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Otitis externa: Why treatment fails and cases re-occur

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Clinical Anatomy – the basics

The ear canal consists of cartilages (both auricular and annular)
and the specialized skin that lines it. The dermis of the ear canal is separated from the auricular cartilages by a subcutis that becomes thinner more distally in the canal.

The auditory canal contains sebaceous glands, producing a lipid-rich secretion and ceruminal (modified apocrine "sweat") glands, producing an aqueous secretion. Ear wax, often referred to as "cerumen" is an emulsion of secretions of these glands combined with sloughed keratinocytes.

The number of hair follicles varies between individuals and breeds and they decrease in number in the horizontal canal. In some individuals, hair tufts may be found immediately surrounding the attachment of the tympanic membrane.

Studies on the ear canal volume of the dog vary. The volume is related to body weight and is of the order of 0.5-1ml

In order of most common, the organisms isolated from the vertical canal of normal dogs ears consist of:

1. Yeast (*Malassezia* spp)
2. Coagulase negative staphylococci and micrococci
3. *Staphylococcus* pseudintermedius and other coagulase positive staphylococci
4. *Corynebacterium* spp

Gram –ve cocci (*Enterococcus* spp) and Gram -ve rods (*Pasteurella* and *Proteus* spp) are found in less than 4% and 2% of ears respectively and are likely to represent transient rather than normal flora.

Normal ear cytology

Data on what constitutes normal findings in ear swabs vary markedly between authors. Based on 400x high power, Genel et al state:

- Mean Malassezia counts of > or = 5 in the dog and > or = 12 in the cat were considered abnormal. The cat value is much higher than other reports and the author prefers to regard numbers of Malassezia in the cat above 5 per HPF to be suspicious.
- Mean bacterial (cocci) counts of > or = 25 in the dog and > or = 15 in the cat were considered abnormal.

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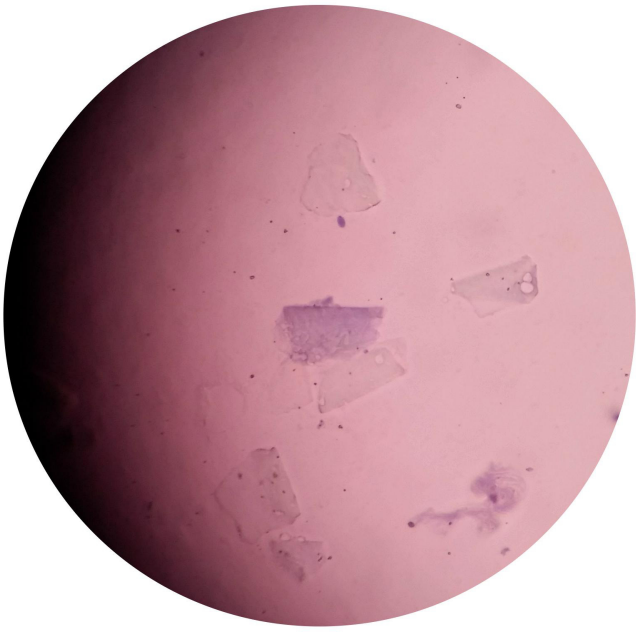
- When used to differentiate normal from inflamed external ear canals, these figures provided a low sensitivity but a specificity of > or = 95%

Tater et al report that *"nucleated keratinocytes were occasionally observed in both species, and should not be mistaken for a pathological process (parakeratotic hyperkeratosis)."*

It is generally agreed that infection is indicated by the presence of gram –ve rod bacteria, neutrophils or cocci/*Malassezia* outside these limits.



Normal ear cytology dog. Scattered squames, cocci and Malassezia bodies. Diff-Quik 2 400x

Microbial Homeostasis in the Ear Canal

Why does a "normal" ear resist overgrowth of paternally pathogenic bacteria and yeast?

- Continuous sequential exfoliation of epidermal cells from distal to proximal creating a mechanical cleaning process.

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- Normal ear wax has antimicrobial effects on yeast and bacteria through antimicrobial peptides and immunoglobulins in normal ceruminal gland secretions and lipids providing an antimicrobial and water repellent role.
- Potential antimicrobial actions of the normal microflora
- A normal epidermis, more resistant to biofilm formation

The response of the ear canal to chronic otitis includes:

- Epidermal and follicular hyperplasia without changes in hair follicle numbers.
- Dermal inflammation and fibrosis
- Grossly dilated ceruminous glands, dominating the cerumen composition.

