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TITLE

Application of soft directional prismatic contact lenses to correct diplopia

Authors

Parolini, Barbara MD; Penzani, Roberta OD; Pascotto, Patrizio OPTOM

Affiliations

Eyecare Clinic, Via Cefalonia 70, Brescia, Italy

Corresponding author

Barbara Parolini, MD parolinibarbara@gmail.com

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Order of Authors:	<p>Barbara Parolini, M.D.</p> <p>roberta penzani, Orthoptist</p> <p>patrizio pascotto, OPTOMETRIST</p>
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Abstract:	<p>BACKGROUND The aim of the present study was to verify if diplopia, due to a small-angle strabismus within 8 dp, could be corrected by applying soft directional prismatic contact lenses (dpCTL) obtaining higher comfort and quality of vision for the Patients.</p> <p>METHODS A prospective study was undertaken by enrolling consecutive patients affected by vertical and / or horizontal diplopia and small angle strabismus within 8 dp. The patients were tested for best corrected visual acuity (BCVA), refraction, Cover Test for near and for distance, ocular motility test, prismatic fit test, corneal topography, tear film evaluation, binocular vision test, head position evaluation, retinography and Optical Coherence Tomography (OCT) of the posterior and anterior segment. Custom soft contact lenses (med-prism) in benz G5X material were designed and developed for this study. All patients were first corrected with prismatic glasses according to their degree of strabismus and ametropia. Then they were asked to wear custom made dpCTL with appropriate simultaneous correction of strabismus and ametropia. The patients were then asked to answer whether the comfort and quality of vision was higher with dpCTL or prismatic glasses.</p> <p>RESULTS Eight patients were enrolled with different causes of diplopia caused by a strabismus £ 8dp. The soft dpCTL could solve diplopia in 100% of patients. All the patients referred a higher comfort and quality of vision with dpCTL.</p> <p>DISCUSSION The study demonstrated that diplopia, resulting from an angle of strabismus within 8pd can be corrected through the use of soft dpCTL obtaining a higher quality of vision free of aberrations.</p>

Author Comments:	
Response to Reviewers:	<p>Reviewers' comments and Authors' answers (in yellow)</p> <p>Reviewer #1:</p> <p>Dear authors,</p> <p>Thank you for this very interesting article regarding a new type of lens and correction which is very useful in small angle strabismus.</p> <p>While I realize that these lenses were specifically created for the study, it would help</p> <ol style="list-style-type: none"> 1. to know how they were created 2. what is the highest-level prism able to be inserted in optical zone without "creating higher order aberrations"? 3. Were these lenses hard to fit? 4. Also, were any of the patients uncomfortable in the lenses as there is sometimes significant discomfort with the inferior prism in toric SCL (although this may not be an issue as you state with prism in the optical zone rather than inferiorly). <p>We thank the Reviewer for the interesting questions, the answers to which will improve our manuscript</p> <p>Following our answers:</p> <ol style="list-style-type: none"> 1. The contact lens design will be explained with an additional Figure. We can disclose that the prism is inserted into the optical zone. The possible lens rotation of the lens is compensated by the geometry of the peripheral area of the lens. 2. We applied a maximum of 3,5 prismatic diopters horizontally and 4,5 with inferior base. The higher the prismatic correction, the thicker the lens. Since the submission of the paper, our application has increased in number. A prism in the optical zone reduces the aberrations significantly compared to standard prism in the peripheral part of the lens. 3. The contact lenses are the same as standard soft toric contact lenses. The comfort is subjective as usual with contact lenses. The patients so far referred good comfort 4. No discomfort was referred due to the current design <p>Additionally, it would help to have an extra column to the table, showing measurements while wearing the contact lenses or were they all orthophoric (distance and near) while wearing the contact lenses?</p> <p>All were orthophoric. It will be added in the text of the manuscript since we think it is not suitable to add to many information in the Table.</p> <p>Furthermore, were the visual acuities as listed in table 1 the acuities with the contact lenses in place or with prismatic glasses? I am curious as to the patients having "higher quality of vision" with the soft contact lenses rather than glasses.</p> <p>ANSWERS</p> <p>The visual acuity in Table 1 was measured with glasses. BCVA remained unchanged with contact lenses. The eyes with BCVA lower than 1 had some form of mild amblyopia. This demonstrated that the prism did not create distortions or aberrations or decrease in vision.</p> <p>We will add this information in the text.</p> <p>I look forward to learning more about the success with these new lenses.</p> <p>Reviewer #2:</p> <p>This is an interesting manuscript presenting a small case series using prismatic contact lenses for small angle strabismus. This is a developing technology that hopefully holds promise. Overall, the manuscript is very difficult to read and requires extensive revision</p>

with and English editor.

