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The Safe-T-Sleep® device: safety and efficacy in maintaining infant sleeping position

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Abstract

Aims The issue of infant sleeping position has socio-political ramifications. Current recommendations endorse supine sleeping as an aid to reducing the risk of sudden infant death syndrome (SIDS). Persistent sleeping of a newborn infant in the same position may induce plagiocephaly without synostosis (PWS). Parents in our craniofacial clinic, whose children present with PWS, often feel torn between apparently conflicting goals – avoiding SIDS and avoiding PWS. The Safe-T-Sleep® device, a form of infant sleep wrap, purportedly allows safe semi-supine positioning, thus ameliorating PWS (by preventing the infant from lying on the cranial 'flat spot') while not increasing the risk of SIDS. Before recommending the device to parents in our plagiocephaly clinics, we designed a prospective, hospital-based trial to assess the safety and efficacy of the device in maintaining selected sleeping positions. This was not a trial of the efficacy of the Safe-T-Sleep® device in treating plagiocephaly.

Methods The devices were trialed on 31 babies, between birth and 11 months of age. A total of 396 hours of observations were recorded.

Results The device maintained the selected body position in 94% of recorded observations and head position in 87%. There were no significant adverse events or complications associated with the use of the Safe-T-Sleep[®] device.

Conclusions The device appears to be safe and effective. It is now being advocated in our clinic as an aid to active counter-positioning strategies to passively correct incipient or established positional plagiocephaly in younger babies.

New Zealand has experienced something of an epidemic of sudden infant death syndrome (SIDS) or cot deaths over recent years. As a result, there has been considerable national debate about the issue and research into causal factors is examined with great interest by a wide range of interested parties. Current recommendations from experts in the field strongly advocate supine positioning for sleeping infants, citing a sixfold reduction in the risk of SIDS when compared with a prone sleeping position, and a threefold reduction when compared with side-lying. 1,2,3

Concomitant with the reduction in SIDS rates that these recommendations have produced, is a marked increase in the number of babies in New Zealand referred for advice regarding plagiocephaly without synostosis (PWS) or 'flat heads'. ⁴ It is axiomatic that if a neonate, and more especially a premature neonate, is positioned consistently in the same attitude, be it supine, supine with the head turned to one side, or side-lying, the cranium will flatten, simply due to the effects of gravity pressing a soft skull against a relatively unyielding surface (the mattress). A comparable rise in the numbers of PWS referrals has been seen in the USA in the years subsequent to the 1992 recommendation from the American Academy of Paediatrics that supine

sleeping was best for babies.^{5,6} It is hard to escape the conclusion that supine sleeping, with a single, maintained attitude, may be causally related to flat-head presentations.

Since most cases of PWS can be prevented, or, if picked up early, resolved by active counter-positioning (ie, never allowing the infant to sleep on the cranial 'flat spot'), it would be useful to be able to offer parents some practical means of applying the principle that the child must not be allowed to sleep on the flattened plane of a deformed skull. That is, some way of being able to select and maintain a sleeping position that is both safe and effective. Too often children of six months or older are referred for consultation regarding a well-established case of PWS; the trouble is that, by this time, not only is the deformity well developed and obvious, but the child is also old enough to have very firm ideas about what is his or her favoured sleeping position and will actively resist parental attempts to modify this. It is much more comfortable for the baby to lie with the flat spot down on the mattress than try to sleep balancing the skull on the adjacent high spot. It is precisely because of this difficulty that some resort to orthotic devices such as the DOC band® and cranial moulding helmets.⁵ Not only are such devices costly and difficult to make, but they need regular adjustment to remain effective as the head shape alters. In many cases they are simply abandoned by parents frustrated by the difficulties of finding a comfortable, efficacious, device that the infant will tolerate wearing. Certainly, PWS is easier to prevent than resolve; while most children, given sufficient time and attention to restricting pressure on the flat spot, will revert towards normal craniofacial symmetry, some are left with significant asymmetry, which even exuberant hair growth cannot fully hide. In the USA, long-term follow-up studies have shown that about 4% of cases remain sufficiently deformed to warrant consideration for surgical correction of the plagiocephaly.

Consequently, when the commercially available Safe-T-Sleep[®] (STS) device came to our attention, it was felt that it might offer a means whereby an infant, presenting with incipient or established PWS, might safely sleep in the semi-supine position, but with the head turned away from the flat spot and mattress pressure confined to the highspot area. In other words, it might offer a means of maintaining control of sleeping position and therefore be useful as an adjunct in the treatment of the burgeoning number of babies presenting with flat heads. Before recommending the device to parents, however, we needed to be certain that it was both safe and effective in maintaining sleeping position. To this end, a prospective, hospital-based trial was designed to assess the STS device. It should be noted that this was **not** a trial of the device's efficacy in the treatment of established PWS or 'flat head', since we have already established that active counter-positioning (ie, prevention of the infant lying on the flat spot), by whatever means achieved, is very effective at correcting plagiocephaly. If it could be shown that the STS device was both safe and effective at maintaining a selected sleeping position, we would be able to recommend it to parents of plagiocephalic infants as a useful adjunct in achieving active counter-positioning.

Methods

A prospective trial was designed in which a number of STS devices were purchased and trialled, according to the manufacturer's instructions, in the wards and special care units of Middlemore Hospital, a large, regional healthcare facility located in suburban South Auckland. The manufacturers of the device had no input into the design of the study or its outcome, and no financial or material benefit accrues to the hospital or the authors as a result of this study. Those involved in the design and execution of the study have no connection whatsoever with the manufacturers of the STS device.

