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Datasheet for the decision of 6 March 2013

Case Number: T 2147/08 - 3.2.02

Application Number: 05027736.7

Publication Number: 1645222

IPC: A61B 3/10, A61F 9/00, A61N 5/06

Language of the proceedings: EN

Title of invention:
System for laser treatment of presbyopia

Applicant:
Visx, Incorporated

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56, 76(1), 84, 123(2)

Keyword:
"Added subject-matter (no, after amendments)"
"Clarity (yes, after amendments)"
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-

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Case Number: T 2147/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 6 March 2013

Appellant: (Applicant)
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Representative:
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 15 May 2008 refusing European patent application No. 05027736.7 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: C. Körber
P. L. P. Weber

Summary of Facts and Submissions

I. On 15 May 2008 the Examining Division posted its decision to refuse European patent application No. 05 027 736.7 for lack of clarity and lack of inventive step.

II. An appeal was lodged against this decision by the applicant by notice received on 23 July 2008, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 24 September 2008.

III. By communication of 25 May 2012, the Board forwarded its provisional opinion to the appellant and summoned it to oral proceedings.

IV. By letter dated 13 August 2012, the appellant requested that its third auxiliary request filed with the statement setting out the grounds of appeal be made the new main request and withdrew all remaining requests. Following a telephone conversation held with the Rapporteur on 4 September 2012, the appellant submitted with letter dated 5 September 2012 an amended version of the main request and of page 11 of the description and requested that the case proceed on that basis.

V. By communication of 6 September 2012 the Board informed the appellant that the oral proceedings were cancelled.

VI. The appellant's final requests were as follows:

1. that the decision under appeal be set aside;

2. that a patent be granted on the basis of claims 1 to 14 filed with letter dated 5 September 2012.

VII. The following prior-art documents are of importance for the present decision:

D1: US-A-5 395 356
D2: WO-A-94/18636
D3: US-A-4 721 379.

VIII. Claim 1 of the main request reads:

"An ophthalmologic surgery system (10-14, 20) for performing selective ablation of an exposed corneal surface (200) of an eye (30) to create a desired shape (450) on the anterior optical surface of the healed cornea (200), the system comprising:
i) a laser (28) for generating a beam of corneal ablation energy;
ii) an optical train (29) in the path of the beam, for manipulating the beam over the cornea (200); and
iii) a processor (10; 21) operatively coupled to the optical train (29) so as to manipulate the beam to effect an ablation reshaping according to an initial ablation shape (460) of the exposed corneal surface (200), the processor (10; 21) being arranged to determine the initial ablation shape (460) from the desired shape (450) according to a desired correction input to the system (10-14, 20),
wherein the processor (10; 21) is arranged to determine the initial ablation shape by estimating a healing-induced change (440) in shape between the initial ablation shape (460) and the desired shape (450), and wherein the estimated healing induced change (440) is

not constant over an ablation optical zone (211) of the cornea (200)."

Claims 2 to 14 are dependent claims.

IX. The appellant's arguments are summarised as follows:

The word "desired" in claim 1 clarified the advantage of the invention in achieving a desired shape following laser ablation, and reflected the wording of the passage on page 22, line 20 to page 23, line 2 of the application as originally filed. Claim 1 required that an initial ablation shape was determined that was different from a shape that corresponded to a correction input to the system. That feature was entirely clear and was defined in technical terms.

The following steps would be required to reach the claimed invention from the disclosure of D3, and none of these steps were suggested by D3:

i) record, in the Module F, information able to identify healing-based changes;
ii) recognise from that information that healing-based changes have occurred following laser ablation;
iii) recognise that the healing-based changes are not constant over an ablation optical zone and are systematic and predictable; and
iv) replace Module F by a module that automatically calculates and compensates for healing-based changes in laser ablation.

These steps constituted much more than mere automation of Module F: they first required recognition that there

was a need to compensate for healing following laser ablation, and that this healing could be predicted. They also required a complete change in the nature of Module F, from an electronic notebook that outputs to a display, to a module that modified the control data sent to the laser sculpting means. There was nothing in D3 to suggest these changes.

