SIGHT-IMPROVING SURGERY: CATARACT SURGERY INVOLVING ARTIFICIAL LENS IMPLANTATION, SURGERY INVOLVING THE VITREOUS BODY, AND SURGERY FOR NEARSIGHTEDNESS

The Swedish Medical Council and the Swedish Planning and Rationalization Institute for the Health Services (Stockholm, Sweden)

CONSENSUS STATEMENT (November 6–8, 1984)

A consensus conference on the topic of sight-improving surgery was arranged by the Swedish Medical Research Council (MFR) and the Swedish Planning and Rationalization Institute for the Health Services (Spri), November 6–8, 1984 in Stockholm, Sweden.

The purpose of the conference was to reach a consensus on three sight-improving surgical methods, namely, cataract surgery involving artificial lens implantation, surgery involving the vitreous body, and surgery for nearsightedness.

A panel, which can be compared with a court jury, answered six questions concerning the safety and efficacy of these methods, and their economic and social importance. Their answers, which appear in the following document, are completely based on facts which were presented by experts through lectures, or arose during discussions between the experts, panel, and audience during the first two days of the conference.

The County Councils were invited to be represented at the conference by elected officials, administrators, physicians, and other medical care personnel. The conference was also open to other interested parties.

The conference was held for the purpose of finding answers to the following questions:

1. What are the advantages and risks of cataract surgery involving artificial lens implantation?
2. Which patients should be offered cataract surgery and artificial lens implantation?
3. What are the indications and when is the most suitable time for surgery involving the vitreous body?
4. Is the experience of surgery for nearsightedness such that the method should be introduced in Sweden?
5. What are the organizational and resource distribution consequences of the new methods for sight-improving surgery?
6. What research information concerning sight-improving surgery is most urgent?

By way of introduction, a few brief explanations are presented here concerning cataract surgery, which was the most discussed method at the conference.

https://doi.org/10.1017/S0266462300003846 Published online by Cambridge University Press

What Are Cataracts?

Cataracts appear as opacities in the lens of the eye. Small opacities normally begin to appear in the lens already at twenty years of age, and they slowly increase throughout life. It is not known why these opacities in some individuals begin to increase so rapidly that the vision is affected while in others the lens stays fairly clear.

How Are Cataracts Treated?

No effective medical treatment for cataract is known, and therefore surgical treatment is usually required. The clouded lens is removed during surgery. For certain types of cataracts, with small, central opacities, the patient's vision can sometimes be temporarily improved with pupil dilating drops. There are two surgical methods:

1. The entire lens, including the capsule, is extracted (intracapsular cataract extraction)
2. Most of the lens capsule is left in the eye, but its contents are removed (extracapsular cataract extraction)

The extracapsular method is the oldest. The remaining capsule might sometimes cause secondary cataracts, which requires the patient to have surgery again, but with a smaller operation.

The advantage of the intracapsular technique is that it immediately results in a clear pupil and carries no risk for secondary cataracts. The technique, therefore, dominated over a long period of time. However, sometimes a swelling of the macula (yellow spot) appeared—i.e., the area of most acute vision in the retina—in connection with this method. Therefore, since the end of the 1970s, the extracapsular method—in a refined form—has become common again.

There is a variant of extracapsular cataract extraction called phacoemulsification. With a special ultrasonic instrument, the lens mass is disintegrated in a way that it can be flushed out. However, the method is technically very demanding and is therefore not suitable as a routine procedure.

In all of the above methods, the removed natural lens can be replaced by an artificial lens, made of plastic. This technique has diffused in Sweden during the 1980s.

Lens implantation can be performed in three ways:

1. The lens is fixated in the anterior chamber.
2. The lens is fixated in the posterior chamber.
3. The lens is supported by the iris.

All three methods have been used during the various phases of development, which still is progressing. Presently, the trend is towards placing the lens in the posterior chamber, which is the location of the natural lens in the eye.

Modern cataract surgery has become highly technological and resource demanding.

Question 1. What are the Advantages and Risks of Cataract Surgery Involving Artificial Lens Implantation?

CONSEQUENCES OF CATARACT SURGERY

The refractive power of the lens system in the eye resides in the cornea and in the lens. When the lens is removed from the eye, the remaining refractive power becomes too weak and must be compensated for by spectacles, contact lens, or an artificial lens implant. Very often a patient suffers from a refractive error of astigmatism. Additionally, it is difficult to choose an artificial lens implant with the correct refractive power. Therefore, one must always assume that the patient will need spectacles after cataract surgery, no matter how it is performed.

