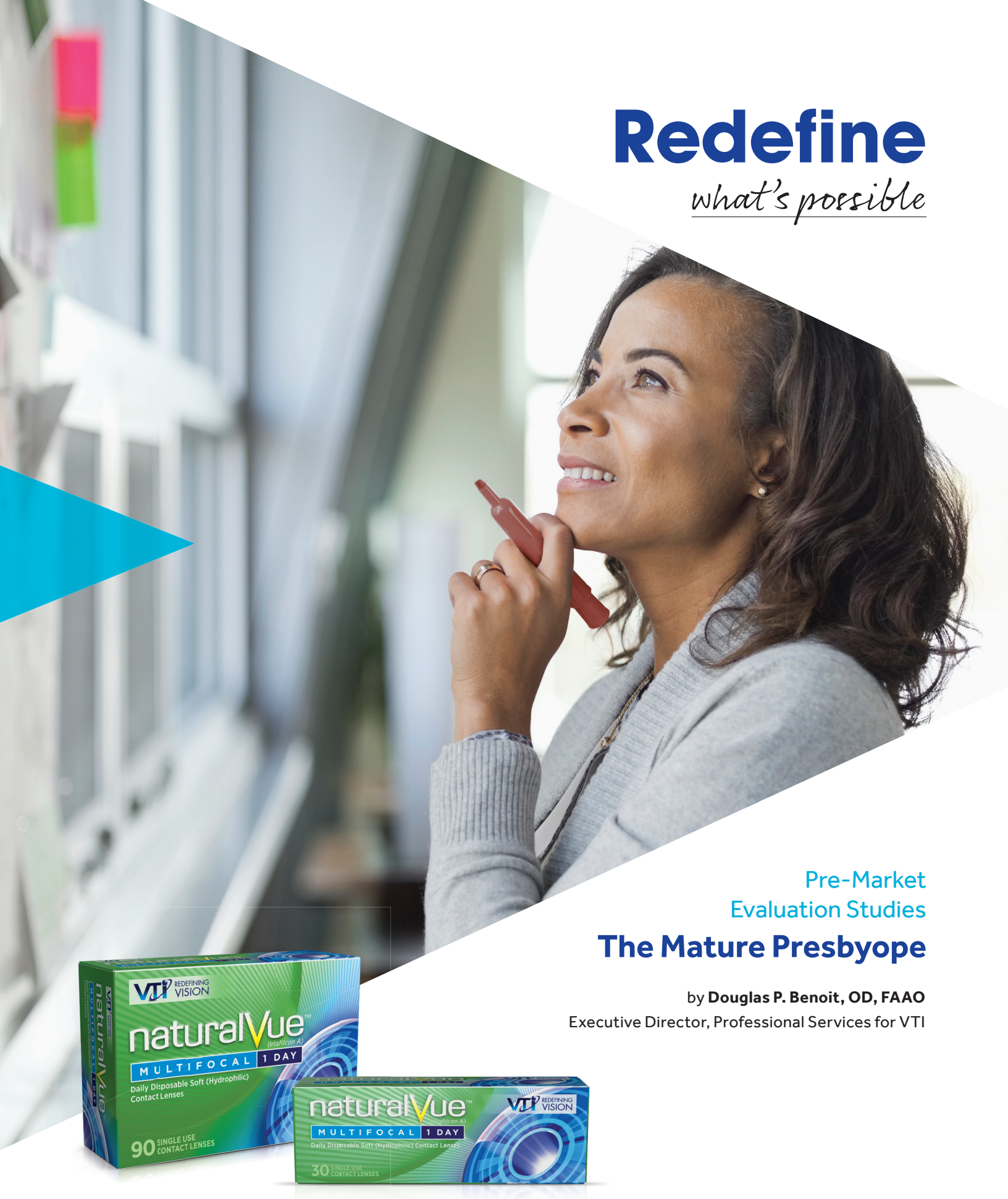
Redefine

what's possible



Pre-Market Evaluation Studies

The Mature Presbyope

by **Douglas P. Benoit, OD, FAAO**
Executive Director, Professional Services for VTI

