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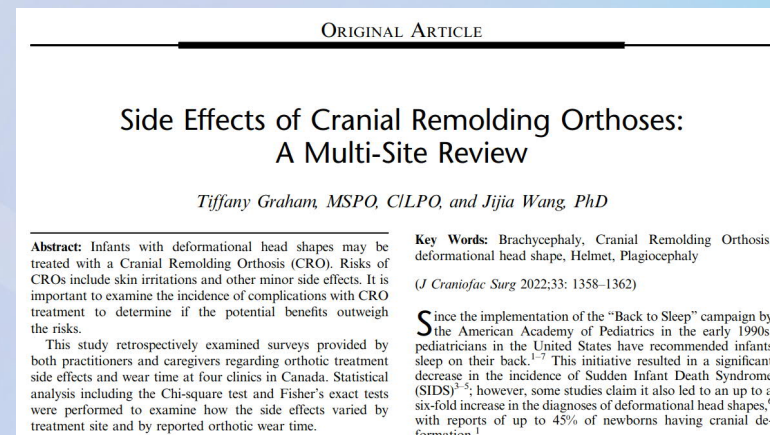
Welcome

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

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Acknowledgement & Disclosure

Jason Goodnough, MSc.



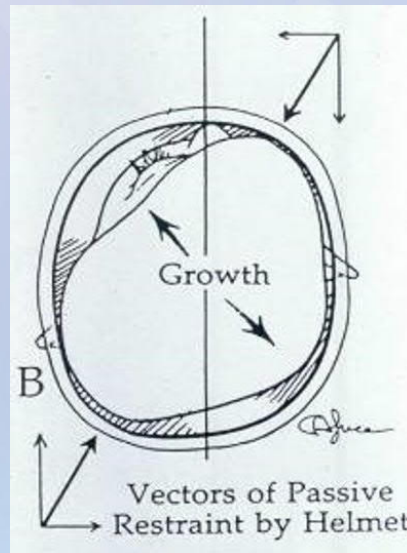
- The article submission fee was paid by HeadStart Medical, Ltd.
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FDA

Cranial Remolding Orthoses (CROs) are Class II Medical Devices

skin checks every 3-4 hours

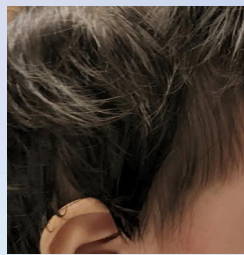
There is a need to "Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of head growth..."



FDA identified the following risks to health associated with this type of device: (1) **Skin irritation**, skin breakdown and subsequent **infection** due to excessive pressure on the skin; (2) **head and neck trauma** due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements; (3) **impairment of brain growth** and development from mechanical restriction of cranial growth; (4) **asphyxiation** due to mechanical failure, poor fit, and/or excessive weight that alters the infant's ability to lift the head; (5) **eye trauma** due to mechanical failure, poor construction and/or inappropriate fit; and (6) **contact dermatitis** due to the materials used in the construction of the device.

Side Effects Reporting

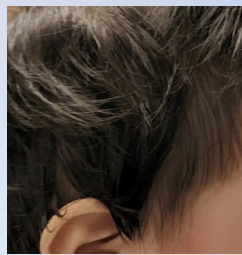
- 2013 (Gump et al)– review of literature - complications were “low or negligible”
 - malodorous perspiration, minor skin irritations, and social stigma
- 2001 (Loveday et al) – side effects include: heat rash, reactions to the materials, and older infants able to remove the CROs
 - complications seen 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%



