Clinical evidence summaries

3M™ DuraPrep™ Surgical Solution

(Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w)

Patient Preoperative Skin Preparation

Summary 1

DuraPrep Surgical Solution associated with lower SSI rates


**Objective**

To compare the effects of different skin preparation solutions on surgical-site infection rates.

**Methodology**

Three skin preparations were compared using a sequential implementation design. Each agent was adopted as the preferred modality for a 6-month period for all general surgery cases.

**Period 1** - povidone-iodine scrub-paint combination (Betadine® Solution) with an isopropyl alcohol application between these steps

**Period 2** - 2% chlorhexidine and 70% isopropyl alcohol (ChloraPrep™ Skin Prep)

**Period 3** - iodine povacrylex in isopropyl alcohol (DuraPrep Surgical Solution)

**Findings**

Surgeries using iodophor/alcohol-based surgical preps (including DuraPrep Surgical Solution) had a significantly lower SSI rate than surgeries using ChloraPrep Skin Prep.

SSI Rate by Prep Received

<table>
<thead>
<tr>
<th>Prep Received</th>
<th>SSI%</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>ChloraPrep®</td>
<td>8.2</td>
<td>.001</td>
</tr>
<tr>
<td>Iodophor-based Surgical Preps</td>
<td>4.8</td>
<td></td>
</tr>
</tbody>
</table>

N = 3,209 General Surgeries
Summary 2

Cardiac bypass surgery: intervention to decrease SSIs


Objective
To decrease SSIs following cardiac bypass surgery. From July 1997 – June 1998, the hospital had 7/152 (4.6%) superficial sternal wound infections and 4/152 (2.6%) deep sternal infections requiring 19 surgical interventions for 4 patients and 372 extra days of hospitalization.

Methodology
Standards of practice were evaluated while 3 major changes were implemented.
1. A physician’s assistant was hired solely to harvest saphenous veins.
2. DuraPrep Surgical Solution* was used as the intraoperative prep.
3. Pre- and post-operative wound care standards were developed and implemented.

Findings
“The implemented changes resulted in a greater than 50% reduction in overall SSI, sternal infection and surgical intervention post-infection. We estimate a reduction of ICU bed days and 15 operative procedures in one year...”

* 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation.

<table>
<thead>
<tr>
<th></th>
<th>Baseline July 1997-June 1998 (n=152)</th>
<th>Practice Changes Implemented July 1998-June 1999 (n=168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total SSI</td>
<td>14 (9.2%)</td>
<td>7 (4.2%)</td>
</tr>
<tr>
<td>Superficial Sternal Infections</td>
<td>7 (4.6%)</td>
<td>0</td>
</tr>
<tr>
<td>Deep Sternal Infections</td>
<td>4 (2.6%)</td>
<td>3 (1.8%)</td>
</tr>
<tr>
<td>Surgical Interventions Needed for Infections</td>
<td>19</td>
<td>7</td>
</tr>
</tbody>
</table>
Summary 3

DuraPrep Surgical Solution and ChloraPrep™ Skin Prep equally effective at reducing microbes on the skin


Objective
The purposes of this study were to identify the common bacteria present on skin overlying lumbar spine and determine the positive bacterial culture rate following skin preparation.

Methodology
In a prospective randomized study, 100 consecutive patients undergoing lumbar spine surgery were prepped with either DuraPrep Surgical Solution* or ChloraPrep skin prep. Cultures were obtained at 3 points (pre-prep, post-prep and post closure) using a validated neutralization sampling solution. Positive cultures and specific bacterial pathogens were recorded.

Findings
DuraPrep Surgical Solution and ChloraPrep skin prep are equally effective skin preparation solutions (P=0.24).

* 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation

Number of positive bacterial isolates found on the skin before preparation (Pre-prep) with either ChloraPrep Skin Prep or DuraPrep Surgical Solution, and after wound closure (Post-closure).

There was a significant increase in positive culture results after wound closure compared with the rate following skin preparation (3% versus 33%, P<0.0001), but there was no difference between the ChloraPrep Skin Prep (34%, seventeen of fifty) and DuraPrep Surgical Solution (32%, sixteen of fifty) groups (chi-square analysis, P = 0.22; 95% CI = 0.284 to 0.483) with regard to post-closure results.
Summary 4

Resistance of preoperative skin preparations to saline rinse


**Objective**

Evaluate the antimicrobial persistence of two commercially-available skin antiseptic agents following saline exposure.

**Methodology**

A prospective, randomized study in healthy subjects using DuraPrep Surgical Solution* and ChloraPrep™ Skin Prep was performed. Preps were applied according to manufacturers’ instructions and allowed to dry. The sites were then exposed to either a saline rinse or to a saline-saturated gauze (sponge), similar to the challenges that preps would face during most surgical procedures. Two analyses were performed:

1. An indicator organism was seeded onto the treated sites. After 30 minutes, samples were collected, surviving bacteria were counted, and log reductions calculated.
2. The saline-saturated gauze was analyzed chemically for the presence of chlorhexidine or iodine.

**Findings**

After the challenge, DuraPrep Surgical Solution had significantly higher log reduction compared to ChloraPrep Skin Prep (*P*=.006). In addition, DuraPrep Surgical Solution demonstrated resistance to removal by saline-soaked gauze (*P*<.0001).
Clinical Evidence Summaries: 3M™ DuraPrep™ Surgical Solution

Summary 5

Resists wash-off and maintains persistence for 48 hours

Antimicrobial Persistence of 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation after 48 hours following exposure to blood and saline*

Objective

To evaluate the durability and antimicrobial effectiveness of DuraPrep Surgical Solution following a blood and saline challenge by measuring the regrowth of normal skin flora on the human back at 48 hours post-prep.

Methodology

Baseline bacterial counts were taken on the backs of ten healthy volunteers. DuraPrep Surgical Solution was applied and allowed to dry. Post-prep counts were taken 10 minutes after prep dried. Half of the remaining prepped area was then challenged with blood-soaked gauze followed by sterile, saline-soaked gauze. After the blood/saline challenge, post-prep sampling was again performed. Remaining sites were covered for 48 hours. After 48 hours, the coverings were removed and the test sites were sampled. All samples were collected with a neutralizing solution.

Findings

DuraPrep Surgical Solution suppresses regrowth of bacteria for at least 48 hours** with and without a blood and saline challenge (to simulate surgical conditions).

* 3M Study-05-010565
**following ASTM E1173

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