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Comparison of design, materials selection and characterization of pacifiers produced in Brazil

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RESEARCH

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Abstract

Background
A pacifier is an object designed for use by children aged two weeks to around five years old. Although a convenient and an efficient alternative to children sucking their thumb, its use is highly questionable. With the advancement of medicine and technology, harms related to its use were discovered and were related to poor development of the teeth. Furthermore, the use of some industrial raw materials may cause damage to the child's health during the growing process.

Method
This study evaluates different models of pacifiers available on the market, taking into consideration the design, materials and attendance to Brazilian Standards.

Results
The Fourier Transform Infrared Spectroscopy (FTIR) analysis of the five different models of pacifiers indicates the use of different materials. For models A, B and E, the nipple is basically composed of silicone, while the guard is made of polycarbonate. For model C and D, the nipple is basically composed of natural rubber, while the guard and the ring are made of polycarbonate. For model D and E, however, the presence of Bisphenol A (BPA) was also used in composition. For the tensile strength tests, only model C was disapproved.

Conclusion
Silicon and natural rubber satisfy the requirements for technical performance. However, this does not take into account hygiene and toxicity as parameters for the selection, which are also important when considering child health.

Key Words
Product design, materials selection, bisphenol A, pacifiers.

Background
A pacifier is an object designed for use by children from two weeks to around five years old. It works replacing mother's breast nipple. It soothes the child, without requiring a lot of energy to suck, good coordination and muscular strength. It was also suggested that the presence of a pacifier in the mouth might prevent the infant from turning his face straight down and thus preventing obstruction of mouth and nose. Furthermore, the continuous sucking would also increase the tension of the muscles of the upper airway, keeping the tongue in a more forward position and so protecting the airway. [1]. The use of non-nutritive sucking devices such as pacifiers has been reported in several studies [2], which highlight that, in Western countries, 75% to 85% of children use a pacifier [3], and in American infants, 68% of the children younger than 6 weeks used a pacifier [4]. Pacifier use during these early months may be advantageous to the infant and parents. According to Niemela et al [5], the infant's need for sucking is greatest during the first 6 months of life. However, this utensil should be just an adjuvant for newborn's well-being and, although it is normal to use the pacifiers in anxiety moments, 96 % of children that embrace pacifiers have some kind of problem with the dental arch.

Pacifiers can be spherical or orthodontic. Both models are basically composed of three main parts, as shown in Figure 1: the nipple, guard and ring. Orthodontic nipples (shown in Fig. 1) are the most indicated by dentists as more appropriate for children due to its ergonomic shape. Its flattened part permits the tongue to be accommodated, because there is more space inside the mouth using an object with this kind of mould. The "neck" of the pacifier should be as narrow as possible. That is important to avoid stimulating incorrect biting techniques and to avert pushing the upper dental arch forwards. It is important that the

pacifier accurately replaces the mother's nipple during nursing. A disadvantage related to the orthodontic design of pacifier is the necessity of keeping the right positioning in the mouth, otherwise, all possible benefits compared to the other nipple's design are reduced.

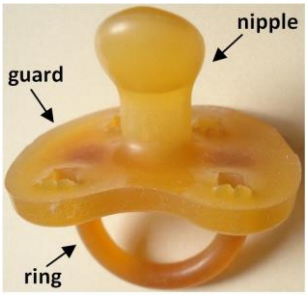

Figure 1. Nomenclature of a pacifier.

However, as mentioned before, the use of pacifiers can be harmful to health. In Brazil, even following the packaging recommendations, according to country's standards, children's health may be compromised. One of the industrial raw materials used in the object's manufacturing, the polycarbonate, includes nitrosamines and bisphenol in its chemical composition [6]. This latter compound, which is added during the pacifier's guard manufacturing process, is well known among medical professionals and scientists as being harmful to health.

