SOFT HYDROGEL LENS PARAMETER CHANGES WITH THE NEW LENSEPT DISINFECTION SYSTEM

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Several hydrogen peroxide systems are currently on the market and available for soft hydrogel lens disinfection. A relatively new system is being marketed by Ciba Vision Corporation named Lensept. This is rather confusing since this two step system now employs a catalase neutralizer instead of a catalytic disc. This system was formally call In A Wink and has been marketed in Canada. It is a two step system which uses 3% hydrogen peroxide in a disinfection cycle and a catalase solution for neutralization. This second step is relatively rapid and is complete in 5 minutes.

In clinical trials several patients in the past have reported slight lens distortion when the lenses were removed from the neutralizing solution. This distortion consisted of edge curling and fluting with the lens not conforming to a round shape. This may be a cause for irritation that has been reported by some patients upon insertion of the lenses.

This study monitored changes in lens diameter, central back surface base curve, and overall back surface base curve over time during the Lensept disinfection cycle. These measurements were taken using Lensept peroxide and AOsept peroxide in combination with the new Lensept neutralizing solution. The disinfection cycle, consisting of a hydrogen peroxide soak followed by Lensept Neutralizer, was run with two different hydrogen peroxide soak periods. The two soak periods of 20 minutes and overnight represent two possible ways the system may be used by patients.

Four lens types were used for this study: Permalens (perfilcon A), Permaflex (surfilcon A), Cibasoft (tefilcon), and Spectrum (vifilcon A). Spectrum is a new lens by Ciba and is not yet on the market. Two trial lenses from the above list were run for each case. Unisol saline

was used for all baseline measurements.

Type and number of trials run:

LENS	LENSEPT OVERNIGHT	LENSEPT 20 MIN.	AOSEPT OVERNIGHT	AOSEPT 20 MIN.
SPECTRUM				
DIAMETER	2	2	2	2
SAG DEPTH	2	2	2	2
PERMALENS				
DIAMETER	2	2	2	2
SAG DEPTH	2	2	2	
PERMAFLEX				
DIAMETER	2	2	2	
SAG DEPTH	2	2	2	
CIBASOFT				
DIAMETER	1		2	
SAG DEPTH	1			

MEASUREMENT EQUIPMENT:

Diameter:

Diameter was measured using a Nikon Profile Projector V-12 at 10 X magnification. This unit gives two diameters at 90 apart.

A 10 X template was used to measure diameter during periods of rapid flux. The template was held against the projection screen of the Nikon and gave two diameters 90 apart.

Sagittal Depth:

Sagittal depth was measured using a Chiltern Optimec Projector. This unit gives a side profile of the lens and measures central back surface sagittal depth. The lens is centered on a pedestal and a central post is raised until the back surface of the lens is touched. Base curve is read off a calibrated dial.

Overall front surface sagittal depth and outside overall diameter was measured using the same device with templates; which were made to match the magnification of the instrument.

METHOD

Diameter:

1. Baseline measurements were taken on lenses in Unisol Saline prior to each run.
2. Lenses were placed in wet cells containing the hydrogen peroxide solution. Cover slips were placed over the cells to prevent lens movement.
3. Diameter measurements were taken over time using the templates and electronic read-out on the Nikon Profile Projector.
4. At the end of the specified time (overnight or 20 minutes) the lenses were placed in a lens vial containing Lensept neutralizing solution. The lenses were kept in the lens vials approximately 2 minutes until bubbling decreased or stopped. The lenses were then placed in a wet cell containing Lensept neutralizer.
5. Diameter measurements were then taken using the Nikon and followed over time. Lenses were removed periodically to remove bubble build up.
6. Time permitting, the lenses were placed in saline after Lensept neutralizer baseline had been reached. The diameter changes were again monitored over time.

Sagittal Depth:

1. Central back surface and overall front surface sag were measured in Unisol Saline prior to test start to achieve saline baseline.

2. Chiltern well was filled with the test hydrogen peroxide solution.
3. Lenses were introduced into the hydrogen peroxide. Central sag was measured over time using the calibrated base curve dial. Overall sag was measured over time using the templates on the projected side profile image of the lens.
4. At the end of the desired soak period, the lenses were placed in a lens vial containing Lensept neutralizing solution. The lenses were kept in the lens vials approximately 2 minutes until bubbling decreased or stopped. Lenses were then placed in the Chiltern well containing Lensept neutralizer.
5. Central and overall sag were monitored over time.
6. Time permitting, the lenses were placed in saline after Lensept neutralizer baseline had been reached and sagittal depth was again monitored over time.

RESULTS

Lensept overnight soak:

Diameter:

Fig. 1 shows the change in diameter of all four lenses as a function of time for an 8 hour Lensept H2O2 soak followed by a 4 hour soak in Lensept Neutralizer. It can be seen from the graph that the Permalens material had the greatest change followed by Spectrum, Permaflex, and cibasoft materials respectively. In general, the lenses showed a rapid increase in diameter over the first five minutes when introduced into the H2O2 solution. This was followed by a gradual decrease in diameter until peroxide baseline was reached. All peroxide baseline diameters were smaller then the original saline diameter. It

is interesting to note the time at which the diameter crosses the saline baseline point and becomes smaller then its original size. These times are longer for the materials that show the largest changes in diameter. After the lenses were placed into the neutralizer there was a gradual increase in diameter until neutralizer baseline was reached. This took up to 35 minutes as in the case of the Permalens material. Table 1 summarizes the changes in diameter through the disinfection cycle and the recovery times for all four lens groups.

The dotted lines in Fig. 1 for the Permalens and Spectrum lenses represent the fact that the lens was not symmetrically round when it was placed in neutralizer. The distortion consisted of edge scalloping or fluting. The lenses could be described as looking like a bottle cap. With the permalens material this fluting was symmetrical around the edges. With the Spectrum lens, fluting was usually asymmetric with the degree of fluting varying over the circumference of the lens.

Fig. 2 shows the degree of fluting corresponding to the length of time in the neutralizer for both materials. As seen from the graph the edge distortion lasted 30 to 40 minutes for both lens materials.

This distortion made it impossible to get accurate diameter readings. Lens diameter was approximated using a concentric circle template centered over the projected lens image. The diameter was estimated as that circle which coincided with the midpoint of the minimum and maximum fluting distortion.

Lens #	max. change in Dia. over initial 10 min. in H2O2	Time for Dia. to cross baseline	endpoint over-night change in dia. for H2O2	Time to reach within 0.2 mm of baseline dia. in neut.
Permalens 1	+3.15 mm	36 min.	-2.73 mm	35 min.
2	+2.68	31	-2.54	40
Avg.	+2.92	33.5	-2.64	38
Spectrum 1	+0.75	12	-1.27	45
2	+0.90	15	-1.20	40
Avg.	+0.82	13.5	-1.24	43
Permaflex 1	-0.37	-	-0.53	<4
2	-0.38	-	-0.43	<4
Avg.	-0.38	-	-0.48	<4
Cibasoft 1	+0.21	13	-0.10	0.
2				
Avg.				

Table 1: Lensept H2O2 overnight soak followed by Neutralizer soak

Base curve:

Figure 3 and 4 show central and overall base curve changes for Spectrum lenses with an 8 hour Lensept peroxide soak followed by a neutralizer soak. Figure 3 is a +5.00 D Spectrum lens while Fig. 4 is of a -3.00 D lens. The two curves have different baseline values representing the fact that the lens does not have a spherical back surface. In all cases, the central base curve was slightly steeper then the overall base curve. This suggests that the lenses are slightly elliptical in their natural state. The dotted lines in these graphs represent times in which data was not able to be collected due to the fact that the changes were off the scale of the equipment being used. These graphs show that base curve changes are not only a function of material, but also the power of the lens plays a key role in these changes. In the case of minus powered lenses both central and overall base curve become flatter initially when introduced into peroxide. This

was followed by a gradual return with an endpoint that was slightly steeper then the starting point. When introduced into the neutralizer there was a gradual return to its original shape. This took up to 80 minutes in the case of the central B.C.