Usually the patient can be provided with spectacles or contact lenses a few weeks after surgery. An artificial lens is usually implanted during the cataract operation, but can also be implanted in a second operation. The number of so-called secondary implants, however, is probably insignificant.

The patient remains in the hospital less than a week. Follow-up treatment with eye drops, and other care, is also necessary. How soon the patient regains functional vision depends greatly on the surgical technique. With lens implants and modern techniques, it is common that the patient regains functional vision within a few weeks, sometimes already on the day of surgery. In the absence of lens implants, the vision is corrected by spectacles. Then it requires several additional weeks before the patient regains functional vision. Of course, it is of great value for the patient to be able to return to a normal life as soon as possible.

Complications Related to Surgery

All cataract surgery involves risk for complications, both in connection with the operation, and postoperatively. Serious complications, for example infections in the eye with permanent loss of visual function, are very rare. Other complications, not resulting in blindness but in visual impairment, can occur several years after surgery. Among these are swelling of the macula lutea (yellow spot), retinal detachment, and swelling of the cornea.

Various reports indicate that the total frequency of complications is between 2 to 7%. U.S. studies indicate that extracapsular operations result in the least complications.

In addition to the complications mentioned above, secondary cataracts can develop after extracapsular surgery. This requires another smaller operation (discission), probably in 25% of the cases.

Artificial lens implantation in connection with cataract surgery does not result in a noticeable increase in the number of complications. Long term (several decades) risks to the cornea are however not yet completely documented.

How is Absence of the Lens Corrected?

APHAKIA SPECTACLES

Spectacles have thus far been the dominant corrective procedure. Today they are most often made of plastic and are specially ground to compensate for the most troublesome imaging errors.

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Advantages
Easy to replace, relatively easy to handle, practically risk free.
Disadvantages
Can be difficult to adapt and adjust.
Results in ring-shaped loss of the visual field (scotoma), which means that a dead angle occurs in the visual field.
Results in an altered spacial orientation.
Results in misjudgment in the location of objects.
Accommodation and convergence with a normal companion eye (not operated for cataract) is impossible.
Aphakia spectacles are heavy and not aesthetically pleasing to many patients.

CONTACT LENSES

Contact lenses have become an alternative to spectacles during recent years. Soft lenses filled with liquid are usually used for aphakia correction. Two major types exist:

1. Lenses which are worn during the daytime.
2. Lenses which are worn day and night over longer periods.

Advantages
Function optically almost as the eye's own lens.
Provide a normal visual field.
Usually accommodation and convergence with a normal companion eye (not operated) is possible.
Aesthetically attractive.
Disadvantages
Require careful and costly care.
Risk of corneal complications, especially if the prescribed length of use is exceeded.
Require frequent visits to a contact lens specialist.
Easy to lose or damage.
Elderly patients often do not manage to deal with their lenses themselves.

Contact lenses are only a complement to spectacles which must be available in reserve in case of allergies, other irritations, etc. Reading spectacles, as a rule, must be worn for reading and other close-up activity.

ARTIFICIAL LENS IMPLANTS

Advantages
Have the same advantages as contact lenses, and in addition:
Provide a natural image.
Especially valuable for patients with age-related macular degeneration.
Rehabilitation is more rapid.
The only possible form of correction for patients with serious handicaps.
Disadvantages
Surgery is more difficult and somewhat prolonged.
Long-term (several decades) experience, however, is lacking.

Comparison of Advantages and Risks

The implanted artificial lens has a clearly superior function. The significantly increased demand for surgery confirms this. The risks related to lens implantation are presently judged to be insignificantly higher than those related to conventional surgery. Long-term (several decades) experience, however, is lacking.

Question 2. Which Patients Should Be Offered Cataract Surgery and Artificial Lens Implantation?

REASONS IN FAVOR OF AND AGAINST CATARACT SURGERY

Cataract surgery ought to be considered when opacity of the lens is determined to be the major reason for the patient's visual problem. This refers not only to impaired visual acuity and reading ability, but also difficulty in, for example, the work environment, when driving, and spare-time occupations. Consideration must also be given to blinding and insufficient spacial orientation. Assessment of the patient's visual impairment requires that the surgeon be sensitive to the patient's problems and needs.

It is important that the surgeon evaluate the risks of surgery, estimate the expected visual improvement, and discuss this with the patient. However, it is unavoidable that different surgeons can have different points of view in this respect.

