Evaluation of Postoperative Povidone-Iodine in Adjustable Suture Strabismus Surgery to Reduce Suture Colonization
A Randomized Clinical Trial

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**IMPORTANCE** Although the association between suture colonization and postoperative infections remains hypothetical, measures to reduce perioperative suture colonization may minimize postoperative infections. The suture colonization rate in adjustable suture strabismus surgery is not well defined, and the effect of povidone-iodine use on suture colonization is unknown.

**OBJECTIVE** To assess whether povidone-iodine application at the end of adjustable suture strabismus surgery decreases the suture colonization rate.

**DESIGN, SETTING, AND PARTICIPANTS** In this randomized clinical trial designed in 2015 and performed from June 1 through October 31, 2015, a total of 65 adjustable and 43 control suture specimens from 65 demographically similar adults undergoing adjustable suture strabismus surgery were studied. A random sampling assigned participants into group 1 (with povidone-iodine) or group 2 (without povidone-iodine) at the end of surgery. A control suture specimen was obtained if ipsilateral nonadjustable surgery was performed. Both groups received antibiotic ointment at the end of the procedure. No patients refused participation or withdrew. Data analysis was performed from October 1 to December 31, 2015. Observers were unaware of patient grouping.

**INTERVENTIONS** One drop of 5% povidone-iodine directly over the sliding noose of the adjustable suture at the end of surgery.

**MAIN OUTCOMES AND MEASURES** The suture colonization rate after adjustment in group 1, group 2, and the control group.

**RESULTS** Of 65 adults undergoing surgery, there were 17 men (49%) and 18 women (51%) in group 1 and 10 men (33%) and 20 women (67%) in group 2, as well as 20 men (47%) and 23 women (53%) in the control group. The mean (SD) age of the patients was 48.5 (16.8) years in group 1, 46.6 (18.1) years in group 2, and 47.7 (17.0) years in the control group. There was no difference in the colonization rate between group 1 (57%) and group 2 (47%) (relative risk [RR], 1.1; 95% CI, 0.6-1.7; \( P = .80 \)), group 1 and the control group (44%) (RR, 1.0; 95% CI, 0.5-1.8; \( P > .99 \)), or group 2 and the control group (RR, 1.3; 95% CI, 0.8-2.1; \( P = .62 \)). Eleven bacterial species were identified. *Staphylococcus epidermidis* was the predominant isolate (40 of 56 [71%]). A longer interval between the end of surgery and adjustment was associated with higher culture positivity (6.3 hours in positive vs 4.4 hours in negative cultures, \( P = .001 \)); however, there was no difference in bacterial growth between the groups. No adverse effects of povidone-iodine were observed.

**CONCLUSIONS AND RELEVANCE** This study was not able to demonstrate that povidone-iodine at the end of adjustable suture strabismus surgery reduces the suture colonization rate.

**TRIAL REGISTRATION** clinicaltrials.gov Identifier: NCT02424357.
Infectious complications of strabismus operations are rare but potentially pose a threat to vision. The incidence of orbital cellulitis is estimated to be 1 in 1100 to 1900 cases, and the incidence of endophthalmitis is approximately 1 in 30,000 to 185,000 operations. The source of the infection after strabismus surgery is thought to be contaminated needles and sutures, with contamination rates ranging from 15.1% to 30.4%. The colonization rate of sutures in adjustable suture strabismus surgery is even higher, possibly as high as 66.1%.

Povidone-iodine has been proven to be beneficial in preoperative preparation of patients for ophthalmic surgery. Its use decreases bacterial colonization by up to 91% and reduces the risk of endophthalmitis in intraocular surgery by up to 75%. When an additional application of 5% povidone-iodine in the conjunctival fornices after draping (ie, dual application) is applied before the initial incision in strabismus surgery, it reduces the colonization of the surgical site and sutures from 25% to 10%. When compared with combined antibiotic and corticosteroid drops, there is no significant difference in the incidence of postoperative infection. In addition, replacing a postoperative antibiotic with povidone-iodine results in significant cost saving, estimated to be US$170,000 in 1074 strabismus operations performed. The present study aims to assess whether adding a drop of povidone-iodine to the standard postoperative prophylaxis at the completion of the adjustable suture strabismus surgery decreases the suture colonization rate.

