

## The use of cranial orthosis treatment for infant deformational plagiocephaly

**Cranial orthoses are helmets or headbands aiming to improve cranial symmetry by applying active or passive pressure to prominent areas of the cranium and enabling growth in the flatter areas of the cranium**

### Health technology description

Cranial orthoses are helmets or headbands which are used for the treatment of deformational plagiocephaly (asymmetrical flattening of the cranium). They aim to improve cranial symmetry by applying active or passive pressure to prominent areas of the cranium and enabling growth in the flatter areas of the cranium.<sup>1</sup> The orthosis may also act by preventing the infant from lying on the flattened area of the head.<sup>2</sup> They are used for infants aged between 6 weeks and one year when the cranium is in the most dynamic growth phase.

Cranial orthoses are custom-fitted using a mould or scan of the infant's head. They can be worn for up to 23 hours daily, for 6 to 24 weeks. Regular assessments (usually 6-weekly) are required to assess cranium growth and possible adverse effects, and to make any necessary adjustments to the orthosis to allow for growth and change of shape of the cranium.<sup>3</sup>

In the UK, cranial orthoses are classified as Class I devices (non-invasive) by the Medicines and Healthcare Products Regulatory Agency.<sup>4</sup>

### Epidemiology

Deformational plagiocephaly is defined as asymmetrical flattening of the cranium in the absence of synostosis (premature or abnormal closure of skull bones), caused by uneven external pressures exerted on the cranium.<sup>1</sup> The condition most commonly manifests as unilateral flattening of the posterior cranium (parieto-occipital area), often associated with prominence of the ipsilateral frontal region. Brachycephaly is a related, but separate condition which involves bilateral flattening of the posterior cranium.<sup>1,5</sup>

Deformational plagiocephaly is usually diagnosed by clinical examination of the head (to rule out synostosis), facial features and head and neck movements. However there is no accepted minimum level of asymmetry for a plagiocephaly diagnosis and no clear definitions of mild, moderate and severe plagiocephaly exist. It can be caused prenatally through foetal



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### Key points

- No randomised controlled trials assessing the effectiveness of cranial orthoses for the treatment of deformational plagiocephaly were identified
- No evidence-based conclusions can be reached on the effectiveness of cranial orthoses due to the limited methodological quality of the available trials
- Further research in the form of a randomised controlled trial is needed to determine the true effectiveness of cranial orthoses
- No published economic evaluations assessing the cost effectiveness of cranial orthoses were found

compression or intrauterine constraint and extrauterine compression, or postnatally through sleeping position, torticollis (a contraction of muscles in the neck resulting in an abnormal position of the head), nervous system disorders or cervical spine defects.<sup>2</sup> Risk factors identified for deformational plagiocephaly include infants of multiple births, firstborn child, premature birth, males, supine sleeping during first 6 weeks without head

repositioning, positional preference when sleeping, bottle feeding, limited supervised time on the stomach and low activity levels.<sup>6,7</sup>

The natural history of the condition is not well documented, but it has been noted that its prevalence decreases as untreated infants grow older implying that many cases resolve spontaneously.<sup>6</sup> Plagiocephaly has not been shown to be associated with any long-term complications such as effects on brain function. Its effects appear to be purely cosmetic, with the main reason for specialist referral being to differentiate the condition from craniosynostosis.<sup>3</sup>

There is no standard treatment for deformational plagiocephaly. Treatment can include counterpositional therapy (actively repositioning the infant's head, encouraging the infant to move its head using stimulating objects and supervised time lying on the stomach), stretching exercises through physiotherapy particularly if torticollis is present, cranial orthoses, education and reassurance of parents, and surgery in severe cases.<sup>1,3</sup>

The exact incidence and prevalence of deformational plagiocephaly in the UK is unknown due to the absence of a specific disorder code and approved diagnosis criteria. Prevalence estimates of 10 to 15% for mild/moderate and 1.5% for severe deformational plagiocephaly have been reported for infants under the age of six months in the USA.<sup>8,9</sup> In New Zealand the prevalence has been estimated to decrease from 19.7% at 4 months of age to 9.2% at 8 months and 3.3% at 24 months in the absence of cranial orthoses.<sup>6</sup>

