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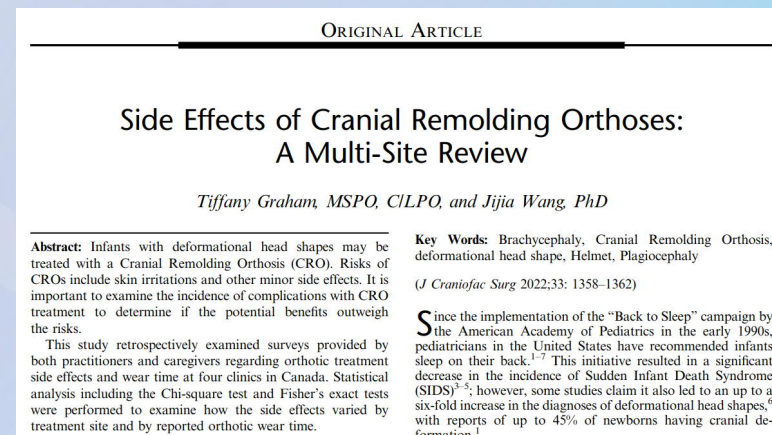
Welcome

Side Effects of Cranial Remolding Orthoses: A Multi-Site Review

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Acknowledgement & Disclosure

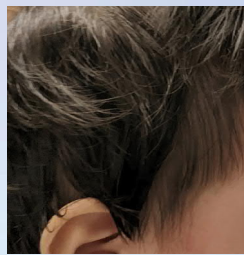
Jason Goodnough, MSc.



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Side Effects Reporting

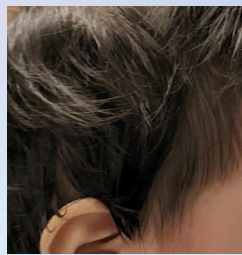
- 2013 (Gump et al)– review of literature - complications were “low or negligible”
 - malodorous perspiration, minor skin irritations, and social stigma
- 2001 (Loveday et al) – side effects include: heat rash, reactions to the materials, and older infants able to remove the CROs
 - complications seen by the 29 patients in their CRO group may have been caused by poorly manufactured or poorly fitted CROs
- 2021 (Takamatsu et al) – may be a link between fit issues and complications
- (personal theory): wear time is inversely correlated with complications



Side Effects Reporting

<u>Side Effect</u>	<u>VanWijk et al</u>
Skin irritations	96%
Augmented sweating	71%
Unpleasant Odour	76%
Difficulty cuddling infant	77%

<u>Side Effect</u>	<u>Lee et al</u>
Rashes	35.4%
Pressure sore / skin breakdown	25.6%
Itching	7.3%
2 or more adverse events	9.8%



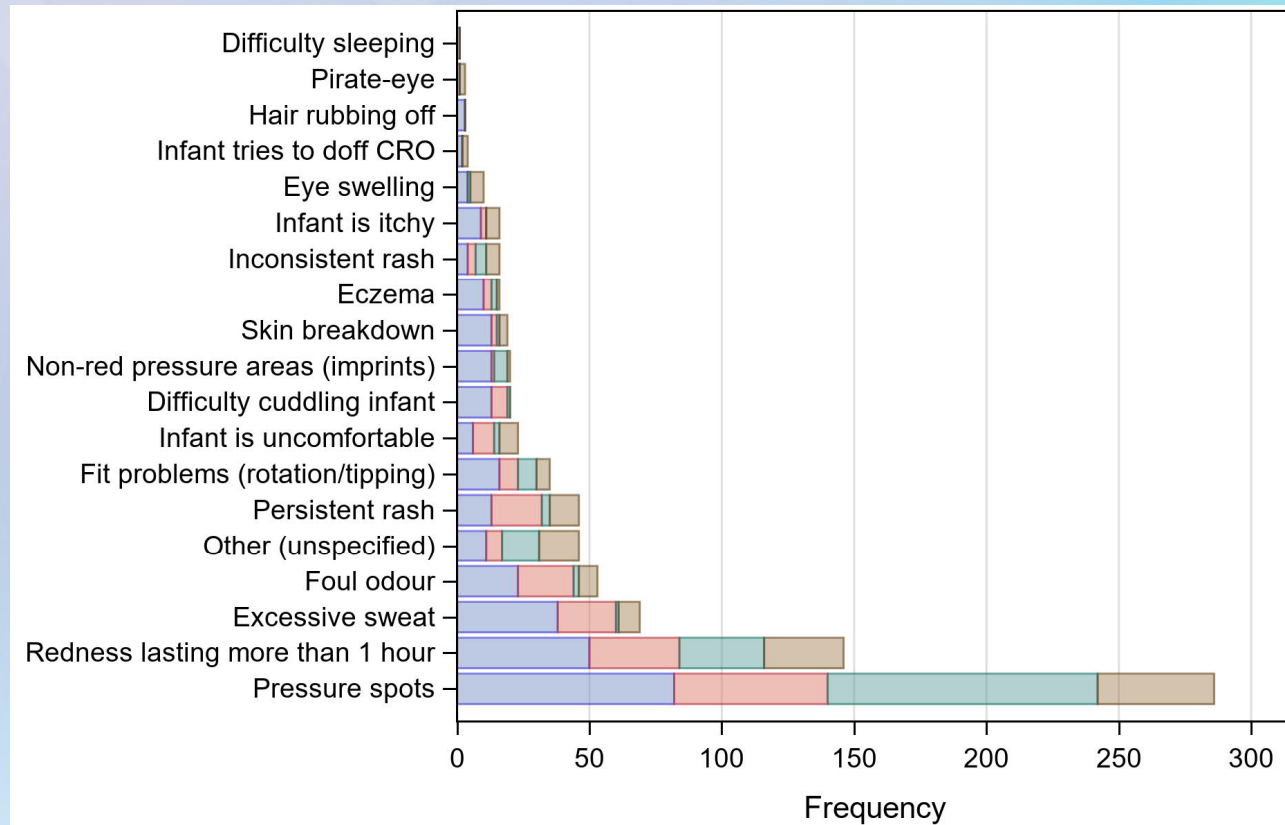
Methods

- Retrospective review of caregiver and practitioner surveys
 - 1/30/2020 to 6/15/2021
 - 4 offices in Canada using SnugKap (now named ROKband):
 - New Westminster, BC, Burlington, ON, Calgary, AB, and Edmonton, AB
- 1 wk; every 3 week follow ups
- Stats done using SAS
 - Chi-Squared test; Fisher's Exact tests; pairwise multiple comparison using Bonferroni's method; sig at 5%



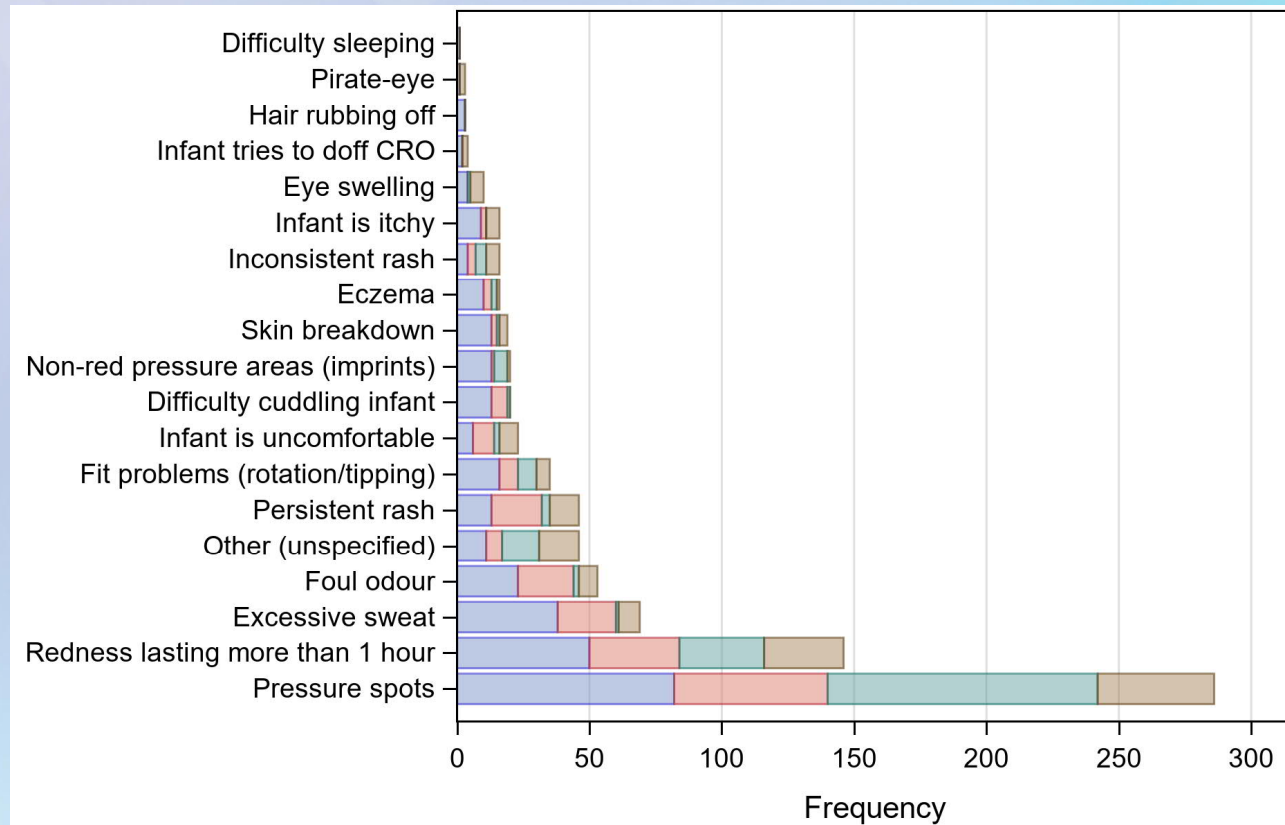
Results

- 4 offices; 453 patients
- 5,025 visits
 - Manually categorized
 - 832 incidences of side-effects
- No significant issues at 4,376 visits (87%)
 - Burlington (89.94%)*
 - Calgary (84.55%)*
 - Edmonton (85.66%)*
 - New Westminister (87.70%)*



