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The eye wipes with polyhexanide (HexaClean) in preoperative prophylaxis of cataract surgery

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ABSTRACT

BACKGROUND: Progressively increasing number of eye surgeries forces the development of simple-to-use, effective methods to reduce the risk of postoperative endophthalmitis. We wondered whether the eyelid margin wipes containing 0,1% polyhexamethylene biguanide (PHMB) (HexaClean, VERCO, Poland) influence the reduction of bacterial flora localized in the conjunctival sac and whether it can be used for prophylaxis before the cataract surgery.
MATERIAL AND METHODS: 95 patients before the cataract surgery were included in the study. The conjunctival swab was collected from patients twice — before using eye wipes and after 5 days of eye wipes usage. The swabs were plated on microbiological enriched media and incubated under aerobic and microaerophilic conditions for 24–48 hours at 35°C ± 2°C. Then the identification of microorganisms was carried out using classic microbiological methods and tests.
RESULTS: Bacterial strains were isolated from the conjunctival sac in 84% of patients before using the eye wipes. The largest group of isolated pathogens was Gram-positive cocci, and these were mainly methicillin-sensitive and methicillin-resistant coagulase-negative staphylococci, which accounted for 72% of isolated strains. When the eye wipes were used, the bacterial flora was eliminated from the conjunctival sac in 54% of patients. A reduction in isolated strains and decreased variety of bacteria was observed in another 22% of patients.
CONCLUSION: These results indicate that the application of eyelid wipes with polyhexanide reduces a significant amount of the conjunctival sac microbiota, which may prevent inflammation after cataract surgery.

KEY WORDS: cataract surgery; PHMB; prophylaxis; eye wipes; eyelid hygiene

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INTRODUCTION

The eye, an extremely sensitive organ, is constantly exposed to harmful environmental agents, especially infectious pathogens. The eyelid margin, conjunctiva, and tear film are often a habitat for potentially dangerous microorganisms, which can

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be responsible for unwanted infections causing even postoperative endophthalmitis among patients undergoing ocular intervention [1–2].

Most cases of endophthalmitis after cataract surgery are exogenous and caused by microbes from the microbiome of the ocular surface or introduced into the eye from external sources (healthcare personnel, surgical instruments, solutions, intraocular lens) [3–4]. According to Durant, significant pathogens responsible for this kind of infection are coagulase-negative staphylococci, *Staphylococcus aureus*, and hemolytic and nonhemolytic streptococci [3]. Dave et al. also report Gram-negative rods such as *Pseudomonas aeruginosa* as one of the commonest microbe, which can lead to fulminant endophthalmitis and evisceration. Rahmani and Eliott also point to the involvement of such species as *Enterococcus sp.*, *Proteus sp.*, or *Haemophilus influenzae* in endophthalmitis [5]. Infections with opportunistic pathogens belonging to *Nocardia sp*, among which there are drug-resistant strains, are also possible [6]. Fungal etiology is also likely, and the infection is mainly caused by species of the genus *Candida* spp., *Aspergillus* spp., or *Fusarium* spp. [7–8]. Unfortunately, despite established treatment regimens and the availability of antifungal agents, a positive therapeutic outcome cannot always be achieved [9]. Although the incidence of postoperative endophthalmitis is low (≤ 0.2%), it may be consistent with serious complications such as decreased vision, eye redness, and pain, especially in immunocompromised patients [10]. The risk of endophthalmitis after cataract surgery is increased mainly among patients aged ≥ 75 years [11]. Progressively increasing amount of eye surgeries forces the development of simple-to-use, effective methods for maintaining a sterile surgical field, which gives a chance to minimize the risk of postoperative complications, especially caused by drug-resistant microorganisms.

Polyhexamethylene biguanide (PHMB) is a biocide killing Gram-negative, Gram-positive, chlamydiae, and mycoplasma bacteria, fungi, and protozoa. Polyhexanide is an antiseptic substance that interacts with negatively charged phospholipids in the bacterial membrane, altering its structure and inhibiting the bacterial cell's metabolism. PHMB has a broad antimicrobial spectrum, low toxicity, good patient tolerance, and high effectiveness. This was noticed during ocular procedures [12–13]. PHMB is a safe substance without reported long-term adverse reactions and no evidence of bacterial resistance [14]. Its less irritant profile and similar antimicrobial activity, compared to commonly used iodopovidone, make it a perfect agent for antisepsis before ophthalmological surgeries [13].

