Preliminary Clinical Results of the Femto-Cataract Procedure Using the VICTUS™ Femtosecond Laser Platform

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Introduction

Cataract surgery techniques have undergone a number of significant advances in recent decades. Notable steps include the move from an extra-capsular cataract extraction (ECCE) procedure to phacoemulsification techniques, the miniaturization of instrumentation and recent advances in IOL technology. These developments have enabled cataract surgery outcomes to improve to a high level of safety and efficacy owing to reduced trauma, progressively smaller incision sizes, improved intra-operative stability and improvement in optical performance of the implanted lenses.[1-3]

With over 15 million cataract surgery procedures performed annually, and this figure forecast to reach 22 million by 2020, research into improving cataract surgery outcomes continues.[4]

This article summarizes findings of an clinical evaluation of performing anterior lens capsulotomy and lens fragmentation with a femtosecond laser, the VICTUS™ Femtosecond Laser Platform (Bausch + Lomb/Technolas Perfect Vision) * (Figure 1).

Figure. 1: The VICTUS™ Femtosecond Laser Platform

Study Objectives and Methods

This prospective, multi-surgeon, comparative feasibility study aimed to evaluate the safety, efficacy and precision of creating an anterior capsulotomy with the femto-cataract procedure on the VICTUS™ Femtosecond Laser Platform versus constructing a capsulorhexis with manual techniques in cataract patients. The primary measured outcomes were the diameter, circularity and centration of the anterior capsulotomy. The intended capsulotomy diameter in the study was 5.5mm, although the software allows the size to be customised.

The femtosecond laser capsulotomy was performed with the VICTUS™ Femtosecond Laser Platform. Integrated real-time OCT was used to plan and monitor the creation of the capsulotomy and allowed it to be observed during surgery.

Figure 2: VICTUS™ Femtosecond Laser Platform Graphic User Interface

All manual capsulorhexes were performed with a 26G bent needle.

Each study group of this ongoing study currently comprised 31 eyes. In the femtosecond group, the mean patient age was 60 ± 10 years (34 – 80 years). The mean cataract grade was 2.6 ± 1.1 (grade 1 to grade 5 white/brown cataracts). In the manual group, the mean patient age was 63 ± 13 years (42 – 90 years), and the mean cataract grade was 2.5 ± 1.1 (grade 1 to grade 5 white cataracts). All treatments were performed at Maxivision Eye Care Centre, Hyderabad, India.

*For International (non-USA) use only, not approved in all countries.

Results

All procedures in both groups were uneventful. Creating the capsulotomy with the femtosecond laser was found to be an efficient and effective technique with easy removal of the rhexis and without any adverse events (Figures 3 and 4).[5]

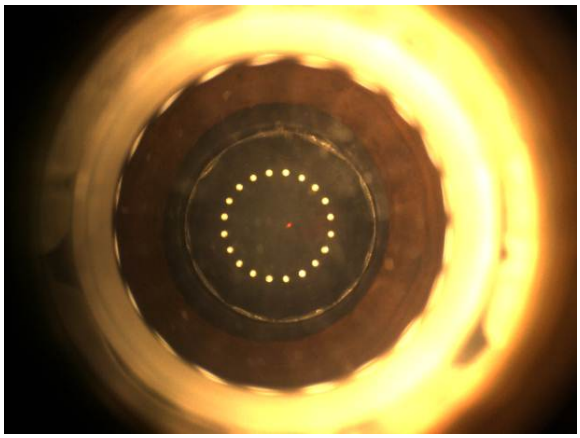

Figure 3: Capsulotomy performed with the femtosecond laser (surgical microscope view)

