

Current medical literature estimates that between 1.7 to 3.8 million traumatic brain injuries occur each year, 173,285 of them being children and adolescents who have sports and recreation-related injuries. The young, less than 20 years of age, are particularly vulnerable and most likely to have the most severe outcomes from even mild brain injuries. Effective immediate treatment is essential. Even with treatment, both short-term and long-term sequelae frequently develop with these injuries. They include:

- Increased propensity to re-injury
- Headaches
- Cognitive slowing
- Early-onset Alzheimer's
- Second Impact Syndrome (SIS)
- Chronic traumatic encephalopathy (CTE)
- Death

Of particular concern in recent literature has been the effect of SIS and CTE on otherwise healthy young people, even with mild traumatic brain injuries (mTBIs, formerly called "concussions"). Our athletes and our service men and women are a particularly vulnerable group and deserve our utmost efforts to lessen the impact of this deadly and disabling phenomenon. Much work is being done in the field of traumatic brain injury, and we at D & Y Laboratories believe that we have a contribution to make to those efforts.

In order to understand our contribution, it is necessary to briefly summarize our discovery and subsequent research, which was published in the October, 2009, Elsevier International Journal of Physics, Physics Letters A: "Evidence for the Existence of Stable Water Clusters at Room Temperature and Normal Pressure," by Dr. Shui-yin Lo, former visiting faculty member, Caltech; Dr. Geng Xu, former chair of physics of Zhongshan (Sun Yet-Sen); and David Gann, of D&Y Laboratories Inc.<sup>2</sup> The particle outlined in this paper is the basis for our current research proposal. The above referenced paper outlines the procedure whereby a solid particle (which under further analysis was found to be  $H_2O$ ) was isolated from ultra-pure water at room temperature. This indicated that an undiscovered state or phase of water exists, and it is our belief that this newly discovered "state or phase" of water has far reaching ramifications in the field of medicine and health in general.

While working on developing a new form of catalyst for gasoline engines, Gann and Lo stumbled upon an unusual catalytic effect in a particular water sample. Because of numerous strange dielectric peculiarities of this particular water sample, Dr. Lo built a mathematical model to explain this hitherto undiscovered phenomenon of a water **particle**. Describing it in the 1996 paper; *Modern Physics Letters B. Vol. 10, No. 19 Anomalous State Of Ice*<sup>3</sup>, Dr. Lo outlined that model and the discovery of the particle. He called the particle *Ie* after *Ice* formed from an *e*lectrical charge. The paper describes what would happen to a water-soluble substance in pure water if diluted to a concentration of one-part-per-million or less. The calculations are based upon the Debye-Huckel set of equations (Nobel Laureate Peter Debye's definitive work on dilute solutions).

Dr. Lo's calculations demonstrated that when the distance between the ions becomes so great that the ions no longer consistently collide, there would be a great probability that the dominant force would be the Coulomb force, (which surrounds the single charged particle), rather than the attractive forces of the oppositely charged ions. If the ion were no longer free to exchange with its oppositely charged ion, it was feasible that a collapsing inward force would be generated. If this force were generated, water molecules would be pulled inward toward the center of the ion. The force and the resultant pressure can be calculated and is approximately 100,000 psi. A known phase of ice (taking the form of a crystal) exists and forms at 100,000 psi, but forms not from temperature, but from pressure. These particles, however, were forming because of an **electrical** pressure. Consequently, they had to represent a new, undiscovered form of particle, which upon further examination proved to be made solely from  $H_2O$ . The particle was then named "Stable-Water Cluster" (SWC).

While taking hundreds of photographs of this new particle using a scanning electron microscope and an atomic force microscope, one particular photo seemed to indicate an antibacterial action on the part of the particle. The particle of water appeared to be "attacking" or "puncturing" a bacterium. The discovery and photo of this phenomenon led to a collaboration between David Gann and Dr. Lo with Dr. Benjamin Bonavida, then Chairman of the Department of Immunology at UCLA. Using a preparation of water containing stable water clusters, which was added to live blood cells *in vitro*, Bonavida found that solutions containing stable-water clusters caused a selective triggering of TH1 vs. TH2 cytokines. In fact, the triggering was hundreds to thousands of times greater than controls. This study was published later that year, and a substantial backlash occurred. This was, in part, because of the parallels between the ultra-dilute solutions employed and the nature of homeopathy.

Nothing was done further with this stable-water cluster investigation as regards human immunology for several years, due to a lack of funding among other things. Then, in 2006, David Gann was asked to give some of the Bonavida preparation of stable water clusters to a family member of a business associate, who was familiar

with the Bonavida study. This family member had pancreatic cancer, had not responded to conventional chemo- and radiation therapies, was in hospice, and was given only a few months to live. She began drinking a solution of the water, went into remission within four months, and is today considered cancer-free. She was the first of, now, several people taking the water who have gone into cancer remission after drinking this water. We have also seen recoveries from a variety of other diseases. Some of the diseases in which we have seen impressive improvement or a complete cessation of symptoms include autism-related disorders and a variety of autoimmune diseases.

