

Clinical evaluation of the Multicare-Bed®



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AIM/BACKGROUND.

- ▶ 20 % of all parents consult because of regurgitation and feeding related infant distress
- ▶ Prokinetics (domperidone): no efficacy data (Pritchard DS. Br J Clin Pharmacol 2005;59:725-9)
- ▶ Anti-acid drug treatment:
 - ◆ not indicated, over-use (Barron JJ. JPGN 2007;45:421-7)
 - ◆ side-effects (Canani RB. Pediatrics. 2007;117:e817-20)
- ▶ Nutritional treatment
- ▶ Positional treatment
 - ◆ Sitting position ⇆ GOR
 - ◆ Right side 1 hr/ Left side 1 hr (Van Wijk, J Pediatr 2007;151:585-90)
 - ◆ Prone-antitrendelenburg: effective but ⇆ SIDS (Tobin JM. Arch Dis Child 1997;76:254-8)
- ▶ Positional treatment: “new AR-bed”?



MATERIAL & METHODS.

1st Pilot study (20 infants):

“AR-mattress” developed in collaboration with Peos® infants “hang” relatively comfortable in 40° inclination in supine position

2nd Efficacy study

- ◆ 25 consecutive babies (3 weeks - 3 months old) referred to the Unit because of frequent regurgitation and inconsolable crying, in which dietary treatment (extensive hydrolysate, AR-formula) and medication (domperidone, H²RA, PPI) had been unsuccessful.
- ◆ Approved ethical committee
- ◆ Diary (frequency of regurgitation, crying time, time asleep, “overall sleep comfort” on a 1-10 scale) during 2 days as baseline and during 1 week intervention.
- ◆ pH monitoring performed before inclusion and after 7 days in 10 infants.

3rd Safety study

- ◆ ? impact on obstructive apnoea (polysomnography about 4 hours in flat-supine and 4 hours in 40°-supine position) in 10 infants with treated GERD (domperidone/ranitidine)

RESULTS.

2nd Efficacy study

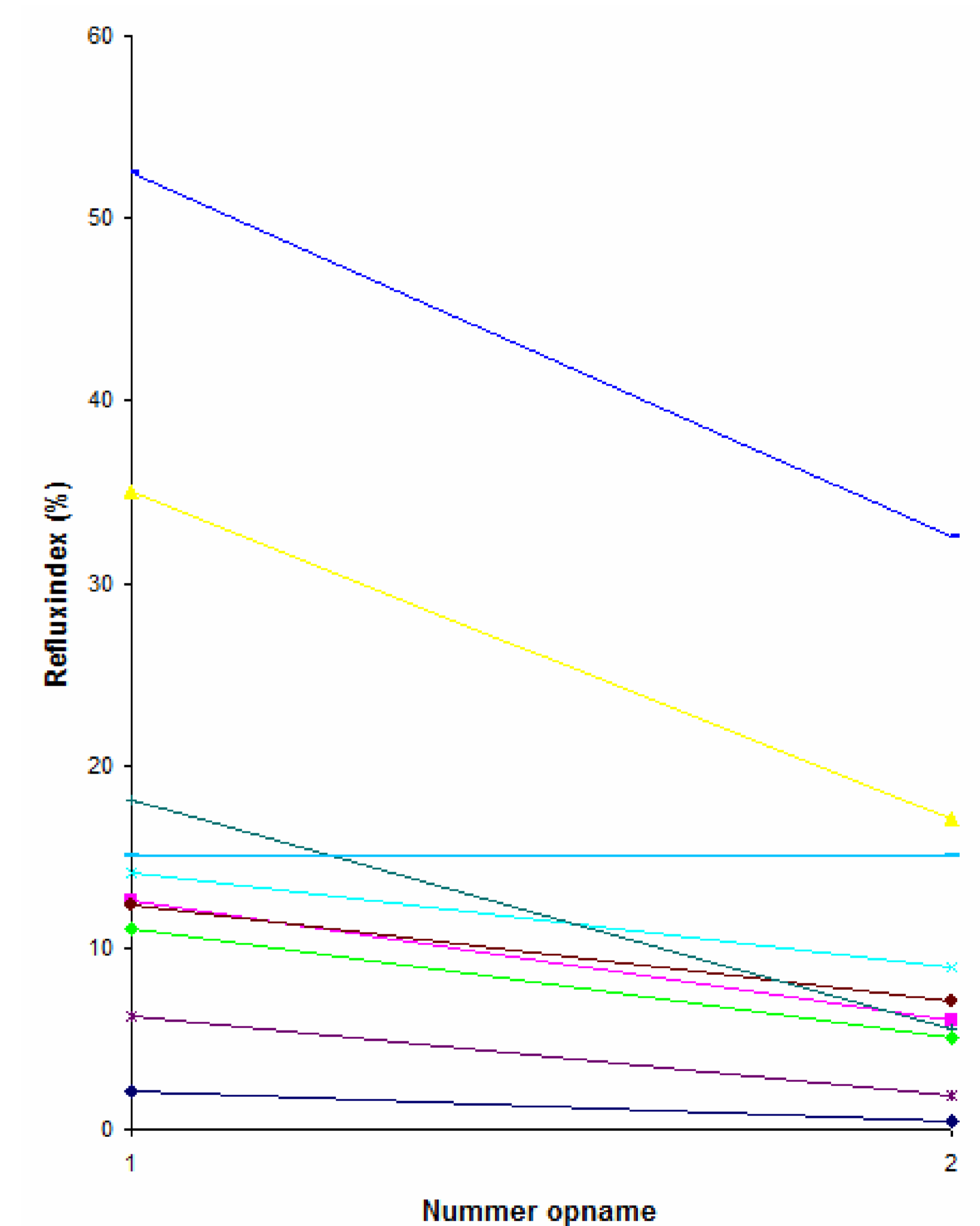
- ▶ 8/25 parents stopped the intervention after the 1st or 2nd day (32% failure) crying ⇆ infant bended over (problem solved with new models of AR-bed)
- ▶ 17/25 parents were satisfied
 - ◆ Median sleep comfort (1-10 scale): “3” before inclusion / “8” after one week
 - ◆ Significant decrease regurgitation score
 - ◆ pH metry (reflux index):

