Effect of a Surgical Safety Checklist for Refractive Procedures

Marie-Claude Robert, MD FRCSC, Catherine J Choi, MD MS
Richard Urman, MD, Fred Shapiro, DO
Samir A Melki, MD PhD

The authors have no financial interests to disclose

Background

Laser vision correction (LVC) :

- Widely accepted as a safe method to correct refractive error and reduce dependency on spectacles or contact lenses.
- ~ 800 thousand LVC procedures are performed in the US per year.
- Vast majority of procedures are performed in an office-based setting under mild sedation.
- Paucity of information and guidelines on safety and prevention of adverse events.

Background

Timeline

- Occurrence of 2 never-events in 2009 and 2011
  - Never-event = serious medical error that is preventable and inexcusable or an error “that should never have happened” (eg: wrong site surgery)
- Development of a pre-operative safety checklist
  - Identification of 28 sources of error
- Implementation of checklist in December 2011
- **Purpose:** To measure the effect of surgical safety checklist implementation in a busy private LVC center on the prevention of medical errors

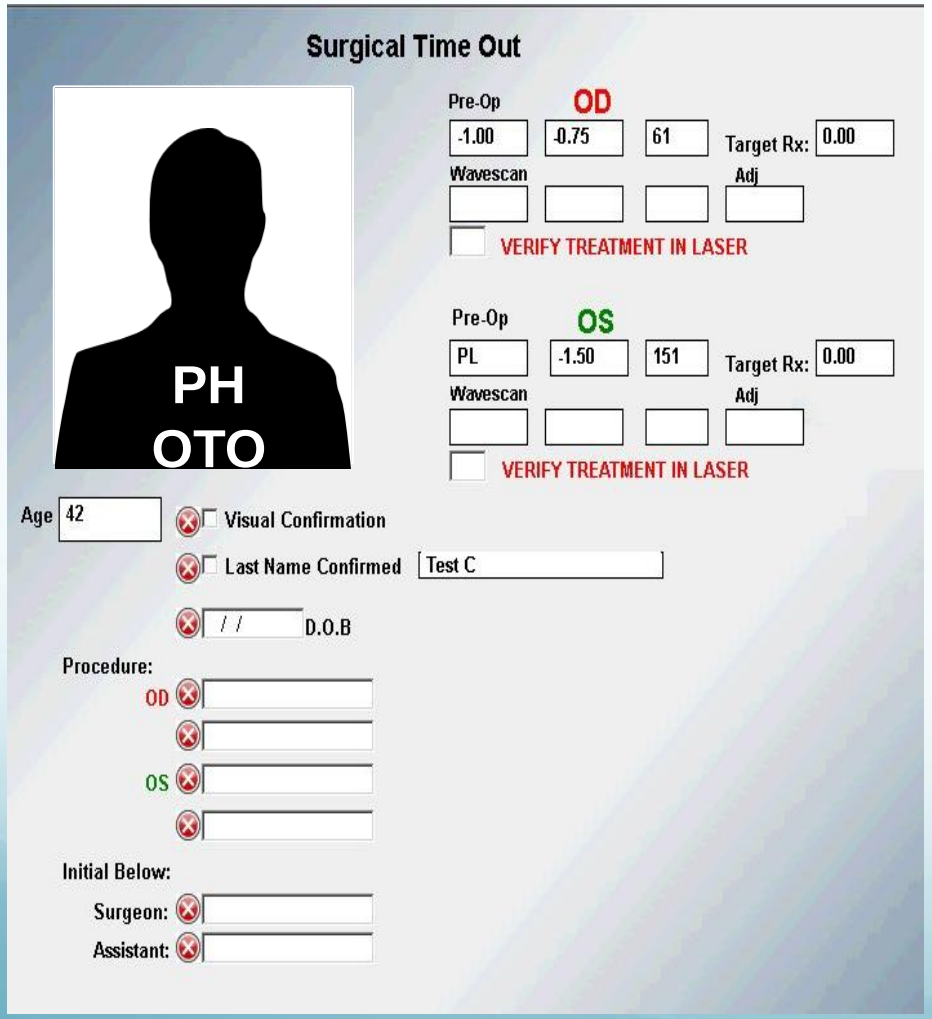
28 sources of error

