A special impression material for pediatric audiology? Why? – Just because!

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Children react more spontaneously and intuitively than adults. They are not yet able to appreciate the therapeutic benefits of a hearing aid. Their willingness to wear such a device on a long-term basis depends more greatly on whether or not it is pleasant and comfortable than with adults. The occurrence of pressure points results in the hearing aid being worn only reluctantly or not at all. Wearing comfort takes on particular importance in order to prevent this rejection and ensure the benefits of a hearing aid. For this reason a perfectly fitted, customized and visually attractive earmold must be created.

Regardless of whether the work is now done using the conventional PNP process or with the modern 3D cast technology, the first step is the impression of the outer ear canal. Despite some efforts to digitize this process using an ear scanner, this method has not been able to achieve much success. Elastomer impression materials continue to be used as before. In order to meet the special demands of pedaudiology, the impression must be absolutely precise and exactly reflect the anatomy. Defects, mistakes, et cetera, cannot be tolerated. A perfect impression is the basic requirement for the further process steps. A faulty result will lead to defective earmolds and possibly cause the hearing aid to be rejected.

The smaller dimensions must be considered when children‘s ear canals are molded. Along with the required accessories, this also applies for the impression material. Following a few brief comments on the (silicon) impression materials in general, the particular features of a special impression material for pediatric audiology will be addressed.

Two-component RTV silicones (RTV = room-temperature curing) have taken hold as the state-of-the-art material for the impression of the outer ear canal.

The benefits of this material class are as follows:

- easy handling
- outstanding reproduction precision of even the finest details
- short residence time in the ear
- good separating properties enable easy removal from the ear
- high elasticity and resilience
- dimensional stability (especially with addition cross-linking systems)
- excellent biocompatibility (especially with addition cross-linking systems)

The first silicone impression materials based on a condensation cross-linking mechanism. More specifically, a catalyzed transesterification of a silicic acid ester with multi-functional hydroxy-terminated silicon oils occurs with this type, whereby an alcohol of low molecular weight is released.

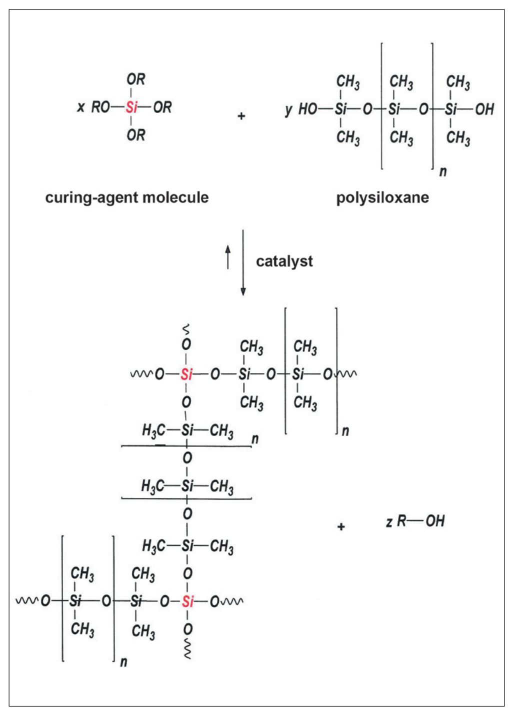


Figure 1: Reaction mechanism of condensation cross-linking silicons

A schematic diagram can be seen in Figure 1. The silicon atoms from the curing-agent molecule are marked in red for better clarity. The complete hardening process occurs over a very long time period until the resulting alcohol has evaporated from the system. It thus continues after the impression has been removed. Since the material may shrink somewhat during this time, the further processing must continue with relative quickness (no later than after 72 hours).