When comparing fig 3 and 4 it can be seen that the curves tend to mirror each other. The minus lens becomes very flat centrally when put into peroxide while the plus lens becomes very steep centrally. This can easily be seen in fig 3a and 4a which show a side profile of each lens when it is in this distorted state. Further examination reveals that the distortion conforms to the central optic zone of the lens. In the case of the plus lens, a well demarcated area can be seen where the lens becomes steeper. This fact, along with the dependence on power, suggests that the thickness profile of the lens plays a key role in these B.C. changes. It should be pointed out that this distortion is transitory and at the end of the 8 hour soak the lens does not exhibit this central distortion.

The -3.00 D Permalens acted similarly to the Spectrum material but the changes were of greater magnitude. During much of the time the parameters were off the scale and could not be read. Very little distortion was seen in both the Lensept peroxide soak or the neutralizer soak with the Permaflex material. The Cibasoft material showed changes very similar to the Permaflex material.

Solution:

It is evident that lenses soaked overnight in Lensept peroxide, depending on the material, may be greatly distorted after the recommended soak period of 5 minutes in the neutralizer. These

parameter changes could effect fitting performance and may be a source of discomfort upon insertion. Further investigation was conducted in order to try to solve this problem.

The first thing that was tried was to limit the Lensept peroxide soak to 20 minutes. When looking at the diameter data, 20 minutes is in the vicinity of where the lenses cross the saline baseline point. Removing lenses at this point would eliminate large changes in diameter between the two solutions.

Figure 6 and 7a^7b show diameter and base curve changes for a -3.00 D Spectrum and Permalens with a 20 minute Lensept peroxide soak followed by a four hour neutralizer soak. Two important differences are found when this is compared to the overnight peroxide soak. The first is that no edge distortion was seen when the lenses were placed in the neutralizer. This is true for both the Spectrum and the Permalens materials. The lenses remained round and no edge fluting was documented. The second important result is the fact that the time in which the lenses took to recover to the baseline point in the neutralizing solution was greatly reduced. With both materials this time was less then 15 minutes. Even after five minutes in the neutralizer changes from baseline were minimal.

The second answer to the distortion problem was found by changing the hydrogen peroxide solution. Lensept peroxide was replaced with AOsept peroxide for the overnight soak. It should be emphasized that a catalytic disc was NOT used. This was a change in peroxide solution only and the Lensept neutralizer was still used for the neutralization process.

Figures 8 and 9a^9b show diameter and base curve changes for both Spectrum and Permalens -3.00 D lenses. Lenses were soaked for eight

hours in AOsept peroxide followed by a four hour neutralizer soak. From these graphs it becomes quit apparent that very small changes in the measured parameters occurred over the entire disinfection cycle. Lens diameter decreased slightly in the AOsept solution and was less then 0.5 mm in the worst case (Permalens). Base curve tended to steepen slightly in the AOsept solution for minus powered lenses and was less then 0.5 mm in the worst case (Permalens). All parameters returned to neutralizer baseline in less then five minutes. Permaflex and Cibasoft materials behaved in a similar fashion with even smaller parameter fluctuations.

DISCUSSION

Catalase has been proven as a very effective means of neutralizing hydrogen peroxide. Gyulai et al, using a similar system named Oxysept, has shown that 1 ml of 3% hydrogen peroxide was neutralized by 7 ml's of catalase, with an activity of 520 units per ml, in 30 seconds. Even when the neutralizer was diluted to one tenth of its original activity, the hydrogen peroxide solution was neutralized in 5.5 minutes.[1] With these fast neutralization times it becomes apparent that the slow recovery times after an 8 hour peroxide soak is not due to the time required to break down the peroxide.

There are primarily two differences between Lensept peroxide and AOsept peroxide. These are pH and tonicity. The actual values can be seen in table 2.[2]

Solution	Lensept 3% peroxide	Lensept Neut.	AOsept 3% peroxide	Tears
pH	3.49	7.18	6.27	7.4
Tonicity mOsm/Kg	897	329	1224	290

Table 2: Tonicity and pH values for Lensept, AOsept, and tears

Tonicity, pH, and solvent effects drive the system at different rates. It is the combination of these three things which create the changes over time in the disinfection cycle. When comparing the above solutions it becomes apparent that the pH difference between Lensept and AOsept most likely plays the largest role. AOsept tonicity is high compared to the neutralizer and tears yet little distortion was seen with this peroxide. It can be concluded, therefore, that the acidic pH of Lensept peroxide is a major contributor to parameter changes. One must keep in mind that pH is a log scale and a difference of 3 pH units represents a 1000 fold change in hydrogen ion content.

When lenses are placed into Lensept peroxide there is a large shift in equilibrium that must take place. When the lenses are removed from Lensept and placed into the neutralizer there is again a large shift in equilibrium that must take place. It is these shifts which distort the lenses. This equilibrium shift can be minimized for the neutralizer step by limiting the soak period in Lensept peroxide and not allowing the lens to fully equilibrate in the peroxide solution. The lens is, therefore, much closer to the neutralization baseline endpoint when it is removed from the peroxide. This, in turn, minimizes the driving force to distort.

When AOsept peroxide is used in place of Lensept peroxide the pH level between the two steps remains relatively close. There is only a

small shift in equilibrium that must take place when lenses are placed into AOsept or moved from AOsept to the neutralizer. This is reflected in the fact that very small parameter changes and no edge fluting is seen with this solution.

L. Janoff has shown that lenses will steepen or flatten after a 24 hour soak in Lensept peroxide depending on the polymer. In this study the power of the lens was not kept constant but was limited to the "heart of the range" in minus power. He also concludes that the presence of significant polymer methacrylic acid levels are believed to account for some steepening of a lens when in an acidic medium such as Lensept.[3]

Janoff's conclusion as to the role of methacrylic acid content on parameter changes is verified in this study. Parameter changes were greatest for the lens which had the greatest MA acid content (Permalens). Spectrum showed the second greatest change and it also contains the second highest content of MA acid. Permaflex, being a high water content, non ionic lens, showed little parameter changes over the cycle. It can be concluded, therefore, that the ionic character of the lens is more critical then the water content. This also supports the above theory that pH is the major driving force to change. The hydrogen ion content of acidic Lensept peroxide would tend to interact with the MA acid groups.

It is also important to realize that the thickness profile of the lens plays a major role in the parameter changes. Base curve changes were very different for plus and minus lenses. The changes in central base curve corresponded to the zone of the central optic where the rate of lens thickness changes the most. This may also help explain why the

edge fluting of the Permalens and Spectrum lenses appear different (fig 3a and 4a). Permalens fluting was symmetrical around the circumference of the lens while Spectrum fluting was not consistent around its boarders. One plausible explanation would be that the edge thickness of the Spectrum lens is not constant about its circumference.

The base curve changes and distortions of the lens, during the Lensept peroxide cycle, may help in explaining the large changes in diameter that are seen with the ionic lenses. The central flattening of minus lenses may contribute to the recordable increase in diameter. The lens may not be expanding the full dimension but rather this flattening could also be adding an addition increase above the expansion factor.

It should be noted that few trials were run for each lens group, lens power, and peroxide type. This was due to the long length of time involved to collect the data for each run. All measurements were done manually and only a small number of lenses could be run at the same time. It is recommended, therefore, that the data presented here be used for general trends only and not taken for its absolute value.

