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Impact of operator variability on the reproducibility of tape stripping results

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Poster #77

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Objective

To evaluate and determine the variability between two different operators (operator 1 and 2) performing two tape stripping clinical studies (lidocaine and diclofenac)

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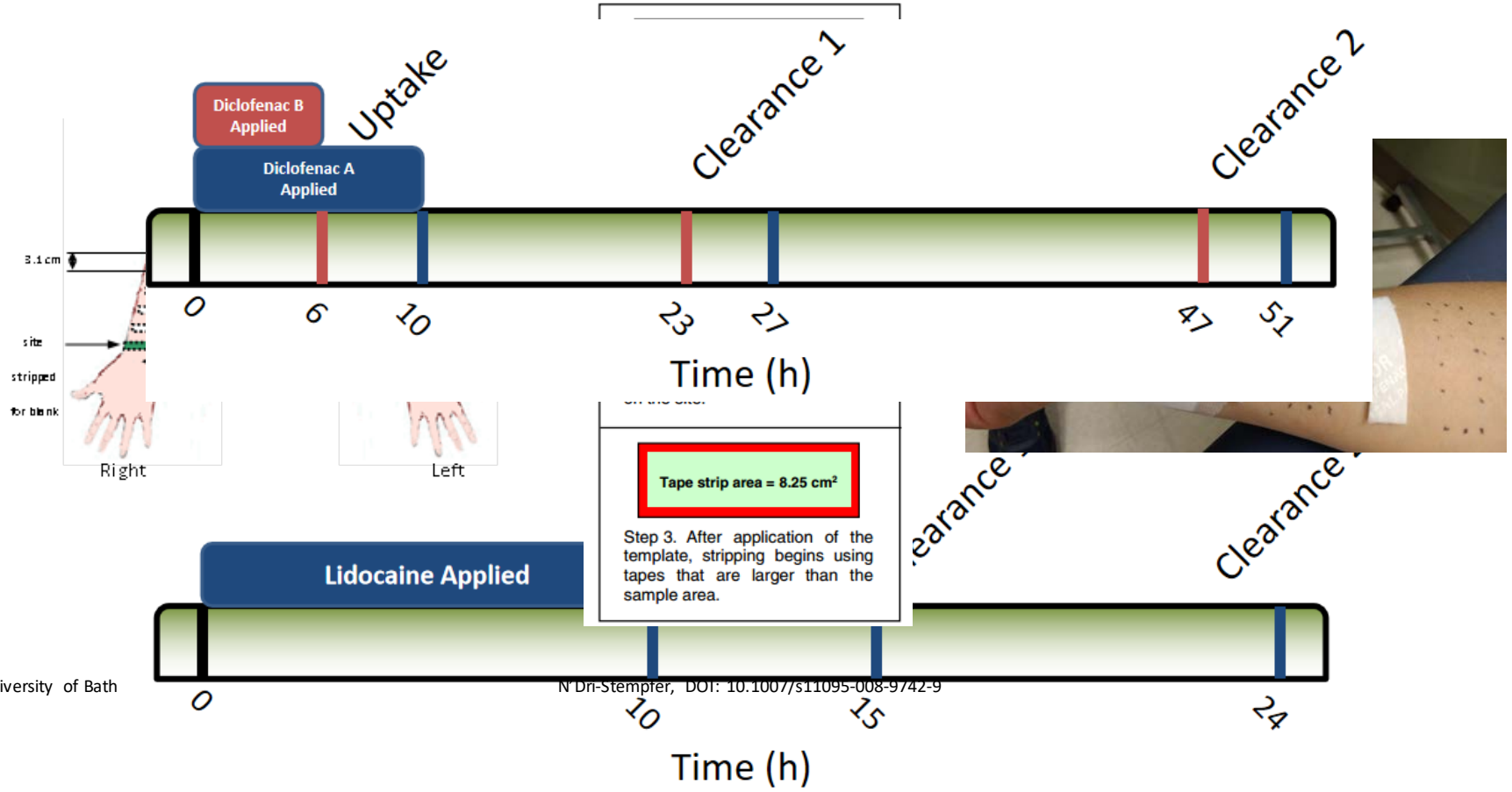
Clinical Study Design