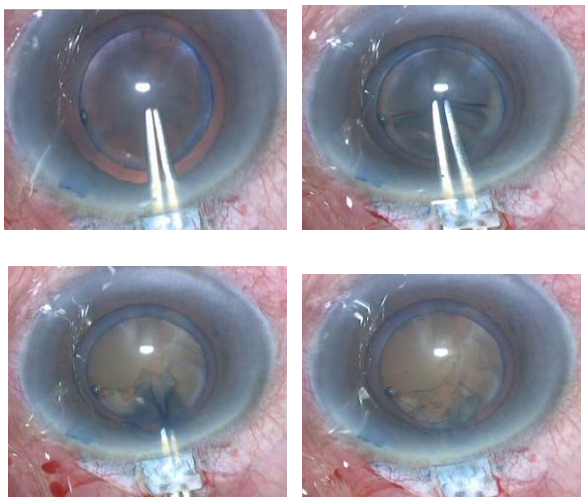

Figure 4: Image series showing easy removal of rhexis

Initial visual inspection of the rhexis from the femtosecond group compared with the manual group shows improved circularity (Figure 5).

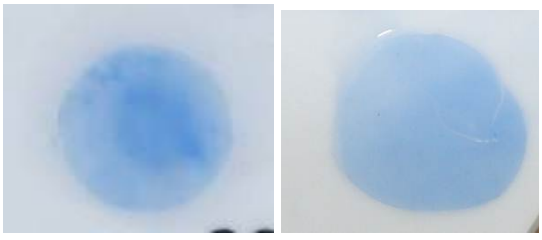

Figure 5: Femtosecond laser versus manual rhexis

Considering the outcomes in more detail:

Centration

An example of the centration achieved using the femtosecond laser is shown in Figure 6. Improved centration with the femtosecond technique was recorded compared with the manual group. The deviation from perfect centration in femtosecond group and the manual group was 95±37µm and 160±90 µm, respectively. This is a statistically significant difference (Figure 7, Table 1).

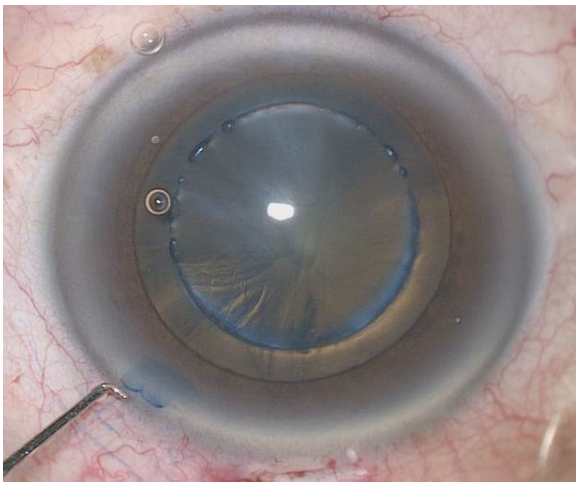

Figure. 6: Excellent centration of capsulotomy with the femtosecond laser

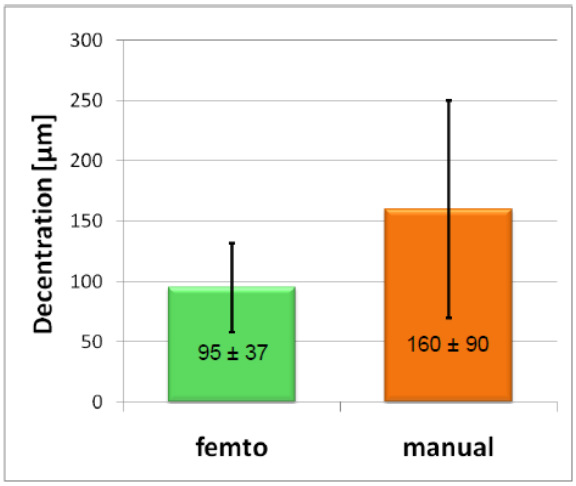

Figure 7. The deviation from perfect centration (□R following the femto-laser-assisted and manual procedure.