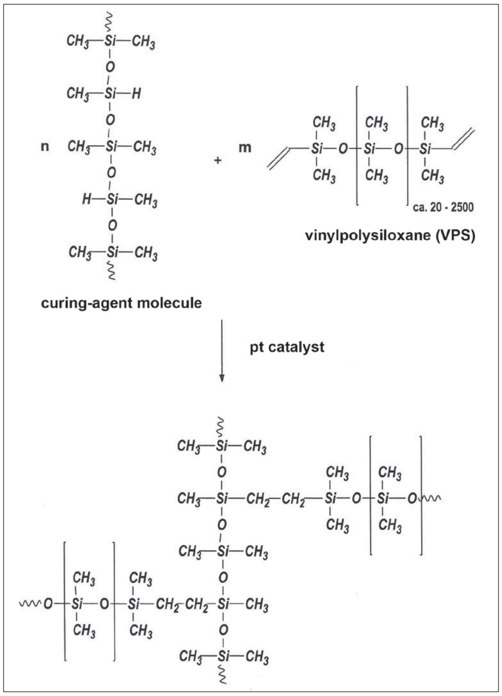


Figure 2: Reaction mechanism of condensation cross-linking silicons

The condensation cross-linking silicones have meanwhile been superseded by the addition cross-linking silicones. The chemical curing process is an addition reaction, or more precisely, a platinum-catalyzed Hydrosilylation. In this process, a polyvalent silicon hydride polymer is adsorbed on the double bond of an α, ω-divinyl silicon polymer (see Figure 2). Since no byproduct forms here which needs to escape from the system, the reaction is practically completed after the impression is removed from the ear. This reduces the total shrinkage on the one hand, and the impression can be stored longer before it is processed.

While the condensation cross-linking silicon materials are offered in very high component mixing ratios (10 parts base to 1 part catalyst) due to the composition of the active species, a mixing ratio of 1:1 is possible with the addition cross-linking material, whereby it can also be applied as cartridge material along with its conventional representation as a modeling clay.

The differences, and the benefits and drawbacks of the individual appearances were discussed in detail by Kunz. For the application in pediatric audiology, these are particularly the arguments of flowability and preliminary cross-linking / pressure buildup which prefer the use of a cartridge material. Modeling clays naturally have much higher viscosity to enable manual processing and are thus less flowable. Moreover, preliminary cross-linking already occurs during the mixing and application of the modeling clay which results in even higher viscosity and an undesired pressure buildup.

Properties which a molding material specially suited to the needs of children should contain are described in the following. The data provided are based on what to our knowledge is the only molding material specially developed for the molding of children‘s ear canals up to now – “addition mini Junior” produced by Detax.

Formulation

The molding material is typically sold in 50 ml two-chamber cartridges. The material is then fed by a dispenser through a static mixer (generally with diameters of 6 or 9 mm and a length of around 8 cm). Due to its size, this design can be quite threatening “for children‘s eyes” (but also for parents). A better alternative is offered by the smaller 10 ml cartridge (“Mini-Mix”). In this design, the material can be directly applied manually using a hand-held “piston rod”. The mixing cannula is also much smaller in size (both in length and diameter). Due to the smaller size of the ear canal in children as compared to that of adults, this enables much more precise work. Moreover, it helps to prevent children from being afraid of the devices (Figure 3 shows the size ratio of the Mini-Mix cartridge and a conventional cartridge with dispenser). If the pressing force feels too great for the user, a dispenser is also available here which is much smaller in size and reduces the force to be applied to a minimum. The advantage of the delicate setup is reduced to a certain extent, however. The atmosphere can be relaxed before the molding process is started by presenting the material and the molding process to the child. It also helps here if the material has an attractive light color (“gender-neutral”, not pink).

Figure 3: Size comparison of standard cartridge with Mini-Mix cartridge.

Consistancy / Material rheology

In general, the absolutely precise molding of the ear canal is the most important condition for producing a perfectly fitting earmold. The following must always be noted: The smaller diameter and thus the much smaller contact surface of the children‘s ear canal causes a much higher pressure due to the highly viscous molding material to be exerted on the ear canal.

A pressure buildup deforms the soft, cartilaginous ear tissue and this deformation is also reproduced by the vulkanization of the molding material (for comparison see Figure 4). Earmolds created with such deformations are too large, can be uncomfortable to wear, and lead to a continuous, but undesired and even harmful widening of the ear canal because the tissue adapts to and evades the new circumstances.

The optimal molding material must have the best possible flowability (without elastic recovery) during the application. This ensures that the material exactly reproduces the small volume and fine details. The material should be as firm as possible following the application to prevent any possibility of it flowing past the eardrum protection or flowing out of the concha. This can be prevented by a cover film. A strong inclined position of the head should be avoided, however.

