

CAPT PROCEDURES FOR FUNDUS PHOTOGRAPHY

1. INTRODUCTION

Good quality photographs are necessary to describe pathology present and to determine whether the eye meets the eligibility criteria. High photographic standards have been established and maintained to prevent otherwise eligible patients from being rejected from the study because of an inability to interpret photographs of poor quality. Photographic techniques have been developed to ensure high photographic quality, standardization of camera equipment, and film development.

In addition, photographers at the clinical centers must demonstrate that they understand the photography protocol and can achieve good quality photography. Certification requirements for photographers can be found in the CAPT Manual of Procedures, Chapter 11.

All photographs must be taken no more than 28 days prior to randomization. Follow-up visit photographs must be taken within 28 days of the visual function testing.

2. CAMERA EQUIPMENT, FILM, AND FILM PROCESSING

- Zeiss 30⁰ or Topcon 35° fundus photograph cameras with 2.5x to 3x magnification should be used for both color photographs and fluorescein angiograms.
- Tri-X or Tmax film should be used for fluorescein angiograms. Color photographs may be taken with either Kodachrome or Ektachrome color slide film; however, the processed film from Initial Visit photographs must be received at the Reading Center within 15 working days. Variances have been granted for use of Fujifilm Neopan 400 black and white film for angiograms, and Fujifilm Sensia color film for CAPT color photographs. Imation/Scotchchrome is not acceptable. Since there may be a slight difference in the color balance of different films, the Reading Center investigators recommend that whenever possible the same film type be used for all photographs for a patient.
- Delori or Spectratech filters should be used for excitation and barrier filtration: SE-40 Excitation, SB-50 Barrier. These filters

- should be changed every 24 months, or when inspection at a site visit proves them to be defective.
- Since the original angiographic negatives are submitted for reading, it is recommended that a high contrast developer be used in order to maximize capillary detail. Kodak D-11, diluted 1:1, should be used at approximately 70^o F for eight minutes. A variance has been granted to use Kodak HC-110, dilution A, at 75^o for six minutes. The exact processing time and temperature can be adjusted by the participating center to compensate for differences in cameras and to provide negative density acceptable to the Reading Center.
 - Color red-free photographs, taken with a Spectratech 540 nanometer filter, are required following treatment, in addition to color photographs, in order to delineate more clearly treatment boundaries and vessel patterns. The Kodak gelatin filter is not acceptable.
 - A cone should not be used in the camera, as some information in the area of eligibility may not be visible when a true field 2 is not taken.

2.1 Modification to Photographic Technique

Acceptable results can be obtained with different development techniques and different films. The continuing advancements in hardware make it possible to say that these recommendations are, in every case, optional and will remain that way throughout the course of CAPT. Therefore, the following provisions are made for exceptions and revisions to this protocol.

- If a photographer at a participating clinical center believes that there is just cause for deviation from protocol he/she may apply to the Reading Center for a variance. The application should include a letter of explanation, and several sample photographs produced by the proposed method. If the Reading Center agrees that the standards of the Study are upheld, the variance will be granted.
- If the Reading Center staff identifies methods that they consider superior to those in use, those methods will be presented to the participating photographers for implementation.

3. COLOR FUNDUS STEREOGRAPHY

Color stereoscopic fundus photographs are to meet the criteria for field definition as described in the DRS Seven Standard Fields of the Fundus.

3.1 Required Fields for CAPT

The color stereoscopic fundus photographs of the disc (DRS Field 1) and the macula (DRS Field 2) of each eye are required at the initial visit. Color stereoscopic photographs of the macula *only* (DRS Field 2) of each eye are required at 6-month follow-up and annual visits.

Immediately after treatment, color stereoscopic and red-free color stereoscopic photographs of the macula of the treated eye should be taken.

3.2 Quality Evaluation of Color Photographs

The quality of the photographs is determined at the Reading Center based on the confidence of the reader to complete the grading form. The focus/clarity of the photograph and stereopsis are evaluated separately for each eye according to the following criteria:

Focus/ Clarity:

Good - All questions on the grading form that require color photographs can be answered.

Fair - Reduced quality of the color photograph interferes with the ability to answer one or more questions on the grading form.

Poor - Unacceptable quality that precludes completing all or part of the grading form requiring color photographs.

Missing - No color photographs are available for the visit.

Stereopsis:

Good – Obvious stereo separation is present, and all questions on the grading form that require stereopsis can be answered.

Fair – Questionable stereo separation is present. Reduced quality of stereopsis interferes with the ability to answer one or more questions on the grading form.

Poor – No stereo separation is present which may preclude completing all or part of the grading form requiring stereopsis. For example, stereopsis is required to determine the presence or absence of a serous pigment epithelial detachment.

Missing - No color photographs are available for the visit or one side of a stereoscopic pair is missing.

4. FUNDUS FLUORESCEIN ANGIOGRAPHY

All fluorescein angiograms should be taken in stereo unless precluded by media problems or borderline pupillary dilatation. Use of the stereo separator is permissible providing that it does not diminish the quality of photography. The sequences of the required fields of each eye are described below. The sequence with the early phase including both eyes is followed for the initial visit and annual visits. At follow-up, when exudation is suspected in one eye, the sequence with the early phase on the eye with suspected exudation is followed.