Specific Comments:

Abstract:

Overall confusing to understand. Why include the phrase "as well as with prismatic glasses" under the background? There are many syntax errors that reflect false cognates, and many incomplete words. Needs an editor and simplification. The abstract and the whole manuscript will undergo a language revision. The sentence "as well as with prismatic glasses" will be deleted.

Introduction/Background:

Needs comprehensive editing.
The manuscript will undergo a language revision.

Simply state some basics about the study. For instance: incidence of diplopia in adults, incidence of small angle strabismus in adults,
Thank you for your input. We will add the requested data with references

briefly review the scant literature of prismatic contact lens for diplopia management in adults,
and briefly describe the optics of this type of lens.
We added in the text the new info

Methods:

Line 27: define "small angle strabismus"
We defined "small angle strabismus" an angle that could be corrected with a prismatic correction of up to 8 prismatic diopters¹.
We will clarify in the manuscript

Lines 33-34: contact lens wearing AND non-contact lens wearing cannot both be inclusion criteria - that would include everyone
We applied these lenses to contact lens-wearers and non contact lens wearers without. We will clarify in the manuscript

Lines 37-38:

What is a "prismatic fit test?"
A prismatic fit test is a test that allows the patient to adjust to prismatic correction for at least one hour in the office.
What is a "binocular vision test?"
The binocular vision test included the Worth Four Dot Test
What type of OCT was conducted (and don't abbreviate OCT)?
All the patients underwent an Optical Coherence Tomography (OCT) exam of the posterior and anterior segment (Canon Xephilio S1) to exclude macular pathology and to study the fit of the contact lens on the cornea.
We will add this in the manuscript

Lines 39-40: expand on the description of the optics of these lenses.

Answer:

The contact lens design is explained in a new Figure. The prism is inserted into the optical zone. The possible lens rotation is compensated by the geometry of the peripheral area of the lens. Each lens is custom made based on topography data

Results:

Lines 52-53: use standard terms (i.e., superior rectus muscle for "upper rectus" and lateral rectus muscle for "external rectus." Strange that a presumed CN VI paresis caused such a small esotropia.
The Nomenclature was corrected in the manuscript
We confirm that the esotropia derived from a lateral rectus muscle paresis

Lines 56-57: "limited deviation on the prismatic adaptations test" is not really a contraindication to strabismus surgery.
Answer: this is true. Strabismus surgery can be offered. However, we demonstrated

that it is possible to offer the alternative of a prismatic contact lens for patients that cannot or do not want to undergo surgery.

Discussion:

Line 66: How would a prismatic contact lens effect a "reduction of deviation in different gaze positions" (I assume these refers to incomitance).

Answer: the correct sentence is "the use of prismatic contact lenses limits diplopia in non-primary gaze positions, while a prismatic correction on spectacles can still allow some degree of diplopia while gazing laterally or superiorly or inferiorly

Line 68: remove "perfect"

Removed

Lines 71-74: What does this mean?

If a lens does not properly fit and needs to be modified, the presence of the marking notches allows to calculate the modification and the degree or rotation needed

References:

References 1 and 4 are the same article

One of the two references will be deleted

Tables

Suggest combining these into 1 table. The reader is most interested in the type of strabismus and amount of prism correction.

Tables have been combined

Figure:

No comments

One figure was added to offer the design of the lens



Brescia June 16th, 2022

Dear Editor,

We thank you for sending the comments of the Reviewers. We are excited to re-submit our manuscript after revision, entitled:

“Application of soft directional prismatic contact lenses to correct diplopia”

regarding a new proposal of treatment of small angle strabismus with the use of soft prismatic contact lens.

Attached you will find the Answers to Reviewers, a revised manuscript, Table and one more Figure, as requested by the Reviewers.

We thank you for considering our work

Sincerely,

The Authors

Barbara Parolini, Roberta Penzani and Patrizio Pascotto

Reviewers' comments and Authors' answers (in yellow)

Reviewer #1:

Dear authors,

Thank you for this very interesting article regarding a new type of lens and correction which is very useful in small angle strabismus.