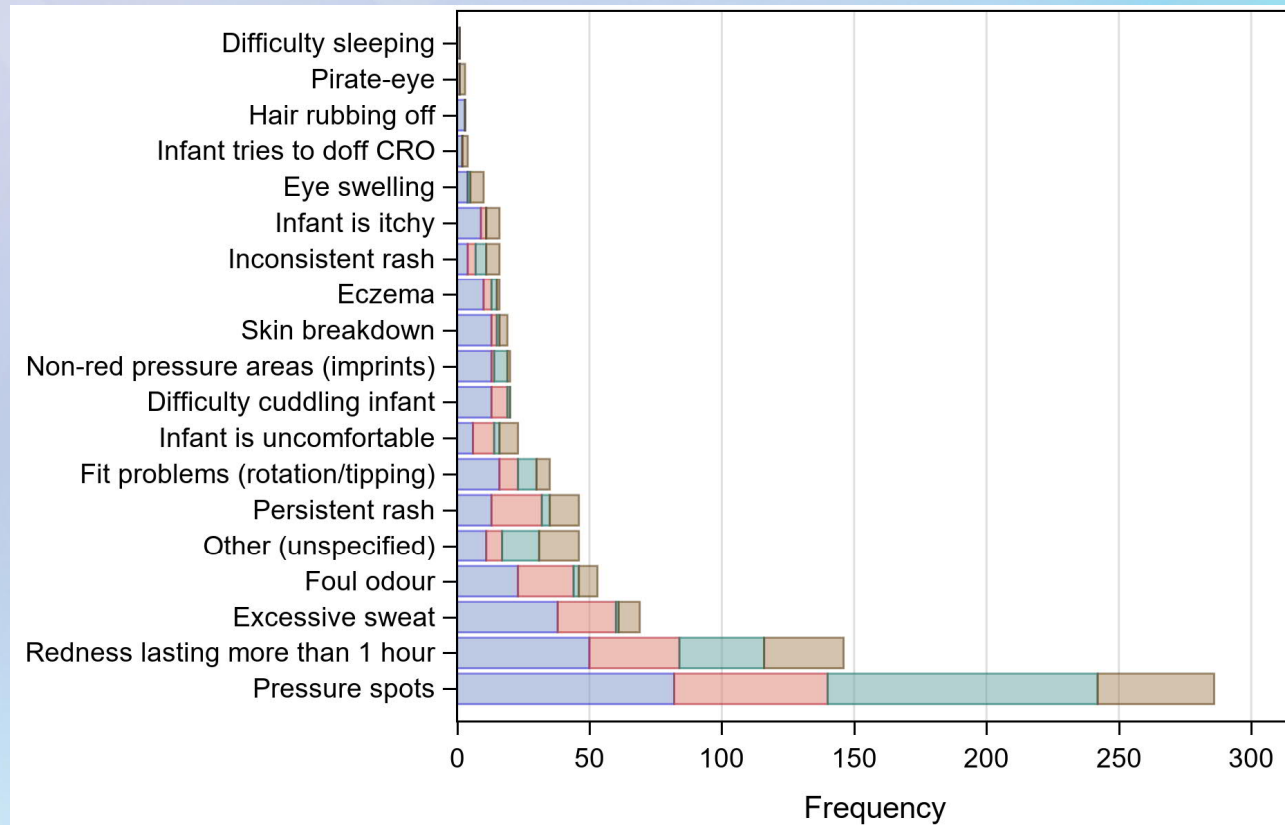
Methods

- 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%



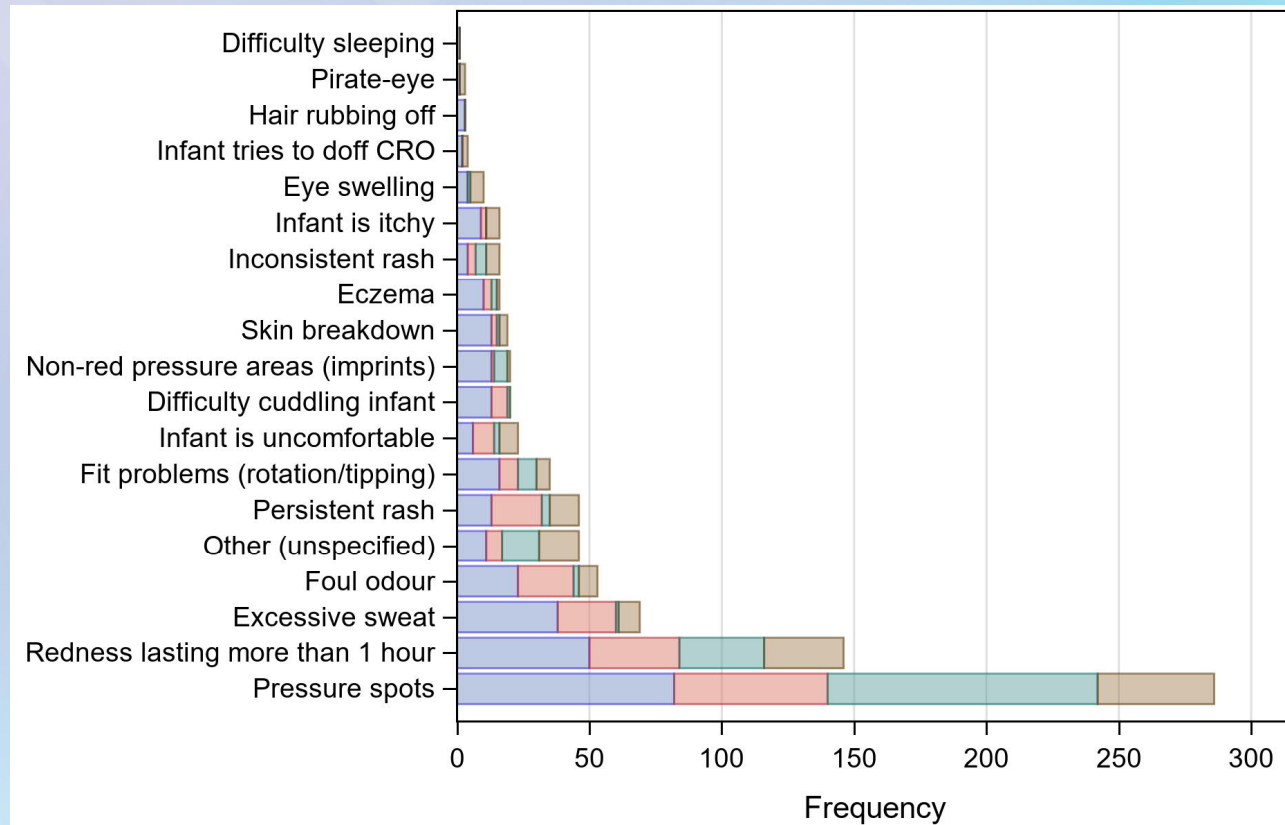
Results

- 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%)*



