Testing of INDERMIL® Flexifuze™ as an effective barrier against microbial penetration.

INDERMIL® flexifuze™

The objective of this study was to determine if INDERMIL® Flexifuze™ provides an effective barrier against penetration by selected bacteria and the yeast fungus *Canidida albicans.*

TEST ORGANISMS

- Staphylococcus aureus ATCC 25923
- Staphylococcus epidermis ATCC 51627
- Candida albicans ATCC 10231
- Escherichia coli ATCC 8739
- Psuedomonas aeruginosa ATCC 9027
- MRSA(Staphylococcus aureus) ATCC 33591
- VRE (Vancomycin Resistant Enterococcus) ATCC 51299

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Methodology

The in vitro effectiveness of INDERMIL® Flexifuze™ was determined by utilising a flat, thin surface, where the product could be applied evenly and allowed to polymerise spontaneously. This system also included conditions for the growth and spread of each test microorganism in the event they managed to progress through the layer of the test product. The flat, thin surface for these purposes was provided by a sterile 55 mm X 55 mm square of Whatman filter paper, with product applied to this surface (and allowed to polymerise). Survival of the inoculum applied to the surface of the product was provided by the letheen broth medium in which the test organism was suspended. Growth support for any organisms progressing through the polymerised product was provided by an underlayment of trypticase-soy agar, where the growth of the organism would be proof of the failure of the product to serve as a barrier.

The testing for permeability or impermeability was done at each test date by lifting the organism/product/filter paper system off of the agar medium. The area on the agar medium immediately beneath where the product had been, was then swab sampled onto a TSA plate. The absence of growth would have proven that the product served successfully as a microbial barrier, while the presence of growth would have proven a failure. A control for each test organism was prepared by repeating the above procedure without the presence of the product. Growth beneath this organism/filter paper control system with product excluded demonstrated the validity of the entire testing procedure.

Finally, it was necessary to determine if the viability of the inoculum was sustained on the upper surface of the product throughout the 8-day duration of the experiment, in order for any of the results of the testing procedure to be valid. The 8-day duration of the testing procedure matches the expected clinical requirement for sustained effectiveness as a microbial barrier on the patient for 8 days. As the results section indicates, all test organisms presented as inoculum loads, displayed significant quantities of viable CFU's throughout the 8-day period of testing.

Microbial barrier properties of INDERMIL® Flexifuze™

Staphylococcus aureus (ATCC 25923)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:1.4x10^4 cfus* *+ = Confluent growth*

Staphylococcus epidermidis (ATCC 51627)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:1.9x10^6 cfus* *+ = Confluent growth*

Candida abicans (ATCC 10231)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:2.4x10^5 cfus* *+ = Confluent growth*

Escherichia coli (ATCC 8739)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:2.9x10^4 cfus* *+ = Confluent growth*

Pseudomonas aeruginosa (ATCC 9027)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:4.1x10^6 cfus* *+ = Confluent growth*

MRSA, Methicillin Resistant Staphylococcus aureus (ATCC 33591)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:3.6x10^4 cfus* *+ = Confluent growth*

VRE, Vancomycin Resistant Enterococcus (ATCC 51299)

Test Conditions	Surviving Cells Recovered on Trypticase Soy Agar		
	Day 2	Day 5	Day 8
Cell mass inoculated on surface of product (Test)*	+	+	+
Cell mass detected below product (Test)	No Growth	No Growth	No Growth
Cell mass on surface of filter paper (Control)	+	+	+
Cell mass below surface of filter (Control)	+	+	+

**Initial inoculum:4.1x10^5 cfus* *+ = Confluent growth*

Conclusion

This in vitro testing procedure was designed to determine if microorganisms, when applied to the surface of polymerized INDERMIL® Flexifuze™, may passively or actively pass through the product. The results show that at least under the in vitro circumstances employed here, none of the test organisms penetrated through the thin layer of product (less than 0.5 mm) to access the growth medium below. The control system chosen here was clearly adequate in having the potential to support abundant growth from all test organisms inoculated onto the surface of the system in the absence of product. The organism/product/filter paper test system and the control system (identical except for the absence of product), approximated as closely as in vitro circumstances allow, the patient use situation in a clinical setting. Furthermore, the test organisms were selected according to their frequent association with wound infections.
The directness of this method strengthens the validity of the conclusions. The mechanism by which this adhesive product prevents penetrability has not been addressed in this project, but the effectiveness of the product as an impenetrable barrier has been proven

This test was carried out independantly by Ronald E. Gain, Ph.D,
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The latest technology in
Cyanoacrylate tissue adhesive.

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