

**A new induction mask for
infants and small children
OR
Columbus' s egg in a new
shape**

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Disclosure

The speaker **was** a consultant of the
CAST SILICONE Comp, Kibutz Anavim,
Israel



Where I am coming from?



11,000 births/year



22,000 students



Let's start with.....

Columbus story

- An egg of Columbus or Columbus's egg refers to a brilliant idea or discovery that seems simple or easy after the fact. The expression refers to a popular story of how [Christopher Columbus](#), having been told that [discovering the Americas](#) was no great accomplishment, challenged his critics to make an [egg](#) stand on its tip. After his challengers gave up, Columbus did it himself by tapping the egg on the table so as to flatten its tip.

The story is often alluded to when discussing [creativity](#).



And forgive
me for
telling you
banalities....

Anesthetizing a small child is not a simple procedure.....

Two sentences express the difficulty of the job

"The goals of an ideal anesthetic induction are to minimize unpleasant experiences and morbidity while ensuring patient's safety"

"Extreme anxiety during the induction of anesthesia is associated with increased occurrence of postoperative behavioral changes"

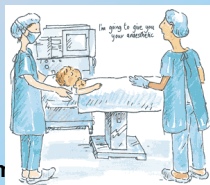


(Kain ZN et al. *Anesth Analg* 1999;88:1042-1047)

(Wetzel and Maxwell in "Principles and Practice of Anesthesiology" of Longnecker, Tinker and Morgan, 1998)

Induction of anesthesia

- Induction could be the most stressful procedure a child experiences during the entire perioperative period
- Many children :
 - *become agitated
 - *increase the muscle tonus
 - *cry
 - *struggle to escape from anesthesia and nursing personnel

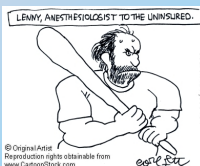


Age-specific anxieties of pediatric patients

(Litman RS. *Pediatric anesthesia*, 2004)

- At the age of 0-6 months:
 - *maximum stress for parents
 - *some stress for infants

- 6 months to 4 years:
 - *maximal fear of separation
 - *not able to understand the explanations
 - *struggling during induction of anesthesia



What do you think?

Why is so difficult to anesthetize a small child?

Because:

This was supposed to be the place for asking the audience specific answers, but NOT THIS AUDIENCE!!!

Two main difficulties

- It is sometimes quite difficult to identify a frightened child
- The “silent child” can become aggressive, because actually they are anxious and some of them have previous traumatic experiences
- The anxiety of the parent!!
This might influence the child condition during induction of anesthesia



Children anxiety is affected by parents psychological status

Kain NZ et al, Anesth Analg 2006;102:81

- Induction room
- Parents classified as anxious or calm
- Children classified as anxious or calm



Anxious children in the presence of a **calm parent** were significantly less anxious during induction as compared with anxious children who did not benefit from the parent's presence

Litman RS in 2004

- It is not unusual for the parents to be frightened and to project their fears and anxiety on the child, thus unintentionally contributing to the child's stress
- As pediatricians often treat the parents more than the child, the pediatric anesthesiologist also often assumes the role as a "family practitioner"

The impact



The postoperative negative behavioral changes

- 60% of small children may develop in the postoperative period symptoms which are similar to the posttraumatic stress distress:
 - *nightmares
 - *separation anxiety
 - *development regression (loss of bladder control, loss of language abilities)
 - *feeding difficulties
 - *aggression toward authority
 - *fear of subsequent medical procedure

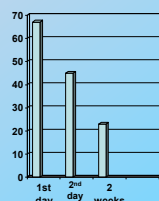


Kain ZN, Anesth Analg 1999;88:1042

The main two conclusions:

1. A child who was more anxious during induction had 3.5 times the risk for behavioral problems compared to a child who was less anxious
2. There was a significant correlation ($p=0.004$) between the anxiety of the child during induction and the excitement score on arrival to the recovery room

Postoperative negative behaviors (in percentage)



What has been done up to now in order to solve the problem?