Bisphenol A (BPA), is an organic compound formed with two phenol functional groups. This compound is added as a stabilizer or antioxidant for many types of polymers and to enhance malleability [7]; in other words, without it the plastic is hard and brittle. Studies have shown that accumulation of this additive can cause cancer and is also associated with premature puberty, since the compound imitates estrogens. Contamination occurs as this harmful component is inserted in the guard and ring of the pacifier, when this is in direct contact with child's mouth the warm and humid environment results in bisphenol migration. In spite of the National Sanitary Surveillance Agency (ANVISA) of Brazil opinion that BPA presence in pacifiers isn't harmful to health, the Paediatric Brazilian Society (SBP) advises suspension of its use in pacifiers, claiming it has no safe levels.

Recent studies showed that the level of BPA migrating from the polymer increases rapidly at temperatures above 80°C. The concentration of BPA able to migrate also increases with time of pacifier use [8]. In this way, the pacifiers that were already used for a period of six months may present higher risks due to the higher release of the present compounds.

Many factors need to be taken into consideration regarding the purchase and use of pacifiers. Broadly, the purpose of this paper is to systematically compare different brands of pacifiers. Besides the mentioned items related to health, the performance and design aspects are also considered

Method

The following features were analyzed for the evaluation of the pacifier: shape and design, dimensions, materials, information on its packaging and mechanical properties. The different models of pacifiers were identified as A, B, C, D and E (Figure 2). The cost of each pacifier is shown in Table 1.

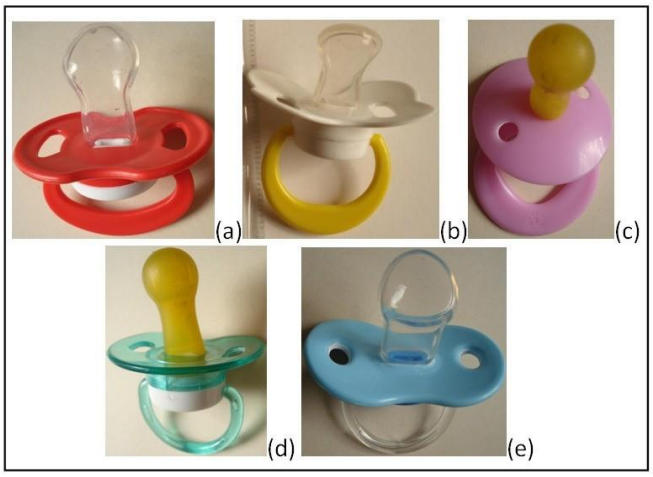

Figure. 2: Classification of passifiers used for analysis: (a) A, (b) B, (c) C, (d), D and (e) E.

Table 1. Prices of the analyzed pacifiers.

Model	*Price*[a]
A	3,67
B	1,71
C[b]	1,62
D[b]	1,62
E	2,70

[a] Paid on Porto Alegre's commerce in May 2010 (in Dollars).
[b] Package with two units.

The methodologies applied for characterization of each pacifier were:

- Identification of appropriate choices of manufacturing materials for this kind of product using the Ashby Materials Diagram.
- Material analysis using FT-IR (Fourier Transform Infrared Spectroscopy).
- Visual analysis of the nipple, 3D laser scanning from different models to compare shape and size.
- Packaging analysis, nipple and orifices dimensions of the guard as well as elongation tests. The criteria followed Brazilian standard regulation.

Ashby Materials Selection Diagram

Using the CES Edupack 2005 software, the possibilities for materials indicated for the fabrication of pacifiers were estimated according to use in their nipples. Different parameters of the materials are considered in the selection progress, such as: maximum glass transition temperature (Tg) of 243 K, higher operating temperature of at least 373 K, very good to average durability in fresh water, very good durability in weak acid and very good to average wear resistance. The relation between the elastic resistance

(Young's Modulus) and density of different materials was also evaluated.

FT-IR
This technique characterized the nipple, guard and ring of the pacifier. For determination of constituent materials of each part the equipment used was Perkim Elmer, model Spectrum Spotlight 200.

Nipple Design
There are two different types of nipple: the spherical and the orthodontic. Each one has its own dimensions and shape as distinguishing characteristics. With 3D digitizing of these models and operation of Geomagic Studio 10, software that enables the creation of accurate digital models from physical parts, it is possible to overlap images from each of the nipples and evaluate differences between their dimensions and morphology.