The aim of the study was to analyze the conjunctival sac bacterial flora before and after 5-day use of the eyelid hygiene wipes with 0,1% polyhexanide in patients before cataract surgery.

MATERIAL AND METHODS

The research was conducted with the approval of the Wroclaw Medical University Ethics Committee (ST-859). Ninety-five patients, 66 females and 29 males, between 54 and 92 years old (y.o.), were included in the study during the 3-month project. An anamnesis and an ophthalmological examination were performed 7–10 days before the eye surgery. After obtaining the patient's informed consent, a conjunctival swab from the selected eye was collected. The patients were instructed to use prescribed eye wipes with polyhexanide (HexaClean, VERCO, Poland) twice daily for five days before the surgery. The control ophthalmological examination was performed the day before the surgery, and the second swab from the conjunctival sac was collected.

The conjunctival swabs were collected with a sterile viscose swab stick (HagMed, Poland) moistened with sterile saline and sent to the laboratory in a transport set within 12 hours. The swabs were placed on microbiological enriched media: Columbia Agar with 5% of sheep blood, Chocolate agar, glucose enrichment broth (Becton Dickinson, United States), and selective media McConkey's agar, Sabouraud agar (Becton Dickinson, United States). The plates were incubated under aerobic and microaerophilic conditions for 24-48 hours at 35°C ± 2°C. After 48 hours, in the absence of growth on solid enriched media, the swabs were plated from liquid media on the aforementioned solid media.

Microorganisms were identified using classic microbiological methods (clumping factor, coagulase test) and identification panels for Gram-positive and Gram-negative bacteria (BBL Crystal Identification System, Becton Dickinson, United States). The cefoxitin susceptibility tests for *Staphylococcus* species were made using the disk diffusion method on Mueller-Hinton Agar (Becton Dickinson, United States), as recommended by European Committee on Antimicrobial Susceptibility Testing (EUCAST v.12.0) [15]. For statistical analysis, the unpaired t-test with Welsch's correction was applied. The results were considered statistically significant when $p < 0.0001$. The GraphPad Prism 8 software was used for statistical calculations.

RESULTS

The influence of eye wipes containing PHMB (HexaClean) used for eyelid margin hygiene on microbiological flora was tested on 95 patients. The positive cultures from the conjunctival sac (which means at least one species of the microorganism cultured), obtained before the use of the eye wipes, occurred in 84% of patients, while in 16% of cases, the swabs were sterile (Tab. 1).

Genera and species of isolated microorganisms from the swabs before and after using eye wipes are shown in Table 2 and Figures 1 and 2.

Before the application of eyelid margin hygiene, the largest group of isolated pathogens were Gram-positive cocci, among them coagulase-negative staphylococci (CoNS) — 72%, of which 75% were methicillin-susceptible (MS), and 25%

Table 1. Results of cultures from the conjunctival sac before using polyhexamethylene biguanide (PHMB) wipes

Culture	Number of cultures	%
Positive	80	84
Sterile	15	16
Total	95	100

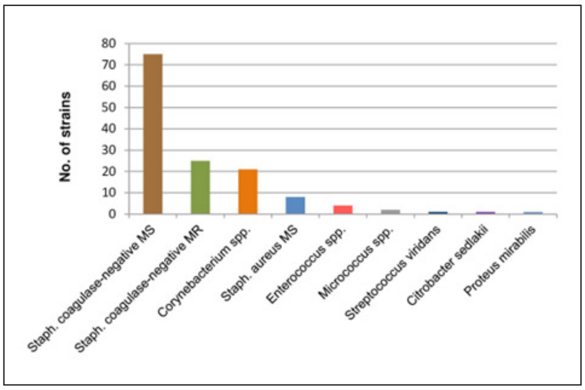

FIGURE 1. Bacterial flora isolated from the swabs before using polyhexamethylene biguanide (PHMB) wipes. MS — methicillin susceptible; MR — methicillin resistant