Here is the list of all the proposals encountered in the literature

Before induction

- Premedication including sedatives
- Parent presence in the induction room
- Hospital-based preparation of the child
- Family-centered preparation
 - Speaking to the child
 - Pre-op hospital tours

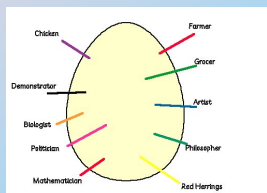
During induction

- Bringing "security objects" belonging to the child
- Fruit-flavoring masks
- Divert kid's attention
- Lollipop narcotics
 - Magic tricks
- Child holding the mask

Almost every single idea was criticized and proved to be inefficient in many cases

Proposals	Criticism
Use of sedatives	*increase cost *delays in OR activity *slow discharge
Parent presence in the induction room	*In many cases does not reduce kid's anxiety *many parents are terrified and faint!
Family-centered preparation	*too complex intervention *no experience with kids < 2 yrs
Explanations to the child	*only for big children, sometimes make the kid more frightened
Hospital tours	*time and money
Lollipop with narcotics	*chest rigidity *delayed emergency

So, let's
go back
to
Columbus
egg!!



A question for the audience

- How many children, aged 0 to 4 yrs, in the developed world, use a pacifier rather than sucking a thumb??!

- 15%
- 25%
- 50%
- 75%



- Two data from literature:

*Howard Cr, *Pediatrics* 1999;103:E33

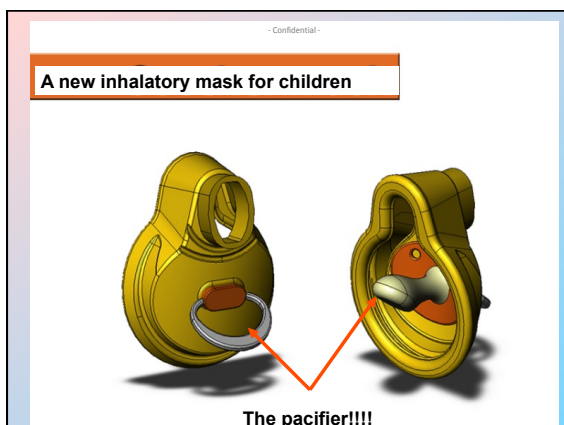
75%

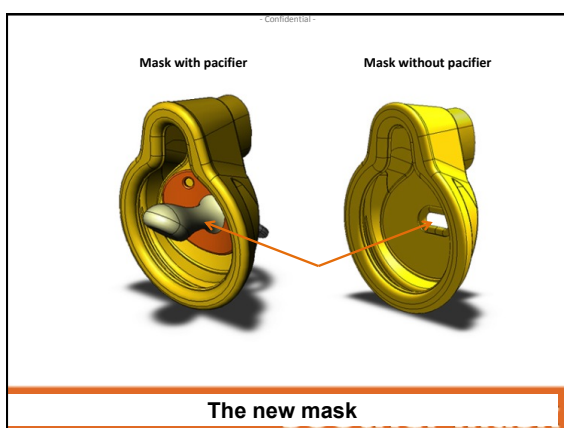
*Stevens LM, *JAMA* 2001;286:374

84%

Here are the news.....

- An Israeli inventor.....
- Got the story of kids struggling when get inhalatory treatment
- Created a special mask and called it EASYHALE
- Initially used it for children getting inhalations to treat asthma.....





And then he thought to use it for anesthesia!!!

