A (prospective/pilot) study evaluating the effect of cataract surgery on the daily activity levels of elderly patients.

Kelley Sedlock, O.D.
Duane Corbett, Ph.D.
Ian McWherter, O.D., F.A.A.O.
Lawerence Tenkman, M.D.
Donald Bennett, O.D., M.D.
Keith Slayden, O.D.

Bennett and Bloom Eye Centers
1935 Bluegrass Ave
Suite 200
Louisville, KY 40215
724-244-4644
ianmcwherter@gmail.com

Title: A (prospective/pilot) study evaluating the effect of cataract surgery on the daily activity levels of elderly patients**.**

Purpose: To evaluate the effect of bilateral cataract surgery with intraocular lens implantation on the daily activity levels of elderly patients.

Objective: The primary endpoint is the comparison of baseline activity levels to post - operative week two activity levels in patients undergoing bilateral cataract surgery using the ActiGraph GT9X wrist monitor.

Background: Cataract formation is a natural aging process that can be influenced by environmental factors such as exposure to ultra violet light and diet (1). Additionally, metabolic disorders, such as diabetes can lead to an earlier development of cataracts (2).

As cataracts develop, a patient's vision can be affected (3). Reduced vision can limit activities of daily living and may even reduce a patient's mobility (4). When this occurs, cataract surgery should be considered to help restore a patient's vision.

With the obesity and diabetic epidemic, proper diet and exercise is a major health initiative to control these diseases (5). If a patient's mobility is reduced as a result of poor vision - their ability to achieve adequate daily physical activity may also be effected (6). It is thought that improvement in vision may increase their activity levels and help combat these health issues.

This study will investigate the activity level of patients before and after undergoing cataract surgery to determine how improved vision quality from removal of the natural lens inside the eye and replacement with an artificial intraocular lens effects their activity level.

Study population: Adult patients undergoing bilateral cataract surgery and adult patients who have cataracts but are not undergoing cataract. Consecutive patients based on the inclusion criteria will be selected for the study.

Study design: Prospective

Masking: None

Randomization: None

Method: Consecutive patients who meet the inclusion criteria will be asked to participate in the study. Patients scheduled for bilateral cataract surgery will be asked to wear a wrist accelerometer (Actigraph Inc, Pensacola, FL) 10 days prior to their cataract surgery in their first eye to determine their baseline activity level (7). The device is the size of a wrist watch and will have minimal burden to patients. Each monitor will be fitted

on the wrist and worn for 24 hours a day, but can be quickly removed for medical procedures, patient care, or hygiene needs. Data, such as steps per day, total movements per day, minutes being sedentary and minutes moving at various intensities (e.g. light, moderate and vigorous), will be collected and analyzed to determine a patients overall general physical activity level. Set standards and cut offs will be used to correlate wrist accelerometry to physical activity and this has been studied previously. The patient will then undergo bilateral cataract surgery, having each eye done a week or two apart and both eyes set for distance. Cataract surgery will be performed in its usual manner using the standard post-operative care. Patients will then be asked to wear the wrist accelerometer again for 10 days following their surgery to measure their post-operative physical activity level. Wrist monitors can be mailed to and from patients using prepaid envelopes. The pre and post-operative data will be analyzed to determine cataract surgery's effect on pre and post-operative activity levels.

To control for placebo effects, a control group of patients who have visually significant cataracts but are not interested in cataract surgery at this time will also be asked to participate in the study. They will wear their wrist monitor for 10 days to collect base line data and the wear the wrist monitor again 14 days later for another 10 days.

Sample size: 30 patients will be enrolled in the study

Length of study: 12 months

Inclusion Criteria:

- Patients undergoing bilateral cataract extraction by phacoemulisficatin with intraocular lens implantation and a planned bilateral distance vision target or patients with bilateral cataracts who are not having cataract surgery
- Patients aged 60 years old or older
- Best corrected visual acuity worse than 20/20 in each eye (meaning 20/25 or worse)
- Non-comanged patients

Exclusion criteria:

- Greater than 0.76 D pre-operative corneal cylinder, if having cataract surgery without a planned astigmatism correction (I.e Limbal relaxing incision or Toric intraocular lens)
- Planned implantation of a multifocal intraocular lens
- Visual field defect which may reduce mobility
- Wheel chair bound patients
- Reduced vision from an ocular disease other than cataracts
- Patients with significant dementia who are not able to fully comprehend the informed consent