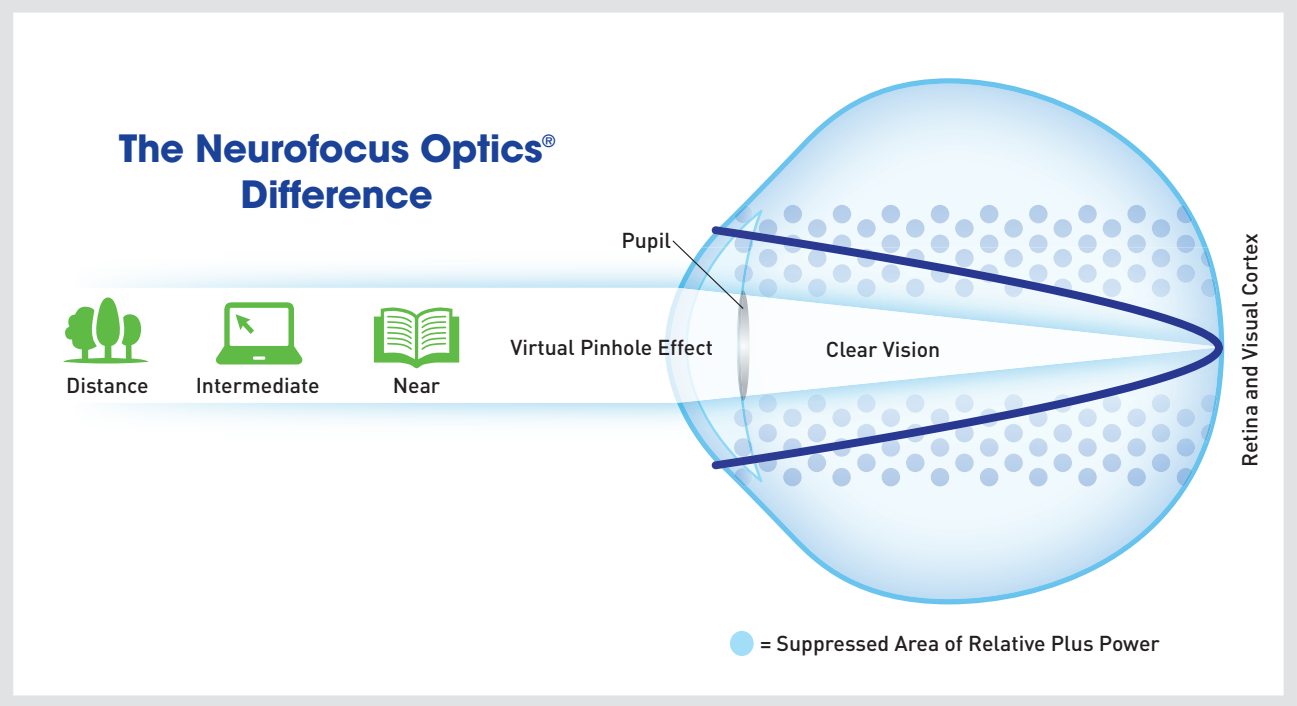
VTI REDEFINING VISION

One of the things that any contact lens company must consider is how well the design of their contact lens is going to work.

It is one thing to have a unique concept, but that might not translate to a practical and successful physical entity. For that reason, almost all contact lens manufacturers will do a pre-market evaluation of their lens.

These are usually small studies, done with just a few investigational sites, who recruit 10–20 subjects each. Ordinarily these trials last just a few weeks which is long enough to evaluate vision and comfort of the new lens and possibly compare it to existing, competitive lenses. It is not often that a contact lens company will test the vision of their lens against spectacle vision.

In 2014, Visioneering Technologies, Inc., began a pre-market evaluation of their new concept. The **NaturalVue® (etafilcon A) Multifocal 1 Day contact lens** is a unique, center-distance, extended depth of focus design. It relies on the visual cortex to suppress the high amount of plus in the lens, thus creating a virtual aperture (optical pinhole) that provides clear vision at distance, intermediate, and near.