We present here the results of a pilot trial, in two Romanian hospitals, in which 106 children got induction to anesthesia by using the special mask



A quick glance on the protocol

- Pre-anesthesia visit included explanations regarding the mask and its use together with the pacifier
- Parents got the mask for being used at home or during the last hours before surgery
- Parents come back the day of surgery with a questionnaire filled up about the mask use at home
- Most of the parents accept to accompany the child in the operating room
- Those who witness the induction process are asked to fill up the second part of the questionnaire
- Induction of anesthesia is performed by using sevoflurane, while the child sucks the pacifier through the mask
- The anesthesiologist in charge with the patient fills up his/her part of the questionnaire
- The study is ended the moment the child falls asleep

For each case, questionnaires have been filled up

● By the **parent**:

- *before getting in contact with the mask
- *after meeting the anesthesiologist
- *just before the induction

● By the **anesthesiologist**:

- *after examining the patient
- *immediately after induction

The pre-induction data

- How much time before induction did the children use the mask with the pacifier?

* <24 hrs : 15

*24-48 hrs: 23

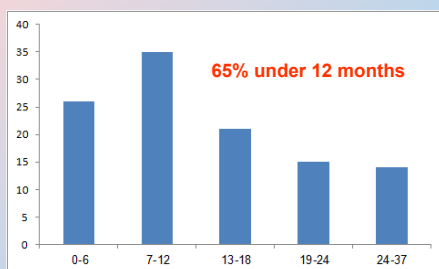
> 48 hrs: 73

- The parent presence in the induction room:

* 58% present

*42% absent

No. of Kids by Age Group (in months)



0-6	26
7-12	35
13-18	21
19-24	15
24-37	14

29

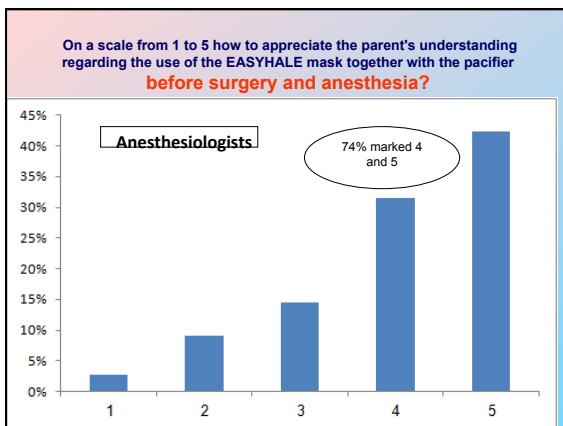
Type of surgery

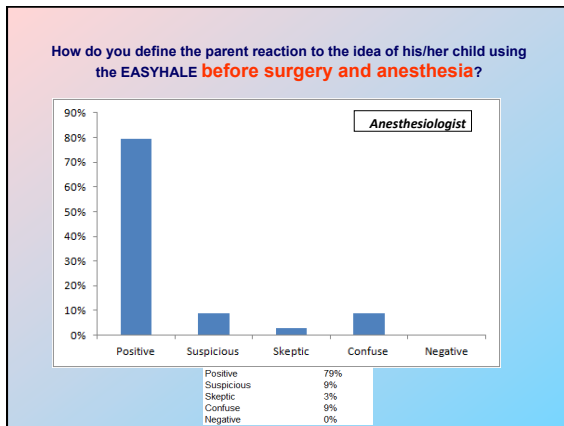
Type of surgery	Nr (111)
Soft tissues	28
Urology (minor)	20
Inguinal/ombilical hernias	15
Limb surgery (minor)	12
GI surgery (stomas)	11
ENT	8
Insertion of central catheters	6
Miscellaneous	11