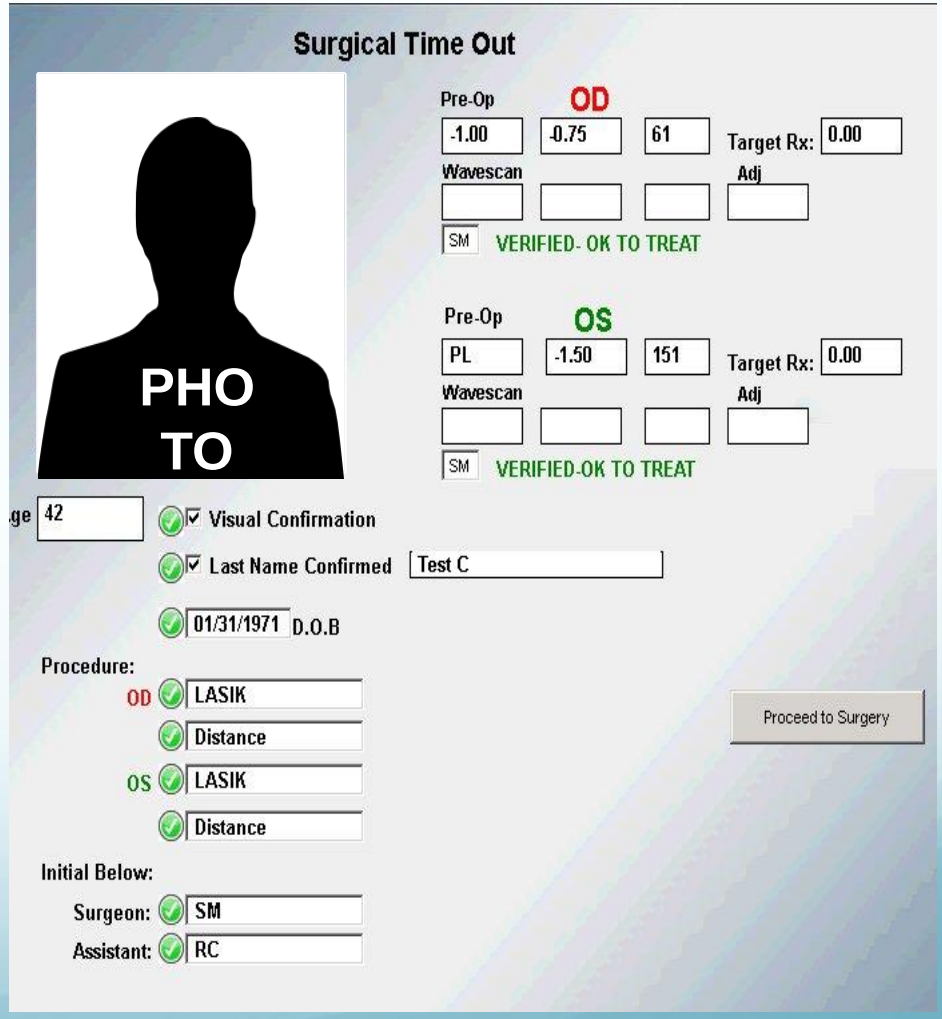
Number	Item
1	Patient name
2	Date of birth
3	Type of procedure (LASIK, PRK)
4	Aim (distance, near)
5	Pre-operative sphere: plus or minus
6	Pre-operative sphere power: first digit
7	Pre-operative sphere: first decimal
8	Pre-operative sphere: second decimal
9	Pre-operative cylinder power: plus or minus
10	Pre-operative cylinder power: first digit
11	Pre-operative cylinder power: first decimal
12	Pre-operative cylinder power: second decimal
13	Pre-operative cylinder axis: first digit
14	Pre-operative cylinder axis: second digit
15	Pre-operative cylinder axis: third digit
16	Wavescan or Laser input sphere: plus or minus
17	Wavescan or Laser input sphere: first digit
18	Wavescan or Laser input sphere: first decimal
19	Wavescan or Laser input sphere: second decimal
20	Wavescan or Laser input cylinder power: plus or minus
21	Wavescan or Laser input cylinder power: first digit
22	Wavescan or Laser input cylinder power: first decimal
23	Wavescan or Laser input cylinder power: second decimal
24	Wavescan or laser input cylinder axis: first digit
25	Wavescan or laser input cylinder axis: second digit
26	Wavescan or laser input cylinder axis: third digit
27	Optical zone
28	Nomogram adjustment