As chronic otitis proceeds:

- The ear canal becomes narrow from proliferative changes
- Self cleaning from sequential exfoliation is lost leading to:
  - Reduced micro-organism clearance
  - Debris and exudate build up
- Ear wax composition is abnormal
- Corrugated epidermis is supports biofilm production

KEY POINT

Once the cycle of infection and loss of homeostasis is set up, the ear disease will progress, independent of the primary cause (often allergy) that initiated it.

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Causes of otitis

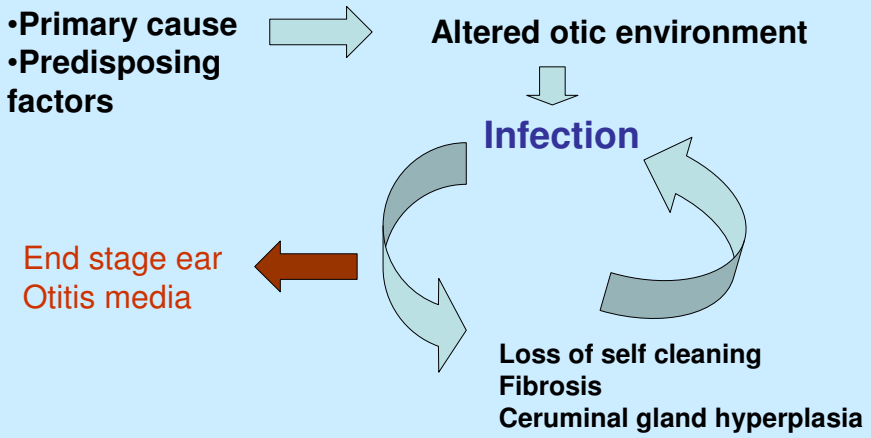
Predisposing

- Anatomic – pendulous, narrow or hairy
- Humidity and moisture
- Inappropriate cleaning interventions

Primary

- Allergy
- Keratinization disorders
- Endocrinopathies
- Immune mediated disease
- Foreign bodies
- Ear mites/parasites
- Foreign bodies
- Tumours

The otic cycle of disaster



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Understanding this process means that treatment needs to be in two phases:

1. Treat the infection until resolution is confirmed both visibly by otoscope and cytologically. "*Treat till you beat*"
2. Institute a maintenance program (initially weekly) with monitoring in the knowledge that a chronically damaged ear canal may NEVER regain full homeostatic function.

It is highly probable that by taking an approach of dispensing aural medication without planned follow-up will result in a re-flare soon after treatment is stopped, usually more severe each time with a progression of infection type from

Yeast and cocci → Staph, Strep, anaerobes → Gram –ve rods,

In the author's experience, most referral cases of otitis represent the same problem that has existed for an extended period without ever being resolved.