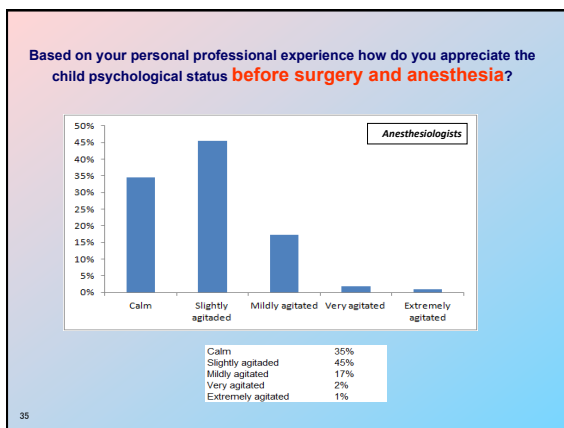
Data on induction			
Degree of agitation during induction		Duration, in seconds, till full sleep	
Degree of agitation	Nr	Duration in seconds	Nr
0	83 (75%)	<30	84 (76%)
1	23	31-60	20
2	3	61-120	6
3	1	>120	1
4	1		
5	0		

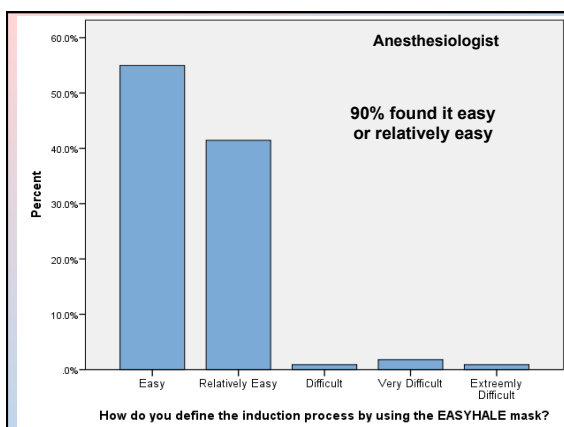
Data collected from the questionnaires filled up by the anesthesiologist