Reviewing the Brazilian standard
According to the Brazilian Standard (NBR 10334), criteria must be followed by pacifier manufacturers to produce items with appropriate quality and necessary information directing to its correct use. The NBR 10334 regulation determines that the following recommendations must be written and shown on the packaging, in the order of priority below:
1. Boiling the pacifier before using.
2. Do not hang the pacifier by necklaces (do not tie the pacifier around the child's neck).
3. Examine regularly, throwing away when shattered.
4. Do not dive the product in sweet substances, in order to prevent tooth decay.

In addition to this information, the name or symbol of its fabricant must be printed on the packaging, as well as the Employer Identification Number (CNPJ). Also, the ensuing phrase needs to be clear: "This pacifier follows NBR 10334 Standard".

Certain measurements must be strictly followed. The pacifier's size can't exceed 30mm to avoid suffocating the child. The guard have to contain at least two holes, which permit air to pass through to the windpipe. The diameter of the utensil must be at least 5 mm and nipple distance from its base from 5 to 6 mm. For the elongation test, the Brazilian standard determines that the nipple of the pacifier must remain intact when a 60 N traction force is applied to the object on the vertical direction.

Results

Ashby Materials Selection Diagram
Following pre-set criteria, the materials selection diagram was generated, relating Young's Modulus and density (Figure 3).

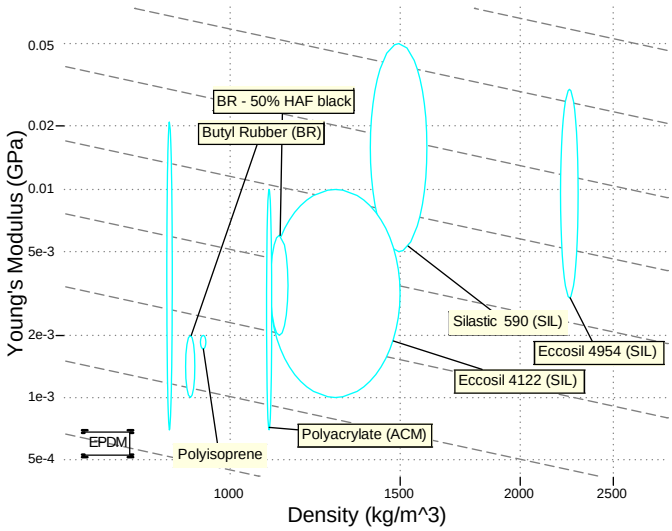

Figure 3. Materials Selection Diagram for constituents of the nipple.

According to the diagram, the materials that meet the requirements for manufacturing of the nipples are butyl rubber, polyacrylate (ACM), polyisoprene, EPDM rubber and silicone.

FT-IR
Using the Fourier Transform Infrared Spectroscopy (FT-IR), the respective IR-spectra for each studied model was generated. Every part was evaluated separately: nipples, guards and the rings. With the assistance of the software search tool, it is possible to identify the chemical composition of the investigated material.

For models A, B and E, the nipple is basically composed of silicone, while the guard is made of polycarbonate. For model C and D, the nipple is basically composed of natural rubber (latex), while the guard and the ring are made of polycarbonate. However, for model D and E, BPA appeared to be included in the composition.

Nipple Design
Table 2 demonstrates which of the two nipple designs each model had.

Table 2: Brands and their respective nipple design.

Model	*Design*
A	orthodontic
B	orthodontic
C	spherical
D	spherical
E	orthodontic

In order to carry out the comparison of nipples' geometry, the two different shapes (spherical and orthodontic) were scanned and the 3D files were overlapped (Figure 4). Gathering these files was possible using the reverse engineering software Geomagic Studio 10, and the 3D laser scanner Digimill 3D, Tecnodrill.