Examinations:

Cataract surgery group

- Baseline/pre-operative exam
- Cataract surgery first eye
- Post-operative exam one, 1-3 days after cataract surgery first eye
- Cataract surgery second eye
- Post-operative exam two, 1-3 days after cataract surgery second eye
- Post-operative exam three, 14-21 days after cataract surgery second eye

Cataract non-surgery group
- Baseline/pre-operative exam

Baseline exam/Pre-Operative exam:

- Ocular history
- Medical history
- Family history
- Social history
- Blood pressure
- Vitals (Pulse, blood pressure)
- Anthropometrics (Height, weight, body mass index)
- Pupils
- Extraocular Muscles
- Confrontation fields
- Best correct visual acuity
- Manifest refraction
- Keratometry
- Intraocular Pressure
- Slit lamp exam
- Dilated fundus exam
- Other various health-related questionnaires (e.g., CHAMPS activity questionnaire)

Post-Operative Exam One

- Visual acuity first eye
- Intraocular Pressure first eye
- Slit Lamp Exam first eye

Post-Operative Exam Two

- Visual acuity both eyes
- Intraocular Pressure both eyes
- Slit Lamp Exam both eyes

Post-Operative Exam Three

- Best Corrected Visual Acuity both eyes
- Manifest refraction

- Intraocular Pressure both eyes
- Slit Lamp Exam both eyes
- Dilated fundus exam both eyes
- Health-related questionnaires (follow-up)

Risk/Safety Information:

A. Potential risks:

The risks of wearing the mobility monitor are similar to wearing a wristwatch. If applied and adjusted properly, there is minimal risk of skin breakdown or sores.

The risk of cataract surgery is not increased in this study and the routine cataract surgery procedure is not consider part of this study. With any surgical procedure there are risks and the standard risk of cataract surgery include infection, inflammation, loss of vision, increased intraocular pressure that may lead to glaucoma, bleeding, retinal detachment, damage to the cornea and corneal edema (swelling of the tissue in the front part of your eye), damage to the iris (the colored part of your eye), cystoid macular edema (swelling of the tissue in the back of your eye), or death, although this would be an extremely rare complication. You may need additional surgery to replace or reposition the intraocular lens or to treat any other ocular complications.

B. Potential benefits to be gained by the subject:

Potential increased physical activity and improvement in vision and activities of daily living would be a benefit to patients undergoing cataract surgery. Patients in both groups may benefit by knowing they are potentially contributing to the increasing body of scientific knowledge.

C. Potential benefits or information which may accrue to science or society in general, as a result of this work.

Evidence to determine if cataract surgery increases physical activity may help patients increase their exercise and combat obesity, diabetes, and heart disease.

D. Potential risks to subjects are reasonable in relation to anticipated benefits.

Cataract surgery is one of the most common surgeries performed in the United States and the risk of serious vision loss is low. Patients undergoing cataract surgery can expect to have an improvement in their vision. The risks from wearing a wrist watch size activity monitor are extremely low and pose a minimum burden to patients.

Monitoring/Reporting Adverse Events:

Adverse events will be monitored by the primary and sub-investigators at each study site. Adverse events will be documented and properly reported to the study IRB when

indicated. All investigators will have direct phone access to the lead investigator 24/7 for emergency situations. Data on adverse events will be reported and checked monthly by the primary investigator at each site as well as the lead investigator to ensure that there is no increased risk to the study subjects.

Study Oversight: This study will be prematurely terminated if the procedure or medications are found to have a risk profile that outweighs their benefit for the study. This determination will be made by the lead investigator/sponsor in conduction with the primary investigators and IRB. The study will provide direct access to the study data for the purposes of monitoring, auditing, IRB review, and regulatory inspection.

Data Management and Safety Monitoring:

A. Who will be responsible for the data and safety monitoring?

The lead investigator and the primary investigator at the research site will be responsible for data safety monitoring. The investigators are not independent from the study.

B. What will be monitored?

Only subjects who meet the study eligibility criteria will be enrolled in this study. Additionally, the informed consent process will be conducted appropriately and informed consent will be obtained prior to any study procedure being performed. Data will be collected and analyzed by the guidelines set forth by the study protocol and adverse events will be reviewed promptly and reported as required to the IRB. HIPPA will be complied with at all times throughout the study and all patients will be assigned unique identifying numbers. The number of study dropouts will also be closely monitored.