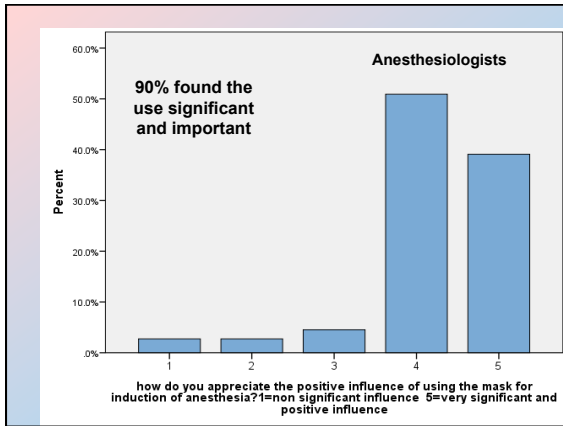


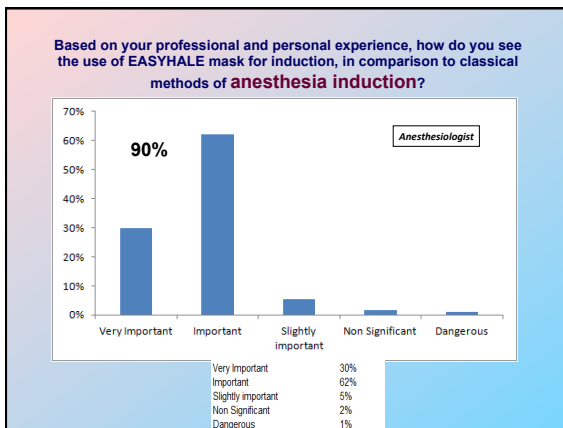




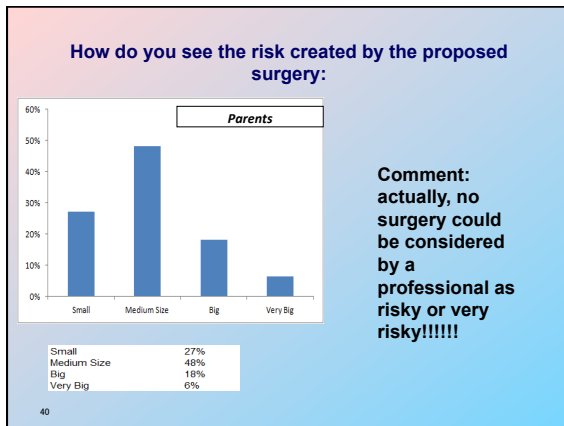


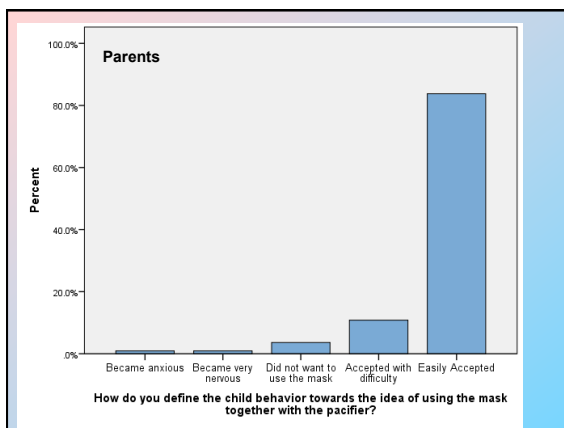


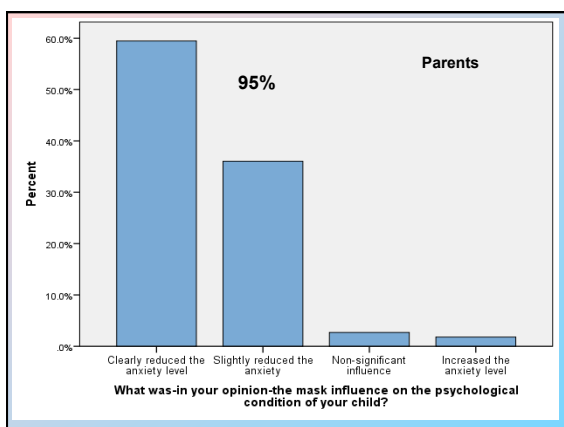


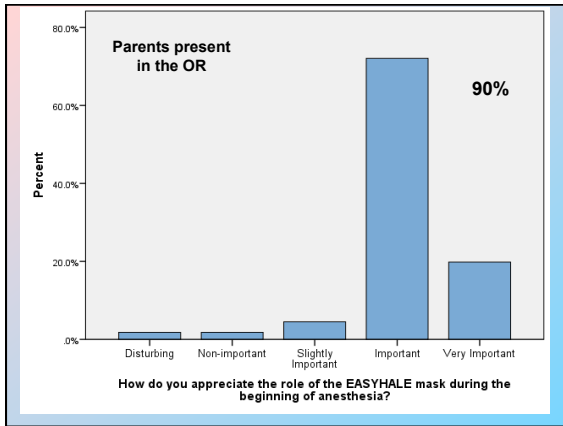


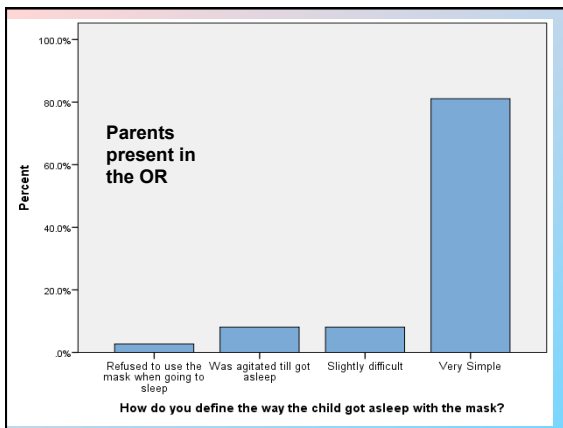
Now let's see the parents opinion about the use of the mask