While I realize that these lenses were specifically created for the study, it would help

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Following our answers:

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ANSWERS

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I look forward to learning more about the success with these new lenses.

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6

7 Affiliations

8 Eyecare Clinic, Via Cefalonia 70, Brescia, Italy

9

10 Corresponding author

11 Barbara Parolini, MD parolinibarbara@gmail.com

12

13

14 **ABSTRACT**

15 **BACKGROUND**

16 The aim of the present study was to verify if diplopia, due to a small-angle strabismus
17 within 8 dp, could be corrected by applying soft directional prismatic contact lenses (dpCTL)
18 obtaining higher comfort and quality of vision for the Patients.

19 **METHODS**

20 A prospective study was undertaken by enrolling consecutive patients affected by vertical
21 and / or horizontal diplopia and small angle strabismus within 8 dp. The patients were
22 tested for best corrected visual acuity (BCVA), refraction, Cover Test for near and for
23 distance, ocular motility test, prismatic fit test, corneal topography, tear film evaluation,
24 binocular vision test, head position evaluation, retinography and Optical Coherence
25 Tomography (OCT) of the posterior and anterior segment. Custom soft contact lenses
26 (med-prism) in benz G5X material were designed and developed for this study. All patients
27 were first corrected with prismatic glasses according to their degree of strabismus and
28 ametropia. Then they were asked to wear custom made dpCTL with appropriate
29 simultaneous correction of strabismus and ametropia. The patients were then asked to
30 answer whether the comfort and quality of vision was higher with dpCTL or prismatic
31 glasses.

32 **RESULTS**

33 Eight patients were enrolled with different causes of diplopia caused by a strabismus ≤ 8 dp.
34 The soft dpCTL could solve diplopia in 100% of patients. All the patients referred a higher
35 comfort and quality of vision with dpCTL.

36

37

38 **DISCUSSION**

39 The study demonstrated that diplopia, resulting from an angle of strabismus within 8pd can
40 be corrected through the use of soft dpCTL obtaining a higher quality of vision free of
41 aberrations.

42

43

44 BACKGROUND

45 Binocular horizontal and vertical diplopia is a significant and disabling disorder affecting a
46 significant number of patients. Although strabismus is primarily thought of as occurring in
47 childhood, approximately 4% of adults are diagnosed with new onset strabismus¹

48 It is reported that more than 850000 diplopia-related visits occurred annually in the United
49 States from 2003 through 2012 ²

50 Small-angle strabismus is defined as strabismus within 8 prismatic diopters³

51 In the largest study to date, Martinez-Thompson et al. report the four most common
52 subtypes of adult strabismus as paralytic (44.2%), convergence insufficiency (15.7%), small-
53 angle strabismus (13.3%), and divergence insufficiency (10.6%)¹

54 The management of binocular diplopia is challenging. Current options to correct diplopia
55 include either eliminating the doubled image through monocular occlusion⁴, with bandage
56 or with intraocular lens (IOL)⁵ and monovision optical correction⁶, or more appropriately
57 through restoring binocularity⁷. Binocularity can be achieved through prism spectacles,
58 strabismus surgery, or botulinum toxin injection into an extraocular muscle⁸.

59 The aim of the present study was to verify if diplopia can be corrected by applying soft
60 directional prismatic contact lenses (dpCTL). Secondary aims were to compare to
61 effectiveness of diplopia correction, comfort and quality of vision obtained with dpCTL to
62 the ones obtained with prismatic glasses.

63 The application of prismatic contact lenses to correct diplopia has been reported in
64 literature as case reports but only hard contact lenses and only to correct vertical diplopia⁹⁻
65 ¹⁰.

66 To the best of our knowledge, the application of soft dpCTL to correct diplopia in any
67 direction has never been published yet.

68

69 **METHODS**

70 A prospective study was undertaken by enrolling consecutive patients affected by vertical
71 and or horizontal diplopia and small-angle strabismus ($\leq 8DP$), consulted at the Eyecare
72 Clinic in Brescia, Italy, between June 2021 and March 2022.

73 A collaborative interdisciplinary work of an ophthalmologist, an orthoptist and an
74 optometrist was therefore started for the application of soft dpCTL that were able to
75 correct the deviation and, if present, both spherical and astigmatic ametropia.

76 Inclusion criteria were a stable angle for at least 6 months, angle of deviation $\leq 8DP$,
77 resolution of diplopia with prismatic optical spectacle correction, no alteration of the tear
78 film and a normal corneal anterior surface, patients looking for alternative treatments in
79 order to avoid the use of glasses and surgery to correct the diplopia.