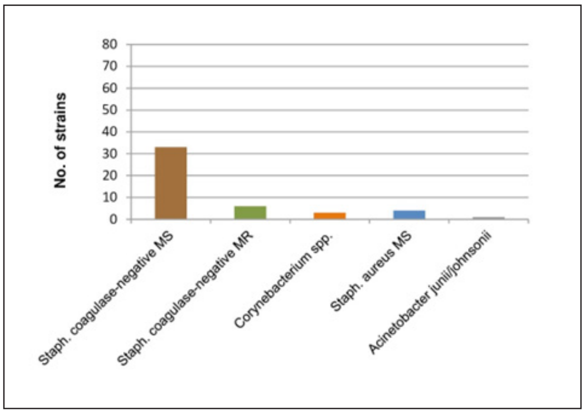

FIGURE 2. Bacterial flora isolated from the patients after using polyhexamethylene biguanide (PHMB) wipes. MS — methicillin susceptible; MR — methicillin resistant

Table 2. The genera and species of isolated bacteria from the swabs before and after using eye wipes with polyhexamethylene biguanide (PHMB) use

Before eyelid margins hygiene	Number of strains (%)	After eyelid margins hygiene	Number of strains (%)
Gram positive cocci			
Coagulase-negative *Staphylococcus* MS[1] Coagulase-negative *Staphylococcus* MR[2] *Staphylococcus aureus* MS *Enterococcus spp* *Micrococcus spp.* *Streptococcus viridans*	75 (54%) 25 (18%) 8 (6%) 4 (3%) 2 (1%) 1 (1%)	Coagulase-negative *Staphylococcus* MS Coagulase-negative *Staphylococcus* MR *Staphylococcus aureus* MS	33 (70%) 6 (13%) 4 (9%)
Gram positive bacilli			
Corynebacterium spp.	21 (15%)	*Corynebacterium spp*.	3 (6%)
Gram negative bacilli			
Citrobacter sedlakii	1 (1%)	*Acinetobacter junii/johnsonii*	1 (2%)
Proteus mirabilis	1 (1%)		
Total	138 (100%)	Total	47 (100%)

MS — methicillin susceptible; MR — methicillin resistant

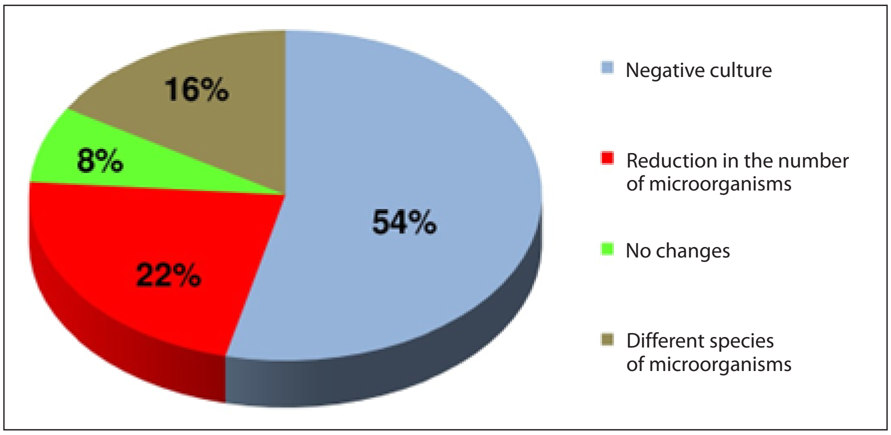

FIGURE 3. The results of cultures after using polyhexamethylene biguanide (PHMB) wipes in patients with previously positive bacterial flora

Table 3. The results of cultures after applying the eyelid wipes to patients with previously cultured bacterial flora

Criterion	Number of cultures	%
Sterile culture	43	54
Reduction in number of isolated strains	18	22
No change of the bacterial flora	6	8
The change in the composition of the bacterial flora	13	16
Total	80	100

were methicillin-resistant strains (MR). *Staphylococcus aureus* was isolated in 6% of cases, and all of them were MS strains characterized by the lack of resistance mechanisms to the majority of beta-lactam antibiotics. A few bacterial species belonging to the *Micrococcus* spp., *Enterococcus* spp., *Streptococcus* spp. were isolated, constituting 5% of all bacterial strains. Among the bacilli, Gram-positive corynebacteria were the most frequently isolated. *Enterobacteriaceae* and *Morganellaceae* were found occasionally. There was no growth of yeast-like fungi in the tested materials. The results of cultures obtained after the use of eyelid wipes with PHMB are shown in Figure 3 and Tables 2 and 3.