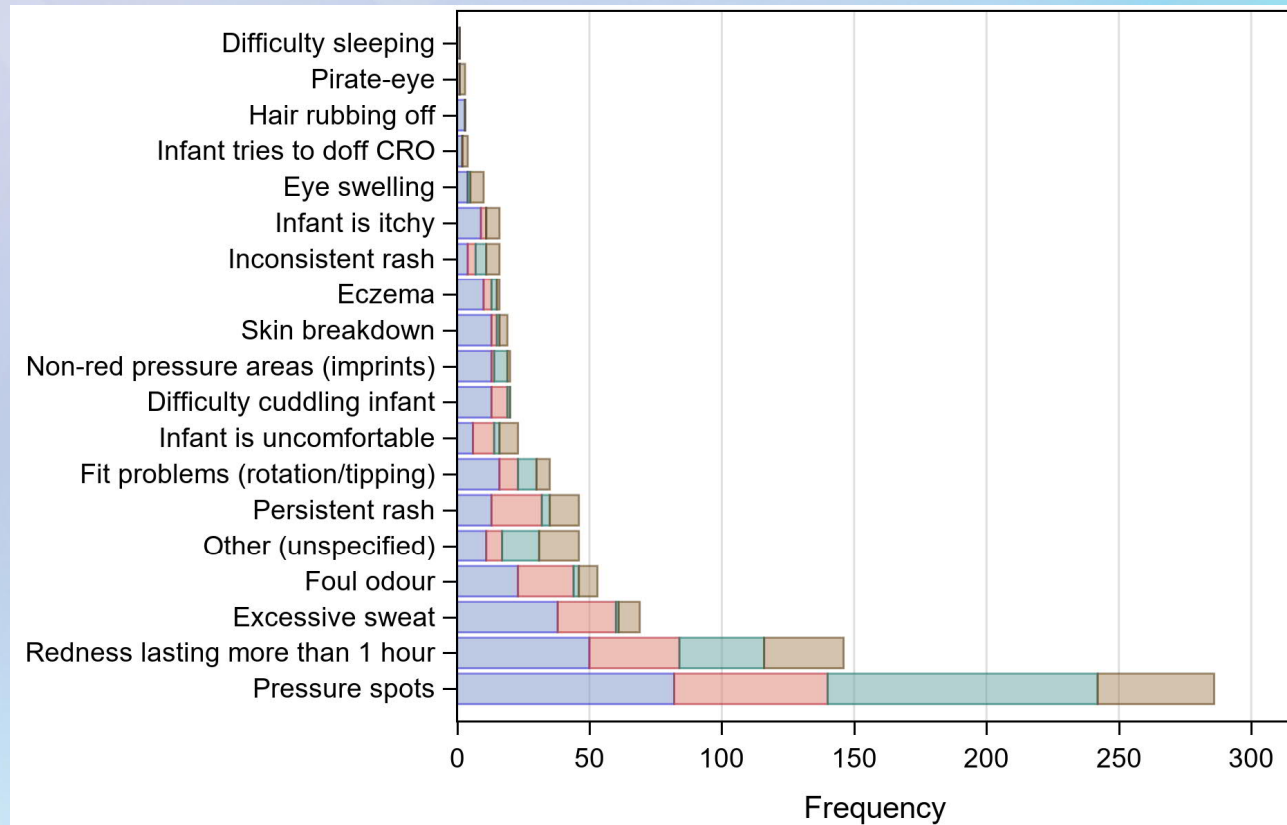
Results by Clinic

- 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

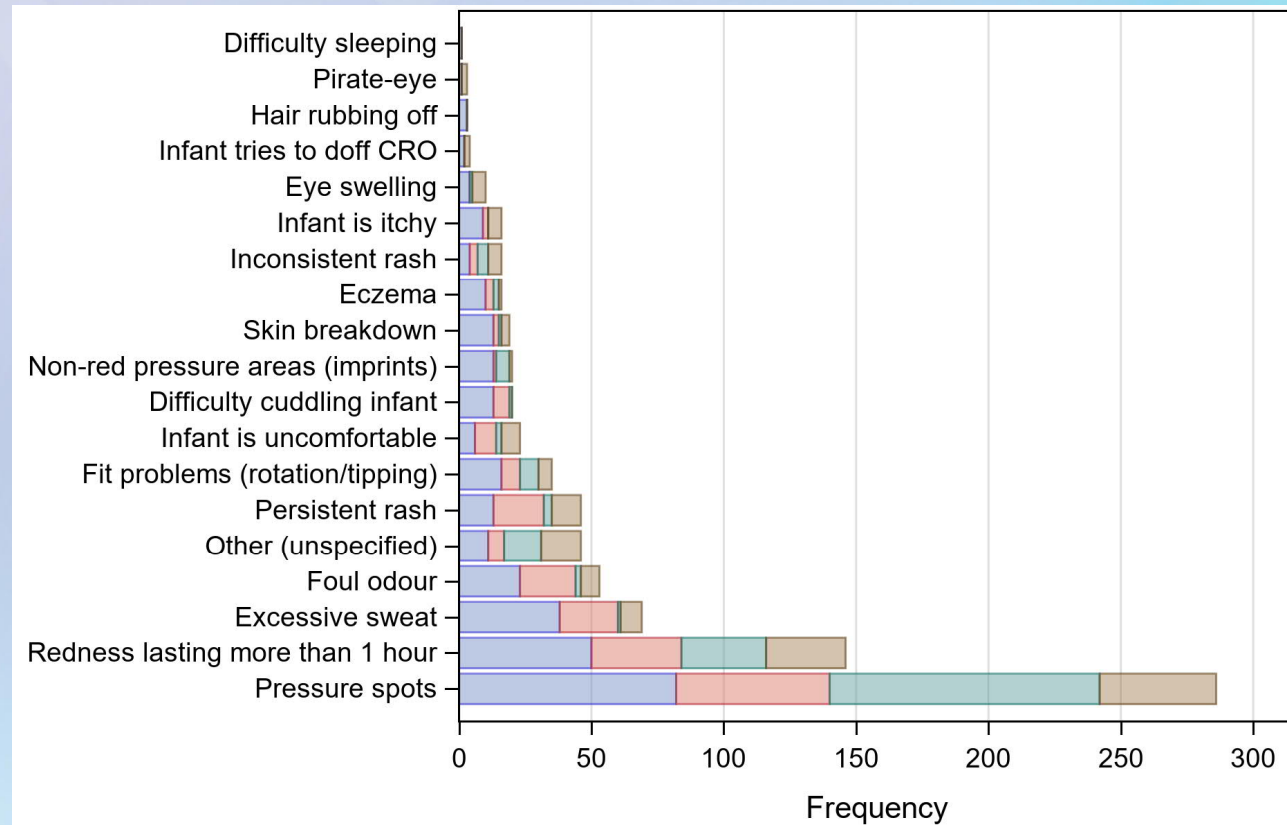
- Statistically different:
 - infant is uncomfortable*
 - fit problems (rotation/tipping)*
 - redness lasting more than 1 hour*
 - hair rubbing off*
 - infant tries to doff CRO*
 - difficulty sleeping*
 - Eczema*
 - "pirate-eye"*
 - inconsistent rash*



