## Are You Putting Your Patients' Health At Risk By Recommending An AREDS Formula with Too Much Zinc?

AREDS Formula Too much zinc?

For thousands of eye health professionals around the country, the nutritional guidelines developed from the NIH's the Age-Related Eye Disease Study (AREDS) have been invaluable. The American Academy of Ophthalmology recommends use of the AREDS2 formulation to help maintain macular health with age.<sup>1</sup>

It offers a solution where once there was nothing.

Dr. Samuel M. Liu, MD, PhD is a board-certified ophthalmologist and Director of Retina & Imaging services at the Princeton Eye Group in New Jersey. Dr. Liu recommends AREDS2 supplementation as a first line of defense to maintain macular health.

Says Dr. Liu, "I tell patients that for macular degeneration, [nutrition] is the only solution at this point. There's no other treatment, no other recommendations that we can do."

Yet while the AREDS trials yielded some useful information, they also raised more questions. And zinc is one of the major points of contention.

AREDS, AREDS2 and other clinical trials have proven without question that zinc alone and in combination with antioxidants makes a difference in macular health.

#### But is the 80 mg of zinc in the original formula too much? Or is this high level of zinc causing harm?

That's what every health professional should be asking before they recommend the original AREDS amount of zinc. And here's why . . .

#### The Problem With Zinc

Zinc is an essential element of life.

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But too much can cause problems.

- Too much zinc can lead to nausea, stomach pains and slightly higher rate of urinary tract infections and kidney stones.<sup>2</sup>
- Zinc also can interfere with the absorption of certain medications like antibiotics and antiviral drugs.<sup>3</sup>
- Zinc can interfere with the body's absorption of other important minerals like iron and copper, leading to anemia and neurological damage.<sup>4</sup>
- Finally, over time, excess zinc in the body can lead to nerve damage in the hands and feet.<sup>5</sup>

For Adults, the RDA for zinc is 8 mg for females and 11 mg for males. The NIH has set 40 mg of zinc per day as the upper tolerable limit intake level (UL).<sup>6</sup>

This puts the original AREDS zinc amount, 80 mg, at double the upper tolerable limit. In addition, many seniors already get zinc in their multivitamins, **bringing their zinc intake to 2-3 times what's considered safe.** 

This became painfully clear during the first AREDS trial. A number of participants were hospitalized for genitourinary tract problems. Researchers and nutrition experts attributed these problems to the 80 mg of zinc.<sup>7</sup>

Concerned with this outcome, researchers decided to assess a lower zinc dosage in the follow up study.

#### **AREDS 2 Clarifies You Don't Need 80 Mg of Zinc!**

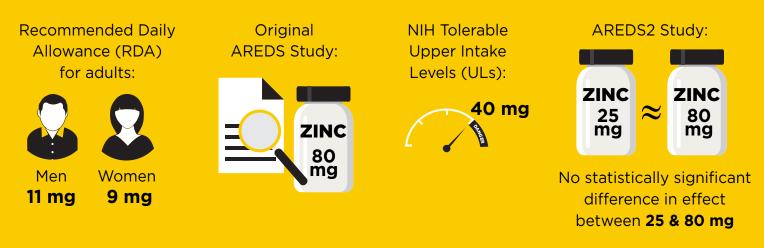
In the AREDS2 study, researchers assessed a lower zinc dose of 25 mg. One subgroup of participants took the AREDS combination of nutrients with a zinc dosage of 25 mg each day. Another subgroup took the AREDS combination with 80 mg of zinc each day.

The eye-opening conclusion?

There was no statistically significant difference in effect between a dosage of 25 mg of Zinc and a dosage of 80 mg.

But this may not be the end of the story . . .

## **How Much Zinc?**



As National Eye Institute (NEI) Division of Epidemiology and Clinical Applications, Dr. Emily Chew, MD, is careful to point out, "While zinc is an important component of the AREDS formulation, based on evidence from AREDS 2 it is unclear how much zinc is necessary."

