CLINICAL INVESTIGATION REPORT (CIR)

PREC-M-001: COMPARISON BETWEEN PSS-ASSISTED VERSUS MANUAL SURGICAL TASKS DURING EPIRETINAL MEMBRANE PEELING

Administrative information

Name of investigational product/device	Preceyes Surgical System (PSS) R1.1#1		
Title of study	Comparison between Preceyes Surgical System (PSS)-Assisted versus Manual Surgical Tasks during Epiretinal Membrane Peeling		
Indications studied	Surgical Steps which are components of an epiretinal peeling procedure but also common to other vitrectomy procedures. Randomized consecutive series of patients operated with an epiretinal membrane assisted in certain tasks by PSS versus conventional (manual) surgery using a 2:1 randomization.		
Name of Sponsor	Preceyes B.V.		
Protocol identification (code or number)	Clinical Protocol ID (Preceyes): PREC-M-001 Clinical Study Institutional ID (primary site): MEC-2018-1582		
Trial Registry	Dutch trial database number NL7376		
Development phase of study	Safety and validation study of Precision and Accuracy		
Date of first patient enrolment	30-Apr-2019		
Date of last patient completed	16-Nov-2020		
Name and affiliation of sponsor's responsible medical officer	Marc D. de Smet, MDCM, PhD, FMH, FRCSC, FRCOphth, FARVO: CMO Preceyes BV		
Name of company/sponsor signatory	Marc D. de Smet, MDCM, PhD, FMH, FRCSC, FRCOphth, FARVO: CMO Preceyes BV		
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1 Synopsis

Sponsor Preceyes B.V.	
Name of finished product Preceyes Surgical System R1.1#1	
Title of Study Comparison between Preceyes Surgical System (PSS) Assisted versus Manual Surgical Tasks during Epiretinal Membrane Peeling	
Investigator(s) K. Faridpooya, MD.	
Study Center(s) Rotterdam Eye Hospital	
Publications (references) None	
Study Period First enrolment: 30-Apr-2019 Last exam 16-Nov-2020	**Phase of development** Safety and validation study
Objectives and purpose Obtain safety data on the of PSS and the use of surgical intraocular instruments in common surgical tasks in an epiretinal membrane procedure and other vitreous retinal surgeries. Of note not all steps required for an epiretinal	
Methodology Randomized open label prospective study of 2:1 assignment between PSS assistance and manual surgery	
Number of patients (planned and analyses) 15 patients planned (16 patients enrolled with 1 patient dropped out prior to surgery and replaced). For video analysis, 13 surgeries were analyzed (missing/poorly recorded data for 2). OCT data was available on all patients.	
Diagnosis and main criteria for inclusion Epiretinal membrane requiring surgery and confirmed on OCT during the pre-surgical exam.	
Test product Preceyes Surgical System and intraocular tools (instruments) coupled to PSS	
Duration of treatment and follow-up Patient were operated for their epiretinal membrane with various steps compared between manual and PSS assistance. Follow-up was initially planned for 3 months and due to COVID extended to 6 + months.	
Reference therapy Manual peeling vitreoretinal surgical procedure	
Criteria for evaluation Efficacy: Duration of surgical steps, overall surgical time, visual recovery during the follow-up period. Satisfaction questionnaires. Safety: retina/ eyewall surgically induced trauma, dropout and PSS malfunction, microhemorrhages, abnormalities on OCT images.	
Statistical methods Descriptive statistics were used in the study, and for vision, a Student's T test for continuous variables	

SUMMARY – CONCLUSIONS

PSS performed as expected in the course of the study. There were no patient related complications caused by the use of the PSS. PSS correctly identified pre-defined operating issues and responded accordingly leading to reinitialization of the system on 2 occasions. The use of PSS increases surgical time with most of the time lost in assembly and draping, issues that can be addressed with design improvements. A learning curve in the use of PSS was visible with a reduction in time with increased consecutive use, though a pause caused a lengthening of the time required to perform steps. Vision improvement showed a trend to faster improvement with PSS use, but which disappeared by 6 months. There were no structural differences noted on the OCTs between the two groups.

Efficacy Results
Vision improvement occurred faster with PSS than with manual surgery. Groups are too small for a significant statistical interpretation, though a trend in favor of PSS was present. There was no difference in vision at 6 months between the 2 groups. There were no differences on OCT in retinal thickness, change in retinal thickness or in the appearance of the nerve fiber layer between the two groups. Surgical time was longer in the PSS assisted group with a trend to less time required for set-up and surgical steps as experience was gained in the use of the system.
PSS performed as expected and required re-initialization or a reboot on 2 occasions as required by its safety programming.

Safety Results
No patient adverse event occurred during the study. There were 47 port entries and approaches to the retina without any adverse events. In 4 patients, device deficiencies that lead to some surgical delay or prolongation occurred but with no consequence to the patient.

Conclusion
From a patient, surgeon and surgical staff perspective there was general agreement that the system worked according to expectations. The total surgical time is 3x longer than with manual surgery but diminished with repeated use of PSS. Time can be reduced by further optimization of the draping and assembly requirements. PSS performed as expected and was safe under conditions of use in a standard operating room setting, in a hospital mainly aimed at a high throughput patient care. There were no surgical complications, and patient recovery was the same in both groups of patients.