# A comparison of techniques: informed consent for resident involvement in cataract surgery

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## **ABSTRACT • RÉSUMÉ**

**Objective:** To compare three different techniques of obtaining informed patient consent and the relative acceptance rates for resident involvement in cataract surgery. The techniques differed with regards to physician-patient interaction, and how resident involvement was presented.

**Design:** A retrospective cohort study in a tertiary care ophthalmology department with a recently established residency training program. **Participants:** 356 patients undergoing informed consent procedure for cataract surgery.

**Methods:** Charts of all patients undergoing cataract surgery by 3 cataract surgeons from October 2009 to March 2010 were reviewed. Patient demographics, the documentation of a specific request for resident participation, and the patient response were recorded. Response rates were analyzed between the three different techniques/surgeons.

**Results:** Consent to resident participation was found to range from 21% to 86%. Higher acceptance rates were associated with direct personal conversation between surgeon and patient.

Conclusion: High acceptance rates for resident involvement in cataract surgery can be achieved with full disclosure of resident involvement to patients.

- **Objet :** Comparaison entre trois différentes techniques visant à obtenir le consentement éclairé des patients et les taux d'acceptation de la participation des résidents à la chirurgie de la cataracte. Les techniques différaient selon l'interaction entre le médecin et le patient, et selon le mode de présentation de la participation du résident.
- Nature : Étude de cohorte rétrospective dans un département de soins tertiaires en ophtalmologie, qui avait récemment institué un programme de résidence.

Participants : 356 patients qui suivaient une procédure de consentement claire pour la chirurgie de la cataracte.

Méthodes : Examen des dossiers de tous les patients qui avaient subi une chirurgie de la cataracte effectuée par trois chirurgiens entre les mois d'octobre 2009 et mars 2010. L'on a pris en notes les données démographiques des patients, la documentation d'une demande particulière concernant la participation d'un résident, et la réaction du patient. L'analyse a porté sur les taux de réponse selon les trois différentes techniques et les chirurgiens.

- Résultats : Le consentement à la participation du résident variait entre 21 % et 86 %. Les taux d'acceptation plus élevés dépendaient de la conversation personnelle entre le chirurgien et le patient.
- **Conclusion :** Les taux élevés d'acceptation de la participation du résident en chirurgie de la cataracte peuvent s'obtenir en informant entièrement le patient sur la participation du résident.

Residency training programs are a crucial component of the future of health care. The surgeons of today were the resident learners of yesterday. The obligation<sup>1</sup> to teach future generations dates back to the days of the Hippocratic Oath.

Previous studies<sup>2-4</sup> assessing the acceptance by patients of residents' participation in or performance of their surgeries have shown conflicting reports, from very low (16%)<sup>2</sup> to very high (95.3%)<sup>3</sup> acceptance levels. Full disclosure to patients regarding who will be taking part in their surgical procedures is necessary for a multitude of reasons. Such disclosure includes not only the risks and benefits of and the alternatives to the surgeries but also the identities and training statuses of all involved in their care.<sup>1</sup> Legal cases referenced in other studies<sup>5</sup> of this issue have held that negligence and even battery have been found in cases in which there was lack of supervision or in which specific agreement about the identity of the operating surgeon was not adhered to. Medical organizations and governing bodies have made the guidelines very clear regarding full disclosure.<sup>1,6-9</sup>

The American Medical Association states that the surgeon who performs the surgery is the operating surgeon and must be identified as such to the patient in the consent process.<sup>6,7</sup> The American College of Surgeons also condemns so called ghost surgery (surgery by residents without explicit consent) and mandates that the staff surgeon be an active participant in the surgery.<sup>8</sup> The Canadian Medical Protective Association states that participation by residents must be made explicit.<sup>9</sup>

A number of the cataract surgeons on staff at McMaster University have recently generated their own techniques of

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obtaining informed consent for the participation of residents. We identified an excellent opportunity to compare these techniques and assess the responses of patients.

The setting of our study is unique in the literature because it consists of private offices linked to a tertiary care academic residency training program. Our residency program was founded in 2005, and we encountered the issue of teaching surgery to residents as the residency program matured. Even though there is a generic statement on hospital consent forms identifying our center as a teaching facility, our faculty surgeons sought to provide patients with more clear information of what that means.