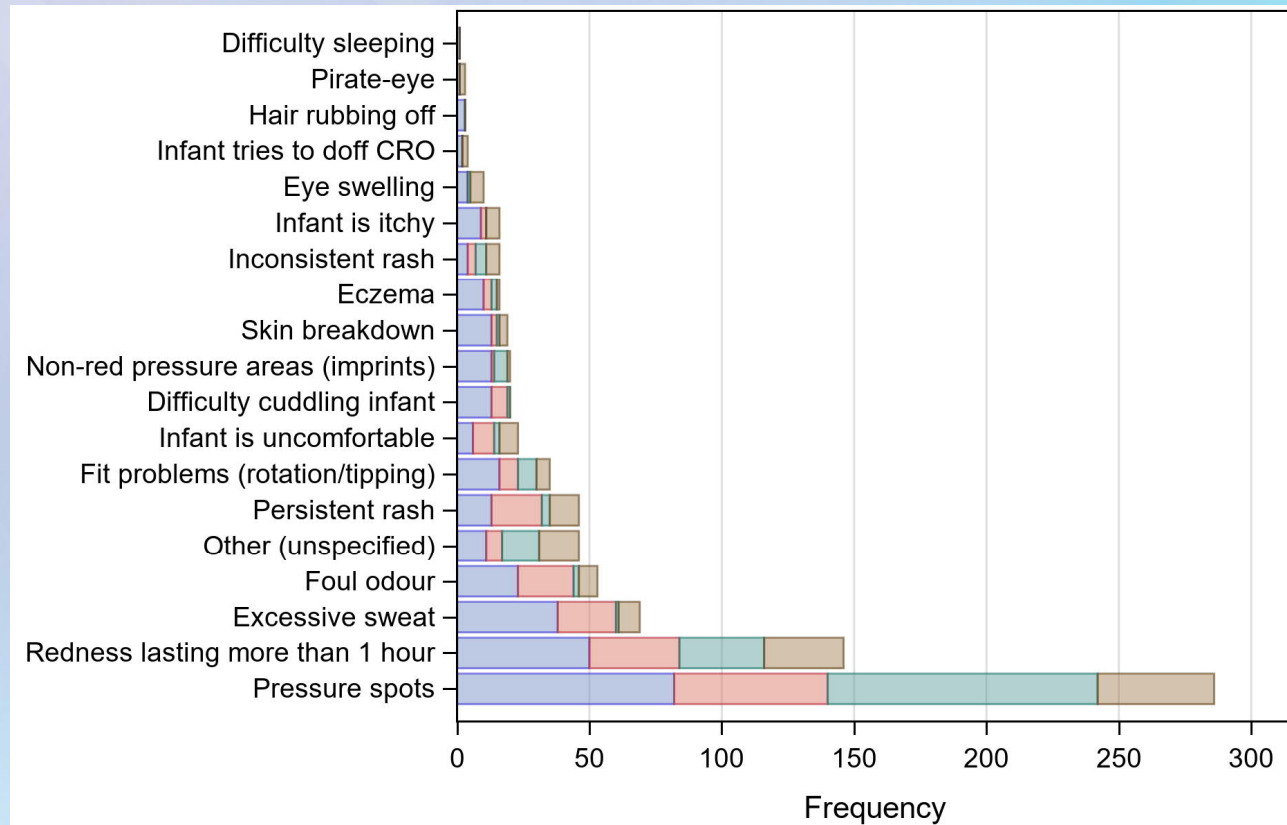
Results by Clinic

- Statistically similar:
 - difficulty cuddling infant
 - persistent rash
 - excessive sweat
 - foul odor
 - infant is itchy
 - pressure spots
 - other side effects
 - eye swelling
 - non-red pressure areas (imprints)
 - skin breakdown



Results by Clinic

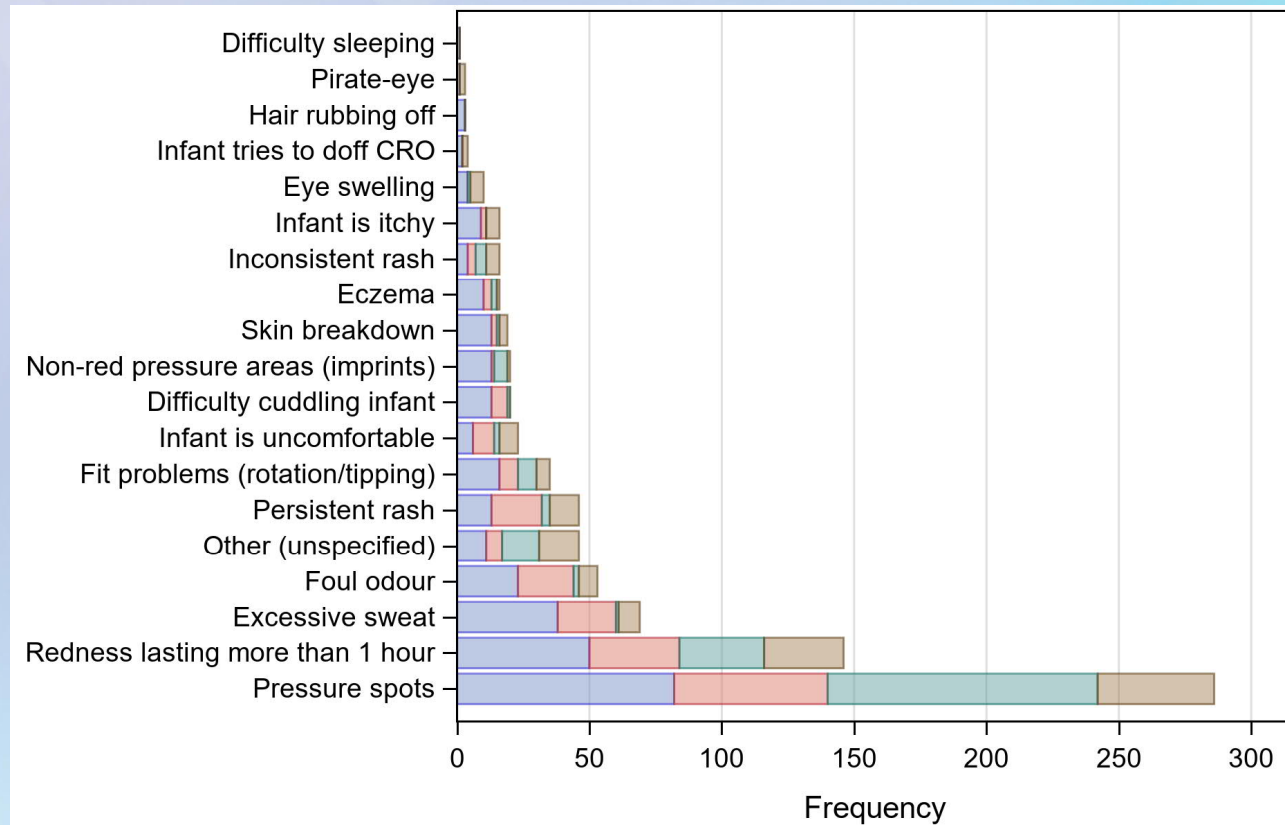
- Statistically different:
 - infant is uncomfortable*
 - fit problems (rotation/tipping)*
 - redness lasting more than 1 hour*
 - hair rubbing off*
 - infant tries to doff CRO*
 - difficulty sleeping*
 - Eczema*
 - "pirate-eye"*
 - inconsistent rash*