Believing that it was better to be bold, they not only tested their new design against existing contact lenses, they tested it against best corrected spectacle vision as well.

Eligible subjects were enrolled and the visual acuity with their current vision correction was evaluated at distance, intermediate, and near. The subjects also answered a number of questions about their current vision correction that covered a variety of daily activities at those distances. Their rankings, on a 0 to 100 scale (where 100 is excellent) were recorded. The habitual correction was removed and an assessment of their external ocular health was performed.

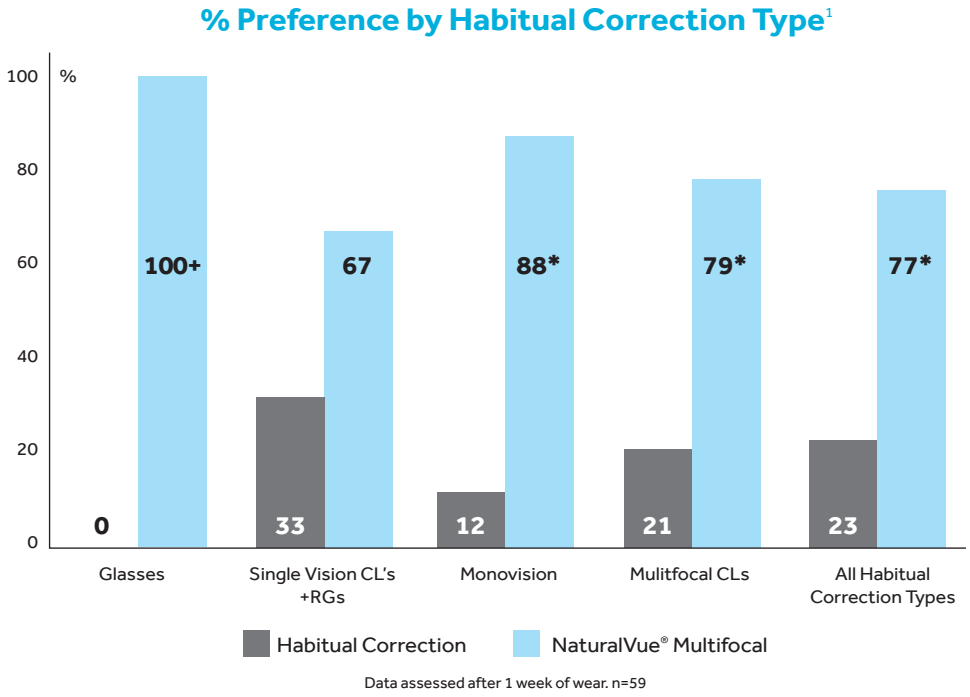
Next, the best corrected spectacle refraction was determined and acuity measured at all three distances, under high and low illumination using high and low contrast logMAR acuity charts. Then the subjects were asked to respond to the same questions and rank their vision under the same situational scenarios.

Finally, the appropriate NaturalVue® Multifocal diagnostic lens powers were determined, the lenses placed on the eyes, and the subject allowed to adapt to the study lenses for at least 10 minutes before vision was evaluated. After the adaptation time had passed, visual acuity was measured at distance, intermediate, and near, using high and low illumination and the same high and low contrast logMAR charts. At the initial and final visits, the range of clear vision (near to intermediate) and stereoacuity were also measured. **Patients were seen after two days** of using the test lenses, to determine if any changes were necessary in the lens powers, and to check ocular health, and comfort with these lenses. If powers needed adjustment, new lens trial packs were dispensed. No adverse events occurred in the two-day period for any subject, nor throughout the study. All patients returned for the final/exit visit after one week. **At this final visit, patients again answered the same group of questions**, ranked their vision at the various distances, and stated a preferred contact lens. Then acuity was measured at distance, intermediate, and near using high and low contrast logMAR charts, under high and low illumination conditions. Needless to say, these study visits took a long time.

