NHS Innovations East Midlands

Description:

Whilst cataract surgery is one of the most commonly performed operations in the world, the majority of complications occur in the opening of the anterior lens, a central circular opening (capsulorrhexis). This most challenging procedure is performed using a needle or forceps to literally “tear” a circle in the capsule. This crude method can produces irregular, inaccurate openings and errant tears run down hill, out of control. Paediatric cataract surgery is often significantly more difficult due to the elasticity of the lens. The Wellcome Trust is supporting the project and has awarded a Translational award of almost £300K. This investment will develop the novel, single use, ophthalmic cutting device which creates an unrivalled precise and predictable capsulorrhexis. This tool will make the procedure quicker and reducing the skill and experience necessary in performing the procedure.

Benefits:

Patient and Surgeon Benefit: Improved Accuracy and Success Rate

Due to the challenge posed by performing the capsulorrhexis in infants and young children, the resultant size of the capsulorrhexis may be highly variable. Complications such as peripheral extension of the radial tear occur more commonly in paediatric surgery. This may result in difficulties implanting an intraocular lens due to lack of capsular support, necessitating secondary lens implantation at a later date. In addition small capsulotomies can result in capsular phimosis, capsular fibrosis and capsular contraction syndrome. Excessive manipulations during the procedure can cause iris damage, prolapse or iridodialysis. This project will further develop a tool with which to accurately perform cataract surgery in both adults and children, reducing the potential for such errors. Whilst the tool does not “deskill” the procedure, it makes the most complicated and yet most important part of the surgery a great deal easier, improving the success rate, especially in children and reduce the incidence of secondary complications.

Paying Body (NHS, Private Hospital, Charity) Benefit: Cost, Affordability and Availability

Cataracts are the single largest cause of blindness with some 25 million people unnecessarily losing their sight. This figure is increasing by 1.5 million every year with the overwhelming majority who are needlessly suffering from cataract blindness in the developing world. Africa, Asia, China and India account for most cases of cataract blindness with over 1 million children affected in Asia alone. This life crippling, yet curable, condition has a profound effect upon children in the developing world with 50% of children dying within two years of going blind and 90% of those who are blind missing out on school. If such a tool is to make an impact where it is needed most, it needs to be affordable. In addition, the reduction of surgical complications requiring further surgeries and therefore faster recovery time, further cost savings will accrue. The small machined Nitinol blade is cheap to produce and the completed tool simple to manufacture, sterilise and package. With a retail price of approx $50/unit, sales to developing countries may

have to be subsidised from sales in the developed nations. In planned discussions with Orbis International regarding the use of the devices in 3rd world countries a plan would be drawn up to distribute the devices to ensure maximum impact. The device will make cataract surgery more accessible as it opens up the number of surgeons who will be able to confidently perform the technique, especially in children. A vast reduction in training time would mean more surgeons available to perform the surgery as the devices removes a level of uncertainty.

Patient Benefit: Reduce Risk of Intraocular Infection

Keyhole or "sutureless" cataract surgery has greatly reduced the incidence of infection following surgery. The tool is designed to be used in such techniques and is designed as a single use tool, thus reducing potential for cross contamination and infection by inadequate sterilisation of instruments. Cases of toxic anterior segment syndrome (TASS) have been reported with the cleaning and sterilization of reused ophthalmic surgical instruments (American Society of Cataract and Refractive Surgery). Residues such as endotoxins can remain on instruments and that has been implicated in the development of TASS. As a disposable tool, the devices do not require the particular care that is associated with reusable products. Surgeons are assured of a clean and sharp instrument at each use.

Patient and Surgeon Benefit: Safety

The retractable blade protects clinicians and patients from accidental sharps injuries during use and disposal. The blade is deployed at the point of cutting, within the eye and retracted before the instrument is removed from the eye. We will also investigate the feasibility of a locking system for the devices once the blade has been retracted, following the incision.

Innovator: Mr John Stokes, Nottingham University Hospitals NHS Trust

Stage of Development: Product Development