

# Evaluation of the Effect of Type and Amount of Plasticizer on Mechanical Properties of Patch-non-Patch® Films



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## AIM OF THE WORK

The Patch-non-Patch® platform is a bioadhesive film with a monolayer structure which includes backing, adhesive and drug reservoir in one layer. Moreover it is not adhesive in the dry state but bioadhesive when applied on wet skin.



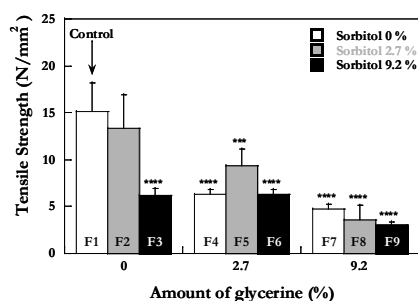
The aim of this work was to verify the effect of the type and amount of plasticizer on the mechanical and adhesive properties of the Patch-non-Patch® film using a factorial design<sup>3,2</sup>.

Formulation	Factor	
	A	B
F1	-	-
F2	-	0
F3	-	+
F4	0	-
F5	0	0
F6	0	+
F7	+	-
F8	+	0
F9	+	+

(A) = glycerin  
 (B) = sorbitol  
 (-) = absence  
 (0) = 2.7%  
 (+) = 9.2%

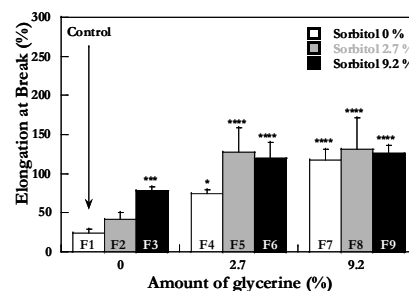
## RESULTS

### Tensile Strength



The addition of plasticizer always produced a significant reduction of the mechanical resistance of the film ( $p < 0.0001$ ). In the case of glycerin, such reduction results to be independent of the amount added (F4 vs F7, n.s.), unlike what happens in the case of sorbitol (F2 vs F3,  $p < 0.0001$ ). The effect of low level of glycerin results analogous to that produced by a high level of sorbitol (F4 vs F3, n.s.). The simultaneous addition of sorbitol and glycerin doesn't improve the T.S. both for low level (F4 vs F5 and F6, n.s.) and high level (F7 vs F8 and F9, n.s.) of glycerin.

### Elongation At Break



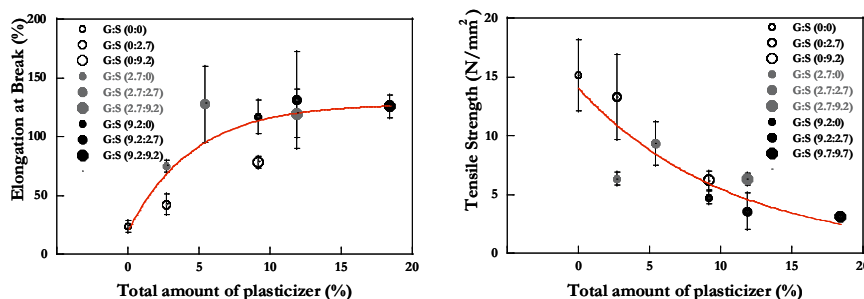
The addition of the plasticizers produces similar effects, but in a opposite way to those produced on the mechanical resistance. The Elongation at Break in fact increases in all cases, with the exception once more for the formulation F2. The increase of the elasticity of the film depends on the amount of plasticizer added in the case of glycerin (F4 vs F7,  $p < 0.05$ ), but not in that of sorbitol (F3 vs F4, n.s.). Small quantities of glycerin produce the same effect as high quantities of sorbitol (F3 vs F4, n.s.). The simultaneous addition of the two plasticizers produces an increase of the elasticity (F4 vs F5 and F6,  $p < 0.001$ ) that however results to be independent of the amount added (F5 vs F6, n.s.). For high levels of glycerin, the presence of sorbitol doesn't produce significant effects on the elasticity of the films (F7 vs F8 and F9, n.s.).

### In-vivo Adhesion

	Force of Adhesion (N)	Work of Adhesion (mJ)
F1	3.19±0.88	85.73±21.23
F2	1.66±0.68 <sup>(a)</sup>	42.35±23.52
F3	2.47±1.11	71.32±45.56
F4	2.41±0.82	55.71±29.79
F5	0.96±0.40 <sup>(c)</sup>	23.66±8.56 <sup>(b)</sup>
F6	1.10±0.35 <sup>(c)</sup>	23.95±7.94 <sup>(b)</sup>
F7	1.92±0.59	38.39±13.58
F8	1.92±0.70	54.73±30.58
F9	1.31±0.38 <sup>(b)</sup>	29.31±13.56 <sup>(a)</sup>

(a):  $p < 0.05$ ; (b):  $p < 0.01$ ; (c):  $p < 0.001$  with respect to control (F1)

### Relationship



## CONCLUSIONS

The addition of a plasticizer to the formulation of Patch-non-

## REFERENCES

1. P. Colombo, et al., World Patent Application WO 02/30402 A2,