A PROSPECTIVE MULTICENTER CLINICAL TRIAL TO EVALUATE THE SAFETY AND EFFECTIVENESS OF THE ACUFOCUS* CORNEAL INLAY ACI 7000PDT IMPLANTED INTRA-STROMALLY FOR MODIFIED MONOVISION IN PRESBYOPIC SUBJECTS

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The objective of this study is to evaluate the safety of the AcuFocusTM ACI 7000PDT corneal inlay implanted intra-stromally in emmetropic presbyopes and the effectiveness of the inlay for improvement of near vision.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Observational invasive

Summary

ID

NL-OMON35740

Source
ToetsingOnline

Brief title
ACU-P10-020B (AcuFocus, ACI 7000PDT)

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
MODIFIED MONOVISION, PRESBYOPIC

Research involving

Human

Sponsors and support

Primary sponsor: AcuFocus, Inc.
Source(s) of monetary or material Support: AcuFocus;Inc.

Intervention

Keyword: ACI 7000PDT, ACU-P10-020B, Corneal Inlay, Presbyopic Patients

Outcome measures

Primary outcome

- Improvement in uncorrected near visual acuity (40cm/16in.) at 12 months. 75%

of eyes should achieve uncorrected near

visual acuity of 20/40 or better.

- Subjective improvement in near vision as measured by subject satisfaction

questionnaire.

Secondary outcome

- Preservation of best-corrected visual acuity

Fewer than 5% of eyes should have a persistent loss of two lines or more of

best-corrected distance visual acuity and less than 1% of eyes with

preoperative best spectacle corrected distance visual acuity of 20/20 should

have bestcorrected distance visual acuity worse than 20/40 at 12

months.

- Mean extent of induced manifest refractive astigmatism

Fewer than 5% of eyes should have postoperative manifest refractive astigmatism that increases from baseline by greater than 2.00 D at the postoperative interval at 12 months.

- Results of slit lamp examination

Fewer than 1% of eyes should have clinically significant haze on slit lamp examination, defined as a decrease in BCDVA of more than two lines not due to irregular astigmatism, at 12 months.

- Cumulative incidence of adverse events

Adverse events related to the device should occur in no more than 5% of eyes and any single adverse event related to the device should occur in no more than 1% of eyes.

Study description

Background summary

The patient is invited to take part in a research study because the patient has prebyopia. This means the patient has difficulty reading or seeing near objects without glasses or contact lenses.

Study objective

The objective of this study is to evaluate the safety of the AcuFocusTM ACI 7000PDT corneal inlay implanted intra-stromally in emmetropic presbyopes and the effectiveness of the inlay for improvement of near vision.

Study design

This will be a prospective multicenter clinical trial in which a maximum of 150 consecutive eyes of 150 patients will be implanted with the ACI 7000PDT and followed with postoperative visits over a 12 month period at a maximum of 12 clinical sites. Each clinical site should contribute a minimum of 15 subjects to the study population, but no more than 25% of the total subjects in the study.

Subjects will be screened for eligibility, and informed consent will be obtained from those who meet the screening criteria and are interested in participation in the study. Eligible subjects will be examined preoperatively to obtain a medical history and to establish a baseline for their ocular condition. Qualified subjects who provide written consent will undergo intrastromal placement of an ACI.

The surgical procedure will be performed by creating a lamellar dissection with a femtosecond laser and placing the ACI under the dissection. The ACI will be implanted in the non-dominant eye unless psychophysical testing determines that the inlay should be implanted in the dominant eye.

Postoperatively, subjects will undergo complete ophthalmic examination at regular intervals to evaluate safety and effectiveness of the ACI in improving near vision.