## METHODS

Each of the three cataract surgeons has a private office in Hamilton, a city of approximately 500,000 people. Our catchment area is roughly 2 million people. Of the 3 surgeons, 2 (J.H.S., L.E.K.) are sole practitioners, and the third surgeon (K.D.M.) shares a practice with 1 other ophthalmologist. One of the 3 surgeons (J.H.S.) had residents rotating through his private office during part of this study period. All 3 surgeons operate at the Hamilton Regional Eye Institute (HREI), which is affiliated with St. Joseph's Healthcare Hamilton. The HREI consists of several clinics and laser and procedure rooms as well as a surgery center where all adult ophthalmic surgery takes place in the city.

A retrospective chart review was undertaken between October 2009 and March 2010. All charts for patients referred for cataract surgery to the 3 surgeons were analyzed. The consent process, the patients' responses, and the patients' demographics were documented for all 3 surgeons. The procedures used for consent are outlined below.

## Surgeon 1

Surgeon 1 (J.H.S.) discussed the standard procedural risks, benefits, and alternatives personally and verbally presented the following scripted statement regarding resident involvement:

When you are in the operating room, you may hear technical talk going on about your surgery. Don't be worried. This discussion is normal in our teaching hospital. I might be operating with a resident (like Dr. X here [the name is used if a resident present]). A resident is a medical doctor training to be an ophthalmologist. Residents participate in the surgery under my close supervision. Some may do very little; others might do a lot more, depending on their levels of training. I never leave them alone in the operating room and am there to guide and assist them so that we function like a team. I just wanted to be sure you are comfortable with this.

In addition, Figure 1 shows the stamped documentation of this discussion as made in the chart by surgeon 1. A yes/no confirmation was required.

## Surgeon 2

Surgeon 2 (L.E.K.) had his office staff present a separate resident participation consent form (Fig. 2) to the patients.

# Surgical Risks and Benefits · <1/1000 blind/loss globe

• 95% success • 5% complications/worse • IOL power/position ± 1% Resident participation: YES NO

Fig. 1-Surgeon 1: Chart documentation of resident participation.

Resident participation was treated as an independent risk factor. The patients were asked to read the form carefully and to indicate their personal choice. No verbal discussion or recommendation was made by any members of the office staff or by the surgeon. The rationale for this approach was to get a true sense of patients' baseline feelings about residents' participation in their surgeries, without any bias.

#### Surgeon 3

After explaining the risks and benefits of cataract surgery, Surgeon 3 (K.D.M.) told patients:

I will perform your surgery at the Surgery Centre, which is a teaching institution, and ophthalmology residents may assist me in the OR. This may include observation and/or performing your surgery under my supervision. Is this is acceptable?

Surgeon 3 then made a notation in his chart regarding residents' assistance (yes or no), and then had the patient sign the standard hospital consent form.

All 3 surgeons also had patients review and sign the standard teaching-hospital consent form. Variants of this form are common in teaching institutions. The relevant paragraph, allowing learner participation, states:

I understand that St. Joseph's Healthcare is a teaching hospital and has students in all health care professions. I consent to have health practitioners, who are training in approved education programs, take part in my care.

All data used in this study were analyzed using IBM SPSS Statistics 19 (SPSS, Chicago, IL). Statistical analysis of quantitative data included frequency and descriptive statistics for cataract surgery performed by staff oph-thalmologists (J.H.S., L.E.K., and K.D.M.) and patient demographics (age, sex, and race). Meanwhile, frequency analysis of patients' responses (yes or no) to consent for residents' participation with each surgeon was performed by the  $\chi^2$  test. All p values were 2-sided and p values less than 0.05 were considered statistically significant. Any bilateral surgery done during this study was counted only once because the consent to residents' observation only was considered a *no* response, and partial or full participation options were considered *yes* responses.

# RESULTS

The numbers of patients were 86, 107, and 163 in the 3 surgeons' practices, respectively. The patients' average ages ranged from 72 to 76 years. The sex distribution ranged

