The Tetraflex™ is CE marked approved
The Tetraflex™ is currently in FDA study, and not yet approved for sale in the US

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Interpretation of iTrace™ Aberrometry For Accommodative Lenses

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This booklet describes the refractive maps produced by the Tracey iTrace™ aberrometer and compares the effects observed in normal phakic patients and with aphakic patients with monofocal or The Tetraflex™ Accommodative IOL.

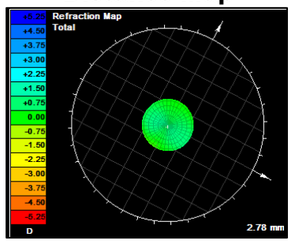
Accommodation—Non-presbyopic patient

The iTrace™ refractive map shows the eye's refractive error at each point within the pupil. The maps shown are 2 dimensional and color-coded. For ease of understanding, hyperopic corrections are coloured blue, emmetropia is shown in green, and myopic corrections are shown in yellow, then orange and then red as the correction increases.

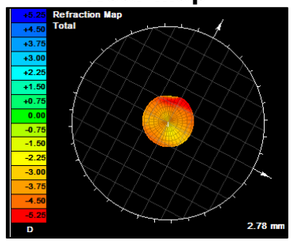
This is the standard refractive map obtained from the iTrace™ aberrometer for a 30 year old non-presbyopic (normal) patient.

The map in the upper left is taken when the patient is viewing a distance target and that on the upper right is when a near accommodative target (an eye chart) is viewed. The lower map presents the difference between the distance and the near maps. In the normal accommodating patient, refraction is close to emmetropia when viewing a distance target and is myopic when viewing a near target.

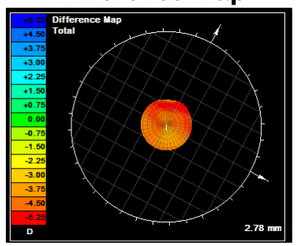
Distance Map



Near Map



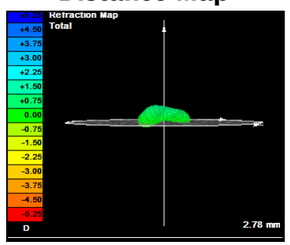
Difference Map



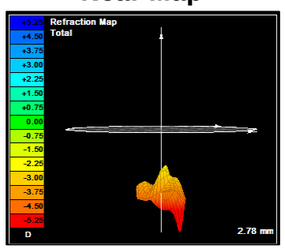
Vertical Refraction Map

The iTrace™ software allows the refraction map to be viewed 3 dimensionally. Below are the same maps viewed 3-dimensionally and tilted 90° to view the map vertically. In this view, it is easier to appreciate the range of refractive error encompassed in each map which is a reasonable measure of depth of focus of the eye.