Circularity

A statistically significant difference in the circularity of the capsulotomy using the femtosecond laser compared with the manual technique was also observed. The circularity achieved in the femtosecond group was 0.97±0.01 compared with 0.93±0.04 in the manual group (Figure 8, Table 1). 1.0 denotes a perfect circle.

Diameter

Using the femtosecond laser to perform the anterior capsulotomy resulted in high consistency to the intended diameter of 5.5mm (Figure 9). Highly accurate and predictable capsulotomy diameter was achieved.

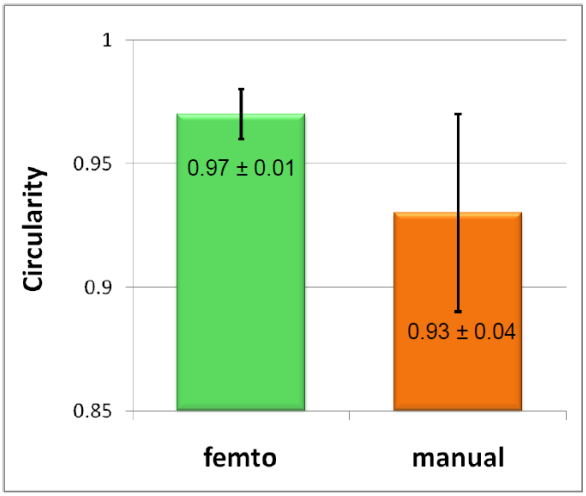

Figure 8. The circularity (ε= Ømin/ Ømax) following the femtosecond laser-assisted and manual capsulorhexis procedure.

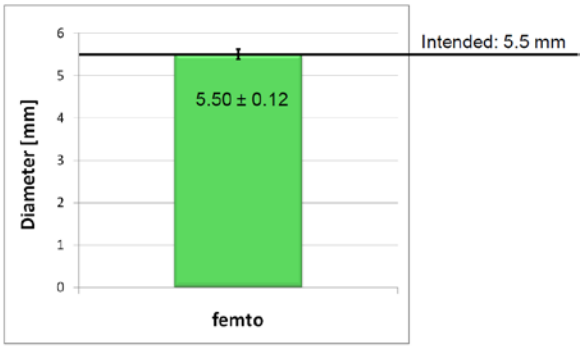

Figure 9. Diameter (Ø) highly accurate and predictable. Intended diameter was 5.5 mm.

A summary of the results is shown in Table 1. A statistically significant difference ($p<<0.001$) between the femtosecond and manual groups in terms of rhexis circularity and centration was demonstrated. The significant difference is not only shown for the average value (μ), indicating higher accuracy, but also for the standard deviation (σ), indicating higher reproducibility of the outcomes.

Parameter	Femto	Manual	μ sign. diff.	σ sign. diff.
Diameter Ø (mm)	5.50 ± 0.12	n/a	n/a	n/a
Circularity ε	0.97 ± 0.01	0.93 ± 0.04	p << 0.001	p << 0.001
Decentration ΔR (μm)	95 ± 37	160 ± 90	p << 0.001	p << 0.001

Table 1: Summary of diameter, centration, and circularity results in the femtosecond and manual groups

Evaluation on lens fragmentation

The femto-cataract procedure is also designed to allow additional key steps of the cataract surgery, lens fragmentation and arcuate incisions, to be performed.

Initial findings for a study performing lens fragmentation with the VICTUS™ Femtosecond Laser Platform indicate that a high degree of control and precision can be achieved with the femtosecond laser, without any adverse events.[5]

A number of different lens fragmentation patterns can be used and applied depending on the cataract grade, e.g. ring or radial cuts (Figures 10 and 11). This technique appears to enable easier cracking of the nucleus following lens fragmentation (Figure 12), which reduces the phaco energy required for lens removal.