Methods

This randomized clinical trial was approved by the University of Miami Institutional Review Board and conducted at the Bascom Palmer Eye Institute in accordance with the principles of the Declaration of Helsinki. After a comprehensive explanation of the procedures that composed the study, written consent was obtained from all participants in adherence with the Health Insurance Portability and Accountability Act. The trial was designed in 2015 and performed from June 1 through October 31, 2015. Data analysis was performed from October 1 through December 31, 2015. All data were deidentified. The trial protocol can be found in Supplement 1.

During a 4-month period, all adult patients (≥18 years old) scheduled to undergo adjustable suture strabismus surgery were invited to participate. Exclusion criteria included the use of topical ocular antibiotics within a month before surgery and a documented hypersensitivity or allergy to iodine.

After enrollment, the random allocation sequence of the patients was generated using a computer program (Research Randomizer; https://www.randomizer.org). Patients were randomized into 1 of 2 groups: those who received 1 drop of 5% povidone-iodine instilled directly over the sliding noose at surgery completion (group 1) and those who did not receive povidone-iodine at the end of the surgery (group 2). The surgeon was unaware of the randomization until the end of the surgery. All microbiology personnel and patients were unaware of the interventional group. The patient allocation was revealed once the study was closed and microbiological analysis was completed.

Institutional standard surgical preparation was performed in all patients with 5% povidone-iodine solution on the periocular skin and eyelid margins, followed by instillation of 1 drop of 5% povidone-iodine into the conjunctival cul-de-sac. Subsequent removal of the excess povidone-iodine with moistened sterile gauze pads was performed.

All operations were performed by one of us (C.A.M. or H.C.) using a sliding noose technique with a polyglactin 6–0 suture (Vicryl, Ethicon Inc). If a patient underwent surgery on more than 1 muscle in the same eye, a 1-cm section of suture proximal to the knot was collected from the nonadjustable suture as a control. The control suture was placed in a tube that contained 2 mL of tryptcase soy broth and agitated for 1 minute. At the end of surgery, patients in group 1 received a drop of povidone-iodine. A strip of neomycin sulfate, polymyxin B sulfate, and dexamethasone ophthalmic ointment was then applied into the lower conjunctival fornix to patients in both groups.

The interval between the end of the surgery and the adjustment procedure was recorded. The adjustment procedure timing varied according to anesthesia duration and/or surgeon preference, and some sutures underwent adjustment the following day. All adjustments started with 1 drop of sterile proparacaine hydrochloride ophthalmic solution administered in the conjunctival fornix. When the appropriate adjustment was completed, a 1-cm section of the suture adjacent to the adjustable knot was placed in a 2-mL tryptcase soy broth tube and agitated for 1 minute. If the patient underwent surgery with adjustable sutures on more than 1 muscle, only the suture from the first adjusted muscle was considered for statistical analysis. The order of the adjustment was determined by clinical examination in which the muscle with the greater residual deviation was the first to be adjusted.

The collected sutures were monitored for bacterial growth for up to 7 days. When bacterial growth was observed, 1 mL of the solution was inoculated on chocolate, MacConkey, and anaerobic blood agars and incubated for an additional 24 to 48 hours to identify organisms and quantify growth. In vitro susceptibility patterns were determined using a combination of minimal inhibitory concentrations (Vitek System, bioMérieux) and disk diffusion. Common antimicrobials included β-lactams, aminoglycosides, fluoroquinolones, mac-

Key Points

**Question** Does a drop of povidone-iodine at the end of adjustable suture strabismus surgery reduce the suture colonization rate?