In other words, if dropping zinc down to 25 mg worked, can you reduce the dosage even further?<sup>8</sup>

The Ocular Nutrition Society picked up on this question in their position paper on the AREDS 2 study, pointing out:

"The amount of zinc recommended in the AREDS 2 formula is over twice the recommended daily intake set by the Institute of Medicine board. While this study did not show the negative effects, it might have been due to the type (oxide) of zinc used. Zinc oxide is not well absorbed into the cells. We look forward to more data and discussion."<sup>9</sup>

So clearly there is no need to stick with the outdated recommendation of 80 mg. Twenty-five milligrams is sufficient. And future research may even establish lower amounts to be effective. Despite this new data, some of the most popular AREDS formulations marketed today still contain 80 mg of zinc. Many health professionals, unaware of the health risks zinc overload can cause, still recommend these formulations.

This is no small oversight. Because the risk of too much zinc was made tragically clear less than a couple decades ago . . .

#### **A Cautionary Tale From Denture Creams**

If you purchase a tube of denture cream today, you might notice on the label "zinc-free" or "no zinc".

This selling point is there for a good reason.

For years, doctors had been reporting mysterious cases of people suffering from a spastic gate, limb weakness and numbness. Even difficulty walking.

It wasn't until some researchers dug a little deeper in 2000 that the reason became clearer. All of these patients were suffering from what's known as "human swayback disease" brought on by copper deficiency. Yet it still took seven more years before the real source of the problem revealed itself: The zinc in denture creams was interfering with copper absorption.

Spurred on by a suggestion of Dr. Marco Spinazzi, MD, Sharon Nations, MD and her colleagues at Texas Southwestern Medical Center looked a little harder at patient records. She found four patients suffering from this problem whose main source of zinc was their denture cream.

Her findings raised the alarm and doctors started identifying this problem around the country.

- A subsequent investigation by another doctor revealed that 11 out the 11 patients suffering from neurological damage from copper deficiency were using excessive amounts of denture cream.
- One Georgia doctor traced the death of his patient back to the zinc overload from denture cream.

In each of these cases, patients were using excessive amounts of denture cream to compensate for poorly fitted dentures. One tube of denture cream contained anywhere from 17 - 34 mg/gm of zinc and was meant to be used over a 6-8 week period of time. Each of the patients experiencing copper deficiency symptoms were using 2-3 tubes a week.

After ABC reported on the zinc overload/copper deficiency problem, denture cream manufacturers sent out a "Dear Doctor" letter, warning dentists and doctors of the dangers of excessive use. They now offer zinc-free denture creams as well.<sup>10</sup>

### People Love Options

Viteyes gives people options:





AREDS 2 based formulation without zinc (a customer favorite)



AREDS 2 based companion multivitamins that do not duplicate AREDS2 formulations



Comprehensive multivitamins that incorporate AREDS 2 based dosages into the formulation

Finally, Viteyes supplements come in a variety of delivery systems – **capsule**, **softgel** and **powder** – to meet different customer preferences.

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#### Your Patients Rely On You

To be clear, there are no documented cases of patients taking AREDS formulations experiencing symptoms as severe as detailed in the denture creams investigation. Indeed, the original AREDS formulation also contains 2 mg of copper to compensate for possible zinc overload induced copper deficiency.

However, it's a cautionary tale eye health professionals need to pay attention to. If vigilant doctors hadn't made the connection between crippling symptoms of copper deficiency and excessive zinc exposure from denture creams, hundreds of patients would still be suffering.

And even with this denture cream tragedy, few doctors are aware of the dangers of zinc overload. Cases of zinc overload induced copper deficiency continue to be missed by health professionals.

A small study published in the *Journal of Clinical Pathology* in 2015 found that doctors often prescribe zinc supplementation in excess while misdiagnosing zinc deficiency.<sup>11</sup> In 5 of the 70 cases reviewed, after starting zinc supplementation, patients experienced anemia, peripheral nerve pain, tingling in their fingers, difficulty with balance and leg nerve pain linked to copper deficiency.

"I think it's incumbent of physicians to understand the latest studies and the latest data," notes Dr. Liu. "These findings underline the lack of awareness of zinc induced copper deficiency," write researchers. "Zinc is an essential trace element, and so clinicians may consider it a safe nutrient rather than a drug carrying potential risk."

AREDS 2 has provided clear evidence that a lower zinc dosage of 25 mg is sufficient for maintaining macula health. And while there is no documentation of patients taking higher doses in AREDS formulas suffering from copper-deficiency induced neurological damage, it doesn't mean this isn't happening undetected.

The dental cream tragedies serve as a warning.