Methods

- Safety checklist incorporated into electronic medical record (EMR)
  - Patient and treatment data entered by assistant/surgeon prior to surgery
  - Can only proceed with surgery if entered data corresponds to existing data in patient chart
- Retrospective cohort
  - 2951 consecutive patients
    - 1534 prior to checklist implementation (07/2009 to 12/2011)
    - 1417 after checklist implementation (12/2011 to 02/2014)
  - Inclusion criteria
    - Adult patient
    - LCV surgery: Primary or enhancement
    - Single location: Boston Eye Group
  - Rate of medical error or "never-events" compared between groups.

EMR safety checklist time-out





Results

- Baseline characteristics

	Pre-checklist	Post-checklist	P value
N Patients Eyes	 1417 2744	 1534 2969	
Age, mean +/- SD	36 +/- 10	36 +/- 10	0.24
Preoperative refraction Sphere Mean +/- SD Cylinder Mean +/- SD	 -3.73 +/- 2.21 -1.02 +/- 0.79	 -3.55 +/- 1.99 -0.89 +/- 0.84	 0.001 <0.0001
% procedure type LASIK LASEK without MMC LASEK with MMC PRK with MMC	 76 7 17 <0	 80 3 16 <0	 0.0002 <0.0001 0.72 0.11
% custom treatments	56	62	0.0001

Statistical software: Graphpad.com; Unpaired 2-tailed T-test for age and preoperative refraction; Fisher's exact test for % procedure type and % custom treatments; N – number, SD – standard deviation, Min – minimum (myopic) refraction, Max – maximum (hyperopic) refraction

Results

- Never-events
  - 2 patients in pre-checklist cohort (0.14%)
  - 0 in post-checklist cohort (0 %)

Fisher's exact test, p= 0.23

- The never-events involved incorrect refractive aim in patient #1 and incorrect procedure/treatment in patient #2.
  - See next slide (medical errors highlighted in red)

	Patient #1	Patient #2
Age	58	35
Planned procedure	LASIK enhancement	Myopic LASIK
Eye laterality	OD	OU
Preoperative refraction	OD: -0.50 -0.75 x 20	OD: -1.25-0.25 x 100 OS: -1.00 – 2.25 x 075
Refractive target	-1.25D (monovision, OD for near)	Plano OU
Actual procedure	LASIK OD	LASEK with MMC OS
Actual laser correction	-0.50 -0.75 x 20 (plano aim)	OD: -4.63 -1.12 x 179 OS: -3.30 -1.25 x 165
Postoperative refraction (UCVA)	+1.75 D (20/20, distance)	OD: +3.50 -0.50 x 100 (20/50, distance) OS: +4.00 -2.50 x 065 (20/100, distance)
Remediation	LASIK OS for near	Hyperopic LASIK OU
Outcome	OD UCVA : 20/20 (distance) OS UCVA: 20/20 (near)	OD and OS UCVA: 20/20 (distance)

UCVA: uncorrected visual acuity

Conclusion

- Multiple potential sources of error in LVC
- Never-events lead to increased patient anxiety, loss of trust and the need for additional surgery.
  - Fortunately, the 2 reported cases recovered vision with additional surgery
- Surgical checklists improve patient safety. However, there are currently no standardized guidelines to prevent errors during office-based LVC.
- Our study demonstrates the effectiveness of a simplified safety checklist encompassing 28 items to minimize and prevent errors during LVC.