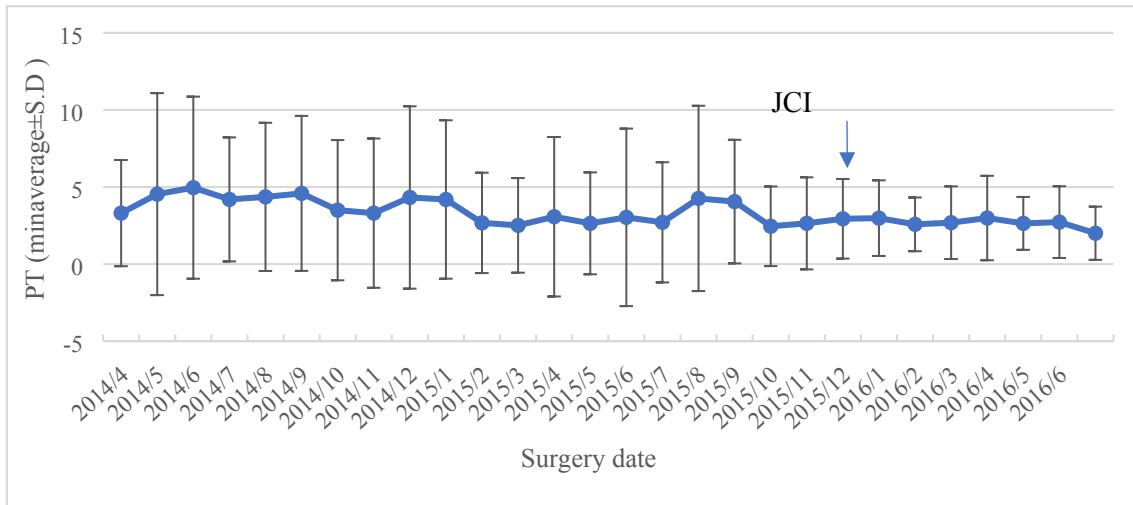
Authors: Yuichi Okumura, Takenori Inomata, Masao Iwagami, Atsuko Eguchi, Ju Mizuno, Tina Shiang, Shiori Kawasaki, Akie Shimada, Eiichi Inada, Atsushi Amano, and Akira Murakami

Supplementary Figure S1. Post hoc descriptive analysis of monthly change in pre-PT, PT, and post-PT. Supplementary Figure 1 A–C shows the monthly average of pre-PT (A), PT (B), and post-PT (C) for the overall temporal trend analysis during the study period (between March 2014 and June 2016). prePT: pre-procedure/surgery time, PT: procedure/surgery time, post-PT: post-procedure/surgery time, JCI: Joint Commission International.

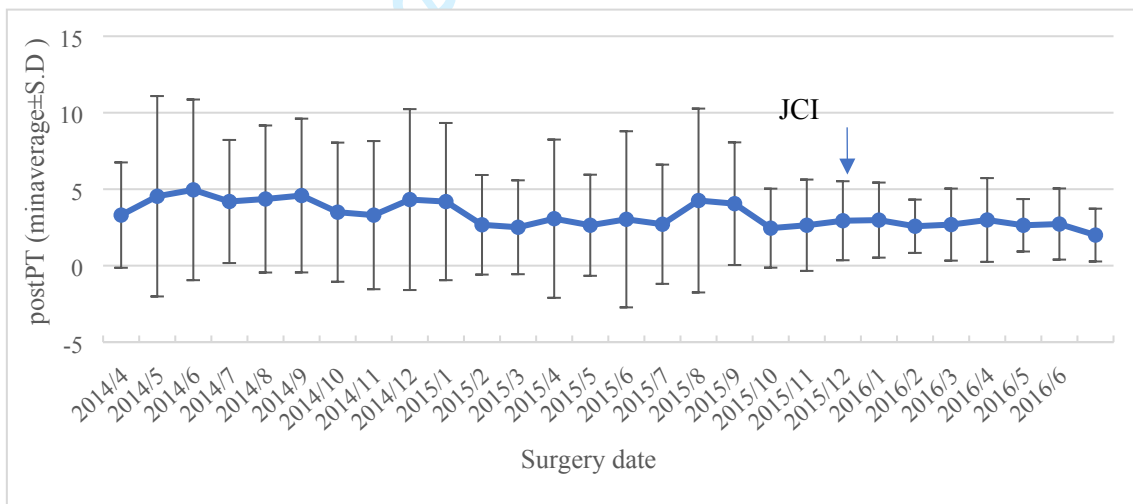
A.



B.



C.



Supplementary Table S1. Complications in cataract surgery

	Before JCI	After JCI		Total
	n = 2,581	n = 546		n = 3,127
Variables	n (%)	n (%)	<i>P</i>	n (%)
Complication (+)	72 (2.8)	18 (3.3)	.483	90 (2.4)
Complication (-)	2509 (97.2)	528 (96.5)		3037 (97.1)
Posterior capsule rupture	9 (0.3)	3 (0.3)		12 (0.4)
Zonule of Zinn rupture	4 (0.2)	0		4 (0.1)
Dropped nucleus	1 (0.0)	0		1 (0.0)
Iris prolapse	27 (1.0)	5 (0.9)		32 (1.0)
CCC incomplete	3 (0.1)	0		3 (0.1)
Capsule tear	28 (1.1)	10 (1.8)		38 (1.2)

CCC: Continuous curvilinear capsulorrhexis, JCI: Joint International Commission, *P* value calculated using the chi-square test.

