# METHOD AND APPARATUS FOR PERFORMING SURGERY WITHOUT TISSUE INCISION

## BACKGROUND OF THE INVENTION

Interior surgical procedures have, in the past, required surgical incisions to expose the operative area. In those instances where the operative area may be directly viewed, as through transparent tissue in the case of eye surgery, or accurately calculated, such as in stationary blood stream clots; the requirement for a surgical incision is not one of viewing but of obtaining instrument access to the area. The invention is particularly applicable to eye surgery and makes possible a new approach to cataract removal, i.e. retention of the crystalline lens capsule. Accordingly, it is this specific application of the invention which has been chosen for illustration and description.

Cataract removal from the human eye, whether in an advanced stage of opacity or at an earlier point in time before the optical fiber discoloration or clouded portion has extended throughout the lens, is normally regarded as major eye surgery requiring a substantial corneal incision of approximately 180° to provide access to the lens and cataract. The lens capsule and its contents, including the cataract, are then excised from the eye. Patient recovery times from such surgical procedures are long, as in the nature of a week; heavy optical corrections are required to supplant the function of the removed crystalline lens; and the incidence of patient satisfaction is discouragingly low. The long patient recovery time is primarily for healing of the massive corneal incision which healing process is inherently slower than most other parts of the human body because of a relatively low corneal vascular supply. Additionally, patients undergoing cataract surgery are, for the most part, elderly which further contributes to a long recovery period. Heretofore, once a cataract has developed, a patient has been confronted with only one of two choices, viz. major surgery which, if successful, will require substantial optical correction for even partial restoration of vision; or a lifetime of impaired vision.

Direct penetration of the cornea with a small surgical tool to reach the lens at first appeared to offer a reasonable alternative to the massive incision previously required. It was hypothecated that if a small hypodermic needle could be inserted to reach the interior of the lens capsule, a small rotating or vibratory tool might be inserted through the needle to masticate the cataract along with the remainder of the lens capsule contents (cortex and nucleus) to be followed by withdrawal of the tool and suction of masticated tissue through the needle while leaving the lens capsule intact to be refilled with an appropriate filler material to restore the original lens function. Theoretically, this approach would appear feasible but for the particular anatomical structures of the cornea and lens capsule through which such a needle must be inserted. Each of the cornea and lens capsule through which the needle must be inserted is so constructed as to practically assure that needle penetration may not be effected with accuracy or without great trauma to the patient. The cornea, itself, offers an almost impenetrable barrier by virtue of the very thick cellular stratum known as the substantia propria which lies just beneath the corneal epithelium. The substantia propria is comprised of approximately sixty flattened, superimposed lamellae which are made up of modified connective tissue. The fibers of each individual lamella are generally parallel with one another but at right angles to those of the next adjacent lamellae and the fibers of all the lamellae are generally directly continuous with the scleral fibers. This fibrous construction of the substantia propria provides one of the toughest and most unyielding tissues in the human body. Efforts to penetrate the substantia propria portion of the cornea, without restraining the eyeball in some manner, have proved to be impossible with even the smallest needle. Indeed, the eyeballs of experimental animals have been forced from their sockets by determined, unsuccessful efforts to force a needle through the cornea. It has been possible to penetrate the cornea by rigidifying the eyeball prior to the attempted penetration but this has involved the introduction of clamps directly into the eyeball which induces trauma at least roughly equivalent to the conventional cataract incisions.

Even if the cornea could be practically penetrated either by direct insertion of a hypodermic needle or by introducing the same through a small surgical incision, as will be discussed infra, any attempt to penetrate the lens with accuracy of location is rendered virtually impossible by the "floating" nature of the same. Although the lens capsule (capsula lentis) does not possess the same unyielding character as the substantia propria, it is highly elastic so that it does offer substantial resistance to penetration and this fact coupled with the suspensory mounting of the lens from the ciliaris muscle via the suspensory ligaments (*Zonula Ciliaris*) insures that the lens body will move upon contact so that lens penetration, if effected at all, is likely to be at a point remote from the intended location.

Thus, from the foregoing, it is apparent that any attempted direct penetration into the crystalline lens in a manner productive of less trauma than conventional cataract surgery is doomed to failure.

It was next thought that a small incision might be made through the cornea and lens capsule to permit the introduction of a small tool into the lens body. This approach, while more feasible than the conventional massive incision, yet does involve an incision which was the thing sought to be avoided by direct penetration as with a hypodermic needle. Even when such a small incision is made through the cornea, the problem of penetrating the "floating" lens yet remains unless it, too, is to be incised. The size of the incision is, of course, a direct function of the tool size to be used in removing the cataract which, if of any substantial size, will dictate an incision which may produce trauma comparable to that of conventional cataract surgery.

In the utilization of small vibrating probes to masticate or liquefy the cataract, the benefits of a small incision in the cornea are frequently offset by additional trauma introduced by the vibrating probe, itself, in the form of tissue damage by heat generation and lack of precise control in that portion of the eye to be subjected to the vibratory effects. An even greater limitation imposed by the introduction of a vibrating probe through an incised cornea and lens is that the structural integrity of the lens capsule is destroyed thus yet requiring total lens capsule removal as through the small corneal incision following a preliminary liquefaction and withdrawal of the lens contents.

The objectives of the invention are basically threefold: