MICROBARIC® OXYGEN THERAPY

A Promising New Medical Treatment for Moderate to Severe Autism

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Microbaric® Oxygen Therapy (MBO_2) is a new medical treatment that has shown promise in helping to improve the quality of life for those affected by moderate to severe autism. It is designed to be used in the home and managed by parents or caregivers. MBO_2 has produced very encouraging results in pilot studies and is now ready to be the subject of randomized, double-blind, placebo-controlled trials – the scientific gold standard for establishing the safety and efficacy of new drugs and treatments. MBO_2 is the culmination of many years' experience in the fields of oxygen in medicine and human physiology, thousands of hours researching the autism literature, and a series of seven pilot studies, the first of which commenced in 2010 to test the concept. The supporting citations listed in this article and many others are discussed in our scientific papers published in 2018 and 2020 respectively. Links to these papers can be found on our website [www.microbaric.com].

MBO_2 involves breathing an elevated concentration of oxygen (i.e., a hyperoxic gas) for therapeutic purposes. The elevated level of oxygen has a powerful anti-inflammatory effect, supports the growth of new capillary beds in regions with low blood flow and improves tissue oxygenation. We believe it promotes normalization of the brain in those regions affected by autism. While MBO_2 utilizes oxygen as the therapeutic medium, it does not require patients to be pressurized in order to be effective. Thus, patients are not encapsulated in any type of whole-body chamber and can enjoy considerable freedom during the course of treatment (Figure 1).

MBO_2 can be administered while the patient is sitting in any room at normal atmospheric pressure. The safety concerns associated with any form of hyperbaric oxygen therapy do not apply. MBO_2 does not require the placement of any type of chamber and associated equipment in the home or travel to a hyperbaric center for treatment on a schedule convenient for the provider.[1]

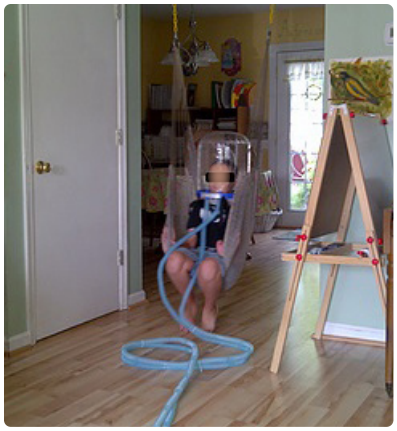

Figure 1: Subject enjoying his swing during treatment.

If you are caring for a family member affected by moderate to severe autism and dealing with problem behaviors, such as violent rages, on a day-to-day basis, you know how exhausting and demoralizing this can be. This was the case with one of the families in our pilot study. We worked with the family's two older boys (of four) who had autism and became Subjects 1 and 2. Before the boys started MBO_2, the parents were considering institutionalizing the oldest boy. At 14, he was bigger and stronger than most men and was inclined to become violent whenever he got "no" for an answer. His parents feared for their own safety, as well as for that of their three youngest boys and the wife's mother who was helping take care of the children. Within six months of starting MBO_2, however, the oldest son had his last episode of violence and has since gone on to be a positive influence in the family.[1]

If your child with autism is old enough, you likely know that there are few, if any, interventions that make major and lasting changes to the quality of life of children with autism who are older than five years of age. What you may not know is that a substantial body of evidence indicates autism is a biological disorder involving hypoperfusion (low blood flow), neuroinflammation (inflammation of nerve tissue) and impaired capillary development (angiogenesis) affecting one or more regions of the brain. This pathology manifests in the behaviors seen with autism.[2] This fact strongly suggests that the psychosocial problems affecting children with moderate to severe autism cannot be significantly addressed unless a treatment becomes available that positively impacts the underlying physiological and pathological issues. Based on our research, we believe that MBO_2 will be found to have such attributes.

The Development of MBO_2

The inspiration for MBO_2 came from an evening we spent with Canadian physician Pierre Marois, M.D., discussing his pioneering research in hyperbaric oxygen therapy for cerebral palsy (CP). In his study, the benefits achieved with the placebo control group who were given air at 1.3 atmospheres were similar to or better than those seen in the treated group who were given oxygen at a pressure of 1.75 atmospheres.[3] These results could be interpreted in two ways: no one benefitted or everyone benefitted. Based on our knowledge and experience, we believed it was the latter. This led us to consider a new approach to hyperoxic therapy for several neurological disorders including autism spectrum disorder (ASD). We also wondered whether increased atmospheric pressure applied in a whole-body chamber was an essential aspect of hyperoxic therapy for such neurological applications to be effective. If this were the case, then we thought it unlikely pressurization in a whole-body chamber was essential to the treatment. This in turn would mean that hyperoxic therapy could be more convenient, safer and less expensive than that involving increased pressure. We determined to find out how effective a therapy for ASD would be that involved breathing hyperoxic gas at normal atmospheric pressure.