**Findings** In a randomized clinical trial, the adjustable suture colonization rate was 52%, with negligible differences identified between the povidone group (57%) and the group without povidone (47%). A longer interval between the end of surgery and adjustment was associated with a higher rate of culture positivity.

**Meaning** This study was not able to demonstrate that povidone-iodine at the end of adjustable suture strabismus surgery reduces the suture colonization rate.
rolides, and others. Organism identification and comparison of antimicrobial susceptibilities were performed using standard microbiological procedures.

The primary outcome was the suture colonization rate. The secondary outcome was the comparison of the antibiotic resistance and microbiological profile between the groups.

**Sample Size**
The sample size was calculated based on a previous study that reported a positive colonization rate of 66% in adjustable strabismus surgery. The study was powered to detect a decrease in colonization by 30% with $P \leq .05$ and a power of 0.8, thus requiring 30 sutures for each group. Patient demographics, details regarding the surgical procedure, and microbiology results were collected.

**Statistical Analysis**
Statistical analysis was performed using STATA statistical software, version 10.1 (StataCorp). The independent-samples paired $t$ test was used to evaluate the correlation among age, interval of the adjustment procedure from the completion of surgery, and suture colonization rate. The Pearson $\chi^2$ test was used to look at the association among sex, muscle (horizontal or vertical) operated on, timing of adjustment procedure, and suture colonization rate. Linear regression analysis was used to evaluate each variable that had statistical significance. The mean difference, relative risk (RR), odds ratio (OR), and 95% CIs were reported. The Fisher exact test was used to compare antimicrobial susceptibilities among the groups. Because only a few isolates had intermediate susceptibility, these specimens were categorized as resistant for statistical considerations.

**Results**
Seventy-one adjustable sutures from 65 consecutive patients were collected. The mean (SD) age of the patients was 48.5 (16.8) years in group 1, 46.6 (18.1) years in group 2, and 47.7 (17.0) years in the control group. There were 17 men (49%) and 18 women (51%) in group 1 and 10 men (33%) and 20 women (67%) in group 2, as well as 20 men (47%) and 23 women (53%) in the control group. Six sutures from 5 patients were discarded because concurrent horizontal and vertical adjustable sutures were used in the same eye. Among the 5 patients with concurrent horizontal and vertical adjustable sutures, 4 inferior rectus and 1 medial rectus muscles were analyzed. Three of the inferior recti were in group 1 and received the additional povidone-iodine treatment. Because of the small number of muscles in this group, statistical significance could not be achieved. Of the 65 sutures, 35 were randomized to group 1 and 30 were randomized to group 2. All sutures were included in the statistical analysis; however, 1 suture from group 2 was contaminated during collection and was discarded. Thus, the primary outcome was calculated with 35 sutures from group 1 and 29 sutures from group 2 (Figure). Forty-three control sutures were collected intraoperatively. No intraoperative or postoperative complications occurred. No adverse effect regarding the use of iodine was observed. There were no protocol deviations.

Patient demographic characteristics are summarized in the Table. Groups 1 and 2 were comparable regarding demographic data, including sex, mean age at surgery, previous history of strabismus surgery, muscle operated on (horizontal vs vertical), or type of anesthesia.

The mean (SD) interval between the end of the surgery and the adjustment procedure was approximately 5 (2.4) hours (range, 2-17 hours). Culture positivity was higher in patients with longer mean intervals between the end of the surgery and the adjustment procedure (6.3 hours in positive vs 4.4 hours in negative cultures; mean difference, 1.9; 95% CI, 0.8-3.1; $P < .001$, paired independent-samples $t$ test). From the regression analysis, every additional hour increased culture positivity (OR, 1.6; 95% CI, 1.2-2.2; $P < .001$). Before 6 hours, 16 of 42 (38%) were colonized, and beyond 6 hours, 16 of 22 (73%) were colonized (OR, 4.3; 95% CI, 1.4-13.4; $P = .008$).