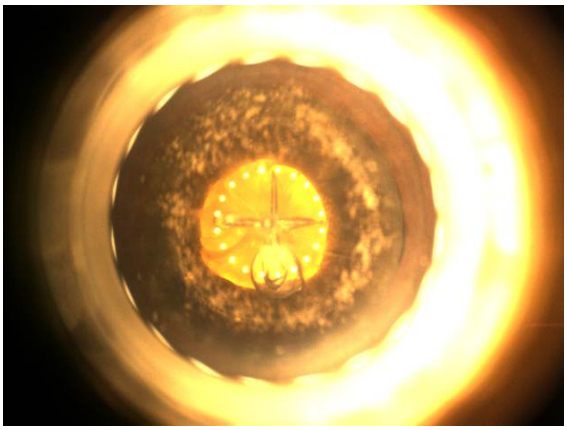

Figure 10: Femtosecond laser procedure: Capsulotomy + lens fragmentation. Visible: Cuts plus gas dissection of nucleus and cortex.

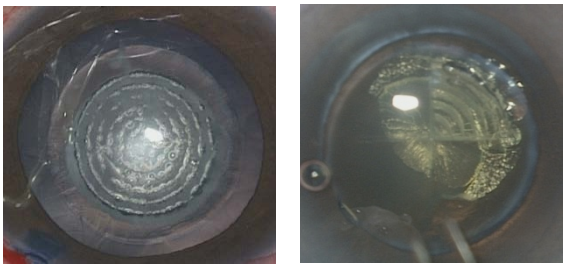

Figure 11: Circular and quadrant lens fragmentation patterns

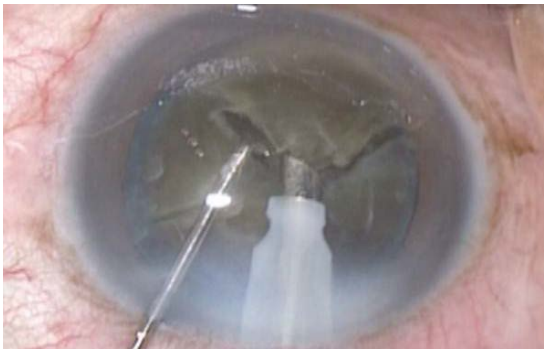

Figure 12: Easy cracking of nucleus following lens fragmentation

In lower grade cataracts, up to a 50% reduction in the phaco energy required to remove the lens following lens fragmentation with the laser was recorded, compared with standard phaco.

Summary

Initial results from this feasibility study investigating the use of the femto-cataract procedure on the VICTUS™ Femtosecond Laser Platform for performing anterior capsulotomy indicate this is a promising new technology. Use of the femtosecond laser can provide improved control and precision, with more reproducible results compared with the manual technique.

Preliminary findings from lens fragmentation evaluations using the femtosecond laser also show this to be an effective procedure, without any adverse events.

Investigations into the key steps of cataract lens fragmentation are ongoing, analysing parameters such as the optimisation of fragmentation patterns.

The incorporation of the real-time OCT allows for the planning and monitoring of treatment. The option to customise all steps of the cataract procedure is also beneficial in terms of reproducibility and control.

Outlook

The possibility to apply the precision, control and reproducibility achieved with a femtosecond laser to cataract surgery could represent a significant advance in the field of cataract surgery. Creating accurate and well-centered anterior capsulotomies may lead to better IOL positioning and overlap.[6-8] Reducing the final phaco energy required to remove the lens should, in principle, reduce endothelial cell loss and trauma to the eye. This could be beneficial for complicated cases, such as weak zonules.

From a research point of view, the ability to produce standardised, reproducible results opens up new opportunities for meticulous analysis of outcomes. In every day practice, it is widely acknowledged that current manual cataract surgery techniques are very safe with good outcomes. However, the standardisation of procedures could potentially improve outcomes and reduce complications. Additional in-depth investigations are required to determine the validity of femtosecond laser assisted cataract surgery. Furthermore, this laser system already provides additional refractive procedures, so there are potential advantages of combining cataract and refractive capabilities in one system which could be evaluated further.

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