Key Point

You can not manage an ear in less than 3 revisits

1. **Treat until visible and cytologic cure**
2. **Maintain and monitor**

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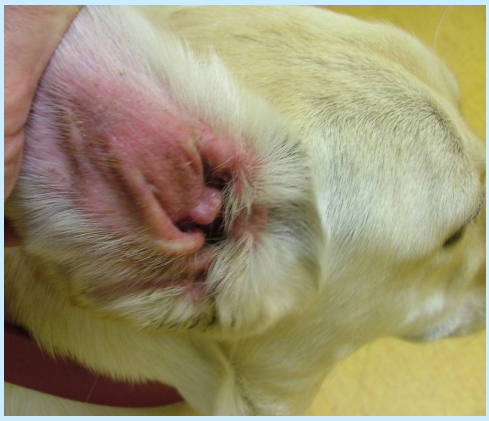
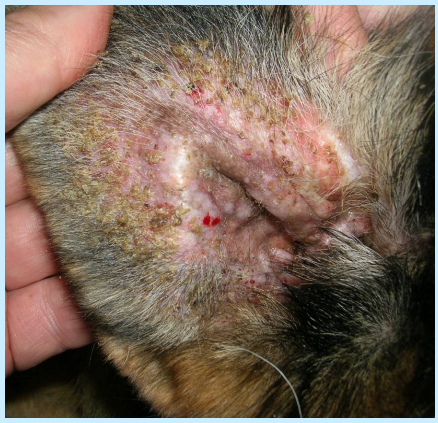
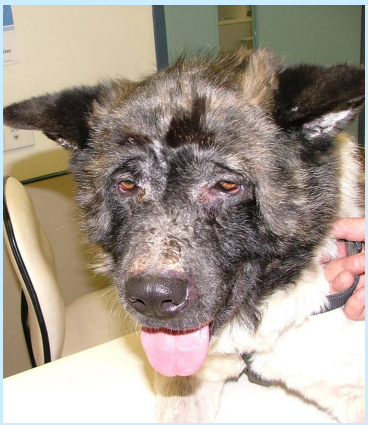
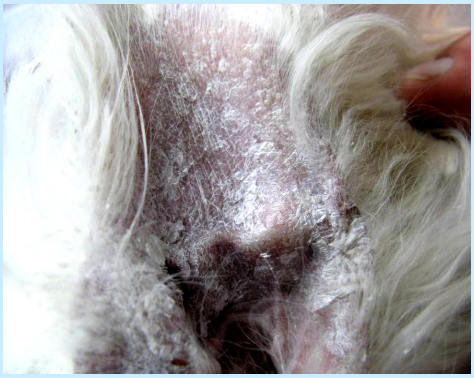


Atopic dermatitis



Pemphigus foliaceus





Scaling disease (sebaceous adenitis) as a primary cause of otitis externa

Examples of primary causes of ear disease

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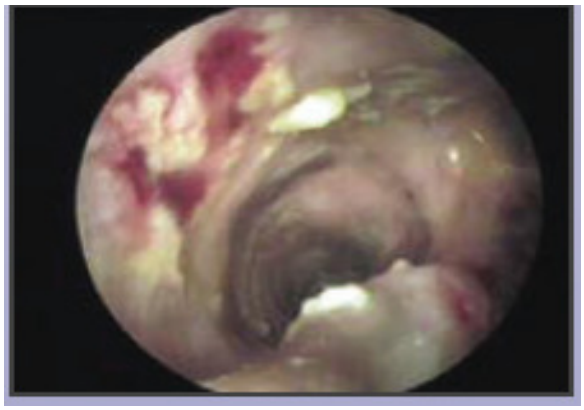

Ruptured tympanic membrane, erosion, ulceration and exudate in a case of Pseudomonas otitis

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Reasons why initial treatment may fail

Canal narrowing and end stage changes: Get the ear open!

Epidermal, ceruminal gland and follicular hyperplasia combined with dermal fibrosis effectively close the ear canal. If the canal can not be made more open to effect cleaning and treatment then the prognosis is much worse. In advanced cases, there may be ossification of the annular cartilages and this carries a poor medical prognosis.

In many cases, it is not possible to otoscopically examine past the proximal vertical canal and effective cleaning is not possible.

All efforts should be made to open the canal as much as possible and cleaning under anaesthesia often needs to be delayed until this is achieved.

The author recommends an otic preparation containing a potent topical corticosteroid which is active both superficially and in the deep dermis. To this end, high potency corticosteroid formulations containing 0.1% mometasone or betamethasone valerate are suitable. Common first line otic preparations containing 0.5-1% prednisolone are NOT recommended these are of the order of 50-100 times less potent with respect to corticosteroid activity at the concentrations used.

Prednisolone systemically is essential unless medically contraindicated. 1mg/kg daily for 8-10 days then every other day for 10-14 days reduces inflammation and pain. Oclacitinib (Apoquel®) is not as effective for reducing canal thickening.

The importance of cleaning. Inadequate cleaning = treatment failure

Serious ear disease needs to be seriously cleaned:

- To decrease the microbial load in the canal by mechanical and antiseptic means
- To remove as much organic material as possible. Many antibiotics especially aminoglycosides (gentamycin etc) and polymyxin are significantly less active in the presence of exudates and organic material
- To check for and remove any distal canal cerumoliths. These concretions of inspissated wax and debris are often found in the distal horizontal canal, forming a plug on the tympanic membrane. If not removed, their behaviour is to act as a foreign body, just like a grass seed
- To break up biofilm (see later)
- To inspect the tympanic membrane and assess if intact. A visually intact tympanic membrane is not a 100% guarantee as to the fact that it is functionally intact.