There was no difference in the colonization rate between groups 1 (57%) and 2 (47%) (RR, 1.1; 95% CI, 0.6-1.7; $P = .80$, Pearson $\chi^2$ test), group 1 and the control group (44% (RR, 1.0; 95% CI, 0.5-1.8; $P > .99$, McNemar $\chi^2$ test), or group 2 and the control group (RR, 1.3; 95% CI, 0.8-2.1; $P = .62$, McNemar $\chi^2$ test). Thirty-four of the 65 adjustable sutures yielded at least 1 bacterial isolate, resulting in a positive colonization rate of 52% (57% in group 1 and 47% in group 2). Nineteen of 43 control sutures yielded at least 1 bacterial isolate, resulting in a 44% positive colonization rate. There were 56 bacterial isolates from the 53 colonized sutures (eTable 1 in Supplement 2). Three sutures (5.7%) yielded 2 bacterial species, 1 each from group 1, group 2, and the control group. Eleven bacterial species were identified. No difference was found in bacterial species between the 2 groups and the control group. Staphylococcus epidermidis was the predominant isolate in all groups, accounting for 40 of the 56 bacterial isolates (71%). Most isolates (96%) had less than 1000 colony-forming units per milliliter.

No difference was found between the susceptibilities of the bacterial isolates from the sutures of group 1, group 2, and the control group (eTable 2 in Supplement 2). Most organisms were
sensitive to aminoglycosides and fluoroquinolones. Organisms were least sensitive to erythromycin. Methicillin-resistant (n = 10) and fluoroquinolone-resistant (n = 3) isolates were susceptible to gentamicin and vancomycin and were not found in the same patient.

Discussion

We assessed the colonization rate and microbiological profile of sutures in patients undergoing adjustable suture strabismus surgery and analyzed the effect of adding a drop of povidone-iodine at the end of surgery. Results were compared with control sutures from the same eye collected intraoperatively.

Eleven bacterial species were identified. A mean of 1.05 different species were seen per suture, which is lower than the mean reported in a previous study in adults (1.47 species) and children (1.14 species). In accordance with previous reports, the isolates consisted predominantly of normal periorcular flora, with the most common isolate being coagulase-negative Staphylococcus. The high prevalence of gram-positive organisms might be explained by its predominance in normal periorcular flora. In addition, there may be possible inhibition of gram-negative flora by postoperative application of neomycin, polymyxin B sulfate, and dexamethasone.

Overall, the adjustable sutures had a 52% positive colonization rate. This rate was lower than but comparable to a previous study that found a 66% colonization rate. Control sutures had a 44% positive colonization rate, which is higher than previously reported in nonadjustable sutures (24.6%-30.4%). Of note, these studies were conducted primarily in children in whom lower colonization rates are expected. Although not unexpected, a longer interval between the end of the surgery and the adjustment was associated with greater colonization (P = .001), which differs from a previous study. The longer contact period between the adjustable suture and the periorcular region may explain the higher colonization rate when compared with nonadjustable suture studies and the control group.

No difference was found in bacterial growth between the adjustable suture groups (P = .80). Unlike a previous study that compared the use of povidone-iodine and antibiotics within the first 24 hours postoperatively, our analysis did not reveal a decrease in colony-forming units with the use of povidone-iodine. Possible explanations include the overall low colony-forming unit count and the limited contact time of the povidone with the sutures. Contact time may be decreased because of reflex tearing secondary to the presence of the adjustable suture or the method by which the povidone was applied in the study. A previous study found that applying antibiotics alone resulted in a decrease in colonization from 28% to 22%, whereas presoaking the sutures with povidone-iodine for 5 minutes and then applying antibiotic ointment reduced the contamination rate from 28% to 8.5%. Therefore, the contact time with povidone-iodine may play a significant role in decreasing the colonization rate. Among the 5 patients with concurrent horizontal and vertical adjustable sutures, 4 were inferior rectus muscles, of which 3 were in the group that received the additional drop of povidone-iodine. Because the inferior rectus muscle might have more contact time with the microbial flora of the tear film and the lower lid, this possibility could have affected the colonization rate for group 1 unfavorably. Unfortunately, because of the small number of muscles in this group, statistical significance could not be achieved.