Testing Our Hypothesis

In 2010, we funded the acquisition of equipment for a prototype treatment system and began a small series of pilot studies of MBO_2. Using these systems, we treated five preteen and teenage boys with autism over periods as long as 18 months. The four families that took part were geographically separated and did not know each other.[1] In January 2020, we began treating five-year-old identical twin girls who, again, are unknown to, and geographically separated from, our other subjects.

For inclusion in a pilot study, a participant was required to have a diagnosis of ASD confirmed by a qualified professional and be within the age range of 5-18 years at the commencement of therapy. We did not specify gender or place any limitations on severity of symptoms. The only exclusions were for individuals using prescription pharmaceutical drugs that might produce a possible adverse reaction to the hyperoxia.[1]

In several of the early cases, the subjects progressed from severe ASD to very mild ASD over the course of some 18 months. This was reflected in a reduction in total ATEC scores of 94 percent or greater (Figures 2 and 3). We are unaware of this level of improvement being reported in the scientific literature, particularly for children as old as the preteens and teenagers in our study. As part of our study protocol, parents/caregivers were asked to submit ATEC reports on a regular basis during the course of treatment. We also asked for short subjective commentaries from each of the mothers to tell us about events that had occurred in the reporting period and that were significant to them. These commentaries were submitted voluntarily. Some notable examples of these events are given below. Many more are detailed in our case report.[1]

Autism **T**reatment **E**valuation **C**hecklist

To establish the severity of autism and monitor change in all our cases, we adopted the Autism Treatment Evaluation Checklist (ATEC) developed by the Autism Research Institute (www.autism.org). The ATEC is an objective tool designed to be completed by parents/caregivers. Its four subscales cover the following areas: Speech/Language/Communication; Sociability; Sensory/Cognitive Awareness; and Health/Physical/Behavior. Scores in each subscale are combined to produce a total score. The higher the score, the more severe the autism of the individual. The highest possible score is 179. A total score of 104 or higher is associated with severe autism; a total score of 30 or less is associated with mild autism.

As previously described, Subjects 1 and 2 (Figures 2 and 3) are brothers. Subject 1, the younger of the two, was 12 and a half years old when we started the therapy program. He had a mean ATEC score of 101, just below the 104 baseline for severe autism. Subject 2 was the older child who suffered from the rages previously described. He was a few weeks away from his 14th birthday when he started MBO_2 and had an average ATEC score of 82. With the treatment, his rages subsided and, by about the sixth month, had ceased. He also began to mature. Sometime before his 15th birthday, he spontaneously threw out his juvenile toys and, for the first time, did not request a toy for his birthday that was geared to a child of a younger chronological age. After about 18 months of regular treatment, both brothers were achieving ATEC scores of about 10, and their mother decided to stop treatments. Their stability has persisted despite several instances of disruption, including the loss of a family pet, moving to a new house, and, for the younger brother, entering puberty. The brothers are now young adults and are actively involved in running a small farm owned by the family (Figure 4). Periodic follow-up of these subjects continues.

Figure 4: Subject 2 getting ready to plow a field at age 19

The most frequent and detailed commentaries we received were from the mother of Subject 4. Her son was severely autistic. At the time we started MBO_2, he was 12 years old and had an average ATEC score of 113. His mother told us of many "firsts" that occurred while he was receiving treatment. These included one instance in which he spontaneously kissed his mother, something he had never done before. Later he cooperated in getting a haircut and in undergoing both a medical examination and a dental checkup, including teeth cleaning in a single week. This was the first time he did not need to be sedated or restrained by several adults in order for the dentist to complete his work.[1] She also sent us a nine-minute video recorded by her husband in which she told us in her own words how MBO_2 has impacted her family. We did some minor editing of the video and titled it "A Caregiver's Story." You can see the video on our website at www.microbaric.com