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Tips on ear cleaning

1. If not already done so, **collect samples** for cytology and if necessary culture (see later)
2. **Delay full cleaning until canal has been medically opened** (see before)
3. **Plan time and cost wise on a full surgical procedure**. To do an effective clean on an ear may easily take 20-30 mins per ear. General anaesthesia is usually required with placement of an endotracheal tube. If the tympanic membrane is ruptured, it is possible fluid may pass down the Eustachian tube.
4. In the past, it was recommended to only use saline as a cleaning solution until the tympanic membrane can be seen and evaluated as **most (all?) past ear cleaners are ototoxic**. Otoflush® Dermcare contains Disodium edetate (tris EDTA) and polyhexamethylene biguanidine hydrochloride (PHMB) in a buffered solution. It is highly effective against all classes of bacteria and fungi. The manufacturer advises that Otoflush is "*not contraindicated in cases where the tympanic membrane integrity is unknown or is ruptured."* The author uses this product for ear cleaning as a matter of standard protocol.

The author's technique

1. **Instrumentation.**
    a. Otoscope with fully charged batteries
    b. IV extension set cut to length for flushing and aspirating (feeding tubes may also be used),
    c. Alligator forceps
    d. A supply of cotton wool.
2. **Clean the medial pinna and its folds first with cotton wool**
3. **Using Dermcare Otoflush®, repeated cycles of flush/suck until the distal horizontal canal comes into view**
4. **Mopping.** To view the distal canals, make a small ball of cotton wool and pass down otoscope cone with alligator forceps to mop up cleaner and remaining debris and inspect. Repeat flush/suck/mop as needed.
5. **Check for a distal canal cerumenoliths.** These can be very difficult to break up by flushing. Picking with the alligator forceps allows the cerumenolith to be broken up, removed in pieces and finally the remnants removed by flush/suck/mop. Care and time is needed to avoid causing haemorrhage or damaging the tympanic membrane
6. **Assess the tympanic membrane.** If the tympanic membrane is clearly ruptured, collect middle ear exudate for comparative cytology and flush the tympanic cavity.
7. **Give systemic corticosteroids and instil an antimicrobial and corticosteroid formulation** based on cytology findings and the status of the tympanic membrane. Systemic antimicrobials are not required unless there is otitis media or if there is extensive canal ulceration and suspected bacterial invasion of the canal lining.

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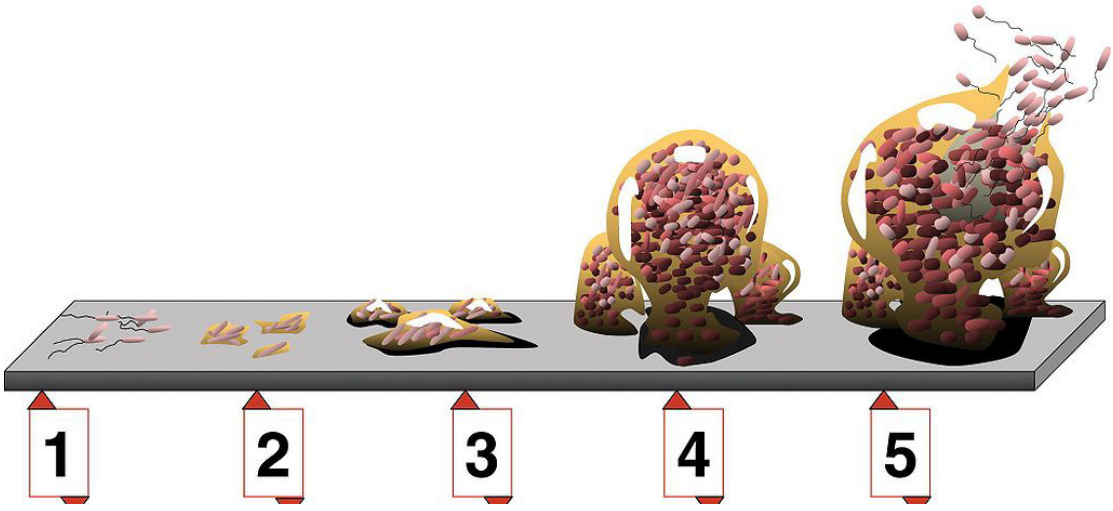
Biofilm – why logical treatment may fail