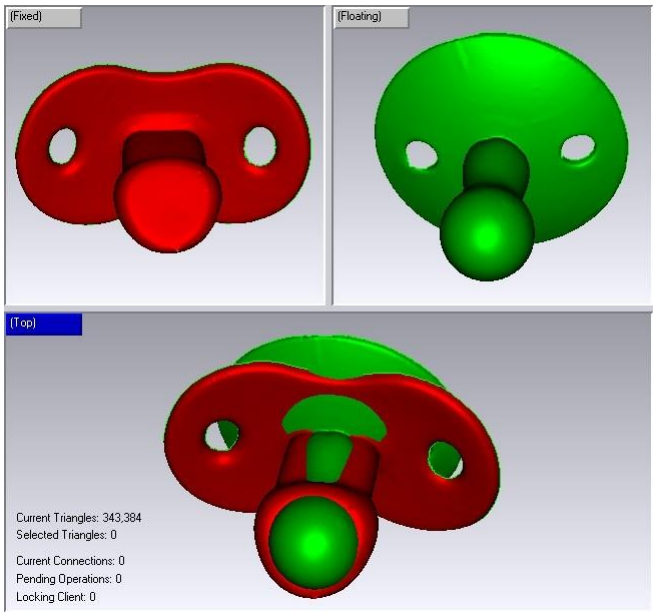

Figure 4. Models C (spherical) and E (orthodontic) overlapped.

As observed in Figure 4, there is a difference between "neck" sizes when both models are overlapped. An ideal model of nipple could be considered as containing a flattened part in order to allow the mouth to close properly. In this way, the neck should be anatomically flattened to track the normal position of the tongue, that spontaneously rests on the palate and the nipple should have a shape that permits the tongue's pressure over the palate and should have adequate volume-to-palate dimensions.

Reviewing the Brazilian standard

Reviewing the Brazilian standard, there is some information that must be displayed on the packaging. Table 3 shows the attendance of the pacifiers to the Standard.

Table 3: Packaging information.

Model	*Boling before use*	*Do not tie it around the neck*	*Regularly examine*
A	Yes	Yes	Yes[a]
B	Yes	Yes	Yes
C	Yes	No	Yes[a]
D	Yes	Yes	Yes
E	Yes	Yes	Yes

Model	*Do not dive in sweet substances*	*Ensuing phrase according to the Standard*	*Name/ Symbol*	*CNPJ*
A	Yes	Yes	Yes	Yes
B	Yes	No	Yes	Yes
C	Yes[a]	Yes	Yes	Yes
D	Yes	No	Yes	Yes
E	Yes	Yes	Yes	Yes

[a] Not in the recommended standard order.

As shown, only pacifier E strictly follows the Standard. All the others fail to present all the required information on their packaging. For pacifier A, the information: "Regularly examine, throwing away when shattered" is on, but does not follow the recommended order. Pacifiers B and D had no recommendations indicating that the product adhered with the standard. Model C has no indication for the instruction about not tying it around the neck and it did not provide the description about regularly examine the object and not diving it in sweet substances in the recommended order.

It is important to point that in all analyzed packaging there was additional information such as: wash it using neutral cleaning products, save packaging for future reference and dates of manufacture.

Regarding the physical dimensions, the results are illustrated in Table 4.

Table 4: Models' dimensions.

Model	*Number of holes*[a]	*Nipple size <30mm*	*Hole's dimensions > 5mm*	*Distance from nipple and holes between 5-6mm*
A	2	Yes	Yes	No (over)
B	2	Yes	Yes	Yes
C	2	Yes	Yes	Yes
D	2	Yes	Yes	Yes
E	2	Yes	Yes	No (over)

[a] The Brazilian Standard requests two (2) holes.

The brands that have adhered to these specifications were the marks B, C and D. The others had spacing between the nipple and the holes above the recommended size.

For tensile resistance evaluation, the Figure 5 shows how the tests were conducted.

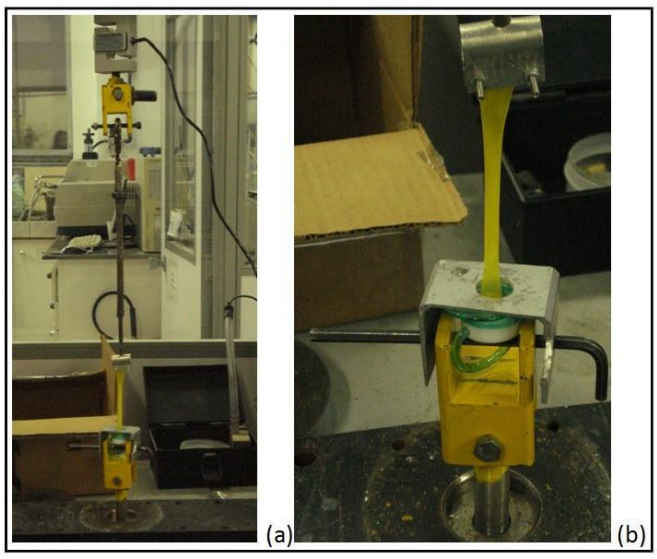

Figure 5. Equipment used to test the traction of pacifiers.