The results of this pre-market study were very positive.

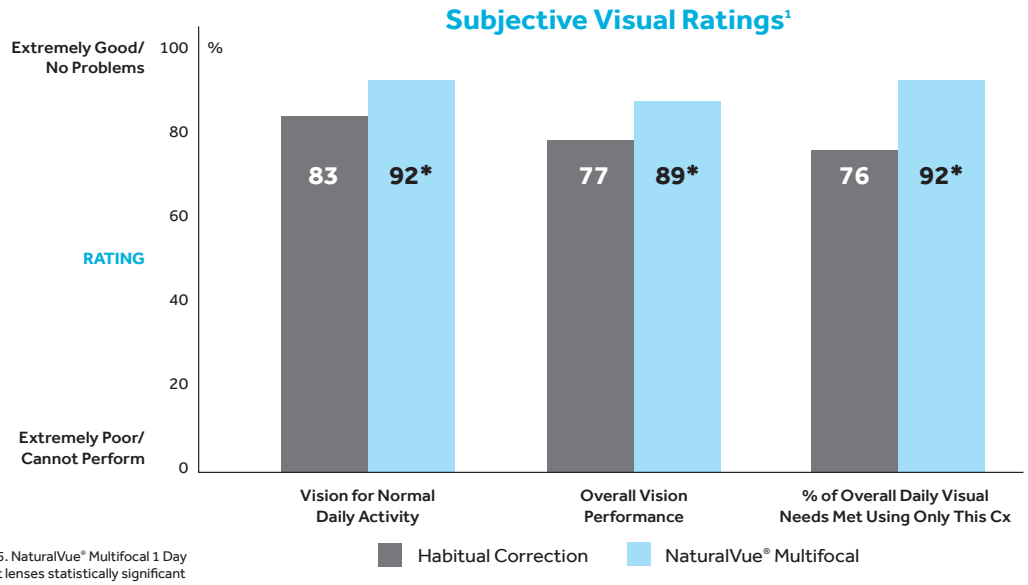
First, among those subjects with a preference, the **NaturalVue® Multifocal was preferred 4:1** over their existing contact lenses. (graph 1)

1 **Patients prefer NaturalVue® Multifocal nearly 4:1 vs. other select multifocal contact lenses.**[1]



Also, **92 % of daily activities could be performed with NaturalVue® Multifocal, without supplemental glasses.** (graph 2)

2 92% of daily visual needs are met with NaturalVue® Multifocal



*p<0.05. NaturalVue® Multifocal 1 Day contact lenses statistically significant difference vs. habitual correction. Data assessed after 1 week of wear. n=59

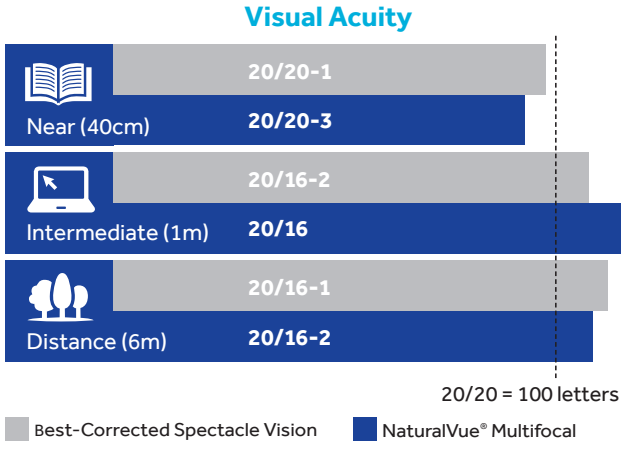
Less reliance on readers for little compromise

Lastly, visual acuity with **NaturalVue® Multifocal was within 2 letters of best corrected spectacle acuity**, at distance, intermediate, and near! (graph 3)[1]

3 NaturalVue® Multifocal provides patients with excellent vision at every distance

Subjective Visual Ratings[1]