Presurgical evaluation is aimed at estimating the risks in each individual case, and the expected visual improvement. This determination requires a careful examination of the entire eye. Choice of the most suitable surgical technique will also be made. If artificial lens implantation is being planned, the power of the lens shall be determined. Today this is facilitated by modern ultrasonic techniques.

Few absolute barriers against operating exist with modern cataract surgery. If the indications are strong enough, the operation is performed, providing it can be expected to achieve visual improvement. The more uncertain the outcome, the more important it is to have detailed patient information.

If the patient has only one functional eye, the motives for surgery must be stronger.

REASONS IN FAVOR OF AND AGAINST ARTIFICIAL LENS IMPLANTATION

Artificial lenses offer great advantages concerning vision, and provide more rapid rehabilitation. Current experiences indicate that lens implantation does not seem to be accompanied by any significantly increased risk for complications.

Based on this information elderly patients in general ought to be offered artificial lens implantation. However, certain important obstacles exist. These include:

Severe nearsightedness.
Serious diabetic complications in the eye.
Inflammations in the eye.
Certain forms of glaucoma.

Currently, we have no reliable basis for determining long-term risks in the younger patient (under 40 years). These patients also accept contact lenses much better. Therefore, in these age groups certain restraint of artificial lens implantation is advised.

It is probably not appropriate to implant an artificial lens in the adolescent patient. Exceptions can be made in cases of injury, but also here experience is very limited.

Surgery in the Companion Eye

When surgery of the first eye has been successful, the question of surgery on the other eye might arise. The risks related to surgery in this eye are the same as for the first, but the advantages are fewer. However, they are not insignificant. Most patients say that after surgery in the second eye, they experienced significantly better spacial orientation, increased reading speed, improved visual field, and decreased sensitivity to blinding.

If surgery in the second eye is felt to be of great value by the patient, this desire ought to be acknowledged.

The considerably improved rehabilitation which modern cataract surgery offers to the patient will result in:

A significant increase in the need for cataract surgery.
A probable further increase in the resources for artificial lens implants.

Question 3: What are the Indications and When is the Most Suitable Time for Surgery Involving the Vitreous Body?

There are two types of surgery involving the vitreous body, anterior and posterior. The anterior techniques have been used in cataract surgery since the end of the 1960s to reduce the risks associated with vitreous loss. Also opacities in the anterior part of the vitreous body from previously performed cataract surgery and injuries can be removed with this type of surgery.

Surgery of the vitreous body as described here, is used to remove diseased vitreous from the posterior part of the eye. In Sweden, this method is called vitrectomy. The technique was developed in the United States during the beginning of the 1970s.

Certain maladies in the vitreous body are related to a general disease, for example, diabetes. Others only affect the eye, such as retinal detachment and injuries.

Earlier, there was no possibility to operate in the vitreous body. In the case of diabetes, one observed how the disease progressed without the possibility to control it. The sometimes harmful effect of the vitreous on the healing process after retinal detachment could not be stopped.

Modern surgical techniques in the vitreous body require different types of remote-controlled cutting instruments, often combined with automated aspiration systems to maintain the pressure in the eye. A fiber optic light source can be connected to this system to illuminate the surgical field in the eye. This light source can also be obtained from the advanced operating microscope which is necessary for the operation. Cauterization techniques involving electrical currents (diathermy) and lasers (photocoagulation) are also used in the eye.

During surgery the surgeon removes pathological changes in the vitreous body which impair vision, for example, blood. Also connective tissue formations (mem-

branes) in the vitreous chamber which pull the retina from its position can be divided and partially removed so that the retina can fall back into its normal position. Connective tissue, which lays very close to the retina, can be "picked" away and membranes situated below the retina can be cut. Sometimes nearly all of the vitreous body must be removed and replaced by suitable material, for example, air, special gases, or silicon oil.

The advantages of this technique are obvious. Patients who, earlier, could not be operated on, can now be treated, in some cases with good results. However, the risks associated with these often difficult operations are relatively high. But one must remember that often there is no other alternative.

Vitrectomy and Diabetes

The most important indications for vitrectomy are diabetic complications, which account for approximately 70% of the operations. In its most simple form it is a matter of blood-saturated vitreous, which is removed. In other cases, it involves removing membranes and newly formed diseased vessels which are located such that the function of the macula is seriously damaged or threatened. Hopefully, treatment such as photocoagulation and improved general diabetic care will decrease the serious injuries which require surgery of the vitreous body. This is also aided by improved examination methods to identify early complications.