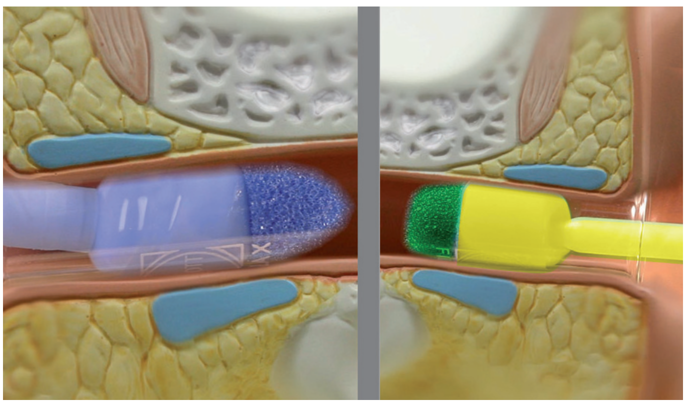


Figure 4: Representation of the pressure buildup in the model

The scientific discipline dealing with the flow properties is rheology. A measure for the flowability and for the flow resistance is the viscosity. The better a material flows, the lower its corresponding viscosity. When we talk about ideally viscous behavior (Newton's fluid), the viscosity does not depend on the shearing (this behavior especially occurs with fluids of low molecular weight such as water, solvents, etc.) This fortunately does not apply for the silicon formulations described here as this would enable the molding material to flow out of the ear again after the application before its viscosity increases due to the curing reaction. The viscosity of children's earmolding materials should be as low as possible when they are applied, i.e. under shearing, and as high as possible "at rest" without shearing. Such behavior is referred to as structural viscosity or shear thinning. Figure 5 shows the relationship between viscosity and shear rate for "addition mini junior" as compared to a material for adults. The viscosity for the children's formula is around 20 000 mPas under shearing (for comparison: the material for adults has a value of 70 000 mPas here, i.e. 3.5 times the value). With no or very little shear loading, the viscosity exceeds 1 000 000 mPas. The difference from the reference material is much less here; it is only around 50 percent, which speaks for a similarly good stability of the children's material.

Dispensing force

As already mentioned, it is advantageous to apply the molding material from a smaller syringe/cartridge without additional mixing guns. It must be ensured here, however, that the required force is not too great and that the material can be dispensed with a steady hand.

The force which must be applied to feed the material through a static mixer can be calculated from the pressure loss (in the mixer). For a specified mixer, this is proportional to its dimensions (length, diameter), the viscosity of the fluid, and the flow velocity. This is also an argument for low viscosity under shearing. The lower diameter here is also beneficial and thus the lower volumetric flow rate with this cartridge as opposed to that of the standard 50-ml cartridge. It follows from Figure 6 that the pressing force is much lower for the children's molding material. A pressing force of 40 N corresponds to a weight of 4 kg and allows the cartridge with the supplied stamp to be used by hand. With a value of 140 N, however, a standard material cannot be fed manually through the smaller mixer.

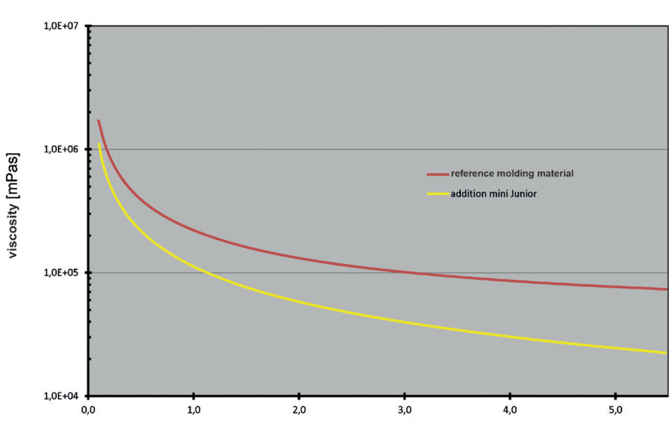


Figure 5: Viscosities as a function of shear rate

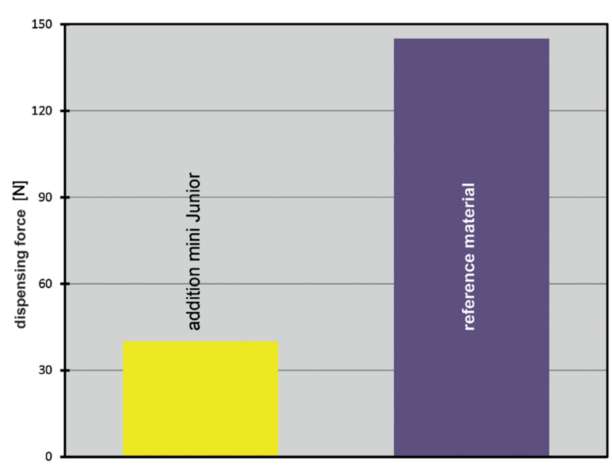


Figure 6: Manual dispensing force when the Minimix cartridge is used.