Following the Bonavida study, in 2007, Gann and Lo together with Dr. Norman Shealy, a neurosurgeon and medical researcher, did a small clinical trial<sup>5</sup>. In this trial, ten healthy subjects had baseline blood drawn to measure TNF-A, IL-1B, IL-6, and IFN-Y (Interferon-Y). Each subject was asked to drink water that contained these stable-water clusters four times a day for 45 days. The results were impressive. The subjects who drank the water showed large increases in Interferon-Y at the end of 45 days. Dr. Shealy stated in the summary of the results: "The water may produce a significant enhancement of immune function in human beings. Larger studies should be done with perhaps a broader overview of immune function. Dysfunctions of the immune system are major factors in allergies, autoimmune diseases, cancer and even atherosclerosis and diabetes. The implications for immune health are obvious." The study was unpublished because of the small numbers.

In 2009, a large study was conducted of this water cluster's immediate effect on the human body. The study consisted of 78 volunteers over the age of 45 and free of acute disease. An infrared image was taken of each volunteer (T0). Each then drank plain distilled water. Ten minutes later, another infrared image was taken (T1). The same volunteers then drank water containing stabilized water clusters. Another twenty minutes later a third infrared image was taken (T2). The temperature changes detected with these infrared pictures were then calculated. Statistically significant differences in the temperature responses were found in all 78 subjects. The body surface temperature differences found before and after drinking the stabilized water cluster solution indicate that these molecules induce a rapid physiological response from human body. Its infrared pattern is entirely different from that of ordinary water molecules. We believe this observation reflects an important role of stabilized water clusters in cell-to-cell communication.

This effect, if demonstrated with human cell culture experiments, could increase our understanding of signal and control processes among cells. It would also shed light on the mechanism of healing damaged tissue, as in the case of revascularization following heart injury. In the human body, the gastrointestinal and reproductive systems are crucial to the survival of individual hosts; experiments with these cell lines could bring exciting new information to disease processes and cure. Currently, we continue to see rapid and dramatic changes in infrared images after

the intake of these water cluster molecules in patients with a variety of medical disease entities.

A preliminary study is underway with children in treatment programs at the Institute for the Achievement of Human Potential (IAHP) in Philadelphia. The goal of therapy at the IAHP is to develop new brain pathways to restore function after brain injury in children and teenagers. In this study, the rehabilitation care teams at IAHP are adding stable water clusters {oral, inhalation (via nebulizer) and topical applications} to the treatment of a small group of brain-damaged children who have reached a plateaued curve of improvement on their current treatment regimen. The categories of brain damage being treated in the study include: failure to thrive, cerebral palsy, autism spectrum disorders, and intractable seizures.

Preliminary results are encouraging. Evaluations during the first few follow-ups have demonstrated across the board improvement in all categories of these children, and they continue to improve. Though numbers are small, the parents and caregivers of these children, as well as their medical teams, have seen enough improvement to warrant further investigation and continued utilization of this tool in their ongoing medical plan. In fact, the number of children treated with SWC is being increased at the IAHP, and the program expanded to include other countries. Though this is still very early in the study, the researchers have been encouraged by new gains in this group of children who had previously failed to show any further improvement on their very complex therapy plan. The hope is to eventually be able to treat these children with a program including stable water clusters as close to the time of brain injury as possible. We believe that doing so might limit the devastating effects of the brain injury in the immediate aftermath.

Other work, done in China, California, and Panama, has demonstrated dramatic improvement in both children and young adults with Autism Spectrum Disorders. Again, a combination of both oral ingestion, inhalation, and topical application of stable water clusters was used. The vast majority of children and teens in this group treated with SWC, have shown ongoing improvement of both physiological and psychosocial parameters. One might postulate that, as we believe is happening in the brain-injured children at IAHP, new pathways are being developed in the brain, perhaps bypassing those that are responsible for the symptoms characteristically thought of as in the spectrum of autism. The possibility in brain injury, both acute and chronic, is that SWC can assist in development of new brain pathways around an area of injury and ameliorate the initial damage by limiting the effect of inflammatory cytokines in the initial period after injury. One wonders what a study utilizing a Functional PET scan would demonstrate as to the function of stable water clusters in acute brain injury. We are currently endeavoring to set up such a study in China.

