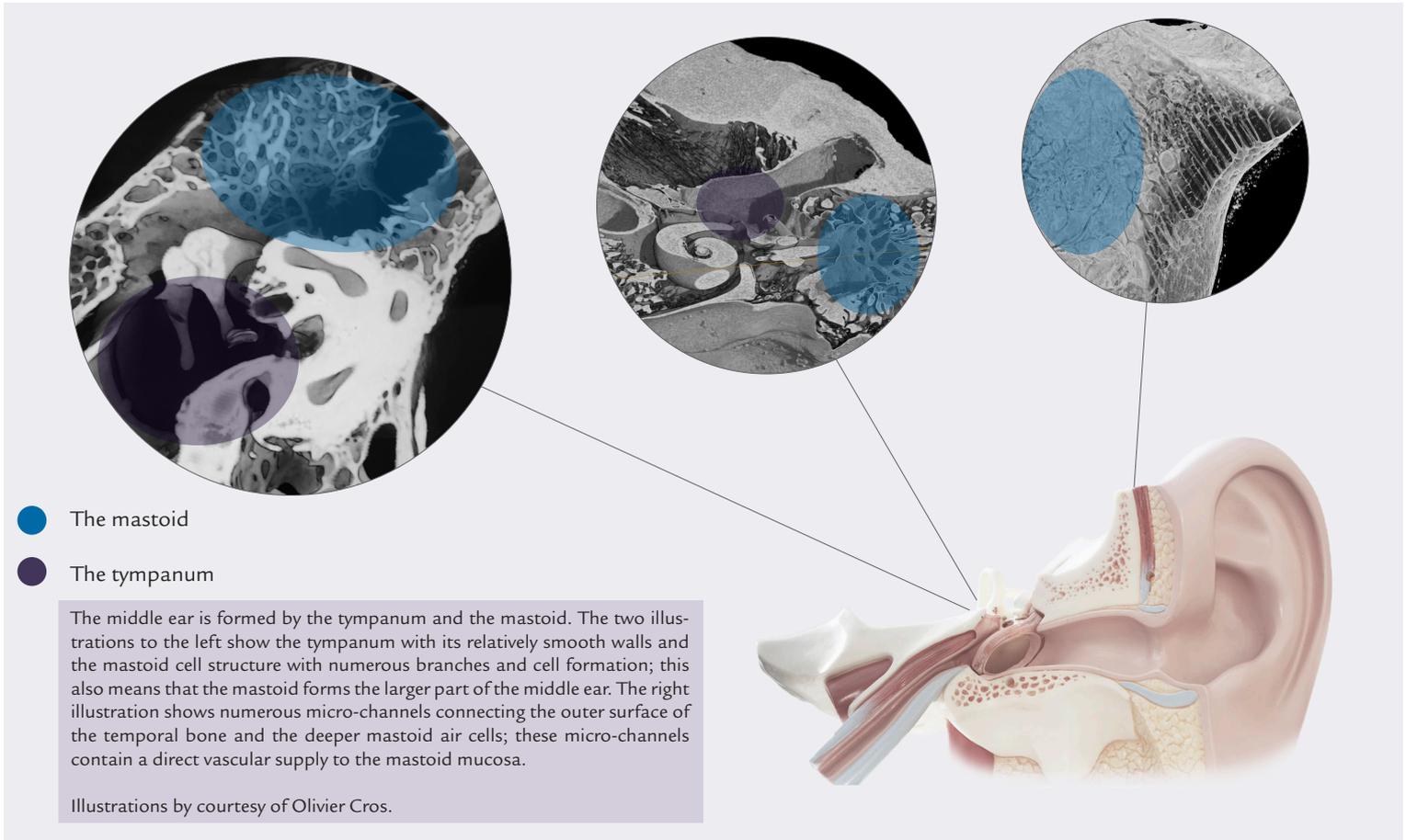


# Treatment of otitis media with retroauricular steroid injection



The middle ear is formed by the tympanum and the mastoid. The two illustrations to the left show the tympanum with its relatively smooth walls and the mastoid cell structure with numerous branches and cell formation; this also means that the mastoid forms the larger part of the middle ear. The right illustration shows numerous micro-channels connecting the outer surface of the temporal bone and the deeper mastoid air cells; these micro-channels contain a direct vascular supply to the mastoid mucosa.

Illustrations by courtesy of Olivier Cros.

## Clinical need

The occurrence of Secretory Otitis Media (SOM) is very high, and 90% of children have experienced at least one episode of SOM before the age of 3-4 years. Similarly, the treatment with ventilation tubes (VT's) is also very frequent, and 30% of children born in Denmark will have at least one episode of VT insertion before the age of 10 years. Further, it is not unusual that these children experience repeated VT insertions. SOM is also described in older children as well as adults, but with lower incidences. The high treatment numbers with VT are mostly in younger children with a peak between 2-4 years.

## Therapeutic sector

In Denmark, the insertion of VT's is performed in ENT specialist practices and represent around 10% of medical insurance costs for ENT practice. In other countries VT are performed in hospitals. Further, the intervention is made under a short anesthesia in children, thus there are additional costs related to this part.

A newly discovered structure behind the outer ear, which consists of numerous micro-channels between the surface of the

mastoid bone and the mastoid air cells deep inside the mastoid, gives us a direct passage to the middle ear. Therefore, a new treatment of SOM could be a subcutaneously injection of depot steroid behind the outer ear, which will deliver a predominantly local effect. The systemic effect, that normally is associated with steroid treatment, is limited. Treatment with steroid injections will eliminate the need for insertion of VT's.

## PARTNERSHIP



### We are looking for:

a partner to develop the optimal steroid and the optimal dosage for this treatment.



### Competitive advantages

The current treatment of SOM is related to high costs for the health authorities as well as a high number of complications. Treatment with steroid injections will eliminate the costs related to insertion of VT's, and the cost of anesthesia related to this procedure. This means that the cost of treatment will become significantly lower. Further, the treatment will eliminate a larger part of the complications associated with SOM, like short-term acute otitis media, which might demand ENT-specialist visit and topical treatment with antibiotics as well as long-term complications of permanent tympanic membrane perforations.

### Current stage of technology

After the identification of the micro-channels that are forming a direct passage to the middle ear (ME), we have been conducting a clinical experiment, which showed that a pharmacological injection in the retro-auricular area could reach the mastoid mucosa and influence the ME. More specifically, adrenaline was injected and tympanometry demonstrated a significant decrease in ME pressure over 5 min's period. This response can only be explained by the transfer of the

drug from the retro-auricular area to the mastoid via the micro-channels. We are at the stage where we want to define and perform clinical trials with depot corticosteroids, and we are looking for a partner to develop the optimal steroid and dosage for these clinical trials.

### IP rights / patent

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