

## Response to the NYT Article Highlighting the BMJ Helmet Study

*In May of 2014, the New York Times highlighted a study from the Netherlands published in the British Medical Journal with an article entitled, "Helmets Do Little To Help Moderate Infant Skull Flattening, Study Finds." This article began a firestorm of controversy regarding the effectiveness and necessity for cranial remolding treatments in America. As is often the case, insurance providers hoping to reduce benefits, and clinicians skeptical regarding the need for cranial remolding orthosis treatment, held the article as proof that cranial remolding orthosis treatment was neither effective, nor necessary. However, close inspection of the study in the British Medical Journal shows that the helmets used in Europe for the study are flawed and can not be compared to the superior products offered in North America. The study itself excludes patients with severe asymmetry and complicating factors, which are the very patients who most need helmets. Unfortunately, the broad brush with which the article paints helmets as ineffective, incorrectly shades the overall effectiveness of cranial remolding treatment.*

*There are several issues with this study, the study excludes severe cases, and those with other complicating factors, including torticollis and developmental delay. Helmets should be recommended for those who we DO NOT expect will be able to resolve on their own based on their age, complicating factors, and severity. Those with severe deformities and complicating factors are the ones for whom we would expect the greatest improvement. Studies like this will be used to justify discontinuation of payment for a broader set of patients instead of excluding those patients that we already tend to exclude on our own. It is not uncommon for us to recommend against cranial remolding treatment when it is not necessary. Generally, we already recommend following patients with mild to moderate deformity, and only recommend treatment when they show worsening with conservative treatment. It is well known that the head shape will generally improve some once the deforming forces have been removed. Therefore, the study focuses on a set of patients that may not have needed the helmet in the first place.*

*Despite the small sample size (35), 73% of families reported dissatisfaction with the fit of the helmet to include shifting and rotating, and one who reported that the helmet "spontaneously came off." Poorly fitting helmets should not be used to judge a device's efficacy. Properly made and fitted helmets should never spontaneously come off. See the figures below to compare the Orthomerica Star Band helmet used by Delatorre Orthotics and Prosthetics versus the helmet used in the Netherlands study. Ironically, the study reports that only 26% (vs. 23% untreated) of the head shapes reached complete resolution with the poorly fitting helmets. My guess would be that only the helmets that stayed on correctly, were the ones that effectively result the head shape asymmetry in their study.*



*The actual measurement techniques used in the study were unclear as to method used, which can cause inter-measurer differences. Measurements can be obtained using a variety of methods including measuring tools like calipers and tape measures, or more advanced three-dimensional digital imaging capture devices may be used. With no clarity on the method of measurement, there can be no guarantee that each person was measuring the children in the same way. This also makes it impossible to duplicate the study to test the author's conclusions. Using Orthomerica's Star Scanner, we are able to obtain a three-dimensional digital model of a child's head without pain or danger, and we are able to accurately measure each child in a reliable and repeatable manner. These advanced measurement techniques also allow us to track the child's progress as he or she wears the helmet to ensure that it is working correctly.*

*The study also reports the high incidence of "side effects" as a reason to consider not beginning helmet treatment. The actual side effects considered included sweating, odor, and skin irritation. All of these things can be managed with proper cleaning and frequent inspection of the skin. In fact, detailed instructions are provided to each family when they receive the helmet in order to make the process as comfortable as possible. The study also considered pain for the child, (although I'm not sure how they could attribute it directly to the helmet), "problems accepting the helmet" and feeling hindered in cuddling, which reflect the parents' attitudes more than an actual side effect. We absolutely understand that beginning cranial remolding treatment can be a very emotional time for the parents. However, in most cases the children quickly become comfortable wearing the helmet, which in turn comforts the family.*

*Finally, the study considers head shape abnormality "largely a cosmetic issue." The study references a correlation with developmental delay, but quickly dismisses it as correlative and not causal. We already know this to be true, but the study never mentions known complications such as TMJ, strabismus (problems with eye alignment), increased otitis media (ear infections), difficulty with stereo vision and hearing, or possible headache. Nor does it ever consider that cranial remolding is a RECONSTRUCTIVE procedure used to bring a child back to normal symmetry, rather than a "cosmetic" procedure intended to enhance a normal structure! In fact, ensuring a positive self-image is still an important consideration when deciding whether to begin helmet treatment and should not be dismissed as frivolous.*

*Cranial remolding helmets manufactured in the United States are held to strict standards monitored by the FDA. They are designed to be safe and effective, and as comfortable as possible. They cannot be compared to the poorly fitted and poorly measured devices used in the Netherlands study. Expert clinicians will only recommend helmets for children who need them and they will monitor their use to ensure their safety and effectiveness. They will also explain how the helmet will be made, how it will work, and the expectations for the treatment to minimize confusion and misunderstanding.*