The exact mechanism of action of this particle is unclear and is not disease-specific. A growing body of evidence suggests that these stable water clusters can act to correct altered cell functions at the molecular level. Dr. Bonavida's latest research,

soon to be published, has expanded on his original study and provides exciting new insight. The results of this research would place the mechanism of action, at least in part, at the DNA/genetic level. In fact, these clusters modify regulation of gene expression.<sup>7</sup> In this study, Bonavida et.al. hypothesized that treatment of cells with a water preparation containing SWC might induce molecular and genetic changes in human cellular systems. They tested this hypothesis on human melanoma cell lines as a model for analysis in vitro. Their results suggested that cells can respond to relatively fewer molecules than the previously thought physiologic levels. They examined the effect of SWC on cell viability, proliferation, expression of immune death receptors, and response to death-ligand-induced apoptosis. In addition, they examined whether genetic changes might also take place. The preliminary findings demonstrate that treatment of melanoma cell lines with SWC inhibits cell proliferation, upregulates the expression of death receptors, sensitizes the tumor cells to FasL-induced apoptosis, and selectively modifies gene products that regulate growth and the apoptotic pathways. The fact that stable water clusters have a proven effect at this level opens the door to the possibilities of other similar actions elsewhere in the body.

Our knowledge of the physics of the particles would seem to indicate that they bring an electrical and vibrational force at the molecular level of DNA and protein synthesis. This force seems to alter the incorrect genetic sequencing responsible for the failure of these cells (T-cells, for example) to function as they were genetically predisposed to do. Likewise, SWC's ability to rapidly reduce and clear the mediators of inflammation would seem to be due to an alteration in the response of T-cells and of their subsequent triggering of inflammatory cytokines. The ability to alter the body's response to injury at this level opens the door to new, more effective, forms of treatment for both brain and spinal cord injury.

The damage to nervous tissue with brain and spinal cord trauma often does not explain the degree of injury to tissue cells, nor does it adequately explain the degree of deterioration often seen days to weeks after injury. In mTBI, brain injury is the result of dysfunction in neuronal metabolism and the microscopic anatomy of the brain. It has two distinct phases. The first phase is the initial injury and is diffuse axonal injury (DAI) caused by direct force.<sup>8</sup> The second, delayed phase, is the more troublesome. A cascade of inflammatory mediators follows the first phase. This cascade produces edema, ischemia, and the presence of free radicals. Excitatory amino acids and ion release follows, with resulting programmed cell death.<sup>9</sup> Disruption of axonal neurofilament organization occurs and impairs axonal transport, leading to axonal swelling, Wallerian degeneration, and transection.<sup>10</sup> Release of the excitatory neurotransmitters acetylcholine, glutamate, and asparate, and the generation of free radicals may also contribute.<sup>11</sup>

When this inflammatory cascade occurs, the quantity and duration of activity of these cytokines can determine the viability of cells in the marginal injury zone, as well the entire injured area. Current therapy seeks to limit this cascade and its

effects. Furthermore, the etiology of SIS would seem to be a loss of the ability of small arterioles to autoregulate, presumably due to the continuing presence of these mediators in injured nervous tissue. Return to normal function and healing of injured tissues is slow and subject to major regression if even mild re-injury occurs. Continued presence of these mediators or scarring due to their lengthy presence may at least contribute to the progression of this process to CTE. It is obvious then, that rapid clearing of the mediators of inflammation and healing of arteriolar tissue is essential to preventing SIS, and by extension, CTE.

Many anecdotal cases have been observed of a profound anti-inflammatory effect of SWC in humans. This is evident in acute and chronic arthritis, burn injuries, and in muscle soreness after exercise. The rapid improvement of signs and symptoms of inflammation in people ingesting SWC is impressive. We know that SWCs disperse rapidly throughout the body, within minutes after oral ingestion and seconds after inhalation or intranasal entry. This would make it especially helpful in the treatment of acute brain injury, as presumably relief from the results of inflammatory cytokines could be achieved rapidly after initiation of treatment.

A study is currently underway measuring the effect of SWC on inflammatory cytokines in mice after stimulation with lipopolysaccharide (LPS). We expect the results will show that after this inflammatory stimulus, mice drinking SWC have a dose-dependent reduction in production of inflammatory cytokines, as compared to mice drinking plain distilled water. Further study is needed, using an animal brain and spinal cord injury model, on the effect of stable water clusters on acute and chronic brain injury. Confirmation is needed as to its rapid disbursement throughout the body and immediate effects. Comparisons of extent of damage and time of healing must be correlated with animals drinking SWC vs. plain distilled water, as well as efficacy of delivery of oral versus inhalation systems. Finally, further research is needed to delve more deeply into the mechanism of action of this highly reactive particle and demonstrate more therapeutic applications.

There is no question that this particle exists and that it is simply water. We have nearly 17 years of study now and have complete certainty on its formation, composition and concentration. Our observations and a growing number of anecdotal cases tell us unequivocally that stable water clusters can benefit in, among other things, disease entities connected with the generation of inflammatory cytokines. Further studies are needed in an animal model to prove beyond question that this benefit exists. The efficacy of this particle in reducing the negative outcomes resulting from an inflammatory cascade should be proven so that it can become a routine part of treatment of mild brain trauma and other nervous tissue injuries. This would be a first big step toward mitigation of the devastating effects of this perplexing and growing problem.

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