Table 1: Helmet vs Conservative Treatment

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Van Wijk et al (2014)	Helmet Therapy in Infants with Positional Skull Deformation: Randomized Controlled Trial	84 infants aged 5-6 months prospectively randomized to custom helmet therapy (n = 42) or to the "natural course of the condition" (n = 42) All patients received physical therapy Mean duration of therapy was 4 months Outcome: change in skull shape from baseline to 24 months, as assessed by 2D anthropometric measures, including oblique diameter difference index	Class II Randomized controlled trial Block randomization schema—infants in the natural course group had more severe deformity and infants in the helmet group had more brachycephaly (significant differences) Blinded outcome assessment Outcome subject to measurement bias Intention-to-treat and per-protocol analysis (7 infants did not start their assigned therapy after randomization) 5 patients lost to follow-up 21% of eligible participants agreed to participate (limits external validity)	No difference in primary outcome between the 2 groups (intention-to-treat and per-protocol analysis similar) No significant differences between treatment groups in secondary outcomes, including parental satisfaction All parents reported one or more side effects of helmet therapy Helmet therapy has no added value in the treatment of moderate-severe positional plagiocephaly

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Kluba et al (2014)	Treatment of Positional Plagiocephaly—Helmet or No Helmet	Prospective analysis of treatment outcomes in 62 patients with plagiocephaly treated with a custom helmet vs 66 patients treated without Brachycephaly patients excluded Patients in both groups asked to continue with any previously instituted therapy (PT, repositioning) Mean age at institution of helmet therapy was 6.3 months Mean duration of helmet therapy was 4 months Outcome: cranial vault asymmetry index at end of therapy	Class II Prospective comparative study Selection bias—groups different at baseline with respect to severity of plagiocephaly at baseline (more severe in the helmet group) Details of previously instituted (and ongoing) non-helmet therapy were not recorded, and may have differed between groups Outcome subject to measurement bias Outcome assessed at different times in the 2 treatment groups (patients in helmet group were assessed at age 10.2 months whereas patients in control group were assessed at 18.5 months)	In both groups, a statistically significant decrease in asymmetry was observed Although children in the helmet group had more severe deformity at baseline, they showed significantly better improvement than the comparison group when the outcome was adjusted for the degree of initial deformity In both groups, a weak positive correlation was observed between the extent of initial asymmetry and the extent of improvement Clinical significance of observed treatment effect unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Plank et al (2006)	Comparison of Infant Head Shape Changes in Deformational Plagiocephaly Following Treatment With a Cranial Remolding Orthosis Using a Noninvasive Laser Shape Digitizer	Prospective comparison of 207 patients with moderate-severe positional plagiocephaly treated with helmet to 17 patients treated without helmet Mean age of patients in both groups not documented Mean duration of therapy in both groups not documented Outcome: an assortment of 3D anthropometric measurements, including CVAI	Class II Prospective comparative study Selection bias—control group comprised of patients who refused helmet. Several control patients later decided to pursue helmet therapy and left the control group Details of therapy provided to control group patients not clearly specified Limited generalizability of laser scan results	Helmet therapy results in statistically significant changes in head shape and symmetry when compared to the control group Clinical significance of observed effect on outcomes is unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Mulliken et al (1999)	Analysis of Posterior Plagiocephaly: Deformational versus Synostotic	Prospective comparison of 36 patients treated with a helmet and 17 patients treated with repositioning Mean age at initiation of helmet therapy was 5.5 months Mean duration of helmet therapy was 4.9 months Outcome: change in oblique transverse cranial diameter pre/post therapy	Class II Prospective comparative study High rate of loss to follow-up; - pre- and post-treatment measures were available for only 17/63 infants in the original repositioning group and 36/51 infants in the original helmet group Measurement bias	Improvement occurred in 52/53 patients Correction of asymmetry was better in those treated with a helmet compared to those managed with repositioning Age at initiation of helmet therapy was unrelated to the degree of improvement