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

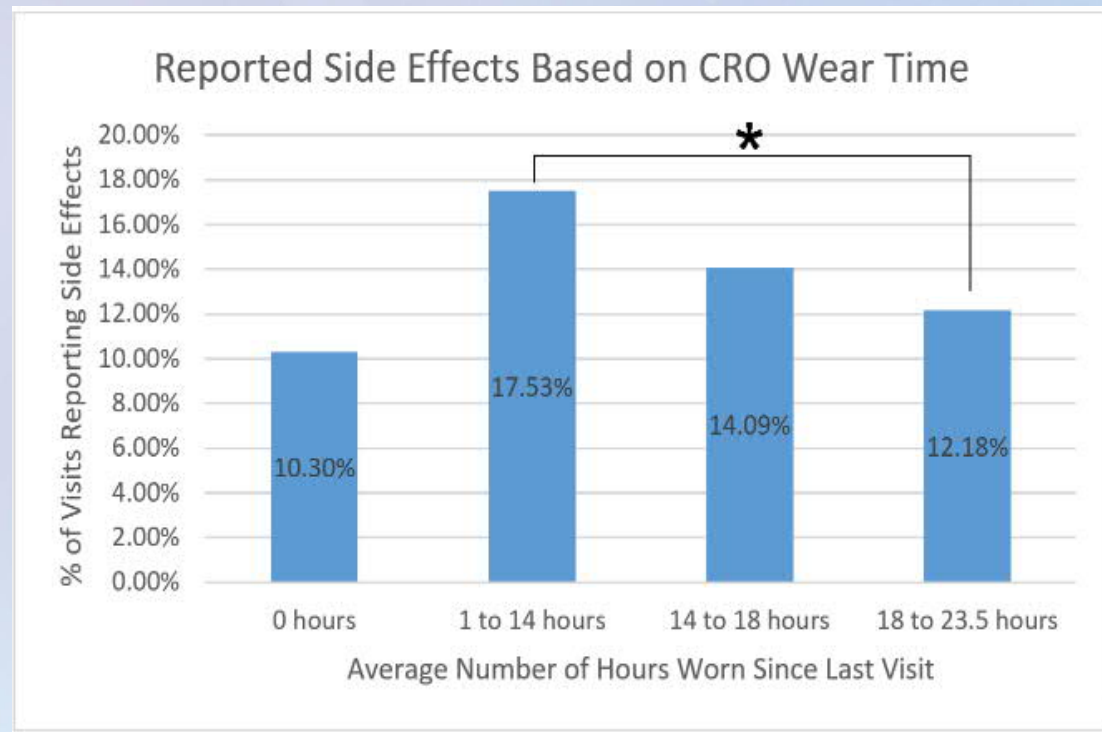
Number of Side Effects	Frequency	Percent
Survey did not report an answer	5	0.10%
No significant issues to report	4376	87.08%
1 side effect reported	503	10.01%
2 side effect reported	101	2.01%
3 side effect reported	33	0.66%
4 side effect reported	7	0.14%
Total Visits	5025	100%

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?



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