The limitations of this study include the absence of a control group without antibiotic treatment to compare the colonization rates. This group could be studied without exposing

Table. Demographic Data Comparing Group 1 (Povidone-Iodine) and Group 2 (No Povidone-Iodine)*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1 (n = 35)</th>
<th>Group 2 (n = 30)</th>
<th>Control Group (n = 43)</th>
<th>P Value</th>
</tr>
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<tr>
<td>Age at surgery, mean (SD), y</td>
<td>48.5 (16.8)</td>
<td>46.6 (18.1)</td>
<td>47.7 (17.0)</td>
<td>.66b</td>
</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17 (49)</td>
<td>10 (33)</td>
<td>20 (47)</td>
<td>.21c</td>
</tr>
<tr>
<td>Female</td>
<td>18 (51)</td>
<td>20 (67)</td>
<td>23 (53)</td>
<td></td>
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<tr>
<td>Muscle operated on</td>
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<td></td>
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<tr>
<td>Horizontal</td>
<td>30 (86)</td>
<td>24 (80)</td>
<td>39 (91)</td>
<td>.54c</td>
</tr>
<tr>
<td>Vertical</td>
<td>5 (14)</td>
<td>6 (20)</td>
<td>4 (9)</td>
<td></td>
</tr>
<tr>
<td>History of previous ocular surgery</td>
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<tr>
<td>No surgery</td>
<td>18 (51)</td>
<td>14 (47)</td>
<td>21 (49)</td>
<td></td>
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<tr>
<td>Eye muscle surgery</td>
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<td>12 (40)</td>
<td>18 (42)</td>
<td>.62d</td>
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<td>Other ocular surgery</td>
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<td>4 (13)</td>
<td>4 (9)</td>
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<td>Adjustment attempted</td>
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<tr>
<td>No</td>
<td>18 (51)</td>
<td>17 (57)</td>
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<td>Yes</td>
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<td>13 (4)</td>
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<td>General</td>
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<td>15 (50)</td>
<td>14 (33)</td>
<td>.20c</td>
</tr>
<tr>
<td>Local</td>
<td>23 (66)</td>
<td>15 (50)</td>
<td>29 (67)</td>
<td></td>
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<td>Interval between end of surgery and adjustment, mean (SD), h</td>
<td>5.2 (1.9)</td>
<td>5.4 (3.0)</td>
<td>NA</td>
<td>NA</td>
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</tbody>
</table>

Abbreviation: NA, not applicable.
* Data are presented as number (percentage) of patients unless otherwise indicated.
\( b \) Paired independent-samples t test.
\( c \) Pearson \( \chi^2 \) test.
\( d \) Fisher exact test.
the patient to additional risk as shown by a double-blind randomized study by Wortham et al., which found no significant difference between prophylactic antibiotic and corticosteroid treatment and placebo after strabismus surgery. The absence of a group without antibiotics makes it difficult to detect the role of the povidone-iodine in decreasing the suture colonization rate and the utility as an alternative, less costly postoperative prophylaxis. Another weakness relates to the culture method because cultures detect fewer bacterial isolates than newer molecular technologies, particularly slow-growing, culture-resistant bacteria and bacteria with unusual growth requirements. Although suture colonization does not necessarily correlate with clinical infection, the presence of culturable bacterial and/or virulent strains may identify patients at higher risk for postoperative infections.

Conclusions

This study suggests that the suture colonization rate in adjustable strabismus surgery is higher than with conventional sutures. This study was not able to demonstrate that povidone-iodine at the end of adjustable suture strabismus surgery reduces the colonization rate of the sutures, possibly because of a limited contact time. When adjustable sutures are exposed, it may be advisable to perform the suture adjustment as soon as possible because longer intervals between surgery and adjustment may be associated with higher suture colonization rates.