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Kim et al (2013)	Comparison of Helmet Therapy and Counter Positioning for Deformational Plagiocephaly	Retrospective chart review of 27 patients with positional plagiocephaly, 21 who had helmet therapy and 6 who underwent counterpositioning Mean age at therapy initiation: 5.6 months for both groups Mean duration of therapy: 4.3 months for helmet vs 4.1 months for counterpositioning Outcome: change in CVAI and other 3D anthropometric measurements	Class II Retrospective comparative study Selection bias—therapy determined by parental preference Exclusion of some populations (eg, neurodevelopmental disabilities) vulnerable to positional plagiocephaly limits generalizability	Statistically significant change in CVAI seen in the helmet group but not in the counterpositioning group Subgroup analysis shows greater effect of helmet in severe vs moderate deformity group Helmet therapy results in more favorable outcomes than counterpositioning in moderate-severe positional plagiocephaly

Wilbrand et al (2013)	Nonsynostotic Cranial Deformity: A Six-Month Matched-Pair Photogrammetric Comparison of Treated and Untreated Infants	Retrospective comparison of 40 patients with positional plagiocephaly treated with helmet vs 40 controls not treated with helmet Physiotherapy and "bedding maneuvers" were recommended to the unhelmeted patients Mean age at baseline evaluation was 6.5 months in the treated group vs 6.8 months in the control group Mean length of helmet therapy was 5.2 months. Outcome was assessed at 5.6 months in the control group Outcome: An assortment of 3D anthropometric measures including cranial vault asymmetry index (CVAI) at the end of therapy	Class II Retrospective comparative study Attempt to match for severity of initial deformity, but initial 3D measures of asymmetry were different in the 2 groups Selection bias—most patients in the control group were not treated with helmet because of advanced age at presentation, mild-moderate deformity, or parental request Outcome assessed at different time points in the 2 groups Limited generalizability of laser scan results	Improvement in asymmetry is seen in helmeted infants, but at the end of treatment, no significant difference is seen in asymmetry between helmeted and unhelmeted infants Nonsynostotic cranial deformity shows some spontaneous correction

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Lipira et al (2010)	Helmet Versus Active Repositioning for Plagiocephaly: A Three-Dimensional Analysis	Retrospective comparison of 35 patients with positional plagiocephaly treated with active repositioning vs 35 custom orthoses Mean age at intake: 4.8 months in repositioning group vs 4.9 months in helmet group Mean duration of therapy was 5.2 months in repositioning group vs 3.1 months in helmet group Helmet prescribed for 23 h/day Outcome: change in 3D anthropometric measure (mean and maximum asymmetry) pre/post therapy	Class II Retrospective comparative study Matched for severity of initial deformity Selection bias—treatment decision was guided by parental preference Selection bias—an additional 17 patients were assigned to repositioning arm but 13 elected to switch to helmet therapy in the midst of treatment, and 4 were lost to follow-up (all of these patients were excluded from analysis) Outcome assessed at different time points in the treatment groups (cessation of treatment guided by parent/clinician satisfaction) Limited generalizability of laser scan results	Statistically significant greater reduction in measures of asymmetry in the helmet group vs the repositioning group, specifically in the posterior head region Mean duration of therapy was shorter in the helmet group No difference in average head growth between the 2 groups at end of treatment Clinical significance of observed effect on outcomes unclear (very small treatment effects)

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Losee et al (2007)	Nonsynostotic Occipital Plagiocephaly: Factors Impacting Onset, treatment and Outcomes	Retrospective comparison of 55 patients treated with conservative repositioning to 45 patients who failed conservative treatment and were subsequently placed in a helmet Mean age at initiation of helmet therapy was 7.5 months Mean duration of helmet therapy was 3.7 months Outcome: subjective surgeon assessment of head shape	Class II Retrospective comparative study Selection bias—parents decided whether to undergo repositioning or helmet therapy Measurement bias—subjective outcome assessed by a single craniofacial surgeon	Improvement in head shape was statistically significantly better in the helmet vs repositioning group

