This study was awarded the AAAHC Institute’s 2014 Bernard A. Kershner Innovations in Quality Improvement Honorable Mention

Performance Improvement Study: Unusual Loss of Pterygium Grafts in 2012
January 2013
By Lucy L. Silva, RN, BSN

Problem/Issue of Concern:
In 2012, our ASC had 3 grafts that failed to adhere after Pterygium procedures. This was a significant increase & highly unusual based on our previous statistics. Our ASC had not had a pterygium graft adherence failures in 6 years. The surgeon states that the only change in the procedure that he has implemented in 2012 is the use of Polydex in lieu of Tobradex ointment post-op. He suspects that there may be a possible ingredient in the Polydex that is denaturing the fibrin glue (Tisseel). We will attempt to rule out any & all causal factors in this study.

Reason to resolve/address issue:
The goal of this study is to identify any possible causal factors in the failure of these grafts to adhere in 2012 & implement corrective actions immediately.

Performance Goal:
1. To identify any causal factors in graft adherence failure & implement corrective actions.
2. To maintain a normal rate of graft adherence success of >99% in 1st & 2nd quarters of 2013.

Data Collection Requirements:
1. Audit the 3 medication records for the pterygium patient cases where the graft did not adhere successfully to verify drug name, lot #’s & expiration dates to ensure staff administered correct post-op ointment.
2. Identify any unusual patient factors tied to these cases that predispose the 3 patients with grafts to not have the grafts successfully adhere post-op.
3. Verify that all applicable RN staff is properly mixing, storing & handling Tisseel per Mfr guidelines.
5. Submit inquiry to Baxter who manufactures Tisseel with ingredients in ointments to verify if they have any research indicating that any of these ingredients have the potential to denature the fibrin glue/Tisseel. Report any findings from Baxter/medical research.
6. Collect patient pterygium post-op graft adherence successes/failures statistics over 1st & 2nd quarter of 2013 for the purpose of this study.

Data:
Medication Record Audit of the 3 Pterygium Charts

<table>
<thead>
<tr>
<th># of charts</th>
<th># with correct medication &amp; lot # listed</th>
<th>% with correct medication &amp; lot # listed</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>3/3</td>
<td>100%</td>
</tr>
</tbody>
</table>

Patient Factors Identified by the Surgeon that Predispose the Case Studies to Losing their Grafts:
NONE REPORTED BY MD/SURGEON

Proper Preparation, Storing & Handling of Tisseel Glue by Staff

<table>
<thead>
<tr>
<th># Staff member preparing glue</th>
<th># Staff correctly preparing &amp; handling Tisseel</th>
<th>Any issues found with staff’s preparation, storing &amp; handling of Tisseel Glue</th>
<th>% of staff correctly preparing, storing &amp; handling of Tisseel Glue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2/2</td>
<td>0</td>
<td>100%</td>
</tr>
</tbody>
</table>

Comparison of TobraDex Ingredients Vs. Polydex by Bausch & Lomb Incorporated

<table>
<thead>
<tr>
<th>Medication:</th>
<th>Tobradex®</th>
<th>Polydex®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Ingredients:</td>
<td>Tobramycin 0.03% (3mg) &amp;</td>
<td>Neomycin Sulfate (equiv. to 3.5mg Neomycin)</td>
</tr>
</tbody>
</table>
Data from Baxter & Research:

- Baxter’s medical science department reported back & forwarded a study (Prentice) that found that Neomycin Sulfate (found in Polydex, but not in Tobradex) has been linked to increased incidences of fibrinolysis. Fibrinolysis is defined as the dissolution of fibrin by enzymatic action.
- Another (more recent) study (Hu, Guo-fu) from which this fibrinolysis effect by Neomycin can be inferred was found upon our further research as well.