The testing machine was adapted for the coupling of the pacifiers, so that the base of the object remained stationary while the machine stretched the nipple attached at the top of the equipment. The result is shown in the Table 5. Pacifier model C was the only one with suboptimal results,

as when put under stress of 60,1 N it suffered tears in the nipple.

Table 5: Maximal tensile strength of the evaluated pacifiers.

Model	*Tensile strength (N)*
A	197,1
B	198,4
C	60,1
D	100,3
E	136,2

Conclusions

Silicon and natural rubber satisfy the requirements for technical performance. However, this does not take into account hygiene and toxicity as parameters for the selection, which are also important when considering child health. The selected material for the manufacture of the guard and ring is unlikely to be appropriate if it contains bisphenol A in its composition. This is because if parents comply with the recommendation to heat the pacifiers, it will result in the ingestion of toxic components, which, according to several authors, are harmful to health and have the potential to cause cancer and early puberty in girls.

When considering the shape and design of the pacifier nipple, this research is not conclusive because the analysis by laser scanning of the models does not confirm the subsequent malformations of the teeth of children and because the suction pressure exerted by the baby's mouth would cause the nipple to change shape inside the mouth, and significance of this has not been studied.

Regarding the Brazilian Standard (NBR 10334), basically all pacifiers studied follow the recommendations and requirements set. However, the Standard has come under question as, according to Nam et al[8], the recommendation to heat the product before use results in the release of compounds such as BPA which has carcinogenic action.

Through testing elongations of the nipple, it was demonstrated that silicone performed better than natural rubber (latex), however, model C was at the limit specified by the Standard. In model E, the nipple fell off the guard during the experiment, indicating that designers and manufactures must pay attention to the elements comprising the junction between sub-systems that make up the pacifier (connections between nipple-guard, guard-ring).

Therefore, comparing the results, it is possible to propose an optimized model, considering the suitable materials, design and performance. One possibility for this optimization would be the use of a mono-material (silicone) in the pacifier, which brings also advantages considering environmental aspects, such as recyclability. In addition, the orthodontic designed nipple and the avoidance of materials with BPA on the composition would make the pacifier less harmful to the child's health.

References

1. Jenik AG, Vain N. The pacifier debate. Early Hum Dev 2009; 85(10): 89-91.
2. Cornelius AM, D´Audria JP, Wise LM. Pacifier use: a systematic review of selected parenting websites. Journal of Pedriatic Healthcare 2008; 22(3):159-65.
3. Niemela M, Uhari M, Hannuksela A. Pacifiers and dental structure as risk factors for otitis media. Int J Pediatr Otorhinolaryngol 1994; 29(2):121-7.
4. Howard CR, Howard FM, Lanphear B, Deblieck EA, Eberly S, Lawrence RA. The effects of early pacifier use on breastfeeding duration. Pediatrics 1999; 103(4):772-7
5. Niemela M, Uhari M, Mottonen MA. Pacifier increases the risk of recurrent acute otitis media in children in daycare centers. Pediatrics 1995; 96:884- 8.
6. Vandenberg L, Hauser R, Marcus M, Olea N, Welshons VW. Human exposure to bisphenol A (BPA). Reproductive Toxicology 2007; 24(2):139-77.
7. Yamamoto T, Yasuhara A. Quantities of bisphenol A leached from plastic waste samples. Chemosphere 1999; 38(11): 2569-76.
8. Nam SH, Seo YM, Kim MG. Bisphenol A migration from polycarbonate baby bottle with repeated use. Chemosphere 2010; 79(9): 949-52.

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PEER REVIEW

Not commissioned, externally peer reviewed

CONFLICTS OF INTEREST

None.