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Graham et al (2005)	Deformational Brachycephaly in Supine Sleeping Infants	Retrospective review of 193 brachycephalic infants, 96 of whom were treated with repositioning and 97 who were treated with a custom orthosis Mean age at therapy initiation was 4.6 months for repositioning and 6.0 months for helmet Mean duration of therapy was 3.1 months for repositioning and 4.3 months for helmet Outcome: change in CI pre/post treatment	Class II Retrospective comparative study Selection bias—initial deformity more severe in helmet group Outcome subject to measurement bias Outcome assessed at different times in the 2 treatment groups	Change in CI for the patients treated with helmet was statistically significant, whereas it was not significant for those treated with positioning For those treated with helmet, treatment at a younger age resulted in more improvement in the CI Clinical significance of observed effect on outcome is unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Graham Jr et al (2005)	Management of Deformational Plagiocephaly: Repositioning Versus Orthotic Therapy	Retrospective review of 298 plagiocephalic infants, of whom 176 underwent repositioning and 159 underwent helmet therapy Thirty-seven patients initially treated with repositioning eventually received helmet Mean age at initiation of therapy was 4.8 months in repositioning group vs 6.6 months in helmet group Mean duration of therapy was 3.5 months in repositioning group vs 4.2 months in helmet group Outcome: reduction in diagonal difference pre/post therapy	Class II Retrospective comparative study Selection bias—initial deformity more severe in helmet group (P = .08) Helmet was recommended for infants >6 months with severe deformity. Patients <4 months were given repositioning. Patients 4-6 months were offered either treatment Outcome subject to measurement bias Outcome assessed at different times in the 2 treatment groups	Infants treated with helmet had improved outcome compared to those treated with repositioning Infants treated with helmet were older and required a longer treatment period Early helmeting (<8 months) resulted in better outcomes compared to late helmeting (>8 months) Clinical significance of observed effect on outcomes is unclear

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Loveday et al (2001)	Active Counterpositioning or Orthotic Device to Treat Positional Plagiocephaly	Random sample of 74 infants with positional plagiocephaly selected from clinic records

Forty-five were repositioned and 29 received helmet

Mean age at initiation of therapy: 38 weeks for repositioning vs 37 weeks for helmet

Mean duration of therapy—64 weeks for repositioning vs 22 weeks for helmet

Initial CVAI: 7.3% for repositioning vs 8.0% for helmet

Outcome: change in CVAI pre/post treatment | Class II

Retrospective comparative study

Selection bias—selection to treatment group based on severity of deformity and preference of surgeon

Some (n = ?) repositioning patients went on to get a helmet and were analyzed as part of the helmet group

Outcome assessed at different times in the 2 treatment groups

Outcome subject to measurement bias

No statistical presentation of results | Change in CVAI similar for both groups at the end of therapy, but change effected with shorter duration of treatment in helmet group

Mean age in helmet group was 37 weeks, which may explain relatively poor helmet results

Clinical significance of findings unclear |

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Vles et al (2000)	Helmet versus Nonhelmet Treatment in Nonsynostotic Positional Posterior Plagiocephaly	Retrospective comparison of 66 patients treated with a helmet and 39 patients treated with repositioning Mean age at initiation of helmet therapy was 5.1 months Outcome: change in parental rating of the severity of skull deformity	Class II Retrospective comparative study Selection bias—choice of treatment alternative made by the parents. This resulted in pre-treatment severity score being significantly worse in the helmet group	Improvement was seen in all patients, although the improvement was significantly better in the helmet group Improvement in the helmet group was seen at a mean of 5.3 weeks after initiation of therapy, vs 24.1 weeks after initiation of therapy in the repositioning group No correlation between age at initiation of helmet treatment and outcome Within the helmet group, more improvement was seen in those with the worse presenting deformity

Author (Year)	Title	Study Description	Data Class, Quality, and Reasons	Results and Conclusions
Clarren (1981)	Plagiocephaly and Torticollis: Etiology, Natural History and Helmet Treatment	Retrospective comparison of 25 infants who completed helmet therapy to 10 infants whose family declined helmet therapy Control infants received passive neck stretching exercises Mean age at initiation of helmet therapy was 5.5 months Mean duration of helmet therapy was 5.3 months Outcome: subjective (surgeon) assessment of head shape	Class II Retrospective comparative study Selection bias—control infants were those who declined helmet Twenty-five of 28 patients in helmet group actually completed therapy Measurement bias	Nineteen patients in the helmet group and 0 patients in the control group achieved a normal head shape An improvement in head shape (but not normalization) was seen in 6/25 of the helmet group and 4/10 of the control group