A **biofilm** is formed by micro-organisms sticking to each other and often adhering to a surface. These adherent cells are frequently embedded within a self-produced matrix of slime-like material consisting of proteins, DNA and polysaccharides. The corrugated and abnormal surface produced by ear canal epidermal hyperplasia supports biofilm adhesion



5 stages of a Pseudomonas aeruginosa biofilm development. Stage 1, initial attachment; stage 2, irreversible attachment; stage 3, maturation I; stage 4, maturation II; stage 5, dispersion

When growing in biofilm, the microbes have a different physiology to the free-living (planktonic) forms. Micro-organisms in a biofilm are semi-dormant at the base and may be refractory to logical antibiotics and can develop increasing antimicrobial resistance. Biofilms are recognised as important on teeth (tartar), on medical implants, in industry and now in tissues such as airways, bone, urinary tract and ear canals. Organisms of veterinary importance that are capable of ear biofilm formation include *Staphylococcus* spp , *Pseudomonas* aeruginosa, *Malassezia* spp, *Streptococcus* spp and a number of other opportunist pathogens.

Diagnosis of biofilm. At present we have no specific means of diagnosing the presence of biofilm but it may be suspected if there is a persistent, possibly slimy, exudate in the canal and that on cytology, the pathogen(s) are not being eliminated by what would be logical therapy.

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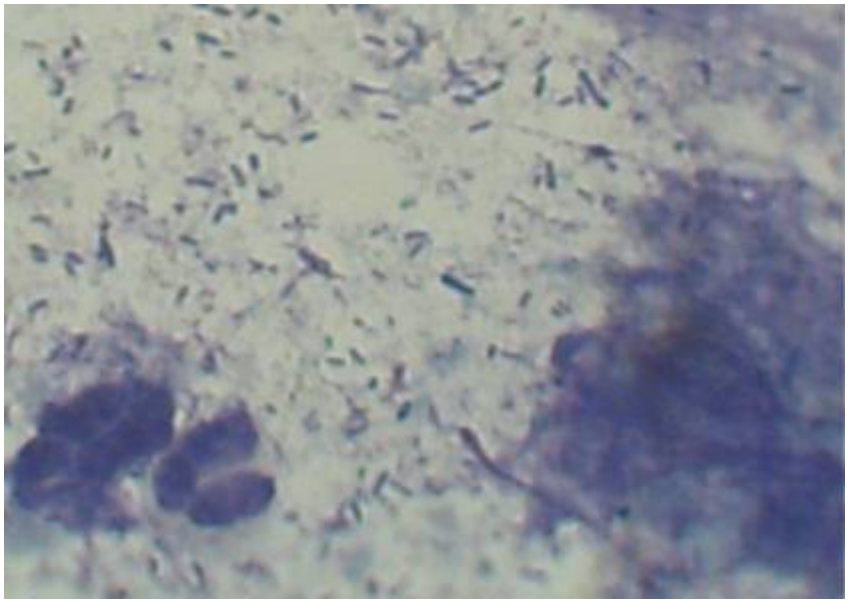
Disruption of ear biofilm. Antibiotics are often ineffective in breaking down biofilm. Veterinary evidence is lacking but studies show the following agents have a disruptive effect on biofilms:

- Triz-EDTA acts through ion chelation and, in addition , has a synergistic action with antiseptics, antibiotics and proteases
- Silver sulphadiazine at higher concentrations has been shown in vitro to disrupt biofilms
- Acetylcysteine has been shown in vitro and in vivo to be a potent disruptor of biofilms. Solutions of 20mg/ml are bactericidal against many bacteria including *Pseudomonas* aeruginosa. There is data to suggest acetylcysteine is fungistatic against *Candida* spp; no data exists for *Malassezia*. In human medicine, combination solutions of acetylcysteine and ciprofloxacin have been found to be potentially synergistic. Anecdotal reports of good results exist for 2% acetylcysteine in combination with 7.5-15mg/ml enrofloxacin. Limited data suggests that solutions <2% have an acceptable low(er) ototoxic potential. 2% acetylcysteine is increasing in use among veterinary dermatologists but specific studies are still lacking.
- Mechanical mopping may assist (see flush/suck/mop technique above)
- In the future, we may see products ,suitable for otic use, containing silver nano/micro-particles, proteolytic enzymes or other novel agents that disrupt biofilms



