



YOUNG EVRS CLUB

Multicenter Trial Proposal

**OUTCOME OF PHACOEMULSIFICATION AFTER
VITREOUS SURGERY FOR MACULAR
DISORDERS**

INTRODUCTION

During the last EVRS meeting that was held in Sopron Mario Facino (Genoa, Italy) presented, during the Young EVRS Club inaugural meeting, the results of a survey he did among the young colleagues in order to know their opinion about some important aspects of the Club. About 95 % of the young ophthalmologists surveyed showed a great interest in multicenter trials.

Finally, the committee members of the Club wish to propose a topic:

“Outcome of phacoemulsification after vitreous surgery for macular disorders”

We think that the vast majority of us (young EVRS Club members) started his surgical activity as cataract surgeon while couldn't be expert in posterior segment surgery yet: this is the reason why we would like to propose this study.

To the best of our knowledge the literature regarding this subject refer to cataract surgery following pars plana vitrectomy for several vitreo-retinal pathologies such as macular disorders (macular pucker, macular hole), PVR cases, diabetic retinopathy, vitreous haemorrhage and so on. As a consequence the visual outcome may be influenced by the underlying pathology: this is the reason why we want to focus on the macular disorders (macular pucker, macular hole etc) to avoid some confounding factors.

Moreover the published papers consist of relatively small series of patients.

If, for instance, a group of 15 young adhered, we could be a strong force! We can imagine 10 cases with a mean follow up of one year for each one of us. We could collect 150 eyes and submit the largest series ever published!

We kindly ask the members of the EVRS Trial Committee to review this proposal in order to get their comments, suggestions and changes about this project.

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MULTICENTER TRIAL

PRIMARY DISEASE:

Cataract

STUDY:

“Outcome of phacoemulsification after vitreous surgery for macular disorders”

STUDY CENTER:

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STUDY CHAIRMAN:

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PURPOSE:

To evaluate the efficacy of phacoemulsification on visual outcome and the intra-operative and post-operative difficulties and complications in eyes that underwent a previous successful pars plana vitrectomy for macular diseases.

STUDY DESIGN:

Prospective multicenter interventional case series.

NUMBER OF PATIENTS ENROLLED:

150

PARTICIPATING CENTERS:

15

FOLLOW UP:

12 months

METHOD:

This study will comprise a series of 150 phacoemulsification with or without intraocular lens implantation performed in 15 different departments of ophthalmology. All the eyes had prior successful pars-plana vitrectomy for macular pucker or macular hole. Best-corrected visual acuity will be measured before and after phacoemulsification; intra and post-operative problems and complications will be also recorded.

MAIN OUTCOME MEASURES:

Best corrected visual acuity improvement of two or more Snellen lines to determine the rate of intra and post-operative complications.

POST MACULAR SURGERY PHACO

REFERRING OPHTHALMOLOGIST _____
E MAIL _____
DEPARTMENT OF OPHTHALMOLOGY _____
CITY _____
STATE _____

PATIENT NUMBER

HISTORY

NAME (INITIAL) _____
SURNAME (INITIAL) _____
AGE _____
GENDER M F
INDICATION FOR VITRECTOMY _____
GAS TAMPONADE (specify) YES (.....) NO
INTERVAL FROM PPV TO FACO (months) _____

PREOPERATIVE EVALUATION

DISTANCE BCVA _____
NEAR BCVA _____
TYPE OF CATARACT (allow to re-tick) NUCLEAR () ANT. CORTICAL POST. CORTICAL
PUPIL DILATATION (mm) _____
SINECHYA YES NO
PHACODONESIS YES NO
OTHERS (please specify) _____

ANAESTHESIA

TOPICAL PERIBULBAR GENERAL

CATARACT SURGERY (PHACOEMULSIFICATION)

DATE OF SURGERY _____
PUPIL DILATATION (mm) _____
MECHANICAL PUPILLARY ENLARGMENT YES NO

PUPIL SIZE FLUCTUATIONS DURING PHACO
 RED FUNDUS REFLEX
 CAPSULOREXIS (mm)
 VISCOELASTIC
 PHACO TECHNIQUE
 BSS BOTTLE HEIGHT
 ANTERIOR CHAMBER DEPTH DURING PHACO
 POSTERIOR CAPSULE FIBROSIS OR PLAQUE
 POSTERIOR CAPSULORHEXIS
 IOL IMPLANTATION
 INTRAOPERATIVE COMPLICATIONS

YES		NO	
PRESENT	INADEQUATE	ABSENT	
CCC ()		TORN	
HIGHLY COHESIV	COHESIV	LOW COHESIV	
4 QUADRANTS	STOP & CHOP	CHOP	
HIGH	MEAN	LOW	
SHALLOW	NORMAL	DEEP	VARIABLE
YES		NO	
YES		NO	
YES		NO	
TORN POSTERIOR CAPSULE DROPPED NUCLEUS OR NUCLEAR FRAGMENTS CORNEAL BURN OTHERS (please specify)			

PHACOEMULSIFICATION LENGTH (min)

POSTOPERATIVE EVALUATION

SINECHYA
 IOL DECENTRATION
 CORNEAL EDEMA
 WOUND LEAK
 OTHERS (please specify)

YES	NO
YES	NO
YES	NO
YES	NO

1 MONTH FOLLOW UP VISIT

DISTANCE BCVA
 NEAR BCVA
 SINECHYA
 IOL DECENTRATION
 CORNEAL EDEMA
 WOUND LEAK
 POSTERIOR CAPSULE OPACIFICATION
 YAG CAPSULOTOMY
 OTHERS (please specify)

YES	NO
YES	NO
YES	NO
YES	NO
YES	NO
YES	NO

3 MONTHS FOLLOW UP VISIT

DISTANCE BCVA

NEAR BCVA

SINECHYA

IOL DECENTRATION

POSTERIOR CAPSULE OPACIFICATION

YAG CAPSULOTOMY

OTHERS (please specify)

YES		NO
YES		NO
YES		NO
YES		NO

6 MONTHS FOLLOW UP VISIT

DISTANCE BCVA

NEAR BCVA

SINECHYA

IOL DECENTRATION

POSTERIOR CAPSULE OPACIFICATION

YAG CAPSULOTOMY

OTHERS (please specify)

YES		NO
YES		NO
YES		NO
YES		NO

12 MONTHS FOLLOW UP VISIT

DISTANCE BCVA

NEAR BCVA

SINECHYA

IOL DECENTRATION

POSTERIOR CAPSULE OPACIFICATION

YAG CAPSULOTOMY

OTHERS (please specify)

YES		NO
YES		NO
YES		NO
YES		NO