4.1 Fluorescein Injection

Five cc of 10% sodium fluorescein should be injected into the antecubital region with a 19 or 21 gauge Butterfly infusion set with a push no longer than 6 seconds in duration. In some patients, the use of 1 cc of 25% fluorescein followed by a saline flush may provide better resolution of the perifoveal capillary net.

4.2 Sequence For Fluorescein Angiography

Sequence with early phase of both eyes:

Prior to fluorescein dye injection, black and white red-free stereo photographs should be taken of the macula of each eye. Begin with the right eye by taking 3 stereo pairs of the macula at 20-35 seconds. Then immediately go to the left eye to take stereo pairs of the macula between 45-50 seconds and again at 60 seconds. Immediately after this, return to the right eye for stereo pairs of the macula between 70-75 seconds, and again at 90 seconds. Return to the left eye for stereo pairs of the macula between 100-110 seconds and again at 120 seconds. Return to the right eye for stereo pairs of the macula between 130-140 seconds and again at 3 minutes. Return to the left eye to take a stereo pair of the macula at 3 ½ -4 minutes. Change film. Begin the second roll of film by taking stereo pairs of both the macula and disc of

the left eye between 5-5½ minutes. Then immediately go to the right eye for stereo pairs of both the macula and disc at 5 ½ -6 minutes. Remain in the right eye to take a stereo pair of the macula at 10 minutes and finally a stereo pair of the macula of the left eye at 10 ½ minutes.

Sequence with early phase of one eye:

If exudation is suspected or known, the following protocol must be followed:

- Prior to the fluorescein dye injection, black and white red free stereo photographs of the macula of both eyes
- Eye with suspected or definite exudation: Stereo pairs of the macula taken at 30, 40, 60 and 90 seconds and 2, 3, 5 and 10 minutes and stereo photographs of the disc taken at anytime after 2 minutes
- Eye without CNV: Stereo pairs of the macula taken after 2 minutes and at 5 and 10 minutes, and stereo disc photos taken anytime after 2 minutes

Note: A second roll of film may be required to obtain all of the required frames.

4.2 Quality Evaluation of Fluorescein Angiograms

The quality of the fluorescein angiogram is determined by one reader at the Reading Center. The quality of the angiogram and stereopsis are evaluated separately for each eye according to the following criteria:

Focus/Clarity:

Good – The entire grading form can be completed, all necessary frames are present.

Fair - One or more pairs are missing or the quality of the stereo makes grading difficult.

Poor - The required angiogram frames are missing or the quality precludes answering one or more questions on the grading form.

Missing - No angiogram is available for grading.

Stereopsis:

Good - All questions on the grading form that require stereopsis can be answered; all necessary pairs are present.

Fair - One or more pairs are missing or the quality of the stereo makes grading difficult.

Poor - The required stereo pairs are missing or the quality of the stereo precludes answering one or more questions on the grading form.

Missing - No angiogram is available for grading.

5. REQUIRED PHOTOGRAPHS BY VISIT

5.1 Initial Visit Photographs

At the Initial Visit, stereoscopic color photographs of each disc and macula of both eyes should be taken for all patients. A fluorescein angiogram is required at Initial Visit with the early phase including both eyes. The color photography and the fluorescein angiograms must be \leq 28 days old at time of randomization.

5.2 Same-Day Laser Treatment Color Photographs

Stereoscopic color photographs and stereoscopic red-free color photographs of the macula of the treated eye only are taken the same day as treatment. If the treatment photographs cannot be taken the same day as treatment, they may be obtained up to 48 hours after treatment. If all of the laser burns are not visible in the Field 2 photographs, additional stereoscopic photographs may be taken. This should be the exception if the treatment protocol is followed.

Patient Preparation for Same-Day Laser Treatment Photographs

To obtain gradeable same-day laser treatment photographs, the treated eye should be thoroughly rinsed out with sterile saline immediately after any treatment when Goniosol (methyl cellulose) is used. Even if the ophthalmologist has rinsed out the eye, either the Coordinator or the Photographer should follow the procedures listed below to ensure a clear view for the same-day laser treatment photographs.

1. Have the patient tilt his/her head back, not beyond a comfortable level.
2. Have the patient hold several tissues under the eye.

3. Have the patient look down and gently lift the upper lid slightly away from the eye.
4. Rinse thoroughly under the eyelid. This is where the Goniosol stays trapped and each time the patient blinks, the view becomes hazy and blurred again. This method may be a bit messy if the patient does not hold the tissues under the eye.
5. Repeat step 4 for the lower lid.

If the photographer finds that the retinal image is still blurred, possibly from the Goniosol, the rinsing procedure should be repeated.

5.3 Follow-up Visits

For all patients, stereoscopic color photographs of the macula only of both eyes should be taken for all patients at 6, 12, 24, 36 48, and 60 months. In addition, a fluorescein angiogram with early phase of both eyes is obtained at all annual visits. In cases when exudation is noted or is suspected at any non-annual visit, a fluorescein angiogram must be obtained. The sequence with the early phase including one eye should be followed for the eye with suspected or obvious exudation.

5.4 Treatment of CNV

When an eye receives treatment for CNV at any time during the study, post-treatment photographs are not required.