80 Patients underwent the following tests prior to the dpCTL prescription: best corrected
81 visual acuity (BCVA), refraction, Cover Test for near and for distance, ocular motility test,
82 prismatic fit test (the Patient was allowed to wear the spectacle prismatic correction for at
83 least 1 hour at baseline consultation), corneal topography, tear film evaluation, binocular
84 vision test with the Worth Four Dots Test, head position evaluation, retinography, Optical
85 Coherence Tomography (OCT) of the posterior and anterior segment (Canon, Xephilio S1,
86 Tokyo, Japan).

87 All patients were first corrected with prismatic glasses according to their degree of
88 strabismus and ametropia. Then they were asked to wear the custom made dfCTL, with
89 appropriate correction of strabismus and ametropia.

90 Custom soft contact lenses (med-prism) in benz G5X material were designed and
91 developed for this study. The design of the dpCTL, explained in Figure 1, is based of
92 topography data and on the result of the orthoptic evaluation of the angle of strabismus.
93 The prism is inserted into the optical zone. The possible lens rotation is compensated by
94 the geometry of the peripheral area of the lens.

95

96 The contact lenses have reference marks (Fig 1). The reference marks on one hand allow
97 the patient to know the direction of fitting and on the other hand allow the consultant to
98 check the rotation both for the axis of the astigmatism when present, and for the direction
99 of the prisms. At the follow up, if the lens does not properly fit and needs to be modified,
100 the presence of the marking notches allows to calculate the modification and the degree or
101 rotation needed

102 The deviation correction was distributed over the two eyes, in order to obtain a good
103 balance of vision. We applied a maximum of 3,5 prismatic diopters horizontally and 4,5 with
104 inferior base.

105 The patients were checked 1 and 6 months after the dpCTL prescription.

106 At the follow up visits, 1 month and 6 months after prescription, the Patients underwent
107 the following tests while wearing the dpCTL: BCVA, refraction, Cover Test for near and for
108 distance, ocular motility test, binocular vision test with Worth Four Dots Test, refraction
109 measure, head position evaluation, Optical Coherence Tomography (OCT) of the anterior
110 segment (Canon, Xephilio S1, Tokyo, Japan). At follow up they were asked to answer
111 whether the comfort and quality of vision was higher with dpCTL or prismatic glasses.

112

113 **RESULTS**

114 Eight patients were enrolled. Demographic and clinical data are summarized in Table 1.
115 The causes of diplopia varied from motility alterations of mechanical origin (presence of
116 buckles under the superior rectus muscle which caused hypotropia of one eye), of paralytic
117 origin (deficit of the lateral rectus which caused an esotropia), of surgical origin (residual
118 angle after strabismus surgery), of syndromic origin (esotropia in Duane syndrome). In one
119 case the deviation was horizontal and vertical.
120 The soft dpCTL could solve diplopia in 100% of patients in a comparable way as with the
121 correction obtained with prism mounted on glasses. All patients were orthophoric while
122 wearing the dpCTL and none referred pain or discomfort due to the lens itself.
123 The use of prismatic contact lenses limited diplopia in the non-primary gaze positions, while
124 the prismatic correction on spectacles could allow some degree of diplopia while gazing
125 laterally or superiorly or inferiorly.
126 BCVA remained unchanged with contact lenses. This demonstrated that the prism did not
127 create distortions or aberrations or decrease in vision.
128 All the patients referred a higher comfort and quality of vision with the use of dpCTL
129 compared with glasses.
130 Figure 2 shows the cornea tomography of an eye while wearing the dpCTL.

131

132 **DISCUSSION**

133 The study demonstrated that diplopia, resulting from a small-angle of strabismus $\leq 8DP$,
134 can be efficiently corrected using soft dpCTL.

135 The advantages of soft dpCTL over spectacle prismatic correction included: the ability to
136 correct diplopia as well as the ametropias; the reduction of optical aberrations given by
137 prismatic spectacle lenses; the reduction of anomalous position of the head when present.

138

139 These contact lenses have an advanced design that allows the correction of low and
140 medium values of horizontal, vertical and oblique prismatic deviations, as well as the
141 correction of a large range of ametropias (+/- sf 30 D cil +/- 6 D). The actual limit of the
142 prismatic design is of 5pd on any axis.