Neutrophils and rod-like bacteria. Suggestive of Pseudomonas otitis Diff-Quik blue , 1000x

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Choosing antimicrobials: Choices and pitfalls

Ear Cytology - How to tips

1. The author collects samples from both ears and by, convention, smears the left ear towards the frosted side of the slide (or make R and L figures on the same slide)
2. If *Otodectes* is suspected, collect a sample using copious quantities of oil AFTER collecting the cytology sample.
3. Rapidly air dry
4. Stain with just Diff-Quik 2 (blue) by putting a drop on the slide and then placing a cover slip. This will stain keratinocytes, bacteria, yeast and the nuclei of leucocytes; what we are generally looking for. It will not highlight fungal hyphae well. By using the fixative, organisms in a waxy base may wash off. The red Diff-Quik stain is only of value for staining eosinophil granules.
5. Diff-Quik stain needs to be replaced regularly. Old stain fails to stain cells, has "pseudobacteria" of stain precipitate and will grow its own culture of contaminant bacteria. The author uses a dropper bottle of Diff Quik 2 that is replaced weekly.
6. Use low power first to find good fields then go to suitable fields with 400x magnification.
7. There is no reason to use oil immersion for ear cytology. In addition to mess and spoiling slides, the field on 1000x is reduced by a factor of 5.25; 1000x makes the evaluation of the slide as a whole more time consuming and does not improve resolution. Ensure the microscope condenser is near the top to maximise resolution and the light beam diaphragm is not closed down. If the microscope does not allow for the differentiation of rods from cocci then it should be serviced or replaced.
8. Streptococci, staphylococci and entrococci are effectively impossible to differentiate on ear smears. Enterococci are Gram –ve cocci. The morphological description of staphylococci forming grape like clusters and streptococci forming chains is more useful in vitro than for ear cytology.
9. Enterobacteria (*Pseudomonas*, E. coli and *Proteus*) form rods about 1.5-2x as long as wide. Small gram positive rods are consistent with *Corynebacterium* and are often seen in mixed cultures.
10. *Pseudomonas* aeruginosa is often seen as a solo infection and is often associated with an outpouring of neutrophils. Classical green tinted pus suggests Pseudomonas infection but a brown exudate does NOT rule it out.
11. Mixed infections with many diverse rods and cocci may be mixed anaerobes
12. Do not rely on colour of ear exudate without cytology. Brown "yeasty" material may contain significant numbers of bacteria, including rods and leukocytes

There is little evidence that culture and sensitivity testing alters outcomes in most cases of otitis externa.

Dermatologists are tending to do fewer cultures and relying more on cytology to select and monitor an initial course of topical medication