CONCLUSIONS

Two answers to the lens distortion problem were realized through this study. These are 1) limit the soak period in Lensept hydrogen peroxide to 20 minutes and do not let the lenses soak overnight before neutralization; 2) use AOsept hydrogen peroxide in place of Lensept peroxide for the disinfection step of the cycle. The second solution is most likely the best approach to take since the length of the soak period is not critical and enables the patient to have more flexibility. It is also safer in the long run due to the fact that there is more contact time for the lenses to be thoroughly disinfected.

It is believed at this time that the major contributor to the distortion problem with Lensept peroxide is its acidic pH. More research in this area must be carried out to fully answer this question. A study using AOsept prepared at varying pH levels may be the best approach to take.

REFERENCES

1. Gyulai, P., et al., Efficacy of Catalase as a Neutralizer of a Hydrogen Peroxide Disinfecting Solution for Soft Contact Lenses. International Eyecare 1986; Vol. 2, Num 8: 418 - 422.

2. Ciba Vision Corporation, Atlanta, GA

3. Janoff, Lester, The Exposure of Various Polymers to a 24 - Hour Soak in Lensept: The effect on Base Curve., JAOA 1985; 56: 222 - 225.

CHILTERN OPTIMEC PROJECTOR CALIBRATION

Magnification determination:

Average pedestal diameter = .33415 inches
= .8487 cm

Projected size of pedestal = 14.213 cm

Magnification = $\frac{14.213 \text{ cm}}{.8487 \text{ cm}}$ = 16.75 X

Calibration of Base curve Dial
of Chiltern projector unit

SCALE READING (from dial)	PROJECTED SAG (cm, projected pedestal ht)	ACTUAL SAG* (mm)	ACTUAL BC**
9.6	1.52	.907	
9.0	1.65	.985	9.6
8.8	1.69	1.009	9.4
8.6	1.73	1.033	9.2
8.4	1.79	1.069	9.0
8.2	1.82	1.087	8.8
8.0	1.90	1.134	8.5
7.8	1.97	1.176	8.25
7.6	2.02	1.206	8.1
7.4	2.10	1.254	7.8
7.2	2.19	1.307	7.55
7.0	2.26	1.349	7.35
6.8	2.35	1.403	7.1
6.6	2.45	1.463	6.9

* Actual Sag calculated from magnification
** Actual base curve calculated knowing pedestal diameter and actual sag

Linear regression was performed on the dial reading vs. actual sagitta height in order to calculate actual sagittal depth from the dial reading on the Chiltern unit.

Back Surface sagittal depth = (Dial reading) x (-.18643) + 2.6482

$$\text{Actual Base Curve} = \frac{S^2 + Y^2}{2S}$$

S = back surface sagittal depth
Y = 1/2 chord diameter
= 1/2 pedestal diameter
= .4244 cm

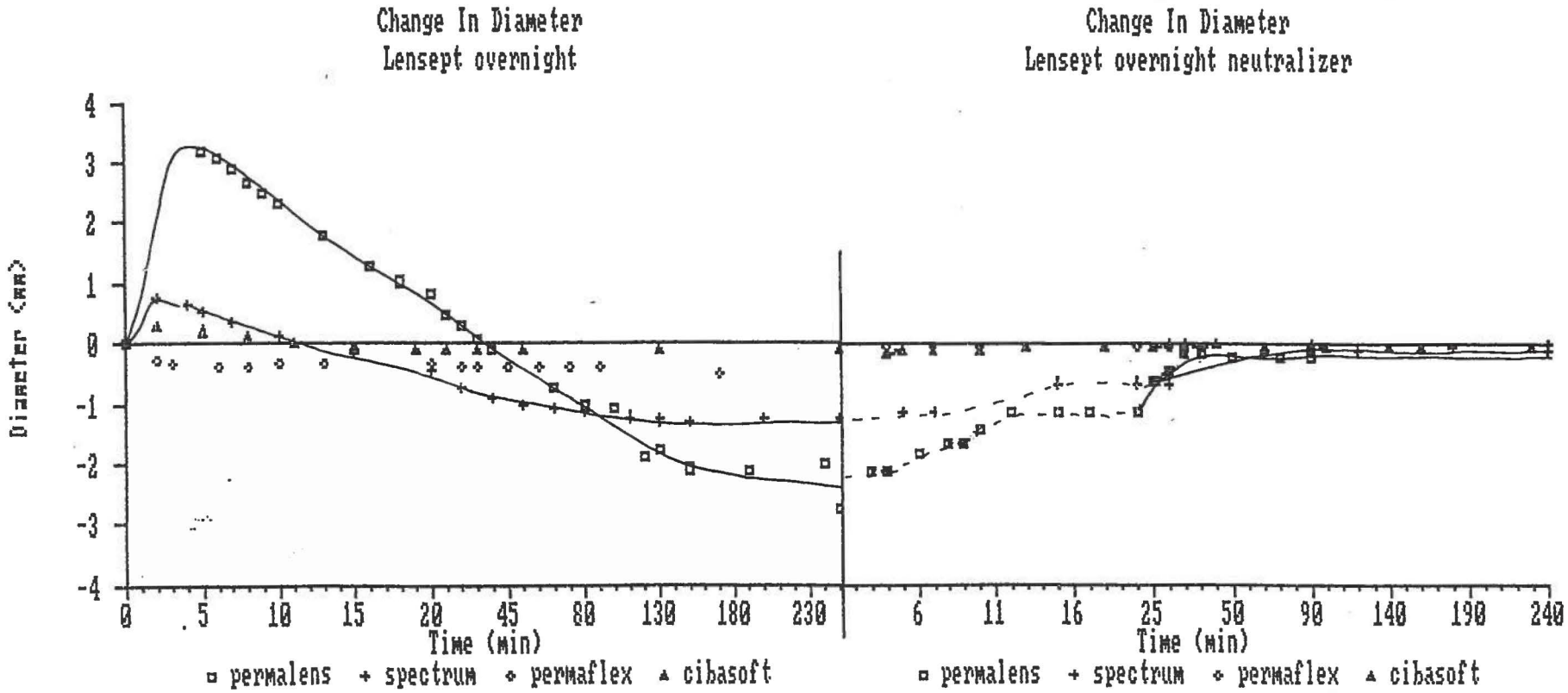
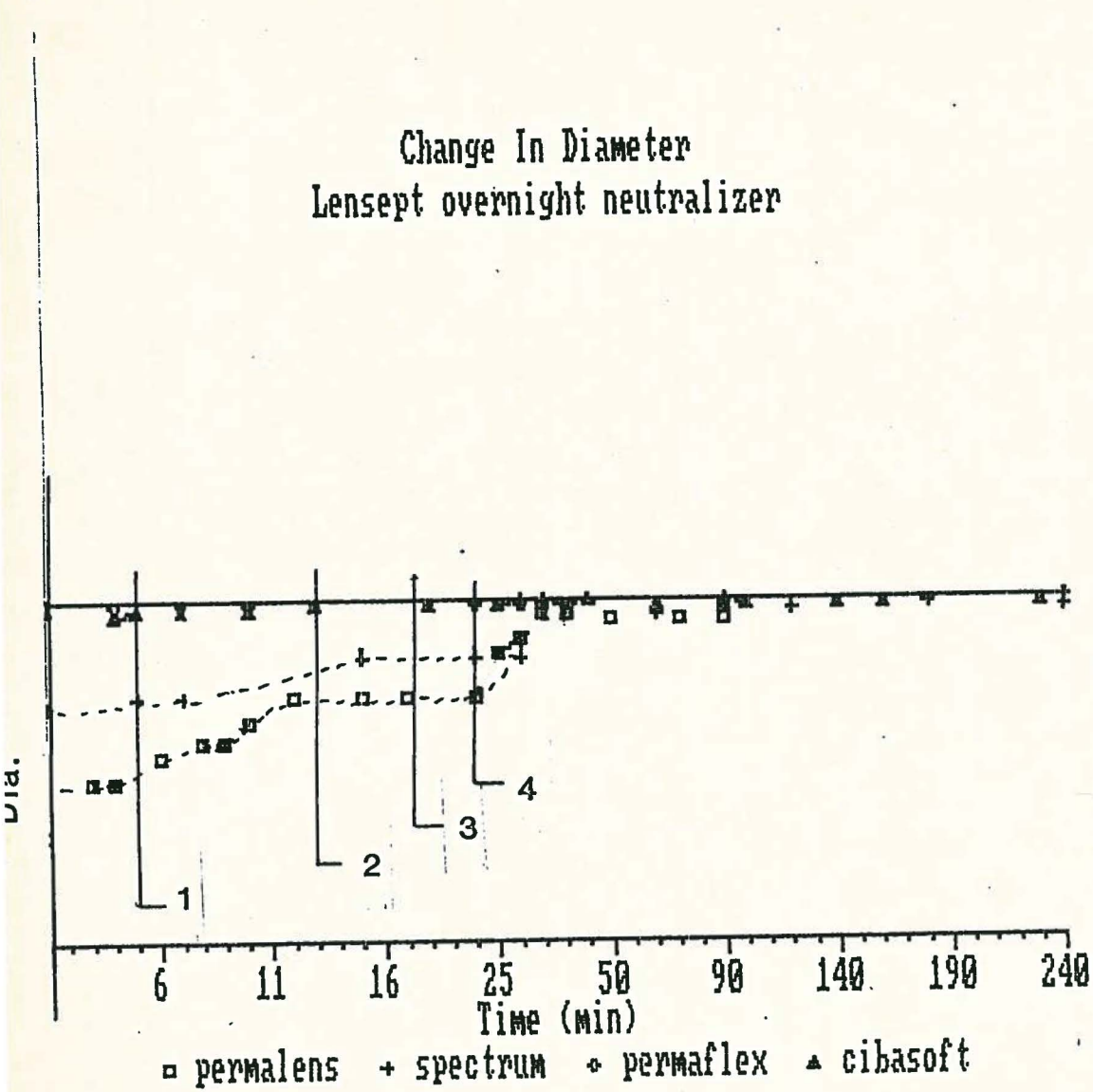