Results

- Fewer than 5 occurrences:
 - difficulty sleeping
 - "pirate-eye"
 - hair rubbing off
 - infant tries to doff CRO

- Greater than 50 occurrences:
 - pressure spots
 - redness lasting for more than 1 hour
 - excessive sweat
 - foul odour



Results – Incidence of Multiple Side Effects

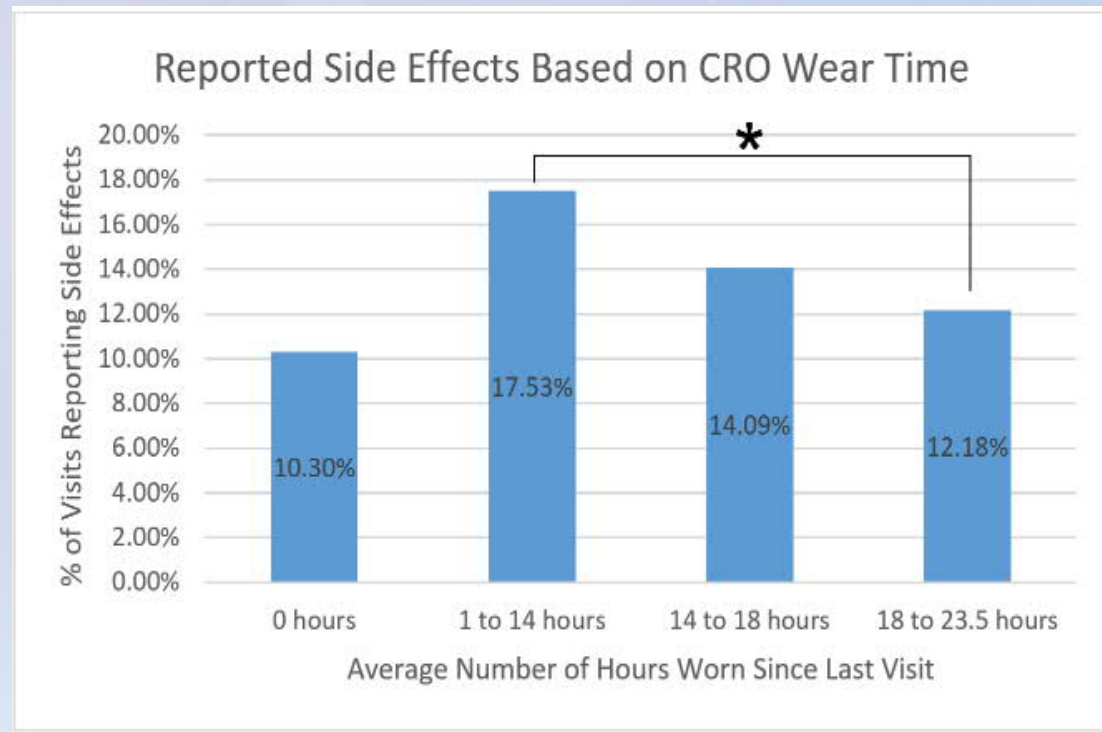
Number of Side Effects	Frequency	Percent
Survey did not report an answer	5	0.10%
No significant issues to report	4376	87.08%
1 side effect reported	503	10.01%
2 side effect reported	101	2.01%
3 side effect reported	33	0.66%
4 side effect reported	7	0.14%
Total Visits	5025	100%

Results – Incidence of Multiple Side Effects

- 35 “fit problems” (rotation/tipping)
 - 0.7% of surveys
- 3 times more likely to report multiple side effects*



Results – Wear Time Analysis of Side Effects



Discussion



Side Effect	Reported	VanWijk, et al
Skin irritations	9.84%	96%
Augmented sweating	1.32%	71%
Unpleasant Odour	1.02%	76%
Difficulty cuddling infant	0.38%	77%

Side Effect	Reported	Lee, et al
Rashes	1.19%	35.4%
Pressure sore / skin breakdown	0.36%	25.6%
Itching	0.31%	7.3%
2 or more adverse events	2.81%	9.8%

Limitations

- Retrospective evaluation of de-identified survey data
 - No average number of visits per patient
 - Side effects reporting may be artificially inflated
- Orthotist interpretation of categories
 - Ex: 'mesh imprints' = non-red pressure marks
 - Might not need adjustments
 - Pressure marks may be over-reported
 - Ex: 1/5 redness may be clinically appropriate
- Subjective side-effects
 - Ex: infant being uncomfortable or difficulty cuddling *infant*



Limitations

- Caregiver-reported wear time
- 1 band, 4 clinics
- Some telehealth surveys
- Climate-based side effects
 - Ex: foul odour and excessive sweat
- Reduced wear-time at end of treatment
 - Orthosis outgrown?