In 54% of patients, the bacterial flora was eliminated from the conjunctival sac due to the wipes mentioned above use. In 22% of patients, a reduction in the number of isolated strains and decreased variety of bacteria were proved.

As shown in Figure 2, the growth of *Streptococcus* spp., *Micrococcus* spp., *Enterococcus* spp., and bacilli from the *Enterobacteriaceae* family and *Morganellaceae* family has not been observed. The number of *Corynebacterium* spp. strains decreased from 21 to 3, and *S. aureus* from 8 to 4. CoNS were the most common in cultures — 83%, of which over 84% were MS strains, and under 16% were MR strains. Microorganisms were isolated more frequently after 24 hours of incubation in a liquid medium, which may indicate that a low number of bacteria was present in the examined material. No impact on the bacterial flora was found in 8% of the patients.

The swabs contained the same species of microorganisms in both cultures (before and after eyelid margin hygiene). The change in the composition of the bacterial flora in the conjunctival sac occurred in 16% of the patients.

Figures 4 and 5 present a comparison of the number of species isolated from individual swabs before and after eyelid hygiene.

After applying the PHMB wipes, a maximum of 2 bacterial species were found in the tested materials, and in more than 70%, only a single bacterial strain was grown. The drop in the number of species isolated from patients undergoing the cleansing procedure was statistically significant ($p < 0.0001$) (Fig. 6).

In patients with primary sterile swabs, colonization of the conjunctival sac with microbes was not observed.

DISCUSSION

Cataract removal procedures are one of the most frequently performed surgeries in ophthalmology, and their number in recent years has been systematically increasing [16–18]. The lens removal is per-

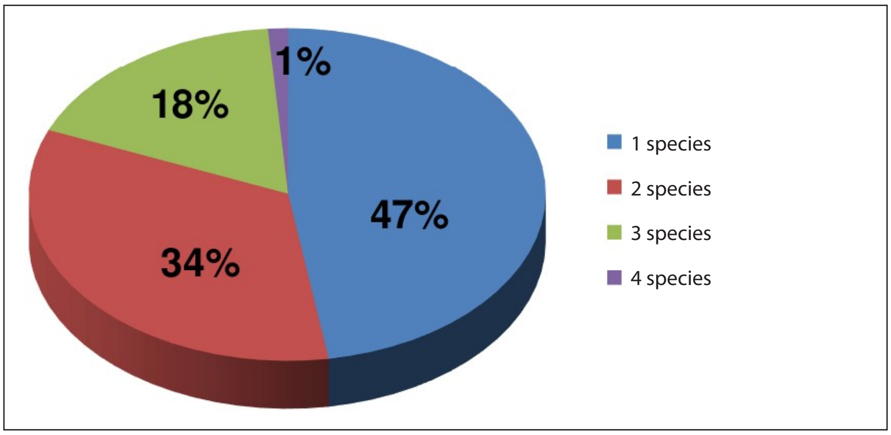

FIGURE 4. The number of isolated species from conjunctival sac before to using polyhexamethylene biguanide (PHMB) wipes