Supplementary Table S2. Variance inflation factors for the examined variables

Variables	VIF
JCI accreditation, yes	1.00
Sex, women (vs. men)	1.02
Age, years	1.02
BCVA, LogMAR	1.00
IOP, mmHg	1.01
Complication, yes	1.00
Mean VIF	1.01

JCI: Joint International Commission, BCVA: best-corrected visual acuity, IOP; intraocular pressure, VIF; variance inflation factor

Supplementary Table S3. Sensitivity analysis

A.

prePT	Coefficient	SE	P value	[95% Conf. Interval]
-------	-------------	----	---------	----------------------

JCI accreditation, yes	-6.272	0.691	***<.001	-7.626	-4.917
Sex, women (vs. men)	0.293	0.538	.586	-0.762	1.349
Age, years	-0.037	0.025	.142	-0.086	0.012
BCVA, LogMAR	-0.149	0.861	.863	-1.839	1.540
IOP, mmHg	-0.033	0.085	.702	-0.200	0.134
Complication, yes	-1.119	1.650	.498	-4.356	2.117

B.

PT	Coefficient	SE	P value	[95% Conf.	Interval]
JCI accreditation, yes	-1.141	0.407	** .005	-1.940	-0.341
Sex, women (vs. men)	-0.611	0.317	.055	-1.233	0.119
Age, years	0.022	0.015	.136	-0.007	0.051
BCVA, LogMAR	2.797	0.508	***<.001	1.800	3.793
IOP, mmHg	-0.001	0.050	.987	-0.099	0.098
Complication, yes	9.941	0.974	***<0.001	8.031	11.851

C.

postPT	Coefficient	SE	P value	[95% Conf.	Interval]
JCI accreditation, yes	-0.642	0.274	*.019	-1.180	-0.010
Sex, women (vs. men)	0.090	0.214	.672	-0.329	0.509
Age, years	-0.012	0.001	.209	-0.032	0.007
BCVA, LogMAR	-0.597	0.342	.081	-1.268	0.734
IOP, mmHg	-0.028	0.034	.412	-0.094	0.385
Complication, yes	1.003	0.655	.126	-0.281	2.288

D.

TPT	Coefficient	SE	P value	[95% Conf.	Interval]
JCI accreditation, yes	-8.054	0.856	***<.001	-9.733	-6.376
Sex, women (vs. men)	-0.227	0.667	.733	-1.535	1.081
Age, years	-0.027	0.031	.380	-0.088	0.034
BCVA, LogMAR	2.050	1.068	.055	-0.043	4.144
IOP, mmHg	-0.611	0.105	.562	-0.268	0.146

Complication, yes	9.825	2.044	***<.001	5.815	13.836
-------------------	-------	-------	----------	-------	--------

Conf.: confidence, JCI: Joint Commission International, BCVA: best-corrected visual acuity, IOP: intraocular pressure, PrePT: pre-procedure/surgery time, PT: procedure/surgical time, postPT: post-procedure/surgery time, SE: standard error. Complications associated with cataract surgery included posterior capsule rupture, Zonule of Zinn rupture, dropped nucleus, iris prolapse, continuous curvilinear capsulorrhexis incomplete, and capsule tear. *P* values were calculated by using an unpaired *t*-test (* < .05, **<.01, *** < .001).

Supplementary Table S4. Invasive procedure safety checklist in Juntendo University Hospital Surgery Room

A. Confirmation steps at the time when a patient enters the operation room (Sign in)

- 1 Identify the patient by his / her name (full name) and date of birth
- 2 Surgical site and operative site of the patient
- 3 Marking of surgical site
- 4 Allergies
- 5 Moving teeth, false teeth, a tooth under treatment
- 6 Restricted limbs, range of joint motion
- 7 A biological monitor is worn by the patient and is operating normally
- 8 Significant changes in vital signs before surgery

B. Confirmation steps at the time when the procedure/ surgery starts (Time out)

- 1 All team members introduce their names and roles by themselves

Confirmation by physician

- 2 Patient name, date of birth
- 3 Surgical method and surgical procedure
- 4 Confirmation of skin incision location and site
- 5 Important points of surgery
- 6 Scheduled operation time
- 7 Expected bleeding volume
- 8 Confirm installation of neutral zone

1
2
3
4
5
6 Confirmation by nursing team

- 7 9 Sterilisation of equipment and materials used for surgery
8
9 10 Problems to be shared within the team regarding allergies and equipment
10
11 11 Display necessary images
12
13 12 Operation of intermittent pneumatic device
14
-

15
16 C. Confirmation steps at the time when patient leaves the operation room (Sign out)
17

18 Confirmation by nursing team

- 19 1 Surgical method and surgical procedure
20
21 2 Equipment, gauzes, and needles used for surgery
22
23 3 Confirmation of the number and name of (pathological) specimens
24
25 4 Confirmation of return of unused blood products
26
27 5 Problems with equipment that must be addressed
28
29 6 Major problems with postoperative recovery and management
30
31 7 Postoperative equipment

32 Proof that the confirmation checklist was used by the physician and nursing team
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4, 5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4, 5, 6
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4, 5, 6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3, 4, 5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4, 5, 6
Bias	9	Describe any efforts to address potential sources of bias	10
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	4,5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	4,5,6
		(b) Describe any methods used to examine subgroups and interactions	4,5,6
		(c) Explain how missing data were addressed	4,5,6
		(d) If applicable, describe analytical methods taking account of sampling strategy	4,5,6
		(e) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A

Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6
		(b) Indicate number of participants with missing data for each variable of interest	N/A
Outcome data	15*	Report numbers of outcome events or summary measures	6,7,8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(b) Report category boundaries when continuous variables were categorized	6
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Supplementary Figure S1
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9,10
Generalisability	21	Discuss the generalisability (external validity) of the study results	10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	11

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.