Setting time

Children are generally very lively and cannot sit calmly for very long. They are happy to get the procedure over with as quickly as possible. This makes a short setting time or residence time in the ear highly advantageous. The time in the ear should be shorter as that for materials for adults, which is around three to five minutes. Nevertheless, an application time of 30 seconds can be guaranteed, as with adults, to enable a careful approach. Figure 7 shows hardening curves for conventional molding material for adults and the corresponding curves for the children‘s molding material "addition mini Junior". They show the viscosity curve (represented logarithmically) as a function of time. The viscosity increases only slightly during the application phase and the material remains malleable, with the children‘s molding material having a low viscosity. In the subsequent curing phase, the viscosity increases much more steeply for the "addition mini junior", i.e. the curing requires much less time. The higher final viscosity value for the adult material correlates with the higher final hardness

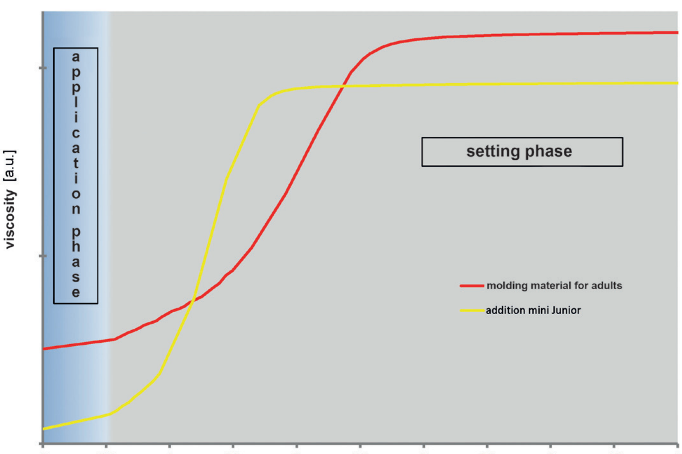


Figure 7: Setting curves of "addition mini junior" as compared to a conventional molding material.

Hardness

The impression must be removed from the ear after hardening. Due to the smaller diameter of the child‘s ear, removal is easier when the material is easily deformed. This is achieved by a reduction in the hardness; with "addition mini junior" this is Shore A25. This makes the impressions supple, enabling them to be removed from the ear canal with very little force and without causing the child any pain. Comparable molding materials for adults, in contrast, have much higher hardnesses of Shore A35 to 40. Although this low level of hardness makes it more difficult to process the impression with conventional shaping, the impressions can be shaped as desired using scissors, a scalpel, or abrasive caps; this should be gladly accepted for the wellbeing of the child.

Mechanical properties

The low hardness and the associated deformation during demolding makes it necessary for the material to have outstanding restoration properties following deformation, in this case stretching. The ISO standard for dental molding materials (DIN EN ISO 4823), often drawn on for comparison with earmolding materials due to their structural similarity, solely considers the restoration following compression. The restoration after a tensile stress can be achieved by a shouldered test bar provided with markings. The spacing of the markings is first determined. In the tensile-stretching test machine, this is then stretched by a selected amount and allowed to relax again (Figure 8). To be on the safe side, the tensile stress for the test should be at least 100 percent. The percentage restoration is determined from the difference in the distances of the markings. Measurements showed the restoration for "addition mini Junior" to be 99.3 percent following a stretch of 100 percent. The deformation of the impression is therefore not an issue, even when it needs to be strongly deformed. Along with the restoration, high mechanical strength of the hardened molding materials is also required to keep the impressions from breaking off during removal and possibly leaving parts in the ear canal, even if the impression doesn‘t have any cracks or defects. The tear resistance of the molding materials is determined according to DIN ISO 34-1 and is defined as the force per mm of sample thickness required to tear a standard specimen of the material. "addition mini Junior" performs very well here with 4.9 N /mm and achieves values comparable to cartridge materials for adults. In contrast to the adult material, "addition mini Junior"

