

3M™ DuraPrep™

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



# A Comparison of Five Studies



	<b>Savage et al.</b> ( <i>The Journal of Bone and Joint Surgery</i> , 2012; 94: 490–494)	<b>Saltzman et al.</b> ( <i>The Journal of Bone and Joint Surgery</i> , 2009; 91: 1949–1953)
<b>Title</b>	Efficacy of Surgical Preparation Solutions in Lumbar Spine Surgery	Efficacy of Surgical Preparation Solutions in Shoulder Surgery
<b>Design</b>	Prospective randomized study, single center	Prospective randomized study, single center
<b>Surgery type</b>	Elective Lumbar Spine Surgery	Shoulder Surgery
<b>Primary Outcome</b>	Identify the common bacteria present and determine the positive culture rate following skin preparation	Identify the common bacteria present and determine the positive culture rate following skin preparation
<b>Secondary Outcome</b>	NA	NA
<b>Number of Subjects</b>	100	150
<b>Neutralization per ASTM Test Methods</b>	YES	NO
<b>Prep Used</b>	PVP-I	NA
	NA	PVP-I scrub and paint (0.75% iodine scrub and 1.0% iodine paint)
	Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w (3M DuraPrep Surgical Solution)*	X
	2% CHG and 70% Isopropyl Alcohol (ChloraPrep Solution)	X
	3% Chloroxylenol [PCMX] (Techni-Care)	NA
<b>Overall SSI Rates</b>	NA	No postoperative wound infections in any of the patients at a minimum of ten months of follow-up
<b>Conclusions</b>	3M DuraPrep Surgical Solution** and ChloraPrep Solution*** are equally effective skin preparation solutions ( $P=0.24$ )	ChloraPrep Solution is more effective than 3M DuraPrep Surgical Solution* and Povidone-Iodine at eliminating total bacteria from the shoulder region ( $P=0.01$ )
<b>Limitations / Study Comments</b>	Used qualitative culture rather than quantitative culture data. Therefore unclear if certain patients had a higher bacterial load at baseline, and whether or not that would have altered the effectiveness of the skin preparation solution and ultimately increased the risk of infection. The manufacturer of one of the skin preparation solutions (3M DuraPrep Surgical Solution) provided funding for the study. The funding was used exclusively for microbiology expenses and evaluation of the neutralization solutions and the company was not involved with the organization or analysis of data. Study not powered to detect the differences in postoperative infection rates	No neutralization method was used when taking culture samples. No control for false positives. Obtained cultures for only one time point following surgical skin preparation. Cultures were obtained prior to surgical preparation for the first 20 patients only. The manufacturers of one of the agents (ChloraPrep Solution) provided funding for the study. The funding was used exclusively for microbiology expenses and the company was not involved with the organization or analysis of data. Used qualitative culture data rather than quantitative culture data

\*Iodine Povacrylex/Alcohol is 3M™ DuraPrep™ Surgical Solution (Iodine Povacrylex [0.7% available iodine] and Isopropyl Alcohol, 74% w/w) Patient Preoperative Skin Preparation. It does not contain PVP-I. It received the USAN adopted name of iodine povacrylex, an iodine acrylate copolymer, to differentiate it from traditional iodophors such as PVP-I.

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

\*\*\*ChloraPrep® Patient Preoperative Skin Preparation 2% Chlorhexidine Gluconate (CHG) & 70% Isopropyl Alcohol (IPA)

<b>Ostrander et al.</b> <i>(The Journal of Bone and Joint Surgery, 2005: 87: 980–985)</i>	<b>Darouiche et al.</b> <i>(The New England Journal of Medicine, 2010; 362: 18–26)</i>	<b>Swenson et al.</b> <i>(Infection Control and Hospital Epidemiology 2009; 30: 964–971)</i>
Efficacy of Surgical Preparation Solutions in Foot and Ankle Surgery	Chlorhexidine-Alcohol versus Povidone-Iodine for Surgical-Site Antisepsis	Effects of Preoperative Skin Preparation on Postoperative Wound Infection Rates: A Prospective Study of 3 Skin Preparation Protocols
Prospective randomized study, single center	Prospective randomized study, six centers	Quasi-experimental (sequential assignment of interventions) single center
Foot and Ankle	Clean-contaminated (included specialty surgeries, <i>EG, GYN, urologic, GI, thoracic</i> )	General Surgery (clean, clean-contaminated, contaminated, dirty)
Quantitative bacterial cultures	Any SSI within 30 days of surgery	Overall rate of surgical-site infection by 6-month period performed in an intent-to-treat manner
NA	Individual types of SSIs	Any SSI within 30 days of surgery tracked by prep received
125	849	3,209
NO	NA	NA
NA	1. PVP-I scrub (application protocol not described, no alcohol used) 2. PVP-I paint (10% PVP-I) – Application protocol not described	1. PVP-I scrub (7.5% PVP-I) 3 consecutive applications 2. Alcohol scrub, as above (70% isopropyl alcohol), single application 3. PVP-I paint (10% PVP-I) 3 consecutive applications 4. Allow prep to dry
X	NA	X
X	X	X
X	NA	NA
<b>Postoperative infections:</b> Chloroxylenol <b>5%</b> Chlorhexidine-alcohol <b>2.5%</b> Iodine povacrylex-alcohol <b>0%</b>	PVP-I 16.1% Chlorhexidine-alcohol 9.5% ( $P=0.004$ )	<b>By Preferred Prep (Study Period):</b> Period 1 PVP-I with alcohol paint <b>6.4%</b> Period 2 Chlorhexidine-alcohol <b>7.1%</b> Period 3 Iodine povacrylex/alcohol <b>3.9%</b> ( $P=0.002$ )  <b>By Prep Actually Received:</b> PVP-I with alcohol paint <b>4.8%</b> Chlorhexidine-alcohol <b>8.2%</b> Iodine povacrylex/alcohol <b>4.8%</b> ( $P=0.001$ )
Of the three solutions tested, ChlorPrep Solution was most effective in eliminating bacteria from the forefoot prior to surgery	Preoperative cleansing of the patients's skin with chlorhexidine-alcohol is superior to cleansing with povidone-iodine for preventing SSI after clean-contaminated surgery	Skin preparation is an important factor in the prevention of SSI. Iodophor-based compounds may be superior to chlorhexidine for SSI prevention in general surgery patients
No neutralization method was used when taking culture samples. Ideal study would have evaluated infection rates. Such a study would have required a much larger population to demonstrate a significant effect. There were three post-op infections in this study – 2 from Techni-care group and 1 from the ChlorPrep Solution group. Did not obtain culture specimens from the foot of each patient prior to surgery to determine baseline bacterial load. Performing a second set of cultures at a later point in time might have been useful (difficult to select a consistent time interval because of the varying surgical durations)	<ul style="list-style-type: none"> <li>• <u>3M DuraPrep Surgical Solution</u>, one of the commonly used one-step skin preps in the USA, was <u>not included</u></li> <li>• Compared CHG/Alcohol with a <u>reference prep containing only PVP-I</u>, without alcohol, despite the well-known synergistic effect of both antiseptics due to their different mechanisms of action</li> <li>• Compared 2 agents with 1 agent</li> </ul>	<ul style="list-style-type: none"> <li>• <u>Not randomized</u> (justification: authors wanted to implement protocol as commonly seen in practice and maximize the consistency of prep applications)</li> <li>• <u>Single Center</u> (local variation in patient populations, compliance, and other standards related to SSI prevention might have influenced the results)</li> <li>• <u>Compliance</u> with prep used by period was only in the 70% range</li> </ul>



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The Way

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