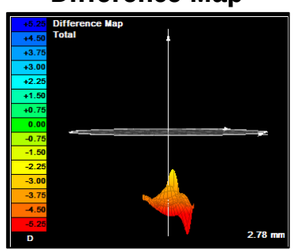
Distance Map



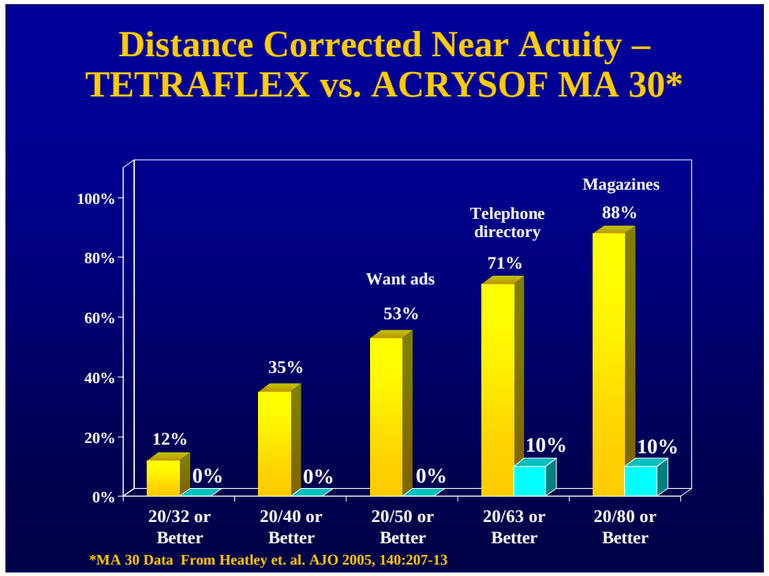
Near Map



Difference Map



Effect on Reading Ability



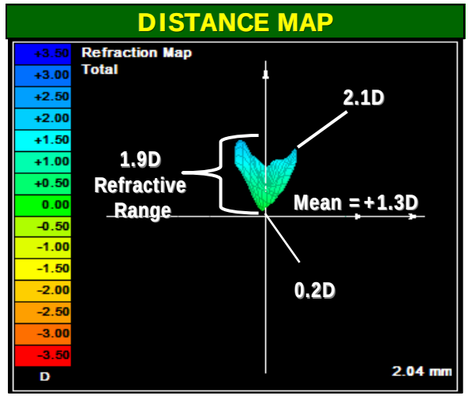
The enhanced depth of field obtained with The Tetraflex lens dramatically improves near vision. Only 10% of monofocal lens patients could read magazines or children's book print size, without the use of reading glasses, but 88% of Tetraflex patients can read magazine print without the use of reading glasses.

SUMMARY

- **The Tetraflex is associated with a widened refractive range and more myopia with near fixation.**
- **Changes in aberrometric profiles produced by The Tetraflex result in improved near vision.**

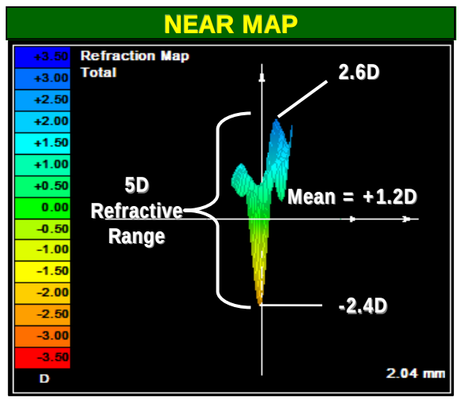
Patient 2: Tetraflex Implant

Below are iTrace refractive maps from a second patient with a Tetraflex implant.



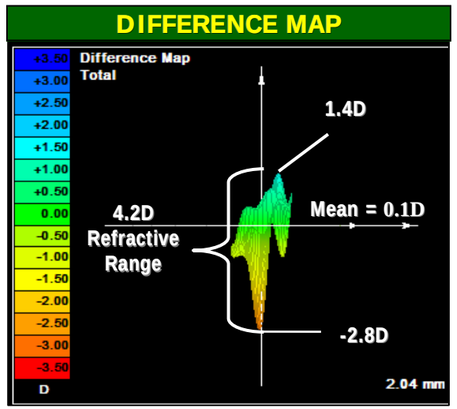
DISTANCE MAP

At distance, the patient shows slightly hyperopic mean refraction with a small refractive range.



NEAR MAP

At near, the patient shows a large refractive range of greater than 4D.

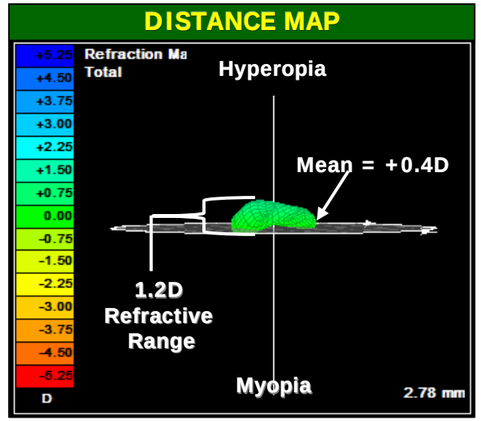


DIFFERENCE MAP

The accommodative response obtained with the Tetraflex implant is a large increase in refractive range (depth of focus) with the same pattern of shift in refraction into the myopic range, with, in this case, as much as 2.8D of myopia.

