



**American Orthotic &  
Prosthetic Association**

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Mr. Thomas Feyer  
Letters Editor  
New York Times  
242 West 41<sup>st</sup> Street  
New York, NY 10036

Dear Mr. Feyer,

Many in the orthotic care community have expressed concern with the article in today's *New York Times* relating to the study released in the *British Medical Journal*, entitled, "Helmet therapy in infants with positional skull deformation: randomised controlled trial." The study reported in BMJ related to one category in the use of cranial helmets, specifically how children who have mild to moderate indicators of positional skull deformation and are treated with cranial helmets progress, as contrasted with other similar patients who do not receive helmets. In this narrow group of patients, the study concluded that helmet treatment "had virtually no treatment effect." Cranial helmets have a long history of being used very effectively in treatment for children with more significant (beyond mild to moderate) symptoms, a usage which has passed muster as to effectiveness under FDA medical device regulations. Nothing in the BMJ article either questioned or studied the appropriateness of treatment with cranial helmets for these patients with more significant symptoms.

As to this BMJ study, science demands replicability, and any new finding must be demonstrated as being capable of validation through similar results reached by other investigators using parallel methods—in short, with rare exception, no single article changes existing science. Moreover, there are some important disparities about this study which ought to prompt pause among those considering trying to evaluate, or ultimately measure the replicability of the findings. The participation rate in the RCT is low (21%). It is recognized across the medical and research communities that evidence from a Randomized Clinical Trial must be supplemented by evidence from clinical effectiveness studies if any attempt is being made to inform best practice. This low level of participation prevents comparisons between sub groups and it is acknowledged by the authors as a limiting factor.

Independent published research that examined the effectiveness of helmet therapy conclude that as many as 95% of patients demonstrate an improvement in head shape symmetry following helmet therapy. The reported 73% incidence of basic fitting problems seems very high. This raises serious concern over the clinical application of the helmets used in this study. The value of this research is fully reliant upon the quality of helmet fit. Anyone seeking to replicate the study, or weigh its importance will need to try to assure significantly better fit. One cannot expect a device which shows many signs of possibly having been fit improperly to yield optimal results.

Very truly yours,

Anita Liberman-Lamphear, M.A.  
President