Study burden and risks

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Subjects must sign and be given a copy of the written Informed Consent form.
2. Subjects must be emmetropes needing a magnitude of +1.00D to +2.50D of reading add.
3. Subjects must have uncorrected near visual acuity worse than 20/40 and better than 20/100 in the eye to be implanted.
4. Subjects must have distance visual acuity correctable to at least 20/20 in both eyes.
5. Subjects must have a preoperative spherical equivalent of plano defined as +0.50D to -0.75D with no more than 0.75D of refractive cylinder as determined by cycloplegic refraction in the eye to be implanted.
6. Subjects must have a stable refraction twelve months prior to ACI implantation: i.e. MRSE within 0.50D over prior twelve months as determined by subject history.
7. Subjects who are soft contact lens wearers must discontinue their contact lenses for at least one week prior to ACI pre-operative examination.
8. Subjects must have a minimum central corneal thickness of >= 500 microns in the eye to be implanted.
9. Subjects must have a corneal power of >= 41.00D and <= 47.00D in all meridians in the eye to be implanted.
10. Subjects must be >= 45 years and <= 60 years of age at the time of subject eligibility visit.
11. Subjects must have an endothelial cell count >= 2000 cells/mm2 in the eye to be implanted.
12. Subjects must be willing and able to return for scheduled follow-up examinations for 12 months after surgery.
13. Subjects must demonstrate tolerance to monovision blur in the eye to be implanted as determined by loose lens blur tolerance or monovision contact lens trial.

Exclusion criteria

1. Subjects with a difference of >1.00D between the spherical equivalent manifest refraction and the spherical equivalent cycloplegic refraction.
2. Subjects with anterior segment pathology, including cataracts, in the eye to be implanted.
3. Subjects with residual, recurrent, active ocular or uncontrolled eyelid disease, or any corneal abnormality (including endothelial dystrophy, guttata, recurrent corneal erosion, etc.) in the eye to be implanted.
4. Subjects with ophthalmoscopic or topographic signs of keratoconus (or keratoconus suspect) or keratoectasia in the eye to be implanted.
5. Subjects with dry eye as determined by objective testing; anesthetized Schirmer*s test result <10 mm or a tear break-up time (TBUT) less than 10 seconds are excluded.
6. Subjects taking chronic systemic medications known to exacerbate or induce moderate to severe dry eye in so far as measures of TBUT and Schirmers are decreased or borderline per Exclusion Criterion #5. Subjects taking the following classes of medications should be evaluated: anti-depressants, anti-histamines, betablockers, phenothiazines, atropine and atropine derivatives, oral contraceptives, anxiolytics, diuretics, anti-cholinergics, and anti-arrhythmics.
7. Subjects with distorted or unclear corneal mires on topography maps of the eye to be implanted.
8. Subjects with macular degeneration, retinal detachment, or any other fundus pathology that would prevent an acceptable visual outcome in the eye to be implanted.
9. Subjects who have worn RGP or PMMA contact lenses within the last 6 months.
10. Subjects who have undergone previous intraocular or corneal surgery, including PRK, LASIK, CK, LASEK, and cataract surgery in the eye to be implanted.
11. Subjects with a history of herpes zoster or herpes simplex keratitis.
12. Subjects who have a history of steroid-responsive rise in intraocular pressure, preoperative IOP > 21 mmHg, glaucoma, ocular hypertension, or are glaucoma suspects.
13. Subjects with an abnormal threshold visual field.
14. Subjects with a history of diagnosed diabetes, diagnosed autoimmune disease, connective tissue disease, or clinically significant atopic syndrome.
15. Subjects on chronic systemic corticosteroids or other immunosuppressive therapy that may affect wound healing, and any immunocompromised subjects.
16. Subjects who are using ophthalmic medication(s) other than artificial tears for treatment of any ocular pathology including ocular allergy.
17. Subjects using systemic medications with significant ocular side effects.
18. Subjects who are pregnant, lactating, or of child-bearing potential and not practicing a medically approved method of birth control.
19. Subjects with known sensitivity to planned study concomitant medications.
20. Subjects who are participating in any other ophthalmic drug or device clinical trial during the time of this clinical investigation.
21. Subjects who require canthotomy to generate a lamellar dissection in the eye to be

implanted.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2012
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	ACUFOCUS CORNEAL INLAY ACI 7000PDT
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-10-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-11-2011
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00850031
CCMO	NL36619.068.11