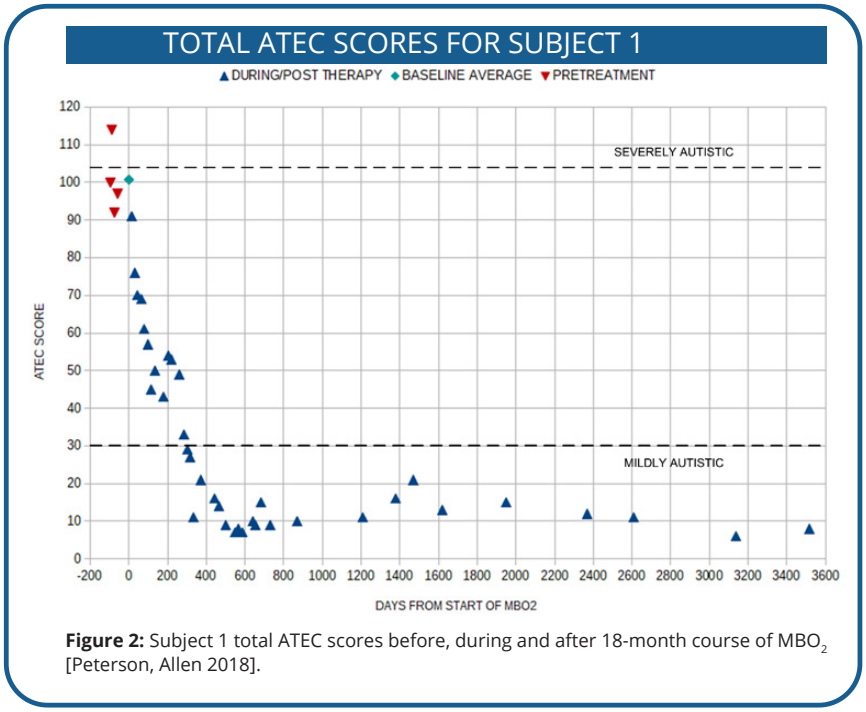

Figure 2: Subject 1 total ATEC scores before, during and after 18-month course of MBO_2 [Peterson, Allen 2018].

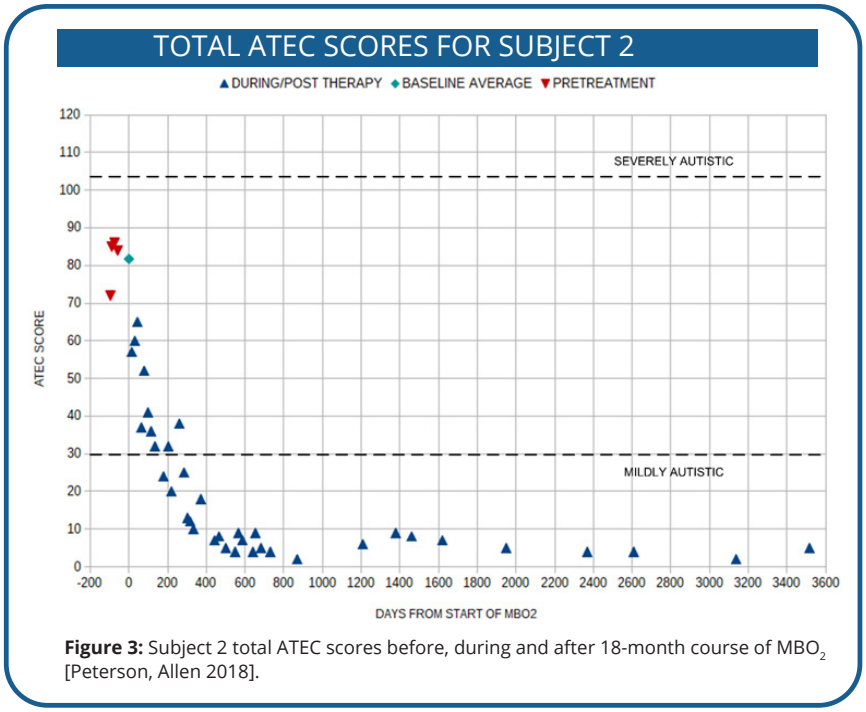

Figure 3: Subject 2 total ATEC scores before, during and after 18-month course of MBO_2 [Peterson, Allen 2018].

Delivering the Therapy

The therapy was administered by the primary caregiver, who happened to be the mother of the children in each case. Prototype equipment was set up in the home in a room of the family's choosing. Treatment was delivered using our protocol at any time of day that fit in with the family's activities. To help with patient acceptance, the systems were set up to allow the children as much freedom of movement as possible and to facilitate both work and play during the treatment (Figure 5).

Figure 5: Home school with Mom

The pilot studies were conducted using our prototype system, which we have since refined with the help of feedback from the families. The improved system will be easy to install and operate, entirely self-contained, generate its own hyperoxic gas, and look like a piece of furniture so that it blends into the room when not in use.