- Vision **comparable to specticales**
- Patient achived average VA within **two letters of best** corrected spectacle vision

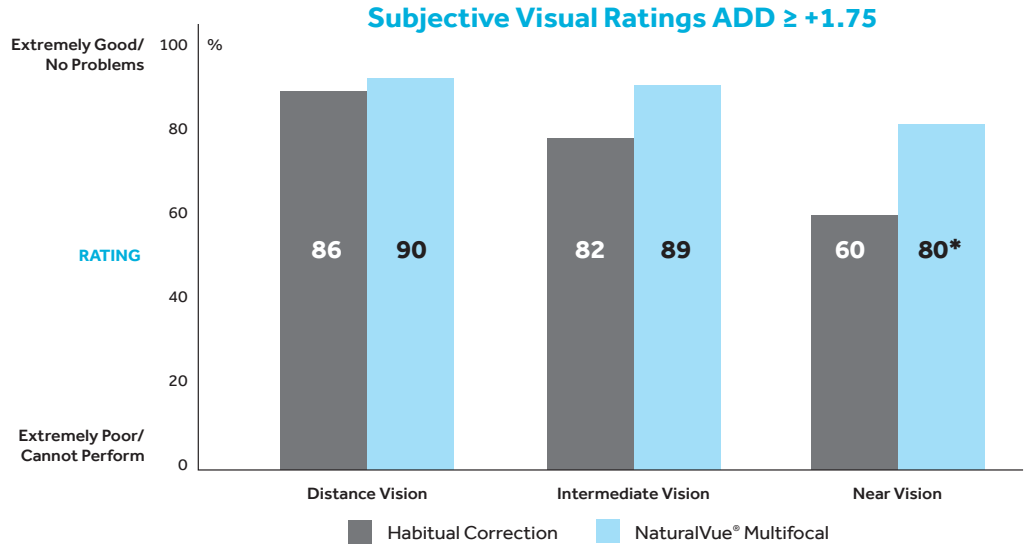


Data assessed after 1 week of wear. No statistical difference in acuity between BCSV and NVMFwas observed. p=0.05

There was a subset of subjects in this study that are often considered more challenging multifocal contact lens patients. That is the group referred to as mature presbyopes. They generally have an ADD requirement of +1.75 and above, and they are frequently 55 and older. The results for this group were equally positive in the pre-market evaluation.

Distance and intermediate vision ranked higher with the NaturalVue® Multifocal (90 and 89, respectively) than with their habitual vision correction (86 and 82, respectively). At near the results were even more impressive. NaturalVue® Multifocal ranked 80 versus 60 with their habitual lenses. (graph 4)