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Choosing the medication

- Cultures are looking for growth inhibition at concentrations reached by systemic dosing (µgm/ml). When topical medication is used, the doses the bacteria are exposed to are mg/ml (of the order of 1000x higher). Hence organisms reported as "resistant" on culture may indeed be sensitive
- Culture is important in cases of otitis media where systemic antibiotics are utilized. It is important to obtain the sample from the middle ear cavity as differing organisms and differing sensitivities may be isolated from different levels of an infected ear canal
- The key is to do cytology before treatment and then look for clearance of the organisms 10-14 days later. Even in severe cases, a 7 day cytology should still show a major reduction in organism numbers if the medication choice, formulation and dose are correct
- Streptococci, anaerobes and enterococci are inherently resistant to gentamycin and enrofloxacin. Failure to clear cocci on cytology suggests the presence of these organisms or a drug-resistant staphylococcus. Many Gram +ve cocci will respond to miconazole/clotrimazole but not all. An empirical choice for persistent cocci is either silver sulphadiazine or chloramphenicol topically (off label use). Topical chloramphenicol (off label) is also often effective for mixed anaerobe infections
- The use of a triz-EDTA flush before instillation of topical medication can synergistically potentiate the antibacterials. Triz-EDTA alone will support yeast and other fungal overgrowth. The addition of PHMB to the buffered Triz-EDTA in the Otoflush® product provides a potent antibacterial and antifungal action.
- Azole (clotrimazole, miconazole) resistance among *Malassezia* spp has been identified. In the author's experience more cases of treatment failure with respect to Malassezia are related to cerumenoliths and inadequate cleaning rather than resistance. Malassezia sensitivity testing is not routinely offered by most laboratories but, fortunately, most azole-resistant cases will respond to nystatin.
- It is important that adequate volumes of antimicrobial medication be instilled and placed deep in the vertical canal at the junction of the horizontal canal. Volumes required vary between 0.5 – 1 ml, depending on the canal volume. To assist in proper placement and correct volume, the author supplies owners with a syringe and a 1 – 1.5cm soft plastic canula made from a cut-down intravenous extension set.
- Systemic treatment for 4 weeks + is indicated for otitis media. There is no substitute for topical treatment. Systemic antibiotics are unlikely to reach

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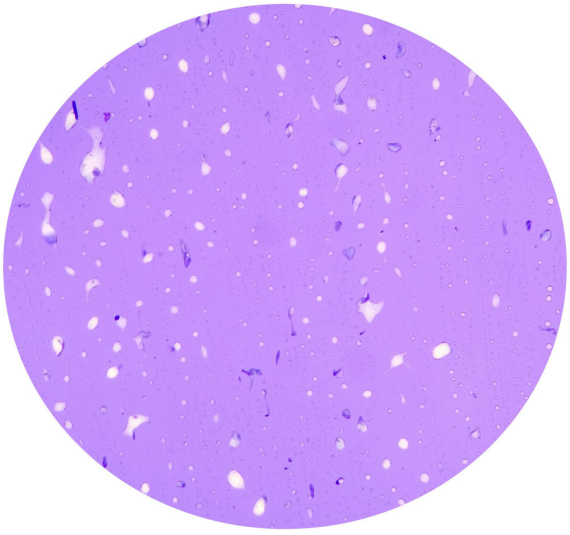
therapeutic levels in the ear canal unless there is erosion/ulceration with serum exudation. Systemic ketoconazole is more of an adjunct treatment of otitis external and should not be relied on for monotherapy.

- Ototoxicity of topical medications depends on BOTH the drug uses and the base. There is data from clinical cases of dogs with otitis and tympanic membrane rupture that Brainstem Auditory Evoked Response (BAER) improved after repeated aqueous instillation of gentamycin in aqueous solutions. There is no safety data on the use of oil or propylene glycol based drops in the presence of a non-intact tympanum and clinical consensus is that these bases are ototoxic and potentially enhance the ototoxicity of the antimicrobials in the preparation.
    - Least ototoxic: Enrofloxacin, silver sulphadiazine, 0.15% chlorhexidine, ketoconazole, dexamethasone, Triz-EDTA-PHMB
    - Increased ototoxic potential: gentamycin, chloramphenicol
    - High ototoxic potential: Polymyxin-B, ticarcillin, amikacin, tobramycin and ANY non-aqueous based medication
- Compounded or specially formulated ear medications are indicated when
    - There is a failure of logical registered treatment applied in appropriate volumes to a cleaned ear.
    - Where there is a ruptured tympanic membrane and registered aqueous ear preparations have failed or are deemed inappropriate.
    - When high volume flushing is needed, for example to assist in treating otitis media.



Cytological resolution post treatment.

Treat till you beat !
It is vital to monitor the patient every 10-14 day and continue topical treatment until visible and cytological resolution of the infection. Then proceed into a maintenance program

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Ointment base with scattered squames. Diff Quik 2 x 400

New Developments

Thermoreversible long acting gels, such as poloxamer based, have been used off label at intervals of 1-2 weeks on an off-label compounded basis in dogs where daily treatment is not possible. Their efficacy and use has been largely anecdotal.