C. What are the procedures for analysis and interpretation of data, the actions to be taken upon specific events or endpoints, the procedures for communication from the data monitor to the IRB and site, and other reporting mechanisms?

The Primary and sub-investigator(s) at the testing site will be responsible for the collection and storage of all study data. Data will be stored in a password protected cloud storage site and organized into an excel spreadsheet. The identity of each patient will be protected using a unique identifying number. A second spreadsheet will match that unique number with that patient's name, and will be stored separately under password protection. The lead and principal investigators will evaluate the current data collection monthly to make sure it is in order and the study performance is progressing without incident. After study completion, all collected data will be analyzed by appropriate statistical tools.

D. What is the frequency of monitoring?

Study data will be grossly monitored on a monthly basis to ensure that the study is

performing smoothly and that all data is being collected in accordance with the set study protocol.

E. What information will be reported to the IRB?

All necessary data will be reported to the IRB in a prompt manner including but not limited to the frequency and dates of data monitoring, a cumulative summary of adverse events, an assessment of new research that could impact the safety of the subjects, a summary of privacy and data confidentiality breaches, and any changes to the procedures risk-benefit ratio.

Informed consent: The protocol, informed consent document, and relevant supporting information will be submitted to the IRB for review and will be approved before the study is initiated. In addition, any subject recruitment materials will be approved by the IRB prior to being used. This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practice and applicable regulatory requirements. The study must be conducted in accordance with the regulations of the United States Food and Drug Administration (FDA) as described in 21 CFR 50 and 56 [add 312 for IND studies or 812 for device studies], applicable laws and the IRB requirements. Any change to the protocol will be submitted to the IRB for review and approval before implementation. A protocol change intended to eliminate an apparent immediate hazard to subjects will be implemented immediately provided the FDA and the reviewing IRB are notified within 10 working days.

It is the responsibility of the investigator to provide each subject with full and adequate verbal and written information using the IRB approved informed consent document, including the objective and procedures of the study and the possible risks involved before inclusion in the study. Informed consent must be obtained prior to performing any study-related procedures, including screening and changes in medications including any washout of medications. A copy of the signed informed consent must be given to the study subject.

1. When and where will consent take place?

Informed consent will take place at the eye care facility during normal business hours in either a private office or exam room. If a patient meets the eligibility requirements as determined by the primary investigator or sub-investigator they will inform the patient of the study and the risks/benefits/alternatives of the procedure in English. The subject will be given adequate time to weigh their options and the risk/benefits/alternatives of the study. If after adequate time is given, and all questions are answered, the subject wishing to participate will sign the informed consent documentation and they will be enrolled in the study. All primary and sub-investigators for the study will be required to pass the National Institute of Health Protecting Human Research Participants certification.

2. How will the subject's privacy be protected during the consent process?

Each testing site will comply with HIPAA guidelines at all times. Informed consent will be performed during normal business hours at the eye care facility. The informed consent will be conducted in a private office or exam room.

Subject Payment and Costs: Subjects will not be paid for participating in this study. Subjects taking part in this study may incur added costs to themselves or their insurance company. The subject or their insurance company will be responsible for the following costs: All standard of care procedures, exams, and testing including cataract surgery and implantation of an intraocular lens. Patients may choose an upgrade cataract surgery package if they wish to reduce their dependence on glasses following cataract surgery.

Confidentiality: Efforts will be made to keep each subject's personal information confidential. All electronic data will be password protected, all paper records will be kept in private locked rooms, and patients in the study will be identified by unique ID numbers. However, we cannot guarantee absolute confidentiality. Personal information may be disclosed if required by law. Subject's identity will be held in confidence in reports in which the study may be published and databases in which results may be stored.

Organizations that may inspect and/or copy the research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the study sponsor, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) [for FDA-regulated research and research involving positron-emission scanning], the National Cancer Institute (NCI) [for research funded or supported by NCI], the National Institutes of Health (NIH) [for research funded or supported by NIH], etc., who may need to access your medical and/or research records.

Intended Use of Data: After all the data has been collected and analyzed a scientific paper addressing the effects of cataract surgery on activity levels in elderly patients, will be written and submitted to a distinguished peer reviewed journal for publication.

References:

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