4 Subjective Visual Ratings ADD ≥ +1.75 at all Distances

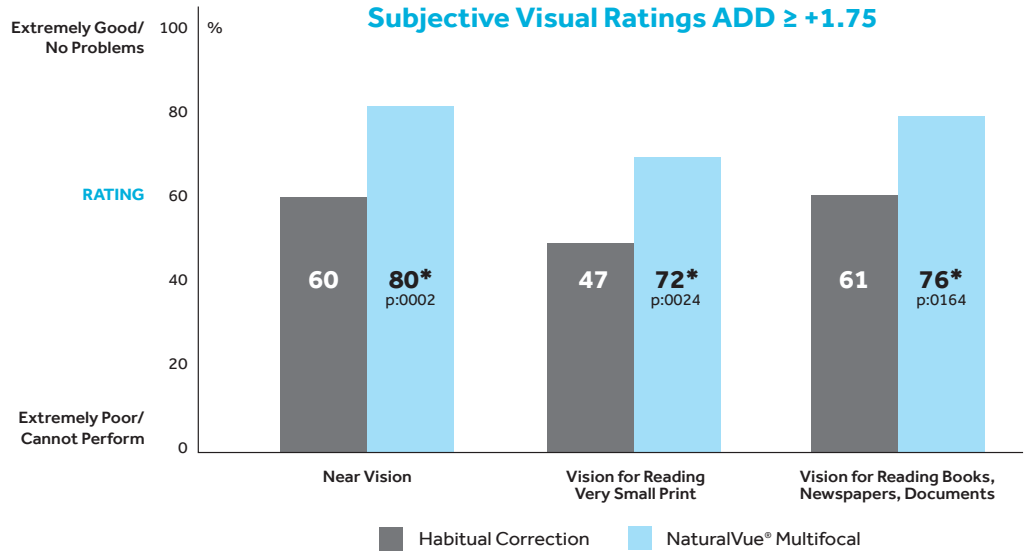


Statistical significance p<0.05. NaturalVue® Multifocal 1 Day contact lenses statistically significant difference vs. habitual correction. Data assessed after 1 week of wear. n=59

Near vision is improved without any decrease in distance or intermediate vision

Lastly, these **patients preferred the vision of NaturalVue® Multifocal for very small near tasks** by a big margin over their habitual correction. (graph 5)

5 Subjective Visual Ratings ADD≥ +1.75 for Near Work and Reading



NaturalVue® Multifocal 1 Day contact lenses statistically significant difference vs. habitual correction. *p<0.05. Data assessed after 1 week of wear. n=59

Near vision is significantly improved, especially for strong reading demands such as for very small print.

A real world case study will illustrate these results.

When the NaturalVue® Multifocal 1 Day contact lenses were commercially available, I was eager to try them on regular patients.

Patient - GR, a 57 year old male insurance executive, new to the office. He was unhappy with the intermediate and near vision with his current center-near multifocal contact lenses. Distance vision was 20/20, intermediate was 20/40, near vision was 20/50.

BCSR: OD -5.50-0.75x180 = 20/20; OS -4.75-0.50x180 = 20/20; OU = 20/20+. Add +2.00 = 20/20. Calculated NaturalVue® Multifocal 1 Day diagnostic lens powers: OD -5.50; OS -4.75. Distance VA = 20/15, Intermediate VA = 20/20, Near VA = 20/20+. At the one-week follow-up visit, the patient reported no VA change and rated vision a 10 at all distances! He was particularly impressed with the ease he had in going from his computer to a contract. He purchased a one-year supply, and **after three years, was still very happy with VA and comfort**. More importantly, despite a change in his near ADD over the three years, he needed no change in his contact lenses.

These results are typical when the fitting guide is followed. This design is a unique, center-distance entity. Fitting it the same way that other soft multifocals are fit, will not be successful. It is a simple process that may seem awkward at first, but will save time in the long run.

Embrace the future with this revolutionary multifocal contact lens! You'll be glad you did.

Results experienced by the patient in this case report may not be representative of every patient.

NaturalVue® Multifocal Pre-Market Evaluation Trial

(n=59)

- Ages 43-65 (Average 50.9 + 5.2)
  - 60% were age 50 or older
  - 78% female, 22% male
- Distance power ranged from -1.00 to -7.25D
- Average Add power +1.81 + 0.41D (Range +1.00 to +2.75)
  - 71% of Add powers were +1.75D or higher
- 3.4% spectacle wearers, 96.6% wearing contact lenses
  - 47.4% in competitive multifocal contact lens brands
  - 35.1% single vision distance lenses with reading glasses
  - 17.5% monovision contact lenses

Contraindications

- Use of any medication that is contraindicated or interferes with contact lens wear, including ocular medications.
- Allergy to any ingredient in the contact lens material.
- History of recurrent eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or an unusual response to contact lens wear.
- Use of any medication that is contraindicated or interferes with contact lens wear, including ocular medications.
- Allergy to any ingredient in the contact lens material.
- History of recurrent eye or eyelid infections, adverse effects associated with contact lens wear, intolerance or an unusual response to contact lens wear.
- The patient is unable or unwilling to follow the Eye Care Professionals' directions for removal and disposal of the lenses or unable to obtain assistance to do so.

Reference: 1. VTI Data on file, 2015.

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