Interpretation of Maps - Normal Accommodation

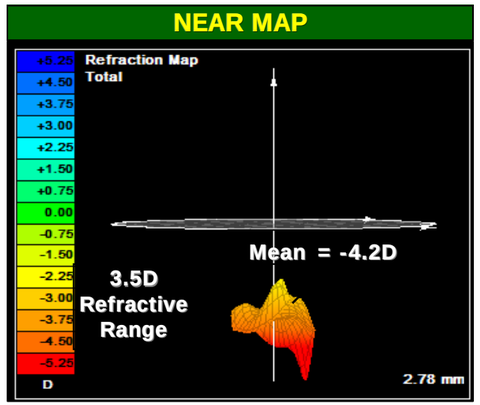
Here we take a closer look at each of the aberrometry maps



DISTANCE MAP

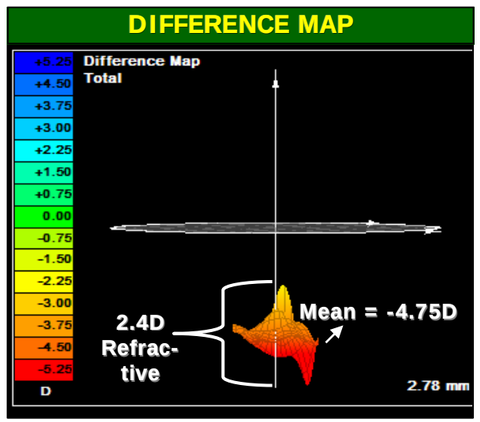
This is the vertical map of the patient viewing a distance target. In this view hyperopic corrections are on top of the axis, emmetropic corrections are in the middle and myopic corrections are on the bottom of the graph. Pupil diameter is represented by the horizontal axis.

In this case the patient has a mean refractive error of +0.40D and a refractive range of 1.2D when viewing a distant target.



NEAR MAP

When this same patient views a near target the mean refractive error within the pupil is -4.2D with almost 3 times the refractive range (3.5D).



DIFFERENCE MAP

The difference map (near minus distance) looks very similar to the near map showing that with accommodative stimulus there is an induced myopia and an increased refractive range.

The difference map is most suited for assessing accommodative amplitude.

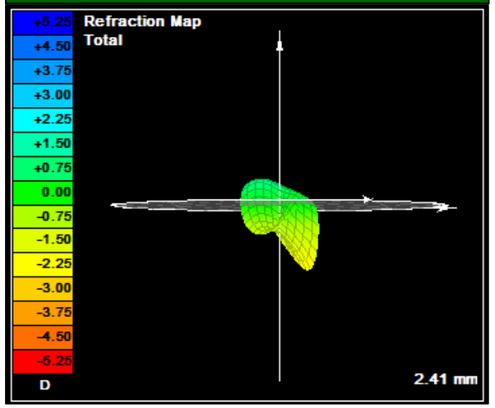
With Normal Accommodation and Near Focus

- **Refraction shifts to more Myopia**
- **Refractive range increases**

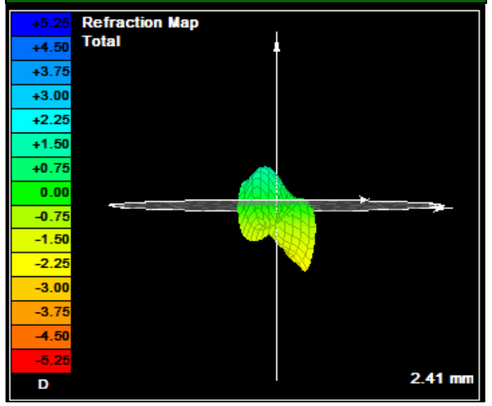
Monofocal IOL - Vertical Refraction Map

On this page is presented the aberrometric profile of a patient with a monofocal IOL in one eye.