Findings:
1. Medications administered post-op were correct & appropriate. Therefore, there we cannot establish a link in this area to the non-adherent grafts.
2. No significant patient predisposing factors in the failed graft cases were noted by the surgeon that would adversely affect their graft adhesion/healing.
3. Upon evaluation, staff appear to be properly preparing, storing & handling the Tisseel fibrin glue product. No link established here.
4. Neomycin, found in Polydex, but not Tobradex has been found to increase the process of fibrin breakdown. The Polydex ointment began being administered immediately post-op in lieu of Tobradex in 2012. This appears to be the most likely link to the unusual trend in post-op graft loss due to poor adherence at our surgery center.
5. Further data collection is necessary to make a more definitive conclusion regarding the denaturing affect of the Neomycin in Polydex on graft adhesion.

Implementation of Corrective Action:
1. We will no longer use the Polydex ointment or any other Neomycin containing medications in the eye post-op for pterygium graft cases & monitor outcomes.

Action to take:
1. We will no longer use the Polydex ointment or any other Neomycin containing medications in the eye post-op for pterygium graft cases
2. All pterygium case outcomes will monitored for the 1st & 2nd quarter of 2013 for graft adherence success/failure stats.
3. Trends will be tracked & reported.
4. Final outcomes will be reported after the 2nd quarter with the hope that we shall have expected outcomes in graft adhesion post-op with the new protocol implemented.
5. If the percentage of graft adherence is still an issue, we will re-evaluate for any other possible factors at that time.

Actions Taken:
1. Effective 1/8/13, CSP will use eye drops that do not contain Neomycin post-op in pterygium cases with autografts.
2. Effective January 2013, we have begun to track outcomes of pterygium grafts for 1st & 2nd quarters of 2013 & report the statistics/findings for the purpose of this study.
3. Any trends or lingering concerns shall be addressed at the conclusion of the data collection time period (end of 2nd quarter).

Evaluation of Implementation of Corrective Action Data Collection Requirements:
Initial measurement of success rate of graft adherence was 92% for 2012
Re-measurement of success rates after corrective actions was 100% for all of 2013

Final Evaluation of Implementation of Corrective Action Data Collection Requirements:
- It is clear that the use of Polydex as suspected interfered with the effectiveness of the Tisseel due to the Neomycin component.
- We have experienced zero recurrences of autograft adherence failures since changing to a different medication which is Neomycin free.
- Our study & corrective actions have proved to be 100% successful.
Additional corrective action needed? If so, please describe the corrective action implemented/rationale, any changes in measurement/rationale, and the results of your new re-measurement versus your performance goal.

No, additional corrective action not indicated.

- We were successful in identifying a specific causal factor (being the use of the medication (Polydex) with the denaturing effect on the fibrinogen within Tisseel glue used to adhere the grafts).
- We were able to confirm that our processes & procedures were appropriate & accurately carried out by reviewing them with our staff & examining the medical records.
- We were able to rule out any other causal factors.

The corrective actions yielded a consistent 100% success rate for all of 2013.

Communication of findings:

The findings & the entire process were reported through the ongoing performance improvement study, QAPI reports, MEC meetings, Governing Board meetings & through surgical staff in-service meetings. We also submitted our study to the ASCRS/ASOA national conference (posters/study submissions) as to share our findings with our colleagues in hopes that if others have had a similar issue with related case scenarios, they may find a solution & improve their patient outcomes.

Works Cited


Abstract
By Stanley H. Feil, M.D.

Title: Iatrogenic angiogenesis inhibition may lead to conjunctival graft loss when using non-suturing techniques

Purpose: To report a possible mechanism of graft loss when performing conjunctival autografting with Tisseel (CAGT).

Methods: A retrospective chart review of patients who had pterygiectomy with CAGT was performed after a cluster of grafts were lost.

Results: 3 cases of CAGT loss occurred during a period of 2 months. A change from one time use of Tobradex to Polydex at the end of surgery was identified. Neomycin, a component of polydex, was found to be an inhibitor of angiogenin-induced angiogenesis.

Conclusion: Neomycin’s inhibition of angiogenesis, which is critical for vascularization of the graft, may result in loss of a conjunctival graft.

Cases of graft loss occurred following pterygiectomy with autografting using Tisseel only (no sutures), after switching from tobradex ointment to polydex (containing neomycin), with no other cases of graft loss occurring before or after switching back to tobradex.

This study was undertaken to try and determine why some autografts were detaching and being lost, after 7 years of never losing a graft during pterygiectomy surgery.