PUTTING OUTCOMES ANALYSES TO PRACTICAL USE IN CATARACT AND REFRACTIVE SURGERY

Data can help physicians improve efficiency, benchmark their performance, and track their results.

BY SUZANN PERSHING, MD, MS

Outcomes analysis is fundamental to the modern practice of medicine. As physicians, we use outcomes analysis in numerous situations, such as to counsel patients on the risks and benefits of treatments (e.g., the risk of endophthalmitis after cataract surgery), to develop new treatments and measure their efficacy (e.g., comparing phacoemulsification with modern small-incision manual extracapsular cataract surgery), and to individually stay up to date and improve our practice (e.g., using customized A-constants for IOL calculations).

Although not a new concept, outcomes analysis is increasingly linking patient care and research in unprecedented ways, driven by the opportunities presented by big data. Substantially more data are available, analytic tools are more widespread, and analysis itself is much faster. These developments now allow practitioners to use data from their own practices, or aggregated data from a whole country or large insurance system, to increase their efficiency, improve their results, and benchmark themselves against the performances of their colleagues.

"BIG DATA
is the next frontier in medicine, complemented by the expanding use of electronic health records."
INTERPRETING OUTCOMES ANALYSIS

As a comprehensive term, outcomes analysis can encompass anything involving investigation of clinical efficacy or effectiveness—randomized clinical trials, retrospective single- and multicenter studies, system-generated physician report cards, and individual physicians’ efforts to evaluate their own results. However, the real evolution in outcomes analysis has been in scale and scope, with new technologies and methods of organization enabling us to follow unprecedented numbers of patients over unparalleled lengths of time, with minimal burden on physicians and practices.

Whether outcomes analyses are derived from peer-reviewed literature, personal data, or reports generated by hospitals, health systems, or insurers, interpretation of their results requires careful consideration of data sources and methods. Particularly, modern outcomes analysis often relies on aggregated empirical data obtained through clinical data registries, which provide the opportunity to answer clinical questions without the time, expense, or inherent constraints of randomized controlled trials. Randomized clinical trials have long been the gold standard, but they are expensive, limited in duration simply due to feasibility, and subject to concerns regarding generalizability. Further, retrospective reviews are usually conducted at one or a few sites, often academic centers, and are fundamentally limited by feasibility and cohort size for less common or rare diseases.

Ideally, sophisticated scrutiny will use both the results of randomized controlled trials and large-scale empirical data, recognizing and balancing the relative strengths and weaknesses of each—length and generalizability concerns for controlled trials, and variability and uncontrolled populations for empirical data analysis. Looking at a spectrum of data sources provides an opportunity to best meet the ultimate goal of counseling patients and practicing better medicine.

Organized clinical data registries are increasing in both number and scope; examples include the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO), the American Academy of Ophthalmology (AAO) Intelligent Research in Sight (IRIS) Registry, EyeNet Sweden, the Malaysian Cataract Surgery Registry, the Fight Retinal Blindness! (FRB!) Project in Australia, data collection initiatives by the UK National Health Service, and efforts in India by Aravind Eye Hospitals, among others (see Organized Clinical Data Registries and Resources).

Fundamentally, analyzing our outcomes implies that we recognize we must understand how we are doing before we can improve. Ideally, these analyses look at the big picture, beyond the level of individual provider. Aggregate data on clinical factors and outcomes are highly variable internationally. National health care systems or initiatives arguably have

### OUTCOMES ANALYSIS:
Encompassing anything involving investigation of clinical efficacy or effectiveness

- Randomized clinical trials
- Retrospective single- and multicenter studies
- System-generated physician report cards
- Individual physicians’ efforts to evaluate their results

### AT A GLANCE
- Physicians can use outcomes analysis to counsel patients on the risks and benefits of treatments, develop new treatments and measure their efficacy, and stay up to date and improve their practices.
- Looking at a spectrum of data sources provides an opportunity to best meet the ultimate goal of counseling patients and practicing better medicine.