Recently, a study has been published comparing the use of two veterinarian applied treatments, 1 week apart, of a terbinafine-florfenicol-betamethasone acetate otic gel, Osurnia, Elanco, compared to once daily with a veterinary licensed otic drop based product along with twice weekly cleaning. The veterinarian-administered otic gel "provided equivalent efficacy and higher quality of life score to dogs with otitis externa and their owners, compared to an owner-administered topical otic therapy". Providing the tympanic membrane is intact, this novel therapy has benefits in those dogs with ear infections susceptible to the constituent agents, particularly those dogs that are difficult to medicate or owner compliance is a concern.

Surgical and other referral

> ***You've got to know when to hold them, know when to fold them, know when to walk away, know when to run.***
> Kenny Rogers, "The Gambler"

Referral for advanced ear evaluation is indicated when middle ear involvement is suspected and the state of the horizontal canal does not permit proper evaluation and treatment. Flexible video otoscope is the optimal medical approach to evaluate and flush a middle ear cavity

Signs of otitis media

- Pain, especially when pressure applied to bulla area
- Facial nerve paralysis (loss of blink reflex)
- Horner's syndrome
- Circling, balance loss and nystagmus (otitis INTERNA)
- Discharge emanating from a ruptured tympanic membrane or less commonly a bulging and possibly discoloured intact-appearing tympanic membrane. CAUTION: With standard otoscopes, especially in a case with chronic changes, the tympanic membrane can be difficult to accurately assess.

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Surgery

A full discussion of surgery techniques is beyond the scope of this article.

Some cases of otitis media required surgical drainage via a bulla osterotomy.

The Zepp lateral ear resection is of value in a limited number of cases. It should be reserved for cases where most of the pathology is in the vertical canal, the owner is aware ongoing cleaning will be needed but is likely to be easier and hearing is present. It is contraindicated in cases with severe or end stage horizontal canal changes, otitis media, when a "cure" is the desired outcome and when the animal will not permit ongoing maintenance.

Total ear canal ablation with bulla osteotomy (TECA) is likely to produce resolution of clinical signs with hearing loss. There are potential complications from the surgery and should only be done by surgeons trained and experienced in the procedure. The indications include:

- Severe ear pain that makes topical treatment impossible.
- Failure of at least two different courses of logical medical treatment
- Proliferative end stage changes in a canal that can not be opened
- Ossification of the aural cartilages carriers a poor medical prognosis
- Refractory otitis media where canal changes render a bulla osteotomy and drainage unlikely to be effective

Maintaining the chronic ear

After long standing infection and inflammation, as described earlier, the ear canal has lost its self cleaning function and possibly may never fully regain it. Maintain and monitor is essential

The author's protocol:
Flush once a week with a gentle ear cleaner that has good antimicrobial properties
30-60 minutes later, instil a corticosteroid steroid-containing medication

- Data exists that ears maintained with a steroid medication in addition to a cleaner have a lower rate of re-infection than just with a cleaner alone.
- This reflects the experience and practice of many dermatologists
- The author's experience is that alcohol-based corticosteroids, particularly hydrocortisone aceponate spray, when used off label in the ear have excessive drying action

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- The author prefers to use a registered otic preparation containing betamethasone valerate despite the fact that the preparation contains antimicrobials. It is the authors opinion that the risk of overgrowth of resistant pathogens is more theoretical than real, especially when an antimicrobial ear flush is used. This is not to say there is no risk and informed consent is needed.

The patient is reviewed at 6-8 weeks otoscopically and cytologically, 6 days after cleaning.

If the response is very good-excellent, the maintenance interval can be extended progressively from 10-14 days, with monitoring every 3 months.

The major risk factor is contact sensitivity developing to components of the flush or steroid-containing otic preparation. While, uncommon it is occasionally seen and needs to be recognised by the clinician. This risk, while small, needs to be balanced against the fact that without maintenance, reinfection is almost certain.

Summary

Failure to control otitis externa can be related to the following factors:

- Not understanding the pathophysiology of chronic otitis
- Failure to control a manageable primary cause
- End stage changes
- Organic material, biological and other foreign material left in ear canal
- Biofilms
- Ineffective medication duration and volumes
- Otitis media
- True resistance
- Failure to monitor and maintain

References are available on request

The author wishes to express his gratitude to Dr. Anne Woolley for her proof reading and corrections to this article.