143

144 These soft contact lenses have references to mark the rotation. This is necessary and
145 allows, when needed at the first follow up visit, the recalculation of the lens with the final
146 shape and design. This procedure is already used also for toric CTL. Unlike toric CTL, in
147 which the prism is built in the lower part of the lens to control the rotation, in this new type
148 of dpCTLs the corrective prism is inserted directly into the optical zone.

149 The optical advantage relies on the use of high-definition surfaces which guarantee optics
150 free of high order aberrations. Compared to hard lenses, soft contact lenses offer greater
151 comfort, stability, and tolerability for patients.

152 The construction of the lenses is of 5 prismatic diopters on any axis. We advise a maximum
153 of 1.5 diopters with superior base. The higher the prismatic correction, the thicker the lens.

154 We applied a maximum of 3,5 prismatic diopters horizontally and 4,5 with inferior base.

155 A prism in the optical zone reduces the aberrations significantly compared to standard
156 prism spectacle-mounted. Furthermore, with contact lenses the eye has no compensatory
157 movement which we observe with standard prismatic lenses.

158 The diplopia in these patients could have been solved with prismatic glasses and in some
159 with surgery as well. However, all the patients reported a higher comfort and quality of
160 vision with dpCTL and refused surgical option.

161 The application of prismatic contact lenses to correct diplopia has been reported in
162 literature as case reports but only hard contact lenses and only to correct vertical diplopia⁹⁻
163 ¹⁰.

164

165 CONCLUSIONS

166 To our knowledge, this is the first study proposing the treatment of vertical and mixed
167 horizontal diplopia using soft contact lenses with incorporated directional prisms.
168 We are convinced that this alternative could improve quality of vision and of life for a
169 selected group of patients.

170

171 REFERENCES

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198

table

Case	Age	Refraction RE	BCVA RE with glasses	Refraction LE	BCVA LE with glasses	History and Ocular Motility	Deviation in prismatic Diopters for distance with spectacles	dpCTLs Re	dpCTLs Le
1	43	-7.25	1	-6.25	1	Deficit Lateral Rectus Muscle RE, Deficit Abduction RE	Esotropia RE 6 dp	Sf -6.50 3dp O 170°	Sf -5.75 3dp O a 10°
2	37	-1.00 -1.00 cyl 180	1	-0.75 -1.00 cyl 5	1	Esophoria not compensated, Normal Motility	Alternant esotropia 6 dp	Sf -1 cil -1x180 3dp O 165	Sf -0.75 cil -1x5 3dp O 15
3	12	-4.00	0,9	-0.75	1	Strabismus surgery for esotropia RE, Normal Motility	Esotropia RE 4 dp	-3.75 2 dp O 170°	Sf -0.75 2 dp O 10°
4	59	-2.00 -1.25 cyl 180	0,8	-0,50 -1.00 cyl 160	1	Episcleral surgery for retinal detachment RE, Deficit SR RE	Hypotropia RE 5 dp	Sf -1.75 cil -1.25 x180 1,5dp O 90°	Sf -0.50 cil -1x160 3.5dp O 270°
5	60	-0.50	1	-0.50 -1.00 cyl 175	1	Phaco +lol in high myopia RE LE, Deficit abduction in Heavy Eye	Alternant esotropia 6 dp	Sf -0,5 3dp O 160°	Sf -0.50 cil -1x1175 3dp O 20°
6	46	-4.00	0,5 (amblyopic eye)	-0.50	1	Macular buckle for retinoschisi RE in high myopia, Deficit abduction RE	Esotropia RE 4 dp Hypotropia RE 3 dp	Sf -3.75 2.5 dp O 143°	Sf -0.50 2,5 dp O 323°
7	47	-0.75	1	-2.25	1	Traumatic Deficit Superior Oblique LE, Deficit SO LE	Hypertropia LE 4 dp	Sf -0.75 1,5dp O 90°	Sf -2.25 2,5dp O 270°
8	25	+2	1	+2.50	1	Duane syndrome LE, Limited abduction LE	Esotropia LE 5 dp	Sf +2 2.5 dp O 170°	Sf +2.50 2.5 dp O 10°