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| SUPPLEMENTARY CONSENT   |   |  |
|---|---|--|
| Dear Patients:  |   |  |
| St. Joseph's Healthcare is a teaching instit<br>doctors who work there, and these individu<br>observe, participate in and may even carry<br>certified ophthalmologist such as myself.                           | ution. As such, I want you to be aware that there are student<br>lats are learning the skills of an ophthalmic surgeon. They<br>out an entire surgical procedure under the supervision of a |  |
| However, you are under no obligation to ha<br>procedure. You can decide whether or not  | ave a student eye surgeon participate in your surgical<br>you wish to have a learner involved in your surgery.  |  |
| I wish to assure you that whether or not yo<br>of your surgery or the booking of your case<br>one you feel most comfortable with so that  | u consent to such participation will have no effect on the timing<br>b. Listed below are some options. I would like you to select the<br>I can inform the staff of your individual desires. |  |
| I consent to having an ophthalmol   | ogy resident (learner) observe my procedure.  |  |
| I consent to allowing the learner assist [Surgeon 2] in the performance of my   |   |  |
| case, including hands on assistance.  |   |  |
| I consent to allowing the student of  | phthalmic surgeon to actually do as much of   |  |
| my case as [Surgeon 2] deems appropriate, even to the extent of carrying out the  |   |  |
| entire procedure.   |   |  |
| I wish to assure you that your wishes will be followed, since these are important matters. Once again, be assured that your selection will in no way affect the timing or placement of your surgical operation. |   |  |
| Patient Name  | Patient Signature   |  |
| Witness   |   |  |

Fig. 2-Surgeon 2 patient consent form.

from 55% to 62% female patient population. The 3 groups were not statistically different.

Consent rates for residents' participation in the 3 surgical practices are summarized in Table 1. Based on the 3 techniques employed in this study, the consent rates for residents' participation in cataract surgery varied from a low of 21% (surgeon 2) to a high of 86% (surgeon 1).

A statistical comparison is reviewed in Table 2. Both surgeon 1 (J.H.S.) (86%) and surgeon 3 (K.D.M.) (67%)

| Table 1—Consent for residents' participation |           |           |           |  |
|--|-----------|-----------|-----------|--|
|  | Surgeon 1 | Surgeon 2 | Surgeon 3 |  |
| Number of patients                           | 86        | 107       | 163       |  |
| Consent for residents'<br>participation      | 74        | 23        | 110       |  |
| Percentage                                   | 86        | 21        | 67        |  |
| For all values, $p < 0.01$ .                 |           |           |           |  |

showed acceptance rates that were statistically higher than those of surgeon 2 (L.E.K.) (21%). Surgeon 1's acceptance rates were also statistically higher than those of surgeon 3.

# DISCUSSION

Patients have the right to know who will participate in their surgeries. A consensus of medicolegal precedent<sup>6-9</sup> acknowledges their right to decline participation in residents' training. This is at times in conflict with the obliga-

| Table 2—Comparisons of groups with $\chi^2$ test |             |                                |  |
|--|-------------|--------------------------------|--|
|  | Surgeon 2   | Surgeon 3                      |  |
| Surgeon 1<br>Surgeon 2                           | p < 0.0001* | $p = 0.02^*$<br>$p < 0.0001^*$ |  |
| *Critical <i>p</i> value = 0                     | .05.        |                                |  |

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Downloaded for Anonymous User (n/a) at University of Pittsburgh from ClinicalKey.com by Elsevier on August 14, 2019. For personal use only. No other uses without permission. Copyright ©2019. Elsevier Inc. All rights reserved. tion of today's surgeons to teach the surgeons of the future. In our study, 3 different approaches were assessed in terms of patients' acceptance of residents' participation in surgery. Previous studies specific to cataract surgery have shown markedly conflicting results with respect to patients' acceptance rates of residents' participation.<sup>2-4</sup>

Wisner et al.<sup>10</sup> conducted a survey of patients being considered for cataract surgery in an academic ophthalmology practice staffed by consultant surgeons. Of respondents, 96% felt it was very important for them to be asked permission for a resident to perform their surgery; 92% of patients felt that the attending staff surgeon should ask this permission; and only 45% agreed that the standard consent form is sufficient to allow for residents' participation. It was found that 49% of patients were likely to allow a resident to perform their surgeries if they had been asked in advance. Finally, 26% of patients stated they would seek care at a nonteaching institution should residents be involved in their cases. Although there may be some confounders in this study regarding the patient population and reporting or selection bias, the overall message supports the finding that patients accept the role of residents in their surgeries.

Nguyen et al.<sup>2</sup>surveyed 5 ophthalmologists in their department and found that only 1 of the surgeons routinely informed patients of residents' participation. Of the 49 patients in this study, only 16% agreed to residents' involvement.

Gan et al.<sup>3</sup> proposed a specifically worded consent that served as a template in our study for surgeon 1. They found a 95.3% acceptance rate of residents' involvement. These findings argue against the idea that the consent process is time intensive and anxiety provoking for patients and suggest that a high acceptance rate can be achieved by using appropriate methodology.