### ORGANIZED CLINICAL DATA REGISTRIES AND RESOURCES

**ICHOM:**
- Cataract surgery: [http://www.ichom.org/project/cataracts/](http://www.ichom.org/project/cataracts/)
- Macular degeneration: [http://www.ichom.org/project/macular-degeneration/](http://www.ichom.org/project/macular-degeneration/)

**EUREQUO:** [http://www.eurequo.org/](http://www.eurequo.org/)

**IRIS Registry:** [http://www.aao.org/iris-registry/](http://www.aao.org/iris-registry/)

**EyeNet Sweden:** [http://www.eyenetsweden.se/](http://www.eyenetsweden.se/)

**Malaysian Cataract Surgery Registry:** [http://www.acrm.my/ned/cataractSurgeryRegistry.html](http://www.acrm.my/ned/cataractSurgeryRegistry.html)


**Aravind Eye Hospitals:** [http://www.aravind.org/](http://www.aravind.org/)
HAMBURG REFRACTIVE DATABASE

By Stephan J. Linke, MD; and Toam Katz, MD
During the past 2 decades, the field of laser refractive surgery has witnessed dramatic advances introduced by new technologies. LASIK has become the most common elective operation, with more than 55 million procedures performed worldwide as of 2012 (2014 Market Scope data).

Several recent reports have provided evidence for a trend toward higher rates of myopia worldwide. Therefore, a greater understanding of both the cause and development of refractive error through basic, clinical, and epidemiologic studies is crucial in order to perfect existing treatments and begin to formulate preventive strategies.

Many studies have analyzed the postoperative outcomes of refractive surgery, but only a few have focused on pre- and intraoperative biometric parameters, flap creation, and ablation nomograms. Controversies regarding the prevalence and impact of ocular residual astigmatism and the influence of age and sex on the efficacy of the laser treatment still exist. These conflicting results may be attributed to difficulties in analyzing and comparing findings among studies that typically include only small numbers of patients and sites and various excimer laser platforms and techniques for flap creation. Lack of standardization in patient assessment and selection leads to a high degree of bias and significant discrepancies in results.

In 2006, the Eye Clinic of the University Medical Center Hamburg Eppendorf and Care Vision initiated a clinical and scientific cooperation, which is the basis of the Hamburg Refractive Database. One strict protocol (last updated November 2014) was implemented at refractive clinics in Hamburg, Berlin, Hannover, Cologne, Frankfurt, Stuttgart, Nuremberg, Munich, and Vienna to regulate preoperative assessment, intraoperative setting, and postoperative regimen, with the ultimate goal of standardizing key perioperative parameters and minimizing potential bias.

In addition to general medical and ophthalmic histories, preoperative measurements include distance UCVA, distance BCVA, manifest refraction, cycloplegic refraction, tonometry, mesopic pupillometry (Colvard pupillometer), pachymetry, corneal topography (Orbscan; Bausch + Lomb and Pentacam; Oculus Optikgeräte), slit-lamp examination of the anterior segment, and fundoscopy. A total of 234 pre-, intra-, and postoperative parameters are automatically documented.

With clinician users following these guidelines, the Hamburg Refractive Database delivers valuable information regarding the prevalence and distribution of refractive error, especially the intraindividual distribution, and helps ensure that clinical decision-making is data-driven.

STUDY POPULATION

The Hamburg Refractive Database is continually expanded and updated. Today, our databank contains 71,098 patients (142,195 eyes) who attended refractive clinics in Germany and Austria between April 2006 and November 2014 for the treatment of ametropias. Most of these patients were candidates for excimer laser (Continued on page 22)

STRENGTH IN NUMBERS

55 MILLION
LASIK procedures performed worldwide as of 2012

142,195
Eyes in the Hamburg Refractive Database

the best opportunity for data collection and the benefit of integrating data from multiple sources. Outcomes data for privatized and even some state health care systems are, ironically, derived mostly from insurance claims data.

IMPROVING CLINICAL PRACTICE

New technology for organized data collection allows organizations or individual clinicians to answer clinical questions more rapidly than previously possible. We no longer have to wait years through trial conception, funding, execution, analysis, and publication, with the risk of the analysis becoming obsolete in the interim. Collection of large aggregate data can now be automated in registries and presented in near real-time analysis, allowing us to answer clinical questions rapidly, although still to some extent bound by time for analysis and publication to disseminate results. This permits a new way of thinking about evidence-based medicine. We can, for example, find out who is implanting the iStent (Glaukos) and whether these devices are working as expected. Or we can measure the relative benefits and impact of laser-assisted cataract surgery compared with standard phacoemulsification.