Change In Diameter
Lensept overnight
Change In Diameter
Lensept overnight neutralizer
Diameter (mm)
4
3
2
1
0
-1
-2
-3
-4
0
.5
10
15
20
45
80
130
180
230
6
11
16
25
50
90
140
190
240
Time (min)
Time (min)
permalens
spectrum
permaflex
cibasoft
permalens
spectrum
permaflex
cibasoft

FIG. 1


Change In Diameter
Lensept overnight neutralizer
Dia.
1
2
3
4
6
11
16
25
50
90
140
190
240
Time (min)
permalens
spectrum
permaflex
cibasoft

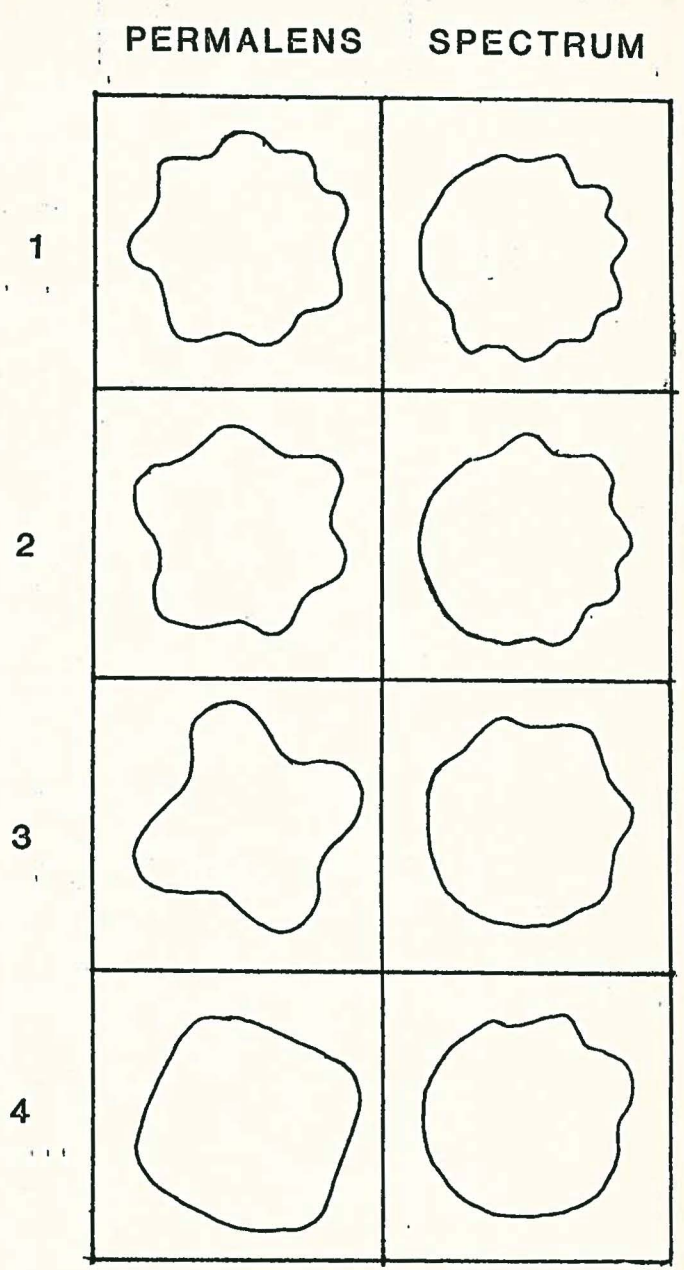

PERMALENS
SPECTRUM
1
2
3
4

FIG. 2

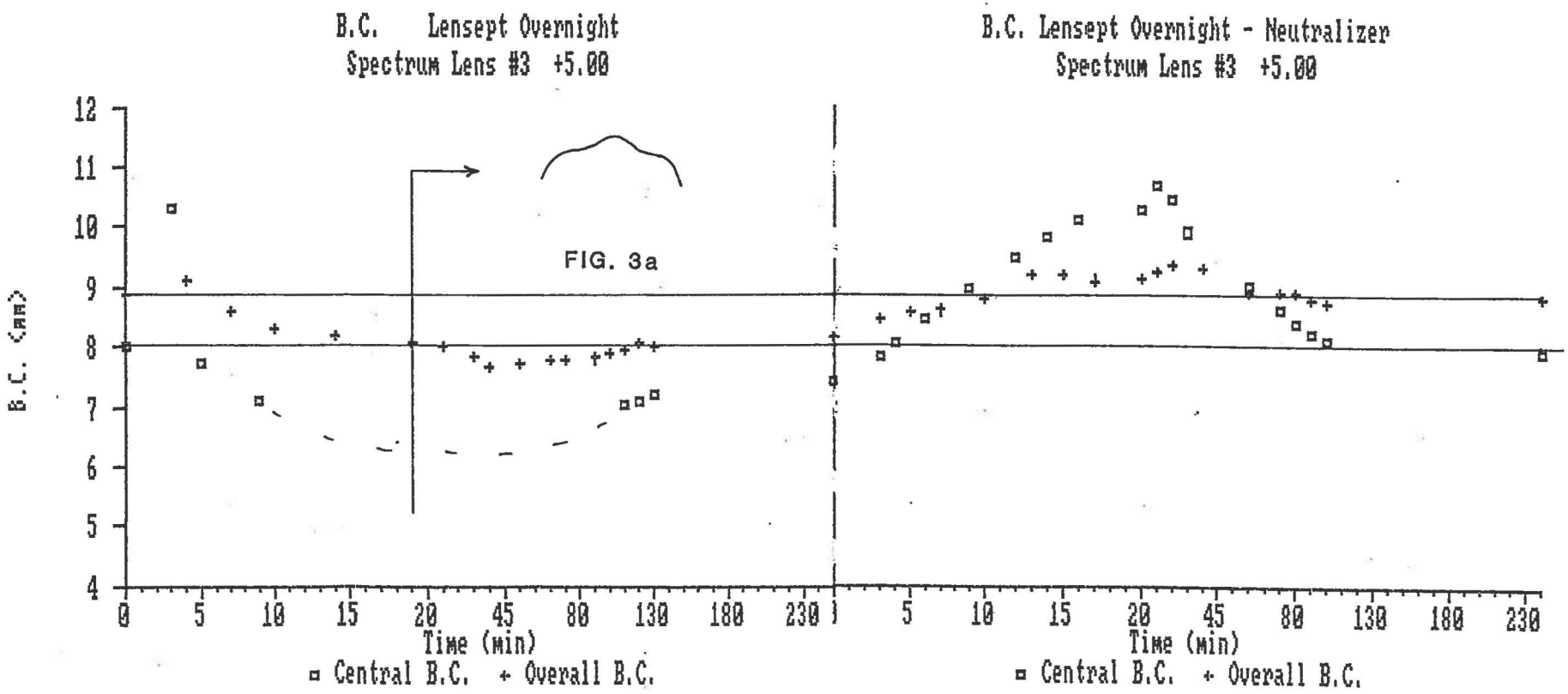

B.C. Lensept Overnight