The results that we saw in the five pilot studies, as well as those we are now seeing in the response of the twin girls, strongly indicate we have developed a highly effective, broad-spectrum medical treatment for ASD that, while still subject to confirmation in controlled clinical trials, is safe and easy for non-medically trained caregivers to administer. We believe MBO_2 is suitable for use in the home by parents. It could also be easily integrated into multiple-user settings, such as schools, care facilities and group assisted-living situations.[1] When applied at the appropriate dosage, it appears likely that MBO_2 will be effective independent of the patient's age, whether very young or an adult.[2]

Final Critical Steps

The changes in autism severity seen during our pilot studies of Microbaric® Oxygen Therapy show it has the potential to be an effective medical treatment that can have a positive impact on the symptoms of autism. The following key factors support our assertion of the therapy's potential.

Regular objective reports submitted by parents/caregivers using the ATEC scoring system show consistent improvement over the periods of the pilot studies.[1]

Subjective observations submitted voluntarily by the caregivers who treated their children using Microbaric® Oxygen Therapy over the periods of the pilot studies also show improvement and support the ATEC results.[1]

Numerous reports in the scientific literature highlight regional hypoperfusion and neuroinflammation in autism brains.[2,4,5,6]

Two studies in the scientific literature report increases in regional perfusion measured in autism brains of 114 children aged 3–16 years following courses of HBO_2.[2,5,7]

A study published in 2016 reported finding *intussusceptive angiogenesis* in regions of donated postmortem autism brains, over a wide age range, but not in non-autistic postmortem "control" brains in the same age range. This finding gave us important insight into what we believe to be the effect of hyperoxia in autism. *Angiogenesis* is the physiological process that forms new blood vessels from preexisting ones. There are two types of angiogenesis: *sprouting* and *intussusceptive*. Sprouting angiogenesis is the most commonly recognized form and supports the growth of the large capillary networks associated with normal tissue and organ development. Intussusceptive angiogenesis, first described in 1986 by Caduff et al., divides existing capillaries to form a denser network within a highly localized, already perfused area. We believe this leads to the creation of the hypoperfused zones seen in regions of scanned autism brains.[2,8,9]

The only critical actions remaining for our therapy are to conduct randomized, blinded studies to confirm the effectiveness and safety of MBO_2 as an intervention for autism to current scientific standards, and then reproduce these results at several different sites. The completion of such studies, with positive outcomes, is a prerequisite for formal governmental healthcare regulatory clearance.

Conclusion

When we started this project over ten years ago, we had no idea how exciting it would be or where it would take us. We feel an obligation to the autism community to carry our work to its conclusion, and do everything we can to confirm the value of MBO_2.

Conducting the required research on the scale necessary is beyond our means as private, self-funded individuals. To date, despite our best efforts, there has been little interest shown by the autism research and support community. As a result, we continue to look at a range of possible alternatives for raising funds. One of these is crowdfunding, which will allow interested individuals to participate at the level of their choosing. We also continue to reach out to foundations and other organizations to obtain support for our research and trials, and to investors who could fund business and product development.

Based on our pilot study results, MBO_2 appears to be an effective method of managing the symptoms of moderate to severe autism. It seems to reduce brain dysfunction and improve capability. As we have seen with the subjects in our pilot studies, it can help them live richer and fuller lives.[1,2]

The potential for improvement in the brain's capacity to develop social, behavioral, awareness, communication and other skills impacted by autism is possible regardless of the subject's age. This means that specialized educational programs, which could be developed from existing interventions, might hold promise for improved and expedited learning in those undergoing MBO_2 treatment.[2]

Should the proposed trials confirm the results of our pilot studies and regulatory approval be achieved, we believe MBO_2 would present a real opportunity to move forward in helping to alleviate some of the problems that families living with moderate to severe autism have been dealing with for decades at a more affordable cost. In conclusion, we hope that detailed review of our hypothesis by others will inspire new lines of research that may lead to a better understanding not only of autism but potentially of other neurological conditions as well.

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Russell E. Peterson, Ph.D., is a Founding Partner and Manager of Microbaric® Oxygen Systems, LLC. He received his Ph.D. in physiology from the University of Pennsylvania with thesis research conducted in the Institute for Environmental Medicine (IFEM), a pressure physiology laboratory directed by Christian J. Lambertsen, M.D. Throughout his career, Russ' passion for applied, rather than basic, science has led him on a path to develop and/or improve practice. Thus, his extensive experience in the related fields of diving medicine and physiology, and hyperbaric oxygen therapy helped him recognize the potential for Microbaric® Oxygen Therapy and participate in its subsequent development.