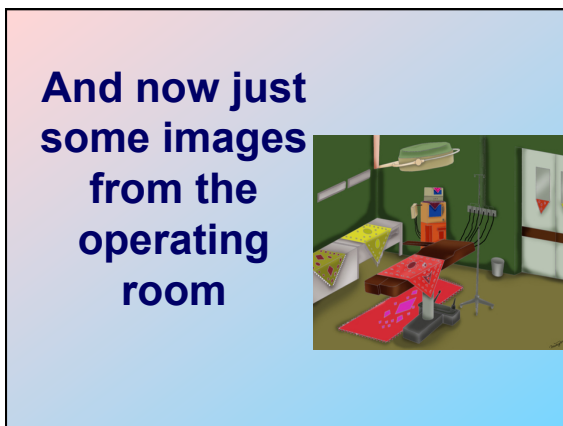






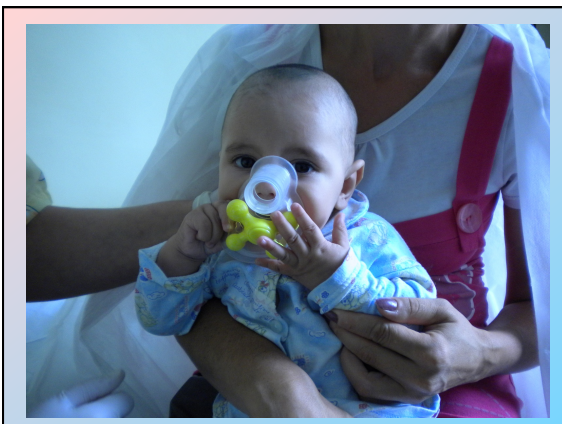
















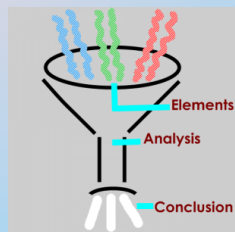


No correlation was found between.....

Child' s fear of separation from the parents →	<i>Anxiety degree before induction</i>
Nr of hours or days of using the pacifier with the mask before induction →	<i>Child' s degree of cooperation during induction</i>

Also, no significant correlation was found between the parent' s presence in the induction room and the child pre-induction anxiety

CONCLUSIONS

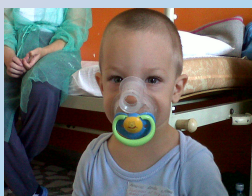


What can be taken home?

- Anesthetizing an infant or a small child could be a very traumatic event because of the struggle during induction period
- All the proposed measures to reduce anxiety have flaws and solve the problem only partially and only in a minority of cases

In contrast, EASYHALE

- Presents a new concept based on a combination between the induction mask and the pacifier used by the kid
- It is easily accepted by both parent and child in the vast majority of cases
- Only few hours of use before induction seem to be enough in order to prevent child's anxiety



Beside....

- By preventing child's struggle with the anesthesia team, the special mask reduces the time of induction
- It seems that the parent's presence in the OR during induction is not compulsory when using the special mask



Questions to be asked



- Is EASYHALE significantly better than any other recommended methods for reducing preinduction's anxiety of the child?

- Is the use of EASYHALE mask a definite progress in the process of reducing the postoperative negative behavior changes?

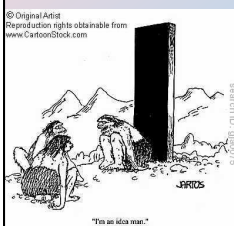
We do plan in the near future a randomized study, including a large cohort of children and using some of the most accepted methods to reduce preop anxiety and try to compare the results with the use of our special induction mask

Special thanks to.....

● Dr Eniko Kovacs-Chairperson,
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Medical Center, Cluj-Napoca

● Dr. Simona Marinescu- Pediatric
Anesthesia Unit, Regional Clinical
Medical Center, Tg Mures

*The real difficulty in changing
the course of any enterprise lies
NOT in developing new ideas
BUT in escaping from the old
ones*



J. M. Keynes

Finally.....



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of Computing and
Technology in
Anesthesia and
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