Spectrum Lens #3 +5.00
B.C. (mm)
12
11
10
9
8
7
6
5
4
0
5
10
15
20
45
80
130
180
230
Time (min)
□ Central B.C. + Overall B.C.
B.C. Lensept Overnight - Neutralizer
Spectrum Lens #3 +5.00
5
10
15
20
45
80
130
180
230
Time (min)
□ Central B.C. + Overall B.C.

FIG. 3a

FIG. 3

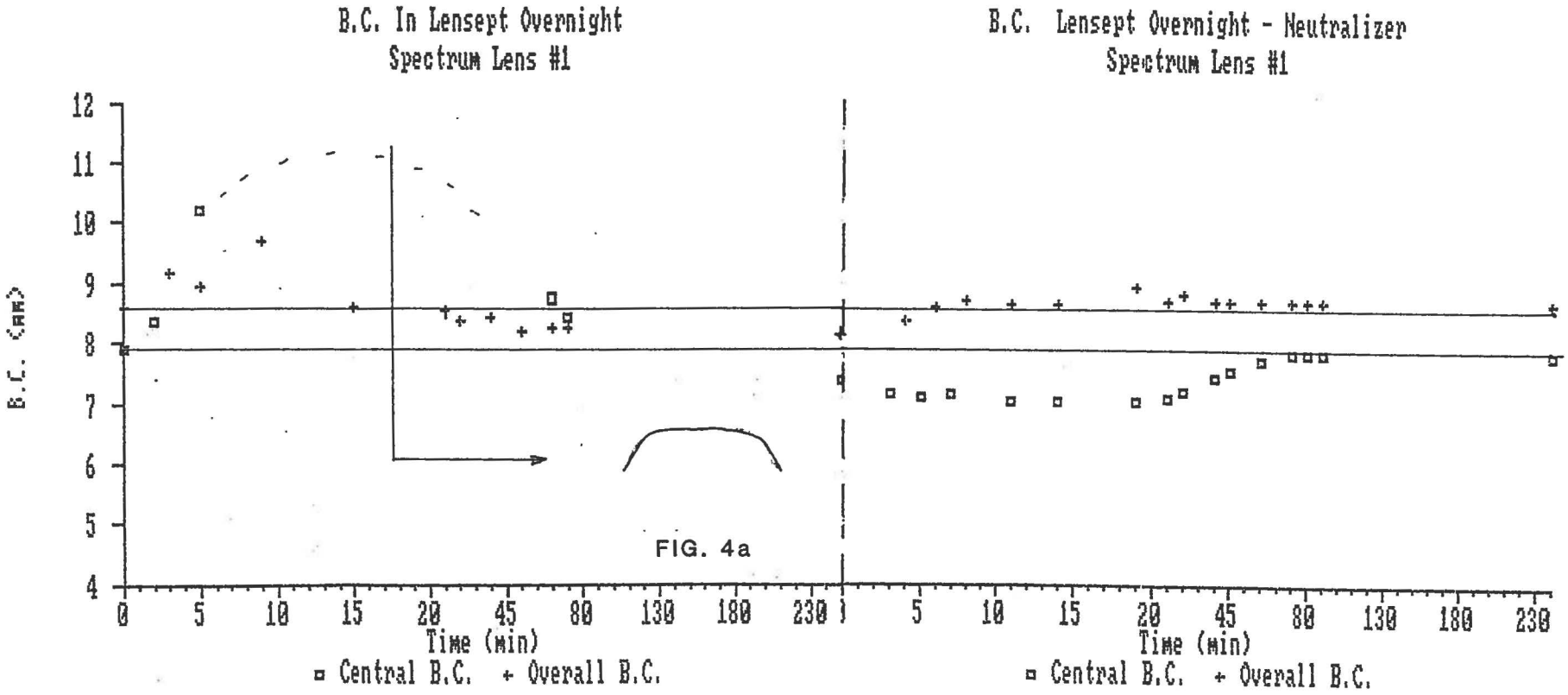

B.C. In Lensept Overnight
Spectrum Lens #1
B.C. (mm)
12
11
10
9
8
7
6
5
4
0
5
10
15
20
45
80
130
180
230
Time (min)
▫ Central B.C. + Overall B.C.
B.C. Lensept Overnight - Neutralizer
Spectrum Lens #1
5
10
15
20
45
80
130
180
230
Time (min)
▫ Central B.C. + Overall B.C.