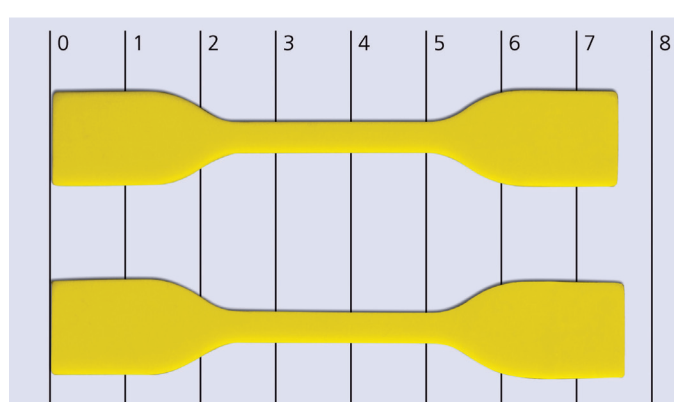
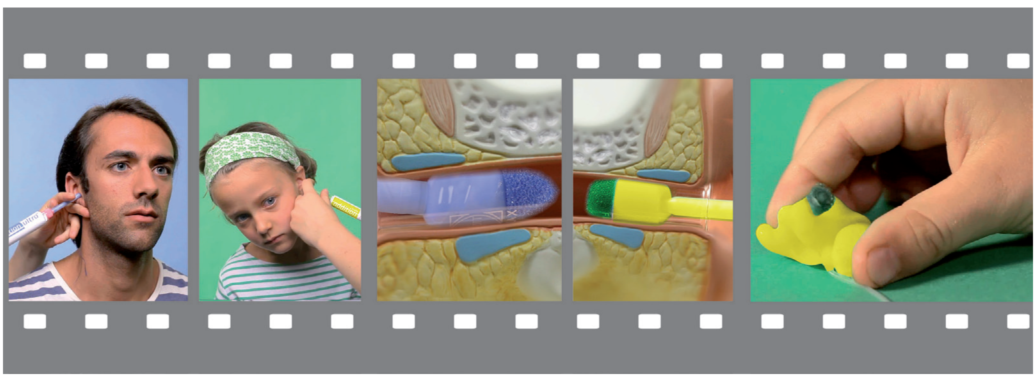


Figure 8: Restoration following an expansion of 100 % (top specimen before stretching, bottom specimen after)

doesn‘t tear until it is stretched much further. The values are also higher than those measured, for example, for workable molding materials (3-4 N /mm).

Summary

Children are not little adults – a frequently quoted statement which holds a great deal of truth. If a child is already forced to undergo an ear-molding procedure, then their needs should at least be addressed to the greatest possible extent. Along with a friendly demeanor which inspires confidence and may reduce fear, this should also be achieved by the choice of material. “addition mini Junior” was specially developed for this purpose, both in terms of material and the choice of dispenser.



https://youtu.be/lQCwHqPhEBM

video clip
addition mini Junior

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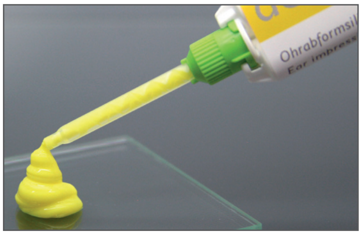
Dr. Bernhard Köhler (himself a father of two children) earned his doctorate in polymer chemistry and has been working intensively since 2006 on the development of special molding silicons for pedaudiology. He studied chemistry at the Technical University of Darmstadt. During his postdoctoral work at the University of California - Santa Barbara, he dealt with the topic “Photo-initiators with high dual-photon absorption”.

Dr. Köhler has been employed at DETAX in Ettlingen since 2007 as the Scientific Director in the area of “Research and development of elastomer molding materials”. Dr. Köhler has been a member of the DIN Dental Standards Committee (Professional committee for molding materials) since 2006.

addition mini Junior

the first ear impression material for kids



Precision ear impression silicone for pediatric adaptions

- low viscous, smooth consistency, non-sticky! highly thixotropic
- no pressure build-up, no displacement of soft tissue, no unwanted run-off
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