Legend

BCVA Best visual acuity in decimal with glasses correction on

RE right eye

LE left eye

LR lateral rectus

SR superior rectus

SO superior oblique

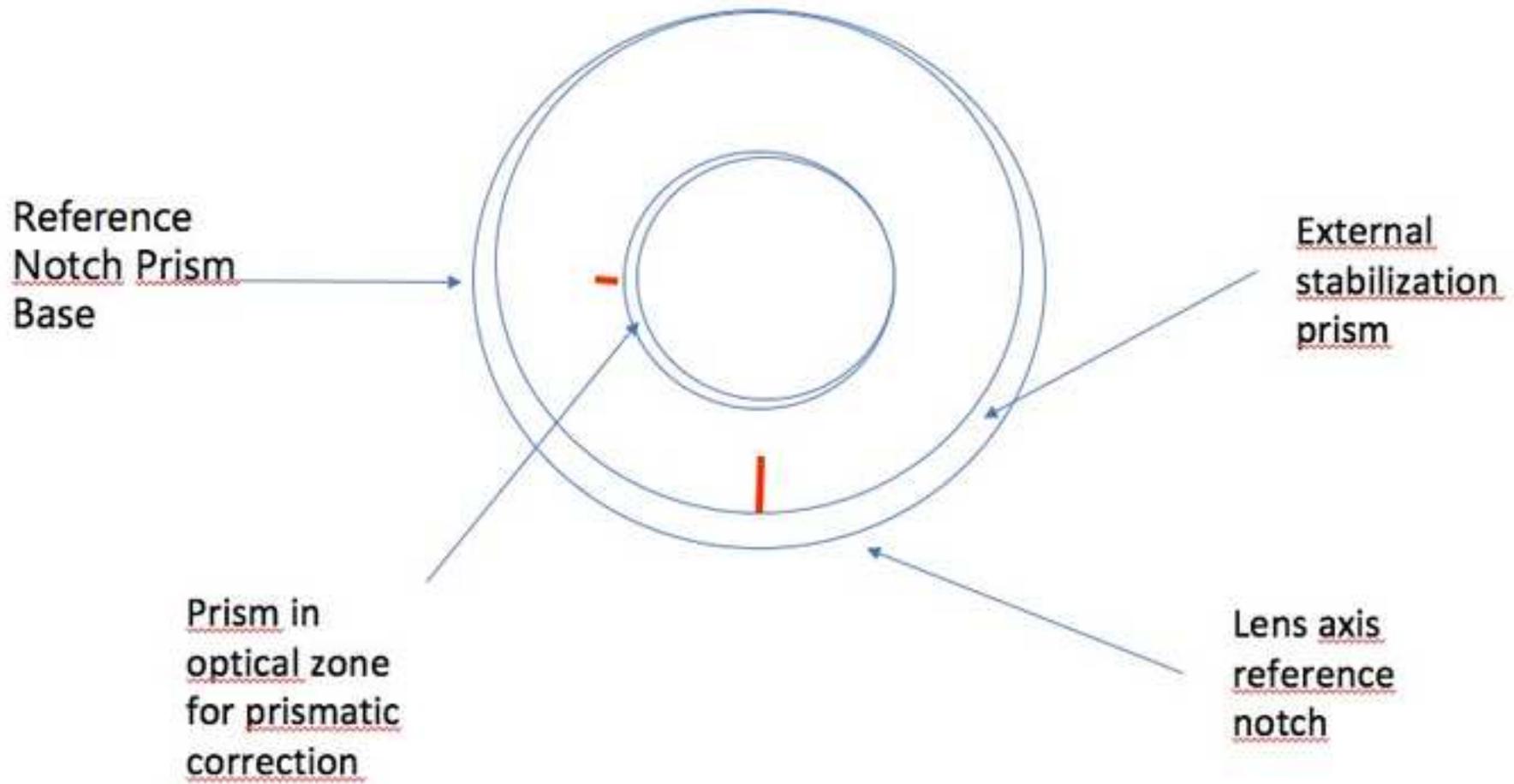
IO inferior oblique

O orientation

Pd prismatic diopters

The right eyes in line n.3,4,6 with BCVA lower than 1 had some form of mild amblyopia.

FRONT DIAGRAM



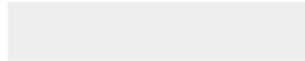




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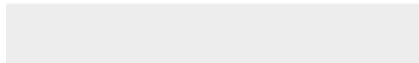
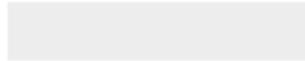


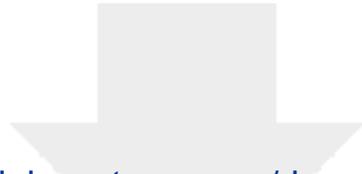


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