After obtaining ethical approval to proceed with the study, and obtaining informed consent from individual parents or caregivers of each baby entered in the trial, the following design was applied. All trial entrants were categorised according to age interval: 0-3 months, 3-6 months, 6-9 months and 9-12 months. Babies were eligible for entry into the trial providing they were not afflicted with PWS and they were spending at least one night in the hospital in the medical or surgical wards. Neonates in the special care baby unit (SCBU) for observation or treatment of a relatively minor complaint, which did not impact significantly on their overall mobility or strength, were also eligible. The primary care physician in charge of each patient, who was not part of the study team, assessed their patient as being suitable for trial entry and parents reserved the right to remove their baby from the trial at any time. Each entrant was placed in an STS device when being put down for a night's sleep and the selected head and body position noted. (See appendix for demonstration of how STS device is fitted.) The starting position was semi-supine or supine, with the head turned to the left or to the right. The immediate care-giving nurse had freedom to select the initial sleeping position, according to the infant's perceived needs. When semi-supine was chosen as the start position, a rolled towel was placed behind the raised shoulder. Every hour thereafter, the observed head and body positions were noted and recorded. Variances from the positions selected were documented, as were difficulties like restlessness, 'escape' from the device, and possible dangerous positioning, such as facial obstruction by bedclothes, soft toys and so on. The data were recorded by night-staff nurses at the bedside, who were otherwise not involved in the study. Data were recorded as hours' observation points, and form the basis of the analyses that follow.

Results

The results of our observations are presented in Tables 1, 2 and 3.

Table 1. Hours of observation of infants wearing STS devices

Age group	Number of babies	Hours of observation
0–3 months	17	240
3–6 months	2	27
6–9 months	10	108
9–12 months	2	21
Total	31	396

Table 2. Proportional maintenance of selected sleeping position

Age group	% body position maintained	% head position maintained
0–3 months	93 (16/240)*	91 (21/240)
3–6 months	95 (1/27)	85 (4/27)
6–9 months	92 (9/108)	80 (22/108)
9–12 months	95 (1/21)	90 (2/21)
Mean	94	87

^{*}numbers in brackets indicate ratio of hours of observation in which position not maintained

Table 3. Adverse events summary

Age group	Incidence of adverse events	Details
0–3 months	2	Device too loose* – unwanted movement
3–6 months	0	
6–9 months	1	Child was febrile – overheated
	1	Very active child – required frequent device adjustment
9–12 months	1	Unwanted head movement

^{*}In no instance was a child actually able to turn into the prone position. However, failure to apply the STS sleep wrap according to the manufacturer's instructions makes this a theoretical risk.

Discussion

In assessing the results of this simple data-collection exercise, several useful points can be made.

In the first instance, it would appear that the younger the baby the easier it is to select and maintain a sleeping position with the STS device. This is probably true of any similar behaviour the parents may be trying to teach the child and probably relates to tolerance; in the neonatal period, novelty is more readily accepted. As the babies become older, they become stronger, louder and less likely to passively accept such impositions as a relatively restrictive positioning device.

Overall, there were very few untoward experiences with the STS device. In no single instance was a child ever at physical risk. However, in two babies in the 0–3 month age group the device was applied too loosely. This allowed a deal of unwanted movement that could conceivably have resulted in an unmonitored child being able to turn over within the device sufficiently to place itself at risk. However, when the device was firmly applied and pinned to the overpants, as recommended by the manufacturer, this did not occur.

Not surprisingly, the babies' heads were free to move more than were their bodies. Nevertheless, for this sample of 31 babies undergoing nearly 400 hours of monitored observation, the STS device was at least 85% (mean 87%) successful in maintaining selected head position, and at least 92% (mean 94%) successful in maintaining body position, across all age groups.

Although the major flaw of very low patient numbers in some of the groups precludes extrapolation to the wider population, it nevertheless appears that the STS device may well be helpful to those wishing to maintain a selected sleeping position in babies. As such it might prove a useful addition to a therapeutic programme of active counterpositioning as treatment for cranial moulding or plagiocephaly. Not surprisingly, it is most readily accepted when introduced early in the baby's life; indeed, its use in the treatment of positional plagiocephaly may be obviated by the early introduction of intelligent advice regarding sleeping position. We tell our families to practise supine sleeping with the head turned to the left on night one, to the right on night two and so on. It is in helping such families to achieve this goal, especially as a training aid in the younger babies, or as a behaviour modifier in the slightly older baby, that such a device would seem to be most useful. Its efficacy in specifically altering the plagiocephalic deformation that is being seen much more commonly today remains to be established (although, anecdotally, it would indeed seem to be very effective in this regard). At the least, however, our data have enabled us to recommend the device to our patients' families as being effective and safe in maintaining a selected sleeping position in babies less than a year of age.

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Appendix

Figure 1. The main component of the Safe-T-Sleep® device wraps around and fastens to the mattress. The central portion, which is sewn to the main mattress-wrap portion is spread out to receive the baby.

Figure 2. The baby is placed supine on the central portion and the velcro-backed straps placed snugly around the central chest and abdomen.





Figure 3. The overpants are pulled up over the lower margin of the central wrap and safety-pinned in place. This prevents the baby wriggling out of the device. To select a semi-supine position, a rolled towel can be placed behind the shoulder (not illustrated).

Figure 4. Detail showing how the overpants are pinned to the central section of the sleep wrap.