There appears to have been a rise in the incidence of deformational plagiocephaly in recent years.<sup>10-12</sup> It has been widely suggested that this rise is associated with the 'back to sleep' campaign, which recommends the placing of babies on their back for sleeping, to reduce the risk of sudden infant death syndrome.<sup>13</sup> Other contributory factors to the increase in deformational plagiocephaly could be a greater awareness of the condition and an increase in the use of child carriers and car seats.<sup>14,15</sup>

## Clinical effectiveness

A number of systematic reviews assessing the effectiveness of cranial orthoses for the treatment of deformational plagiocephaly were identified.<sup>1,2,5,15-17</sup> The most up-to-date of these, with literature searches up to August 2005, had robust methodology and hence forms the basis of this clinical effectiveness summary.<sup>1</sup>

The systematic review identified six non-randomised controlled trials comparing cranial orthoses to any comparator treatment for deformational plagiocephaly or no treatment.<sup>11,13,18-21</sup> However, four of these trials were excluded due to the quality of the outcome data being too low to be reliable.<sup>11,18,19,21</sup> The remaining two included trials compared cranial orthosis treatment to counterpositional therapy.<sup>13,20</sup> Both trials reported measures of cranial vault asymmetry, which is defined as the difference between the measurements of the left eyebrow diagonally to the right parieto-occipital area and the right eyebrow to the left parieto-occipital area.

One trial (including 114 infants) found that cranial orthoses reduced cranial asymmetry more than counterpositional therapy (0.6 cm change score vs 0.2 cm change score).<sup>13</sup> However, it was not reported whether this difference is statistically significant. In addition, the results of this trial should be treated with extreme caution due to a lack of randomisation to ensure comparability between the treatment groups (parents were allowed to choose treatment allocation) and high lost to follow-up rates (86.8%) in the counterpositional therapy group.

The second trial (including 74 infants) found that cranial orthoses and counterpositional therapy had similar improvements in cranial vault asymmetry (1.8% change score vs 1.9% change score).<sup>20</sup> This trial also measured cranial index, defined as the head width divided by the head length, and again found similar outcomes between the two treatments (2.0% change score vs 1.8% change score). However, these results should be treated with caution due to the lack of randomisation and limited reporting on methods of treatment allocation and follow-up rates.

The systematic review highlighted the paucity of randomised controlled trials and the poor quality of the existing controlled trials. In light of this, no evidence-based conclusions could be reached on the effectiveness of cranial orthosis treatment for deformational plagiocephaly.

The other reviews identified, included case series as well as controlled trials. However, being uncontrolled, case series do not add any information to the controlled trials identified above as they cannot provide evidence on the comparative effectiveness of cranial orthoses. In addition, they do not take into account any spontaneous resolution of deformational plagiocephaly.

## Safety

Adverse events include skin irritation, rashes, skin ulcers, scalp odour, contact dermatitis, distress of infant and embarrassment of caregivers and family. Adverse event rates of 1.3%, 100% and 7.1% for minor skin rashes and irritations,<sup>22</sup> scalp odour<sup>11</sup> and contact dermatitis<sup>11</sup> respectively, have been reported. The US Food and Drug Administration estimate the prevalence of skin irritation and skin breakdown due to cranial orthoses to be 6.8% and 4.2% respectively.<sup>23</sup>

## Economic implications

No published economic evaluations assessing the cost effectiveness of cranial orthosis treatment for deformational plagiocephaly were found. The estimated cost of cranial orthoses in the UK ranges from £1,850-£2,000 which mostly includes the costs of consultations, scans, casting, fitting and assessment visits, but does not include parent expenses such as transport and accommodation, if required. At present, cranial orthoses are not procured at a national level so any purchasing of the devices would be performed by NHS Boards in Scotland.

## Ongoing research

No ongoing controlled trials were identified.

## Further information

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- To propose a topic for an Evidence Note, email [evidencenotes@nhshealthquality.org](mailto:evidencenotes@nhshealthquality.org)
- References can be accessed via the e-library ([www.elib.scot.nhs.uk](http://www.elib.scot.nhs.uk)), or by contacting your local library and information service

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Ms Lisa Patel – Author, Research Reviewer, University of Birmingham

Ms Anne Fry-Smith – Information Specialist, University of Birmingham

Dr Yen-Fu Chen – Research Reviewer, University of Birmingham

Dr David Moore – Senior Research Reviewer, University of Birmingham

Dr Eimear Nic Lochlainn – Consultant Evidence Notes Coordinator

Ms Jennifer Graham – NHS QIS Evidence Notes Project Officer

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