FIG. 4a

FIG. 4

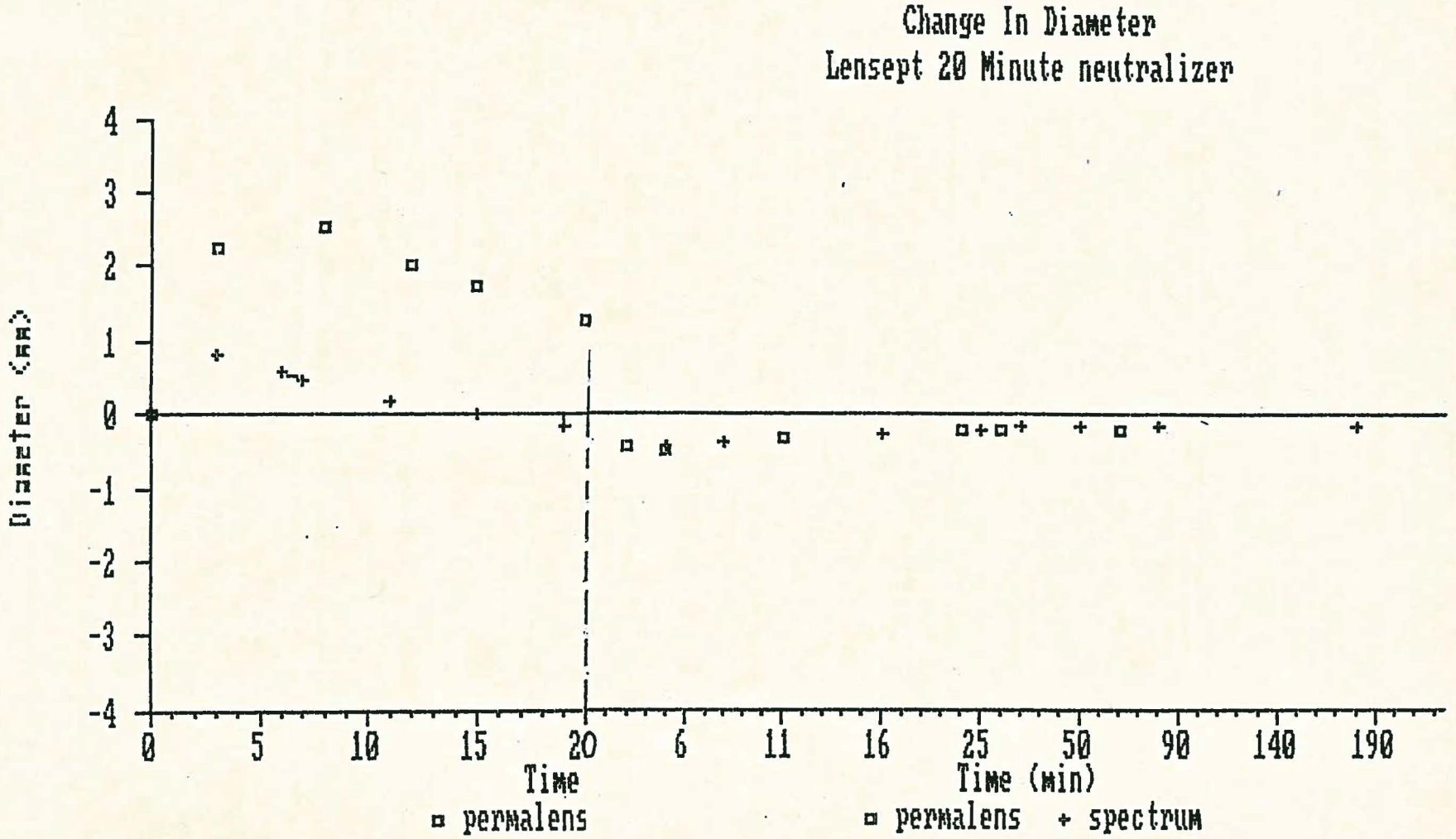

Change In Diameter
Lensept 20 Minute neutralizer
Diameter (mm)
4
3
2
1
0
-1
-2
-3
-4
0
5
10
15
20
6
11
16
25
50
90
140
190
Time
Time (min)
permalens
permalens
spectrum

FIG. 6

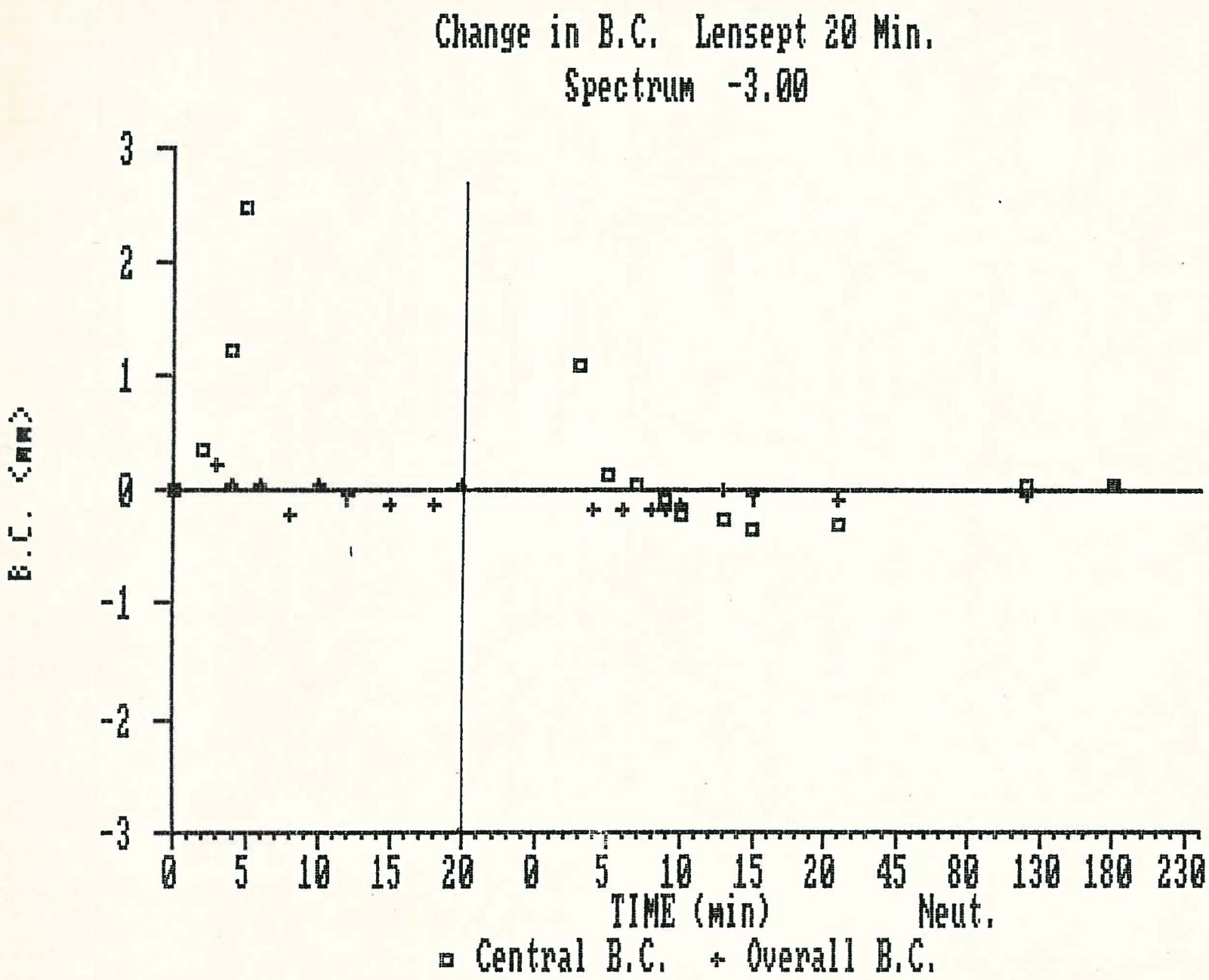

Change in B.C. Lensept 20 Min.
Spectrum -3.00
B.C. (mm)
3
2
1
0
-1
-2
-3
0 5 10 15 20 0 5 10 15 20 45 80 130 180 230
TIME (min) Neut.
▫ Central B.C. + Overall B.C.