Baseline 18.6 % (median 14.1; range 2.1 - 52.5)

After 1 week 10.1 % (median 7.1; range 32.5-0.5)

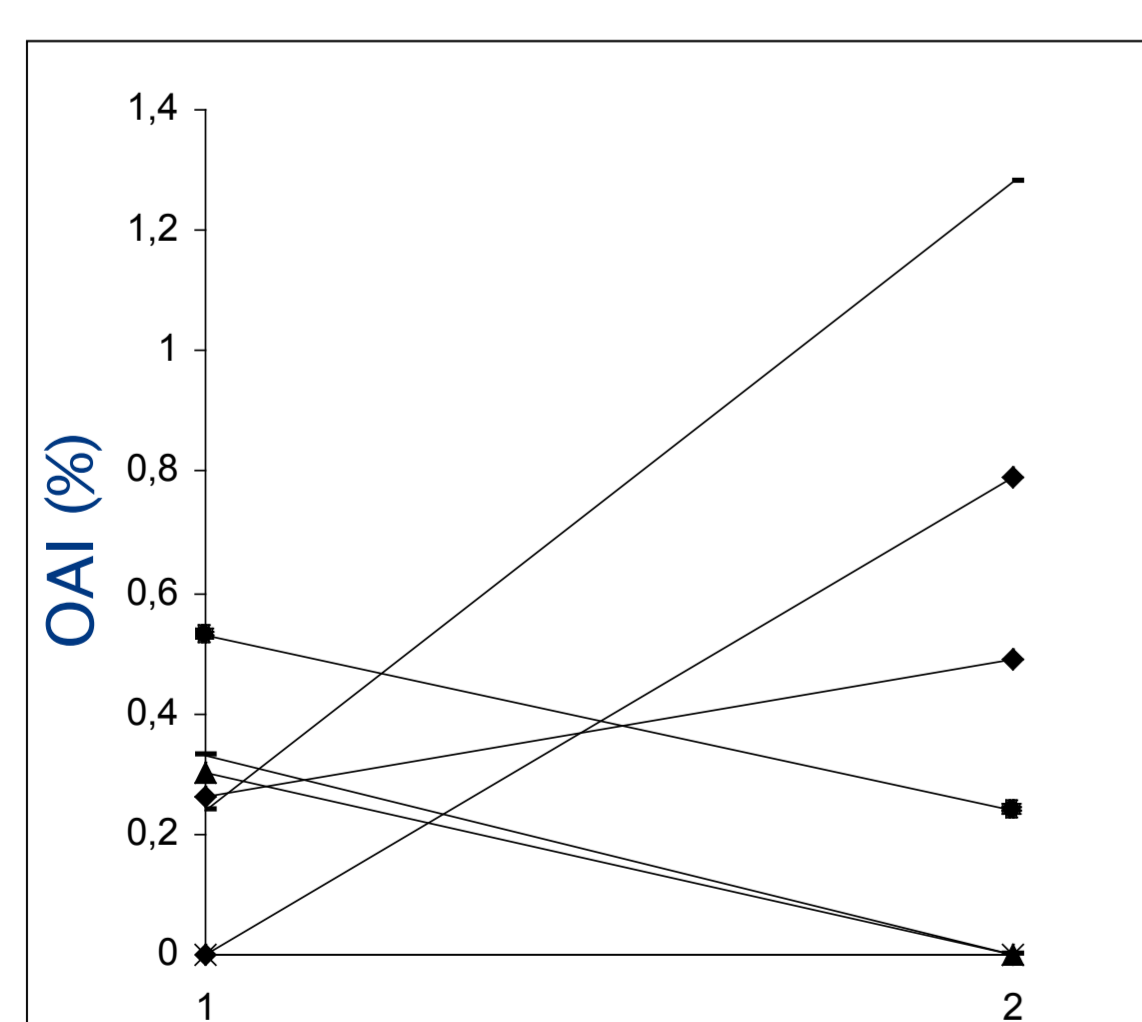
(p: 0.008 Wilcoxon-test).

