FLACS STUDY
New registry-based study to compare femto cataract surgery with conventional phaco
by Roibeard O’hEineachain in Verona

The ESCRS has launched the first study to directly compare the outcomes of femtosecond laser-assisted cataract surgery (FLACS) with the outcomes achieved in standard phacoemulsification, Paul Rosen FRCS, Oxford, UK told Femto 2013, an international meeting on anterior segment surgery.

“This study will provide the first opportunity to evaluate the outcomes of femto-phaco in a coordinated, multinational study and provide comparison with matched patients undergoing routine phaco,” Dr Rosen said.

The study will utilise the EUREQUO platform (www.eurequo.org) which was developed by the ESCRS and co-financed by the EU in 2008. The FLACS study is being funded entirely by the ESCRS without the participation of industry.

Dr Rosen emphasised that this study is not a clinical trial. The study will compare the outcomes of two different treatment groups in terms of visual acuity, surgically induced astigmatism, complications and biometric error. Individual surgeons, clinics and patients are anonymous in the database to facilitate honest reporting. The outcomes of FLACS will be compared with control cases from the EUREQUO database.

“There has been a gradual development of the use of lasers in cataract surgery and we now have a platform, a principal way of delivering the laser which looks like it’s here to stay, and the question we want to answer is, ‘is it better for our patients?’” Dr Rosen said.

The control cases in the FLACS study will be randomly selected and will have undergone cataract extractions using conventional ultrasound phacoemulsification technique. They will include twice the number of cases as those undergoing FLACS and will be matched regarding age, gender, preoperative visual acuity and preoperative risk factors.

The EUREQUO system has been expanded to include parameters related to FLACS. The FLACS study’s protocol will include mandatory variables in preoperative, surgical and follow-up forms. Each registered case must be saved and completed in the system when all data of the case has been entered.

Each participating clinic will provide a registry manager to supervise the study in that clinic and collect the data online. The ESCRS will train the registry manager for this study.

The outcomes data to be entered into the registry will include unaided and best-corrected visual outcomes at six to 60 days, the difference between target refraction and final refraction, the achieved spherical and cylinder refraction, and complications that occur during surgery and/or within 30 days after surgery. “It is important to remember that all patient and clinic data is anonymous. Each surgeon can have access to their own data, each clinic can have access to its own data, but you can’t see my data and I can’t see your data. The whole of the data can be accessed by the ESCRS but again it’s anonymous,” Dr Rosen said.

To avoid bias from a learning curve, all contributing surgeons must have previously completed 50 FLACS. The study will include all available platforms for FLACS but will not identify the platform in the database.

“Any femtosecond laser platform can be used but we will not be comparing different platforms, we are comparing the processes of using femto versus ultrasound phaco,” Dr Rosen said.

He noted that the ESCRS pioneered the collection of surgical outcome data through its EUREQUO platform. To date, 1,195,998 patient data has been entered into the EUREQUO system from 16 countries and there have been several publications that have appeared in the literature in recent years.

“The idea was to improve treatment and standards of care for cataract refractive surgery. We wanted to develop evidence-based guidelines for cataract and refractive surgery across Europe and make a significant impact on the exchange of best practice in relation to patient safety,” Dr Rosen said.

The FLACS study will start as soon as all arrangements are finalised. A preliminary report will be released at the XXXII Congress of the ESCRS in London in September 2014. “The invitation is extended to everyone who wishes to participate and be a co-author on the project so we need your help. This will be a unique project using a unique data collection system for what is going to be very exciting,” Dr Rosen added.

Those wishing to participate in the FLACS study should contact Carol Fitzpatrick by email: carol.fitzpatrick@escrs.org.