## **Relevant Criterias for the Analysis of Studies with Cranial Orthoses**

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## Commentary

In the area of physiotherapy, specifically in the case of cranial orthoses, many times, research often fails to meet practical requirements that will only be noticed by specialists in the subject. The studies may even have a good question, an adequate hypothesis, and although the design is considered ideal, even a randomized clinical trial may lose its strength if the applied practice and data analysis do not occur properly.

Of course, being put in a critical situation is much more comfortable than developing a study, but it is important that there is a definition and consensus of what can be accepted so that researches can have a minimum standard of acceptability. In some cases, we see articles with few clinical criteria published by a good study design, but without the reproducibility capability for failures that only an experienced orthotist could detect. A number of revisions have been made about the treatment of cranial asymmetries, but it is useless that such revisions point to the likely shortcomings of current studies if improvements are not applied in subsequent studies [1,2].

Initially defining the method used to diagnose asymmetry is essential and clearly who, even if 3D analysis is not always possible, it is imperative that it be an evaluation method already analyzed as reliable, reproducible and valid and that has its protocol well described. Reliable instruments are essential for diagnosis, classification and monitoring and need to be based on clear benchmarks, which can be a key point for reproducibility, as well as the analysis of repeatable measures that need to be explicit and explained so that different "nominas" do not occur, since there is still no homogeneity of cranial measurements worldwide [3,4]. Still important is that parents understand the exam and that they are able to follow the evolution of the format of their baby's head [5,6].

Of course, subjective impression is always subject to bias, but it is extremely important to understand that it is the parents and the baby itself and not the doctors who will always live with the result of an indication of the orthosis treatment or lack thereof. Relevant also that they understand that the diagnostic differentiation between positional asymmetry and cranioestenosis occurs, in great majority, clinically without the need of the tomography (CT); since the CT scan exposes the child to irradiation and sometimes sedation, it has already been shown its potential to induce malignancy later in life and therefore the impact of such exposure is questionable and controversial [4,7].

The research must also make clear: what protocol is used for the indication (screening of patients who need cranial orthesis), treatment (how the patient was assessed, the helmet used, how often the helmet is adjusted, the effects of the helmet and the results achieved), discharge criteria of the child and what the goals to be achieved clinically are. For this, one of the most important issues is to describe the technique of making the orthosis used, which is the chosen orthosis, its model and what the professional experience accompanying the studied infant. This is because different forms of mold capture may interfere with the quality of the device used, which will directly affect the result achieved. In recent times, however, this aspect has been neglected even by the clinical trials that have most affected the scientific community [8,9].

A helmet requires matching accuracy to achieve adequate symmetry gain as the areas of flattening and bulging of the child's head are delimited and inaccurate confection of the bracing or adjustments made there to may directly affect a result achieved. For this reason, the orthosis used must, without a doubt, be described in any study, because besides allowing reproducibility it allows the scientific society to separate the "wheat tares" and to be able to answer if that device is suitable for the analysis in question. In addition, it is necessary to know the period of adjustments, the degree of adhesion (which is still difficult to measure objectively, but which clinically can be perceived by any experienced clinician since an orthosis without regular use will certainly determine problems of fitting and possible skin lesions known as "red spots", which are the result of excessive pressure in the support areas precisely caused by the irregular use of undesired growth in these areas) and objectives and subjectives discharge parameters [9].

The consequences of the use of orthosis should be emphasized, possible problems of fit and its corrective attitudes, skin irritations and problems of pressure areas, as these consequences can give a broad view of the level of demand of the adjustments offered for the device studied as well as its degree of accuracy [10].

The non-equivalence of statistical significance and clinical importance has been recognized for some time, but due to the

scarce studies with good study design in the case of cranial orthoses, in some cases only a suitable design is enough to guarantee a bustle in the research on the use of helmets. As clinicians it is essential to decide if the findings are clinically significant, since claims of no effect or no difference may lead them not to indicate to their patients interventions with important beneficial results only because when the sample size is small or sample size is large but the correct denominator for the outcome in question is not used misinterpretations will determine the care to be guaranteed to our babies. We must be cautious and not accept results from a single clinical trial by doing a more comprehensive investigation under different conditions with clinical accuracy and reproducibility to ensure proper care [11].

To ensure that the results are adequate, it is necessary to separate the asymmetry groups and to explore the clinical compromises presented by the child (such as face asymmetry, displacement of the ears, etc.). Generally for the analysis of brachycephaly and scaphocephaly, it is recommended to use the cephalic index, for the analysis of plagiocephaly CVA (cranial vault asymmetry) and CVAI (cranial vault asymmetry index) and for situations in which more than one symmetry is done presented the indexes are also used together. The volumetric indexes have also had, in turn, their importance shown. Studies have shown that the symmetry index variables are the best representatives of the clinically presented asymmetry (CVAI, radial symmetry ratio, posterior symmetry ratio and overall symmetry ratio). In general terms it is important that the author present clearly and didactically the measures used since the terminology is not yet consistent [12].

Ellie Boomer has already demonstrated in her article "Helmet Study Highlighted in The New York Times Is Flawed" that even if we ignore all the obvious adjustment and follow-up problems that a study may have any clinical relevance to the study is removed because if the final statistical analysis involves the mean of the results for the three different conditions (plagiocephaly, brachycephaly and combo) and that to have a clinically relevant study, researchers need to use either asymmetric type only or have a population sufficient to show statistical significance with each of the three positional asymmetries. All this to enable the outcome measures to reflect the clinical practice so that the study can be relevant and informative seeking and helping decision making [8,9].

Of course the purpose of this review is not to raise all the factors that statistically matter for any clinical trial (such as sample size and its determinant variables like effect size, variability of the effect, etc...; loss of follow-up of the study, family compliance, losses during the treatment process, drop in and drop out, consent term, definition of appropriate inclusion and exclusion criteria, authorization of ethics committee, among other impacting aspects), since this would be the subject for another extensive study, but rather present clinically relevant questions that have been several times ignored for studies with cranial orthoses.

Another factor of extreme importance in the studies is the presence of cervical alterations, whether congenital or postural torticollis. In any case, reporting the presence of it can be a powerful factor in the achieved outcomes, just as excluding babies with torticollis from the plagiocephaly study group would assume that there is no correlation between torticollis and asymmetry, and many authors consider that , in fact, this relationship is "underreported" and that therefore such problems end up being treated in isolation when biomechanically the torsion that the cervical imbalance can provoke affects the base torsion of the child's still malleable skull and consequently affect the asymmetry found. Consider, therefore such findings are essential since they strongly affect the short- and long-term results [7,13].

As obvious as all these aspects may seem many studies do not meet these minimal clinical requirements and may therefore present results that are impracticable affecting a whole indication of treatment and consequently an entire medical society that need to be alerted to factors of clinical importance. Parents will live with this choice and on several occasions their doubts only reach the specialized teams with older babies, still without resolution of the asymmetry presented and when it will not be possible to reach the same result [14]. Therefore, in order to avoid inconsistencies, in a summarized way, if the reader's desire is to study asymmetries, or even to read the studies under a critical aspect, all the topics described should be taken into account as a rule for clinical acceptability and that will allow extrapolating the results for the daily practice.

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