

3. Consent form for was was not signed. There was no way of determining whether consent was obtained before or after surgery to the right eye on 12/4/97, due to lack of a date next to patients' signature.

According to the //intra-operative form

EXHIBIT#18 had right eye myopic surgery
on 12/4/97.

Page 9 of the patient information and consent form **EXHIBIT #19** indicates the patient signed the form however, the date is missing. Therefore, it is not certain what date the patient actually signed the consent form.

Therefore assured me this was merely a mistake and that all patients read and sign consent forms before surgery.

4. Consent forms for were signed and dated (2/20/98) one day after surgery to the right eye was performed (2/19/98).

The /intra-operative form for EXHIBIT #20 and EXHIBIT #22 verify both had surgery on their right eyes for myopia on 2/19/98.

However, page 9 of the patient information and consent forms, **EXHIBIT #21**, **EXHIBIT #23**, respectively show a date next to the patients signature of 2/20/98. This indicates the patients signed the consent forms one day after they had surgery.

stated it might appear the patients signed the consent forms one day after surgery however, this was a mistake made by someone on his staff.

on 8/13/98. However, the patient information and consent form which was approved for use by the IRB on 7/17/98, was not present in the patient file or made available upon request.