DISTANCE MAP

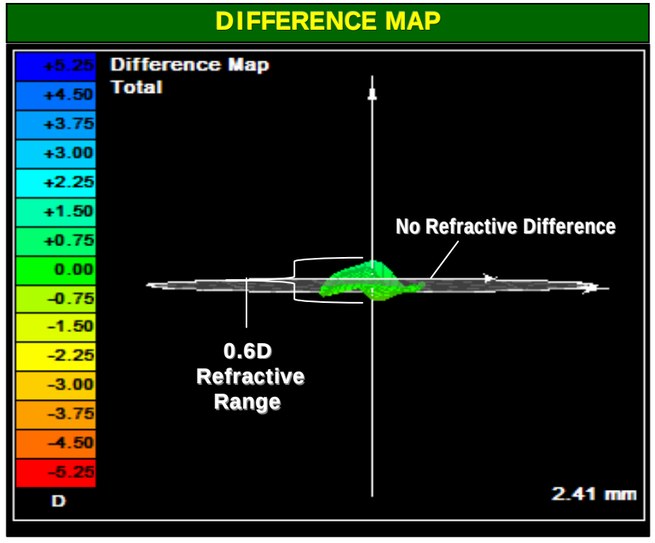


NEAR MAP



Note that the distance and near refraction maps look virtually identical with very little difference observed in the difference map.

DIFFERENCE MAP



A close view of the difference map shows essentially no refractive difference and a small 0.6D refractive range. Thus the monofocal lens yields very little accommodative amplitude.

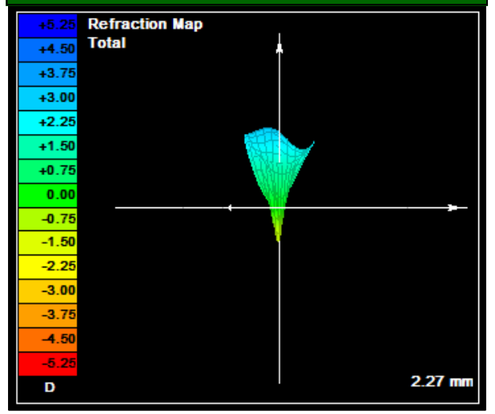
With a Monofocal IOL and Near Focus

- **Refraction remains invariant**
- **Refractive range does not increase**

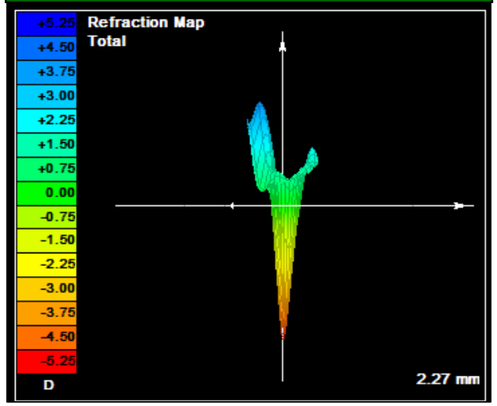
Tetraflex - Vertical Refraction Map

Below is presented the aberrometric profile of a Tetraflex lens implanted in the fellow eye of the same patient.

DISTANCE MAP

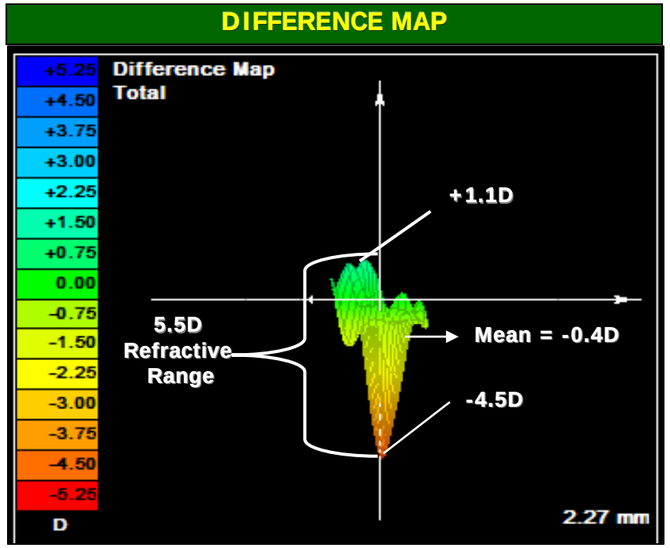


NEAR MAP



In comparison with the monofocal IOL The Tetraflex shows a larger refractive range in both distance and near maps, largely due to more myopic refraction.

DIFFERENCE MAP



A close view of the difference map shows a large depth of field produced by accommodative stimulus.

With The Tetraflex and Near Focus

- **Refraction moves towards Myopia**
- **Refractive range increases**
- ***Accommodative response mirrors normal accommodation***