"I think it's incumbent of physicians to understand the latest studies and the latest data," notes Dr. Liu. "Just like I think it would be malpractice for a physician to say a blood glucose level of 200 is acceptable even though that was fine when I was in medical school. It's the same with the AREDS formulation. The AREDS formulation with the lower zinc level has been shown to have the same efficacy but with lower side effects. And that's something I think all clinicians should pay attention to."

# Protect Your Patients' Wellbeing With A Low or No-Zinc Formulation Recommendation

As evidenced by a smattering of blog entries, consumers are becoming aware of the importance of using zinc cautiously. However, consumer awareness of this issue is still marginal. As NEI director Paul A. Sieving, MD, Ph. D points out: "Millions of older Americans take nutritional supplements to protect their sight without clear guidance regarding benefit and risk."

There is no longer any justification for recommending one of the popular AREDS formulations with 80 mg of zinc to your patients. It's up to eye health professionals to help consumers navigate the updated data and find a safe and effective supplement. As explained here, there is no longer any justification for recommending one of the popular AREDS formulations with 80 mg of zinc to your patients.

Fortunately, it's easy to recommend an alternative. Supplement manufacturers like Viteyes have done the work to carefully monitor updated data and create formulations that meet the latest science. Viteyes' AREDS 2 formulations contain either 25 mg or 0 mg of zinc.

Losing your vision is a frightening prospect. Vision loss jeopardizes your independence as well as your enjoyment of life. No wonder so many eye health professionals are excited to offer their patients the concrete vision support found in AREDS formulations.

Now, thanks to updated data and formulations, you can continue to offer these formulations with full confidence. With a low- or no-zinc formulation, you know these formulations will only support health – not put your patients' health at risk.

#### **About Viteyes**

Founded in 2002, Viteyes' broad spectrum of products helps keep your eyes healthy. We work closely with our professional customers and consumers to develop products that fit the spectrum of needs. When combined with an attention to the latest science and quality ingredients, you can see how our products work effectively to help people keep their vision sharp. So they can enjoy life fully. Our vision is built on four core values: Education, Quality Products, Customer Experience and Advocacy.

For more information about our eye health products or to find out about our wholesale or direct-to-consumer options, please contact our sales team. We are happy to provide literature and patient samples to interested professionals upon request.

To order samples, go to **www.viteyes.com/samples** Physician line **248-599-9222** Email **physicians@viteyes.com** 



<sup>1</sup> NIH study provides clarity on supplements for protection against blinding eye disease. NIH press release. May 5, 2013. Viewed 2/10/20 at https://www.nih.gov/news-events/news-releases/ nih-study-provides-clarity-supplements-protection-against-blinding-eye-disease

<sup>2</sup> DeNoon DJ. Zinc poisoning linked to popular denture creams. Web MD. Feb 15, 2011.

 <sup>3</sup> Zinc. Linus Pauling Website. Viewed 2/10/20 at https://lpi.oregonstate.edu/mic/minerals/zinc
<sup>4</sup> Health Professional fact sheet on zinc. NIH website. Viewed 2/10/20 at https://ods.od.nih.gov/ factsheets/Zinc-HealthProfessional/

<sup>5</sup> Denture adhesives. FDA website. Viewed 2/10/20 at https://www.fda.gov/medical-devices/ dental-devices/denture-adhesives#zinc

<sup>6</sup> Linus Pauling website.

<sup>7</sup> Age-Related Eye Disease Study Research Group. A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8 [published correction appears in Arch Ophthalmol. 2008 Sep;126(9):1251]. Arch Ophthalmol. 2001;119(10):1417–1436. doi:10.1001/archopht.119.10.1417

<sup>8</sup> NIH study provides clarity on supplements for protection against blinding eye disease. NIH press release. May 5, 2013. Viewed 2/10/20 at https://www.nih.gov/news-events/news-releases/ nih-study-provides-clarity-supplements-protection-against-blinding-eye-disease
<sup>9</sup> Position statement on AREDS2. Ocular Wellness and Nutrition Society website. Viewed 2/12/20 at https://www.ocularnutritionsociety.org/position-statement-on-areds2
<sup>10</sup> DeNoon, 2011

<sup>11</sup> BMJ. "Doctors often misdiagnose zinc deficiency, unaware of impact of excess zinc: Too much dietary zinc linked to copper deficiency, neurological problems." ScienceDaily. ScienceDaily, 19 June 2015. <www.sciencedaily.com/releases/2015/06/150619085536.htm>.

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