References

1. Binkiewicz-Glinńska A, Mianowska A, Sokół M, et al. Early diagnosis and treatment of children with skull deformations. The challenge of modern medicine. *Dev Period Med* 2016;20:289–295
 2. Mortenson P, Steinbok P, Smith D. Deformational plagiocephaly and orthotic treatment: indications and limitations. *Childs Nerv Syst* 2012;28:1407–1412
 3. Steinberg JP, Rawlani R, Humphries LS, et al. Effectiveness of conservative therapy and helmet therapy for positional cranial deformation. *Plast Reconstr Surg* 2015;135:833–842
 4. Freudlsperger C, Steinmacher S, Saure D, et al. Impact of severity and therapy onset on helmet therapy in positional plagiocephaly. *J Craniomaxillofac Surg* 2016;44:110–115
 5. Dörhage KWW, Beck-Broichsitter BE, von Grabe V, et al. Therapy effects of head orthoses in positional plagiocephaly. *J Craniomaxillofac Surg* 2016;44:1508–1514
 6. Loveday BP, de Chalmers TB. Active counterpositioning or orthotic device to treat positional plagiocephaly? *J Craniofac Surg* 2001;12:308–313
 7. Yoo HS, Rah DK, Kim YO. Outcome analysis of cranial molding therapy in nonsynostotic plagiocephaly. *Arch Plast Surg* 2012;39:338–344
 8. Gump WC, Mutchnick IS, Moriarty TM. Complications associated with molding helmet therapy for positional plagiocephaly: a review. *Neurosurg Focus* 2013;35:E3
 9. Kelly KM, Joganic EF, Beals SP, et al. Helmet Treatment of Infants With Deformational Brachycephaly. *Glob Pediatr Health* 2018;5:2333794X18805618
 10. Kim SJ, Lee KJ, Lee SH, et al. Morphologic relationship between the cranial base and the mandible in patients with facial asymmetry and mandibular prognathism. *Am J Orthod Dentofac Orthop* 2013;144:330–340
 11. Kluba S, Schreiber R, Kraut W, et al. Does helmet therapy influence the ear shift in positional plagiocephaly? *J Craniofac Surg* 2012;23:1301–1305
 12. Flannery AM, Tamber MS, Mazzola C, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guidelines for the Management of Patients With Positional Plagiocephaly: Executive Summary. *Neurosurgery* 2016;79:623–624
 13. Fish D, Lima D. An Overview of Positional Plagiocephaly and Cranial Remolding Orthoses. *J Prosth Orth* 2003;15:37–45
- Graham and Wang *The Journal of Craniofacial Surgery* Volume 33, Number 00, Month 2022, 4 # 2022 Mutaz B. Habal, MD Copyright © 2022 Mutaz B. Habal, MD. Unauthorized reproduction of this article is prohibited. CE: D.C.; SCS-22-0005; Total nos of Pages: 5; SCS-22-0005
14. Seruya M, Oh AK, Taylor JH, et al. Helmet treatment of deformational plagiocephaly: the relationship between age at initiation and rate of correction. *Plast Reconstr Surg* 2013;131:55e–61e
 15. Department of Health and Human Services: Food and Drug Administration. Neurological devices; classification of cranial orthoses FDA. Final Rule. *Fed Regist* 1998;63:40650–40652
 16. Freudlsperger C, Bodem JP, Kargus S, et al. The Incidence of Complications Associated With Molding Helmet Therapy: An Avoidable Risk in the Treatment of Positional Head Deformities? *J Craniofac Surg* 2015;26:e299–302
 17. Van Wijk RM, Boere-Boonekamp MM, Groothuis-Oudshoorn CGM, et al. Helmet therapy Assessment in Infants with Deformed Skulls (HEADS): Protocol for a randomised controlled trial. *Trials* 2012;13:
 18. Takamatsu A, Hikosaka M, Kaneko T, et al. Evaluation of the molding helmet therapy for Japanese infants with deformational Plagiocephaly. *JMA J* 2021;4:50–60
 19. Lee S, Kim SJ, Kwon J. Parents' perspectives and clinical effectiveness of cranial-molding orthoses in infants with Plagiocephaly. *Ann Rehabil Med* 2018;42:737–747
 20. www.rokband.com

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