Fig. 7a

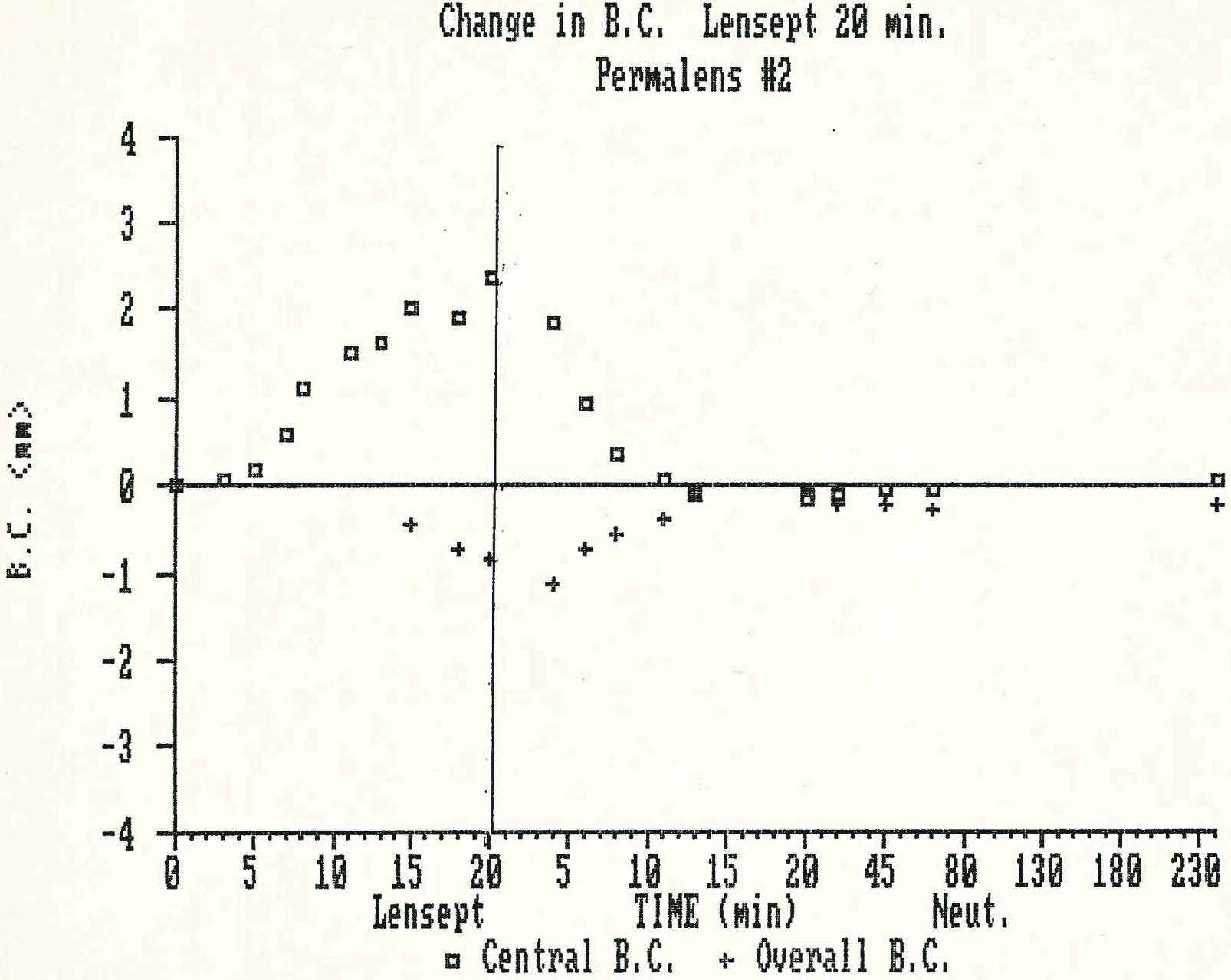

Change in B.C. Lensept 20 min.
Permalens #2
B.C. (mm)
4
3
2
1
0
-1
-2
-3
-4
0 5 10 15 20 5 10 15 20 45 80 130 180 230
Lensept
TIME (min)
Neut.
□ Central B.C. + Overall B.C.

Fig. 7b

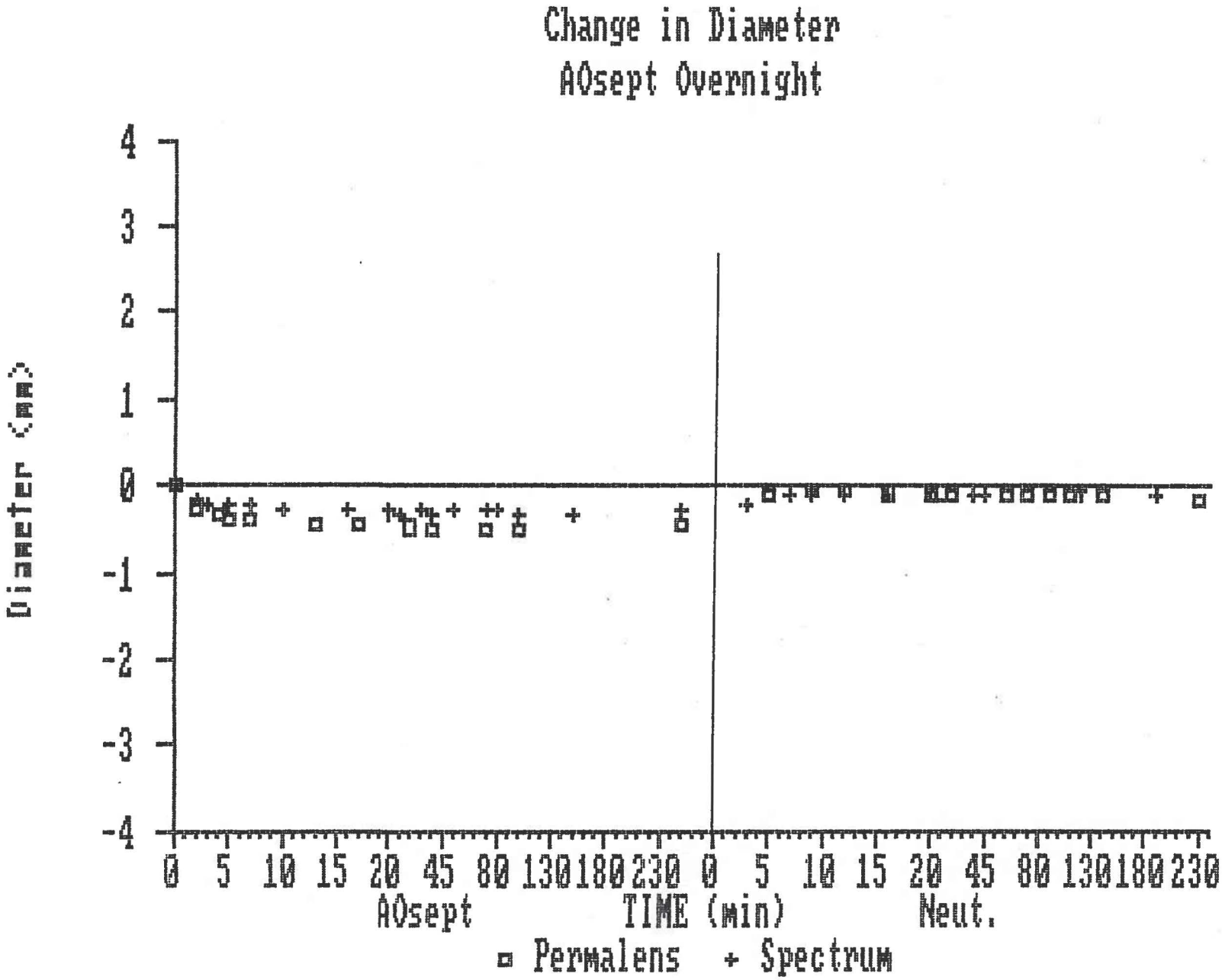

Change in Diameter
AOsept Overnight
Diameter (mm)
4
3
2
1
0
-1
-2
-3
-4
0 5 10 15 20 45 80 130 180 230 0 5 10 15 20 45 80 130 180 230
AOsept
TIME (min)
Neut.
Permalens
Spectrum