Results in the presence of diabetes can be regarded as good and—what is more important and remarkable—surprisingly lasting, considering that it concerns a progressive common disease. Of the cases which have been judged appropriate for surgery, about one-half improve.

Vitrectomy and Retinal Detachment

The indications for vitrectomy in relation to retinal detachment have expanded. Certain types, for example, those caused by massive breaks in the retina and those which involve degeneration of the detached retina, almost always require vitrectomy in order for surgery to have a chance of being successful. Also in the case of retinal detachment involving a large hemorrhage in the vitreous body, vitrectomy is favored as the primary measure in certain cases.

Documentation addressing the serious forms of retinal detachment indicate that eyes which earlier did not heal, now more often can regain a certain degree of visual function.

Vitrectomy and Eye Injuries

Vitrectomy is also used for injuries in the inner part of the eye. These injuries often affect young and completely healthy individuals. A timely operation in the vitreous body before atrophy of the connective tissue and retinal detachment has occurred means that both eye and sight can often be saved.

Question 4. Is the Experience of Surgery for Nearsightedness Such That the Method Should be Introduced in Sweden?

Nearsightedness is a frequently occurring refractive error where the image falls in front of the retina. This refractive error often arises during school age. The nearsighted person has blurred distant vision, but often has good reading ability.

Nearsightedness has historically been corrected by spectacles, which still is the most common procedure. However, during recent years, contact lenses have gained more widespread diffusion.

Spectacles and contact lenses both have certain disadvantages. This explains the interest in avoiding dependence on these aids through surgery. Since the cornea contributes the major portion of the eye's total refractive strength, it is natural that attempts have been made to reduce the eye's refractive strength, and thereby nearsightedness, through various corneal operations.

There are several surgical methods, of which a few are complicated and require specialized and costly equipment. Therefore, they have not diffused significantly.

A method called radial keratotomy has drawn great attention in professional journals and the mass media during recent years. This method involves the use of a special knife to make a number of radial (spokelike) incisions in the cornea, to a depth of approximately 90–95% of the thickness of the cornea. The incisions are placed in a way that an untouched zone is left in the center. Through this technique, the cornea becomes more flat and less refractive, thereby decreasing or eliminating nearsightedness.

Swedish experience is lacking. The most completely documented clinical experience comes from the United States, where the method was introduced in 1978. The method has been, and still is, controversial, since healthy eyes are operated on and complications can appear.

A controlled clinical trial is currently being conducted in the United States to try to assess the risks and effects of this method. From reports published so far, it is evident that in the most beneficial cases, nearsighted individuals do not require spectacles after surgery. Experience indicates that it is difficult to predict the outcome of the operation. Problems with blinding, which has persisted at least a year after surgery, have been reported in some cases. In isolated cases, serious complications have been reported.

The complications are not totally negligible, and long-term effects are not yet known. Considering this, and that the operation is performed in healthy eyes which, through spectacles or contact lenses, maintain full visual acuity, the method should not be introduced in Sweden at the present time.

Question 5. What Are the Organizational and Resource Distribution Consequences of the New Methods for Sight-Improving Surgery?

CATARACT SURGERY

Cataract surgery is available at all ophthalmology departments in Sweden. The total number of cataract operations in 1980 was approximately 8,000 and has increased to about 11,000 in 1983. New surgical techniques involving artificial lens implants are a significant factor in this development. Despite higher surgical frequency, most ophthalmology departments have seen a significant increase in waiting time and in the number of persons on the waiting list during the past year. This has caused problems concerning which patients should be given priority.

Both the extent of cataract surgery and the percentage of operations involving artificial lens implantation vary among medical care districts. The percentage of

operations involving lens implants in 1983 averaged 40% for the country as a whole. In some areas the figure was as high as 90%.

The occurrence of visual impairment due to cataract increases significantly after age 70. However, exact figures describing the rate of occurrence are lacking, especially for the higher age groups. It is evident that the growing percentage in the uppermost age groups in the population during the coming decades will result in a greater demand for increased resources. Added to this are the expanded indications permitted by new surgical techniques and the increased demand for improved sight which can be expected from the patients.

No preventive measures, which can decrease the occurrence of cataract, are known today.

No population-based studies which unequivocally clarify the extent of cataract, less the need for surgery, exist. However, based on foreign studies, present frequencies of surgery in various parts of Sweden, and growing waiting lists, the future need for cataract surgery is estimated to more than double for the country as a whole. In individual medical care districts, the figures might vary depending on the present frequency of surgery, age composition of the population, etc.