Participation in data registries enables physicians to use benchmarking as a tool to increase their efficiency, improve their day-to-day work, or comply with mandated regulations. With these research tools, individual physicians can answer specific clinical questions, performing risk adjustment
or demonstrating quality for value-based reimbursement arrangements. They can seamlessly collate their postoperative refractions to customize A-constants for cataract surgery; either LASIK or PRK. Those whose refractive errors exceeded the treatment range for laser vision correction were candidates for phakic IOL implantation or clear lens extraction.

Patients were excluded from the study for any of the following diagnoses: history of ocular surgery, including cataract or refractive surgery; prothesis; clinically significant retinal pathology; glaucoma; and optic neuropathy. The study protocol was conducted according to the tenets of the World Medical Association’s Declaration of Helsinki regarding scientific research on human patients. Informed consent was obtained from the patients after explanation of the nature and possible consequences of the study. The analysis of the data was approved by the local ethics committee.

STATISTICAL ANALYSIS

After data were compiled, they were entered into a spreadsheet program (Excel; Hamburg Refractive Database) and further statistically analyzed with SPSS software (version 15.0).

A study was initiated recently to determine the amount of topographic astigmatism (also termed ocular residual astigmatism, or ORA) in eyes that have no refractive cylinder. This study included 267 eyes of 267 consecutive myopic patients with refractive plano cylinder whose data were entered into the Hamburg Refractive Database. Receiver operating characteristic analysis was used to find the cutoff values of preoperative ORA that can best discriminate between groups of efficacy and safety indices in preoperative plano refractive cylinder eyes. A significantly greater efficacy index was achieved in eyes with low preoperative ORA. Bivariate ordinary least squares regression showed that there was a statistically significant negative correlation between preoperative ORA magnitude and efficacy index. Each diopter of preoperative ORA reduced efficacy by 0.07. Results of this study were also presented at the 19th ESCRS Winter Meeting in Istanbul.

OUTLOOK

Studies derived from the Hamburg Refractive Database64 to date have revealed valuable normative parameters and their correlations in the largest cohort of Central European refractive surgery candidates. Based on these results, we have initiated further studies to explore the impact of preoperative parameters on the postoperative safety, efficacy, predictability, and refractive stability of laser vision correction and to transfer the obtained normative parameters to better define cutoff values between normal and diseased corneas, as in keratoconus.

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CONCLUSION

Achieving consistency across registries is a goal that will ultimately provide reliable, meaningful value and opportunities to mine data on a large scale, accounting for variations in comorbidities, demographic differences, and population mobility and allowing long-term monitoring of trends.

However, the greatest potential value of outcomes analysis lies in the vision of what it can be—a new technology enabling us to extract information from medical records and process it in ways previously impossible. We are now able to do more with less, using data that already exist. By automating the identification and processing of information directly from patients’ medical records, the burden on physicians and practices can be minimized. A system with a dashboard that can deliver near real-time processing and

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customized data extraction will allow outcomes analysis to transition from retrospective to prospective and enable customized predictions—for example, providing patients (and physicians) with a quantitative estimate of their own risk for specific complications from cataract surgery and the likely impact on visual function if a complication occurs. These results will also be useful as teaching tools.

This vision for outcomes analysis will not be realized immediately, but big data is the next frontier in medicine, complemented by the expanding use of electronic health records. Ophthalmology has been a pioneer in registry development internationally, compared with other specialties. Most data are currently obtained through customized structured data entry fields, but data extraction via natural language processing of free-text visit notes is already a reality, likely only to spread.

We can realistically predict true large-scale empirical databases, offering insights into rare diseases, patient perspectives, surveillance of postmarket drug and device performance, and real-world outcomes—balancing the weaknesses of randomized controlled clinical trials with the variability of clinical practice. Real-time feedback will provide a continuous quality improvement loop for internal and external benchmarking. In this not-too-distant future, ophthalmologists will have aggregate empiric clinical outcomes data as a powerful tool to revolutionize the practice of evidence-based medicine.

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