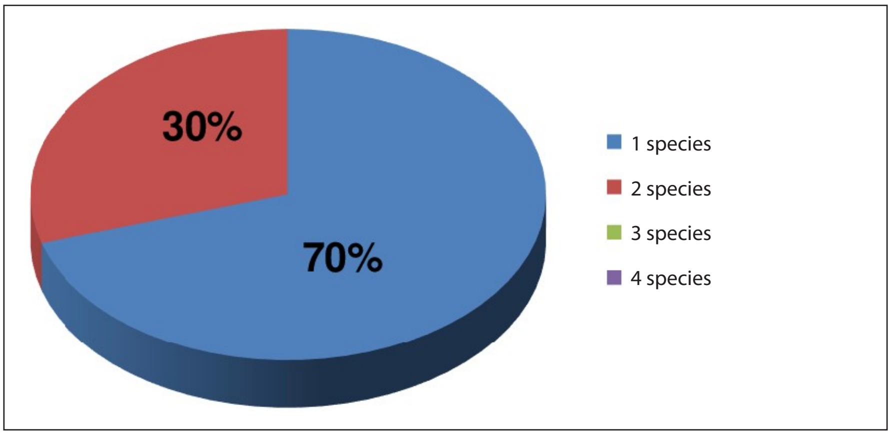

FIGURE 5. The number of isolated species from conjunctival sac after using polyhexamethylene biguanide (PHMB) wipes

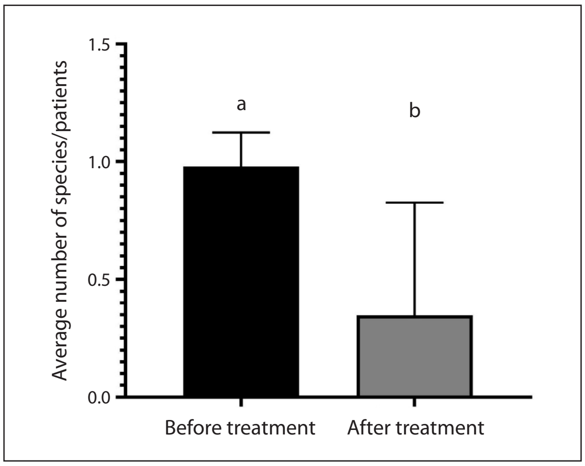

FIGURE 6. The average number of species isolated per patient before and after treatment. [a, b]statistical significance between the two analyzed groups ($p < 0.0001$, unpaired t-test with Welsch's correction)

formed not only in the situation of its cloudiness and decreased visual acuity but also as a refractive procedure or in the case of angle-closure glaucoma [19]. The success of the surgery depends on properly performed preoperative, intraoperative, and postoperative procedures. Preoperative prophylaxis is crucial, securing the surgical field and its surroundings against the penetration of microorganisms and the development of complications. In recent publications, eyelid hygiene is one of the recommended methods [20]. The conjunctival sac and the eye margins can be colonized with microflora, which includes *Staphylococcus epidermidis*, *Corynebacterium* spp., *Neisseria* spp., *Moraxella* spp., and also temporarily *Staphylococcus aureus.* Correctly performed preoperative prophylaxis reduces the risk of complications, especially the most dangerous endophthalmitis, which can lead to irreversible vision loss in the operated eye. Determination of the microorganism types colonizing the conjunctival sac is essential.

The results obtained by several authors vary. Barria et al. examined 118 patients, obtaining positive cultures in 89.8% of cases, which is similar to the results obtained in the presented study (84%) on a similarly sized group [21]. The studies conducted by Suto et al. on a much larger number of patients (579) have shown the presence of bacteria in 39,2% of patients. In the study of Mahmud-Ajeigbe et al. on 157 patients, only 35% of cultures were positive [22–23]. In our research, the most frequently isolated microorganism was methicillin-susceptible (54%) and methicillin-resistant coagulase-negative *Staphylococcus* (18%), followed by *Corynebacterium* spp. (15%) and *Staphylococcus aureus* MS (6%). A similar profile of microorganisms was isolated by Barria et al., where staphylococci were present in 76.1% of cases, of which coagulase-negative strains were found in 82.6% and *Staphylococcus aureus* in 17.4% [21].

The antiseptic of choice used in preoperative prophylaxis applicated into the conjunctival sac is a 5% aqueous solution of iodopovidone. So far, its optimal concentration, which can be used for this purpose, has yet to be determined [20]. In the studies by Hansmann et al., iodopovidone at a concentration of 1.25% is not toxic to the eye's surface [24]. The authors also compared the effectiveness of 1.25% iodopovidone to 0,02% PHMB in preoperative prophylaxis in 29 patients achieving similar effects of both agents. An additional advantage of PHMB was a longer antiseptic effect compared to iodopovidone [25].