3rd safety study

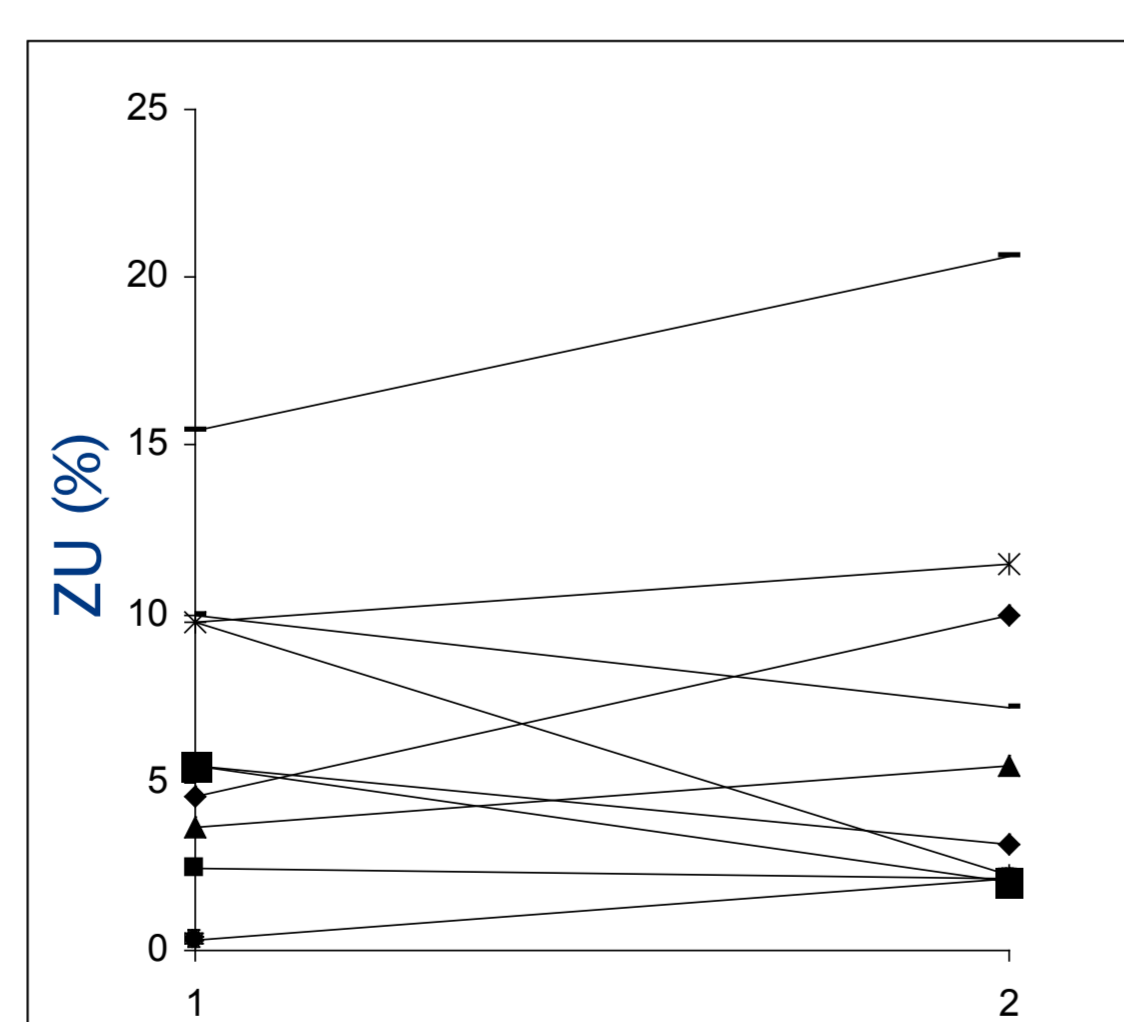


Median	Horizontal	Anti-Trendelenb	P
N° obstr apnoea/hr	0.28	0.64	0.767
N° sighs/hr	5.48	4.30	0.878
N° arousals/hr	10.14	7.15	0.575