It appeared from Dl and D2 that there was a prejudice in the art against compensation for healing effects following laser ablation, based on an assumption that such healing effects would not affect the optical properties of the cornea, as stated by Dl. D2, though concerned with modelling the immediate effects of both keratectotomy and keratotomy, notably discussed healing effects only in the context of keratotomy. The passage on page 27, lines 32 and 33 also mentioned the possibility of modelling healing effects of incisions, but there was no reference to healing following ablation. The passage on page 3, lines 33 and 34 just referred to modelling the immediate effect. There is nothing in D2 to suggest a need to compensate for healing following ablation.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

Claim 1 is based on claims 1 to 3 and page 22, lines 31 to 32, of the description as originally filed. Claims 2 to 4 and 6 to 14 correspond to claims 4, 6, 7, 9 and 12

to 19 as originally filed. Claim 5 is based on page 22, lines 18 to 19.

The basis for claim 1 in the parent application as published (WO-A-99/44492) is found in claims 47 to 49 and at page 22, lines 4 to 10 and 20 to 32, of the description. The basis of claims 2 to 6 may be found at page 22, and that of claim 7 at page 13, lines 10 to 12. Claims 8 to 14 correspond to claims 14 to 20 of the parent application.

Accordingly, the Board is satisfied that the requirements of Articles 123(2) and 76(1) EPC are met.

3. Clarity

The clarity objections raised in the impugned decision (points 1, 1.1 and 1.2 of the Reasons) are no longer applicable to the amended set of claims as the wording of the features in question has been clarified and missing features have been added. The Board considers that the requirements of Article 84 EPC are met.

4. Inventiveness

4.1 Document D3, acknowledged at page 1, lines 10 to 12 of the description, is the closest state of the art and discloses (Figure 1 and claims 1 and 3 of D3) an ophthalmologic surgery system for performing selective ablation of an exposed corneal surface of an eye to create a desired shape on the anterior optical surface of the cornea. Control parameters are used for automated operation of laser-incisional/sculpting displacements via a laser sculpting means (Module G).

The idealized topography of the anterior optical surface of the cornea in Module E is transferred via Module D to Module G comprising the laser sculpturing means. D3 further teaches accumulating a "fund of experiences" gathered by various surgeons, including "longer-term effects attributable to the operation" in a data bank (Module F), which can be output to Module D and thus be made available to the surgeon when deciding to perform a particular corneal operation (column 6, line 31 to column 7, line 23; column 2, lines 46 to 57). However, D3 does not specifically address healing-induced change, let alone the aspect that it is not constant over the ablation zone.

4.2 The subject-matter of claim 1 is distinguished from D3 by a processor arranged to determine the initial ablation shape by estimating a healing-induced change in shape between the initial ablation shape and the desired shape, and wherein the estimated healing-induced change is not constant over an ablation optical zone of the cornea.

4.3 The invention is based on the recognition that healing-induced changes occur following laser ablation, that these changes, which are not constant over the ablation zone, are systematic and predictable and can thus be estimated and compensated for. The technical effect of the distinguishing features is that the shape of the cornea after ablation and subsequent healing more closely matches the desired shape.

4.4 The objective technical problem to be solved by the invention is to provide an ophthalmologic surgery

system that permits a more precise correction of refractive errors.

4.5 None of the available prior art documents gives a hint in the direction of the solution according to claim 1. D3 itself does not suggest deviating from the concept described above in point 4.1 and considering healing effects.

D2 is mainly concerned with modelling the post-operative curvature of the cornea as a result of incisions, excisions or ablations, taking into account the increase of intraocular pressure until a final "equilibrium state" is reached (paragraph bridging pages 5 and 6). At page 27, lines 30 to 35 it is also stated in a general manner that healing of an incision affects the eventual curvature, and that healing effects can be included in a model to predict the final curvatures. However, D2 fails to recognize that healing-induced changes are not constant over the ablation zone and, being systematic and predictable, can be compensated for.

D1 describes that after ablation the epithelium regrows post-operatively with a **uniform** thickness and thus leads to a new curvature (column 13, lines 50 to 53; column 3, lines 35 to 38). It is further said that changes in the ablated shape remain substantially **constant** during healing (column 3, lines 12 to 20). Accordingly, the teaching of D1 does not lead towards the invention.

4.6 The Board therefore considers that the subject-matter of claim 1 is based on an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order that a patent be granted on the basis of the following documents:

Claims:
1 to 14 according to the main request filed with letter dated 5 September 2012;

Description:
pages 1, 4 to 10, 12, 15 and 20 filed with letter dated 13 August 2012;
page 11 filed with letter dated 5 September 2012;
page 3 filed with letter dated 4 December 2006;
pages 2, 13, 14, 16 to 19 and 21 to 25 as originally filed;

Drawings:
sheets 1/9 to 9/9 as originally filed.

The Registrar: The Chairman:

L. Fernández Gómez E. Dufrasne