Cataract surgery is estimated to cost approximately SEK 10,000, 1984 monetary value. The benefit of restoring a person's visual ability is obvious. In addition, cataract surgery has positive health economic and social economic effects. Available health economic estimates clearly indicate that the economic benefits exceed the costs for surgery, even when the expanded indications are included. Cataract extraction followed by intraocular lens implantation, is less costly than surgery followed by correction using aphakic spectacles or contact lenses.

The increase in the number of cataract operations which has been achieved during recent years is due to several factors. An increased number of eye specialists, freed surgical capacity through technical development within other areas in ophthalmology, and internal reallocation and improved organization can be mentioned. Most opthalmology departments indicate that there is no capacity for additional cataract surgery with present resources. The desired volume increase must thus occur primarily through new resources. The resource requirements needed vary among medical care districts. However, it is obvious that there is a general need for more personnel, operating room time, material, and technical equipment. However, probably no additional hospital beds are required.

The group of patients felt to require artificial lens implantation after previously performed cataract surgery is small. It ought to be possible to include these within the scope of resources mentioned above.

Surgery of the Vitreous Body

Surgical activity involving the vitreous body is considerably less than cataract surgery. Presently 400–500 operations are performed, and these are concentrated in a few larger hospitals. No significant waiting lists exist, save a few isolated exceptions. An attempt has been made to estimate the need for the total number of operations. A very uncertain estimate, 600–1,000 operations per year by the end of the 1980s, has been given. A continued concentration of activity to a few units is necessary, among other reasons, because of the costly equipment and

because the specially trained personnel must be provided with enough patients to maintain their competence and skill.

Patients requiring surgery of the vitreous body cannot, without great risk for permanent visual impairment, wait very long for surgery. In certain cases, for example, threatened retinal detachment, immediate surgery is necessary. The expected increase in activity can probably be handled within the framework of additional limited resources. The need for replacing equipment in pace with technical developments also ought to be considered.

The cost for surgery in the vitreous body is approximately SEK 20,000, 1984 monetary value. The majority of patients requiring surgery in the vitreous body are of working age. Without surgery, continued employment is impossible in most cases. The economic benefits—measured in terms of decreased sacrifices by patient and family, fewer days of care, decreased length of sick leave, etc.—far exceed the costs related to surgery in the vitreous body.

Question 6. What Research Information Concerning Sight-Improving Surgery Is Most Urgent?

Generally speaking, the entire area of sight-improving surgery ought to be studied more systematically than what has thus far been the case, for example, concerning the frequency of various pathological changes and the need for surgery. Carefully controlled studies, which, compare results of different surgical methods, are also important. The Swedish medical care organization provides excellent opportunities for long-term observation of patients. This type of research and product control ought to be regarded as a natural component in the efforts to advance medical care. National and Scandinavian cooperation is essential. Research ought to also be directed at efforts to decrease the need for sight-improving surgery. Basic research concerning the cornea, lens, vitreous body, and retina is therefore very important.

CATARACT RESEARCH

It is important to further analyze the cause of cataract. This might include the relationship of various types of radiation, professions, medications, and general diseases.

Important tasks for basic research are: a continued investigation of the construction of the normal lens, its metabolism and function, and a survey of the changes related to cataract. Research to prevent the occurrence of cataract is also very important. Applied research concerning protection against radiation and eye injuries is essential.

Removal of the lens in the eye—total or partial—which occurs during cataract surgery involves significant change in the eye's metabolism. Research in this area is urgent since it can contribute to a decrease in postoperative complications.

Presently there are no pharmaceuticals which counteract cataract development. Such pharmaceuticals would be very desirable, and research is in progress. Advancement in basic research is a prerequisite for the development of such pharmaceuticals.

Essential clinical research includes prevention of complications related to surgery, for example, secondary cataracts. It would also be of significant value

to develop improved lens materials. The long-term effects of artificial lens implants ought to be systematically evaluated. Furthermore, investigations ought to be conducted to determine if the lenses should filter out short-wavelength light to reduce the risk for retinal damage.

VITREOUS BODY RESEARCH

In the area of vitreous body surgery, research addressing membrane formation in the posterior segment of the eye is essential. In recent years, the use of certain pharmaceuticals against such membrane formation has been attempted. Continued research concerning such pharmaceuticals is needed. Surgical techniques to remove these membranes can probably also be refined.

PATIENT CARE RESEARCH

Research can identify pressing patient care problems related to sight-improving surgery and contribute to solutions. Development of methods for improved patient information, especially in connection with shortened care episodes, is included in this activity.

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