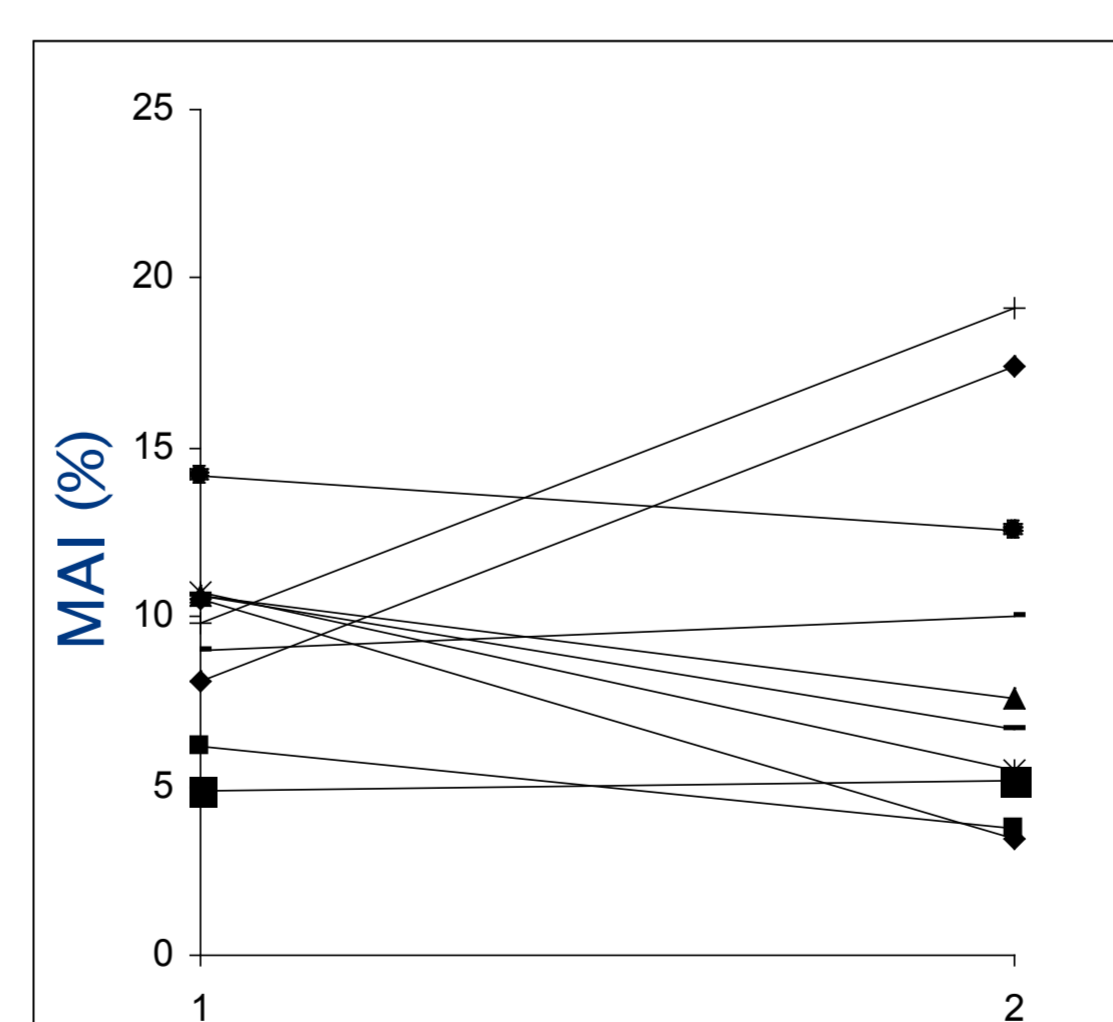
Arousals: parameter for quality of sleep



OBSTRUCTIVE APNOEA INDEX



n° OF SIGHs



AROUSAL INDEX

CONCLUSION

The Multicare-Mattress® is reasonable effective in the majority of a group of infants presenting with persistent crying and frequent regurgitation not responding to reflux medication (domperidone, H²RA, PPI) and dietary treatment (AR formula, extensive hydrolysate). A significant decrease of oesophageal acid exposure is demonstrated. The particular (sleeping) position seems not to influence quality of sleep. The Multicare-Mattress® can be considered especially in infants in whom history suggests a close time relation between feeding and regurgitation and distress.