Vallance et al.<sup>4</sup> assessed patients' recall of the consent process immediately after consent was obtained and 1 month postoperatively. This study also showed that the consent process did not change the anxiety levels of patients. Patients' recall of the consent process was poor; only 18% recalled the risk for major complications. In addition, after consent, 67% of patients recalled being informed about trainees' performance of their surgeries, and these patients were much less concerned regarding trainee involvement when compared to those patients who did not recall being informed. In their study, 50% of cases were performed by residents.

Our results show great variability, from 21% to 86%, in consent for residents' participation. These patients are drawn from the same city, and there is no reason to believe a difference in patient population exists among the 3 offices; yet there is great disparity in their responses. The offices with the highest and lowest acceptance rates are only 6 km from one another. We will examine some possible reasons for this effect. In regard to the lowest response rate (21%; surgeon 2), the rationale for not involving the staff or surgeon in the consent process with regard to residents' participation was to ascertain the "true" opinions of the patients, free from bias. In theory this is a reasonable concept. However, studies<sup>11,12</sup> have shown that patients are commonly unaware of the various levels of medical training. Pallin et al.<sup>11</sup> conducted a study of informed consent in the emergency department setting, where only 35% of patients questioned knew what an intern or resident was. So, much like our surgical consents need to be informed so does the specific consent obtained regarding resident participation, including the nature and boundaries of training.

The staff surgeon can be an ambassador for his trainees and for the surgical training program as a whole. Patients need to see that the surgeon is confident about residents' participation, and that positive attitude of confidence is likely to be factored into patients' decision making. Removing the personal discussion and physicians' recommendations probably had a significant impact on the low acceptance rate for surgeon 2. Both methods that allowed personal surgeon-patient interaction and discussion in the consent process achieved satisfactory acceptance rates. The more detailed and scripted discussion by surgeon 1, which stressed supervision and established the team nature of staff surgeon and residents, achieved an even higher acceptance rate than did the simpler discussion of surgeon 3.

We recognize the possibility that the personal surgeonpatient interaction introduces bias, because patients may be more likely to agree to residents' involvement in order to support or please their surgeons. Surgeons' attitudes, nonverbal communications, and personalities may influence patients' decisions.

To remove these potential biases, a possible prospective follow-up study would randomize the approach used by each of the 3 surgeons and again ascertain the acceptance rates.

This study looks at some of the points not addressed in the previous literature:

- (1) We explore the consent process in the settings of private offices affiliated with academic teaching programs. This scenario, in full or in part, is not uncommon in teaching environments. Many academic centres rely on this private-practice stream to teach their residents.
- (2) In contrast to the work of Gan et al,<sup>3</sup> no cases were excluded because of technical difficulty. It is important for senior residents to gain experience in challenging cases according to the graded responsibility model. Patients who were told that their cases posed greater challenges were still willing to accept residents' involvement in their cases.
- (3) Residents' involvement was not included as part of the standard consent package but was addressed independently. Separate documentation over and above the hospital consent form was used.

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The most important factor to explain the differences in our 3 groups is how consent is obtained rather than the specific wording used. The approach used by surgeons 1 and 3 differed greatly from that of surgeon 2 with respect to direct physician-patient interaction. The difference between surgeons 1 and 3 consent process was the more detailed and scripted discussion that surgeon 1 had with his patients. Both methods produced an acceptable patient acceptance rate, but the more robust discussion produced a higher result. Both methods produced an acceptable patient acceptance rate, but the more robust discussion produced a higher result.

As we all know through our clinical experiences, the fiduciary relationship between doctors and patients is crucial to patients' experiences. We also know that because of this, physicians' biases can be expressed easily to the patient and thus can influence their understanding and, ultimately, their decisions.

The fiduciary relationship empowers doctors to have great influence and also imposes great moral and ethical responsibilities. With positive attitudes, staff surgeons can be ambassadors for their trainees and for surgical training programs as a whole. Patients need to be assured that everything done will be in their best interests, that residents will be closely supervised, and that they will participate under supervision according to their levels of ability and no further.

Studies have shown that surgeons recognize the trust that patients place in them, and they often feel comfortable allowing residents to operate with graded responsibilities, but they often do not voluntarily inform patients of residents' involvement.<sup>2,13</sup> Reasons given for nondisclosure include (*i*) the excess amount of time required to explain the situation to patients is prohibitive; and (*ii*) there is fear of loss of patients.<sup>2,13</sup> These reasons have been disproven in the literature.<sup>3,4</sup>

Surgeons must balance their responsibilities as ambassadors for their residents and their role as patient advocates. These 2 roles do not have to be in conflict, as we have demonstrated in our study.

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