Although iodopovidone was used in preoperative prophylaxis Kivanc et al. reported the presence of bacterial flora in the corneal incision in the final stage of cataract surgery before administration of the antibiotic into the anterior chamber. Data showed in 35.3% of cases of coagulase-negative staphylococci, 29.4% *Bacillus cereus*, and in 5.9% of *Pseudomonas* spp. [26]. Iodopovidone also can not be used in patients with hypersensitivity reactions to this antiseptic [20].

The use of an additional procedure before the surgery in the form of eyelid margin hygiene can reduce the risk of postoperative complications. There are few publications regarding this topic in the literature. External agents applied to the eyelid margin, and intraoperatively administered antibiotics to the anterior chamber were examined. In a study conducted by Peral et al. on 45 patients, a 5-day use of micellar fluid containing hyaluronic acid, extract from *Iris Florentina* and *Centella Asiatica* (Blephasol, Théa) before cataract surgery caused a 53% reduction in the number of microorganisms on day 3 and 63% on day 5. *S. epidermidis* was most frequently isolated (94.7%), followed by *Corynebacterium* spp. (32.9%), the others were *S. aureus* (6.3%), *Micrococcus* spp. (8.5%), and *Bacillus* spp. (1%) [27].

In the control examinations carried out by the authors, after 5 days of using PHMB wipes, 54% of the cultures were sterile, and 22% showed a reduction in the number of isolated microorganisms. Only in 8% of the examined materials no effect on the conjunctival microflora was observed, and in 16%, there was a change in its composition. The profile of isolated microorganisms was very similar to that before using the wipes with PHMB and to the results obtained by other authors. The greatest reduction was recorded for coagulase-negative staphylococci strains, followed by *Corynebacterium* spp. and *S. aureus*. Before using the wipes, the number of microorganisms species isolated from the tested materials ranged from 1 to 4. After the hygiene of the eyelid margin, a maximum of 2 bacterial species were found in the collected swabs. This indicates the effectiveness of the wipes with PHMB on bacteria that colonize the conjunctival sac.

Antiseptic agents are also used in the prophylaxis of infection during intravitreal injections. There are no uniform guidelines regarding antibiotic prevention before such procedures. However, in the era of rapidly increasing resistance of microorganisms, the abuse of their use creates additional risks of this phenomenon. Studies conducted by Bhavsar et al. have shown that eliminating topically applied antibiotics in patients who have been given intravitreal injections does not increase the risk of endophthalmitis while keeping prophylaxis with iodopovidone [28].

In light of these studies, using PHMB wipes before ophthalmic surgery may cause a reduction of the risk of postoperative endophthalmitis because of a significant decrease in microorganisms colonizing the conjunctival sac. Therefore it may lead to limitation of antibiotic use in preoperative prophylaxis and the development of bacterial resistance.

CONCLUSIONS

Iodopovidone and antibiotics are currently used in the prophylaxis of cataract surgery. Frequent use of antibiotics increases resistance to these substances. Eyelid wipes with PHMB reduce a significant amount of the conjunctival sac flora, and their use may reduce the risk of postoperative inflammation. So far, no antagonism has been described between iodopovidone and polyhexanide. A comparison of the effects of PHMB eyelid wipes used together with iodopovidone, and evaluation of their effects on the development of postoperative infections require further clinical studies.

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Authors' contributions

Conceptualization — J.R-Z. and A.H-B.; methodology — J.R-Z and E.P.; formal analysis — J.R-Z., A.H-B. and E.P.; investigation — J.R-Z., E.P. and A.H-B.; resources — A.H-B.; data curation — E.P.; writing original draft preparation — J. R-Z., E.P., M.M. and K.B.; writing review and editing — J.R-Z.; supervision — J.R-Z. and A.H-B.; project administration — J.R-Z and E.P.; funding acquisition — M.M-H. All authors have read and agreed to the published version of the manuscript.

Statement of ethics

All subjects gave informed consent for inclusion before participating in the study. The study was conducted in accordance with the World Medical Association Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Wroclaw Medical University (ST-859).

Conflict of interest

The authors have no conflicts of interest to declare.

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Data availability

The datasets generated during and/or analysed during the current study are available on request from the corresponding author.

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