Fig 8

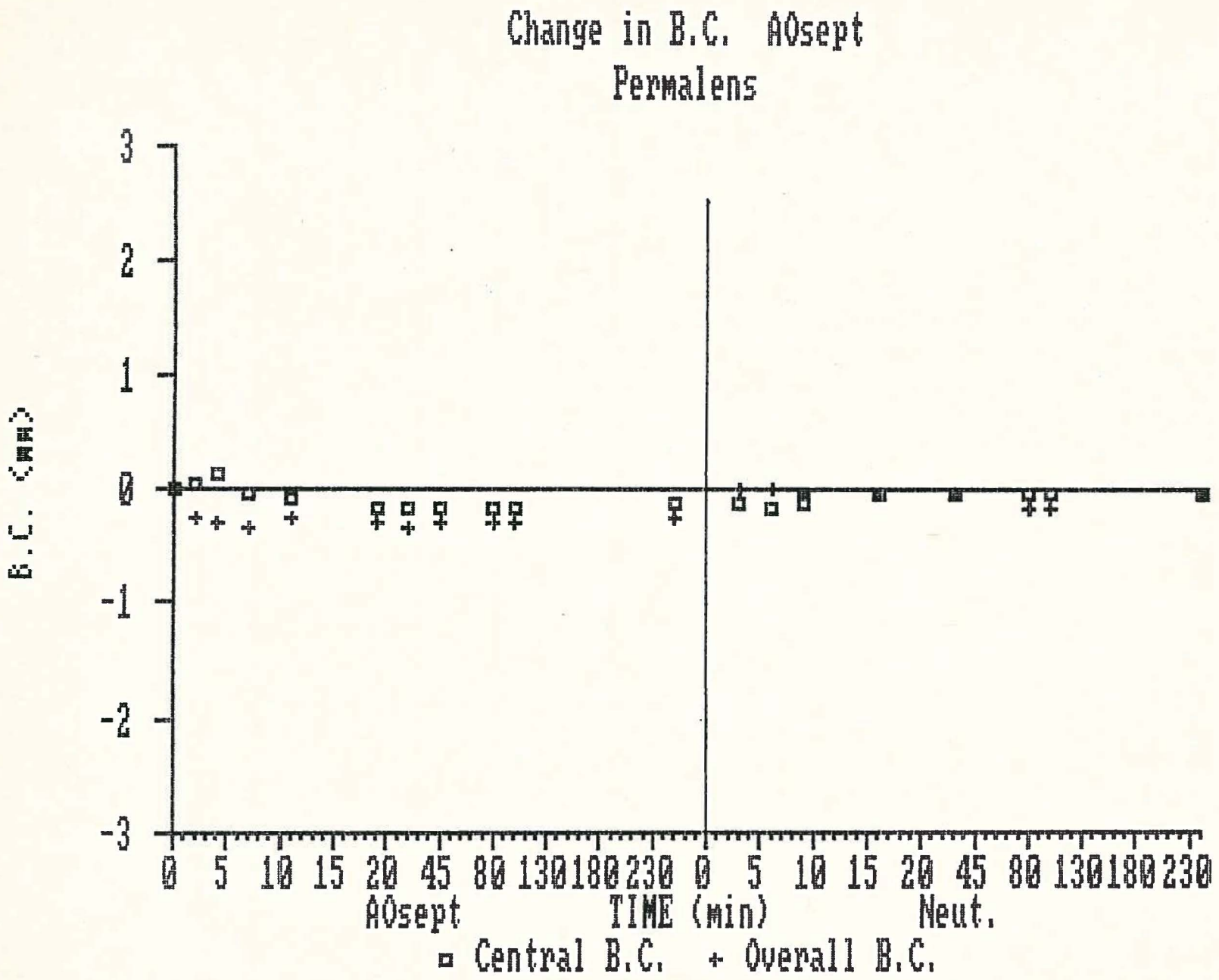

Change in B.C. AOsept
Permalens
B.C. (mm)
3
2
1
0
-1
-2
-3
0 5 10 15 20 45 80 130 180 230 0 5 10 15 20 45 80 130 180 230
AOsept
TIME (min)
Neut.
▫ Central B.C. + Overall B.C.

FIG 9a

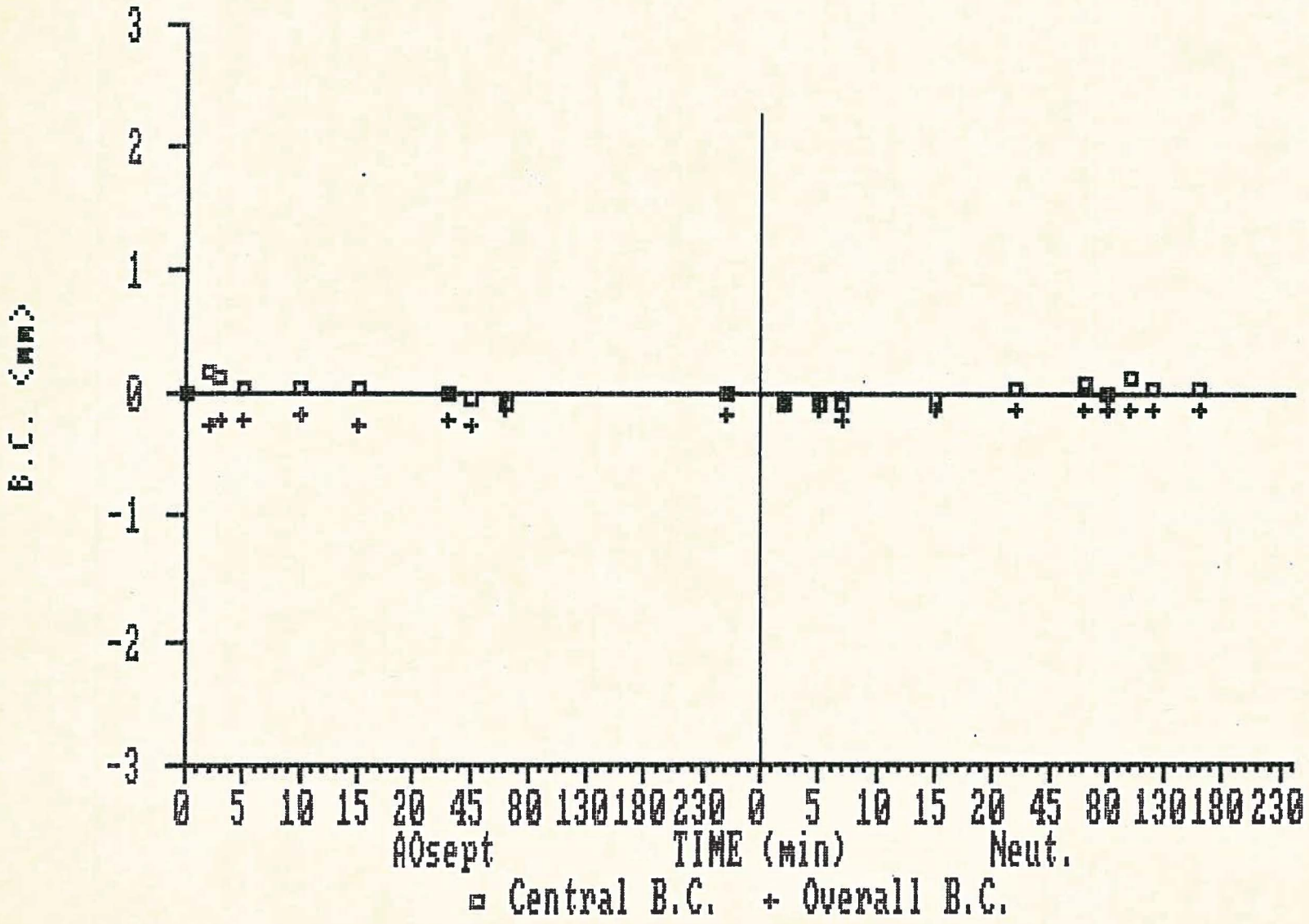

Change in B.C. AOsept
Spectrum
B.C. (mm)
3
2
1
0
-1
-2
-3
0 5 10 15 20 45 80 130 180 230 0 5 10 15 20 45 80 130 180 230
AOsept
TIME (min)
Neut.
□ Central B.C. + Overall B.C.

Fig 9b