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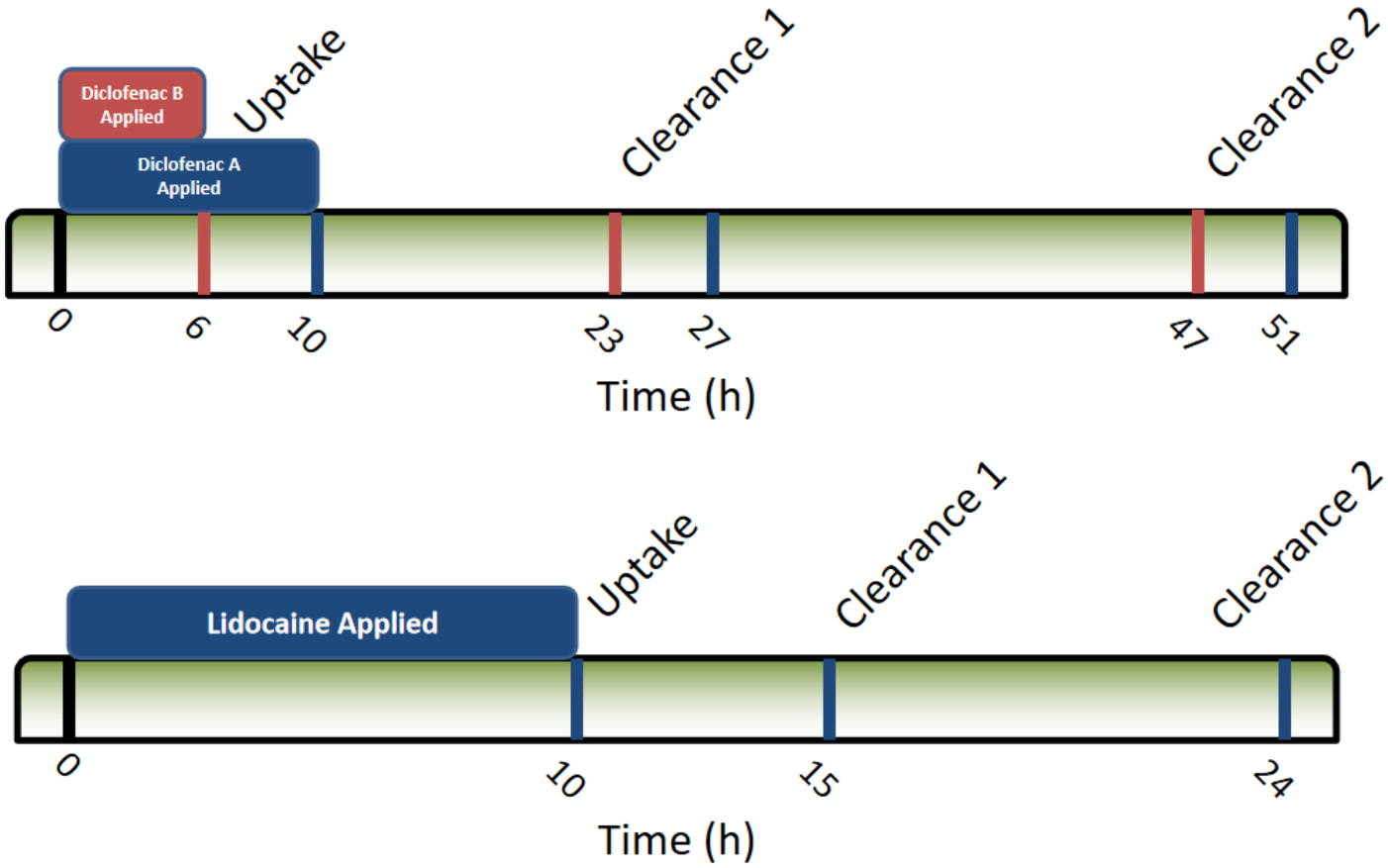
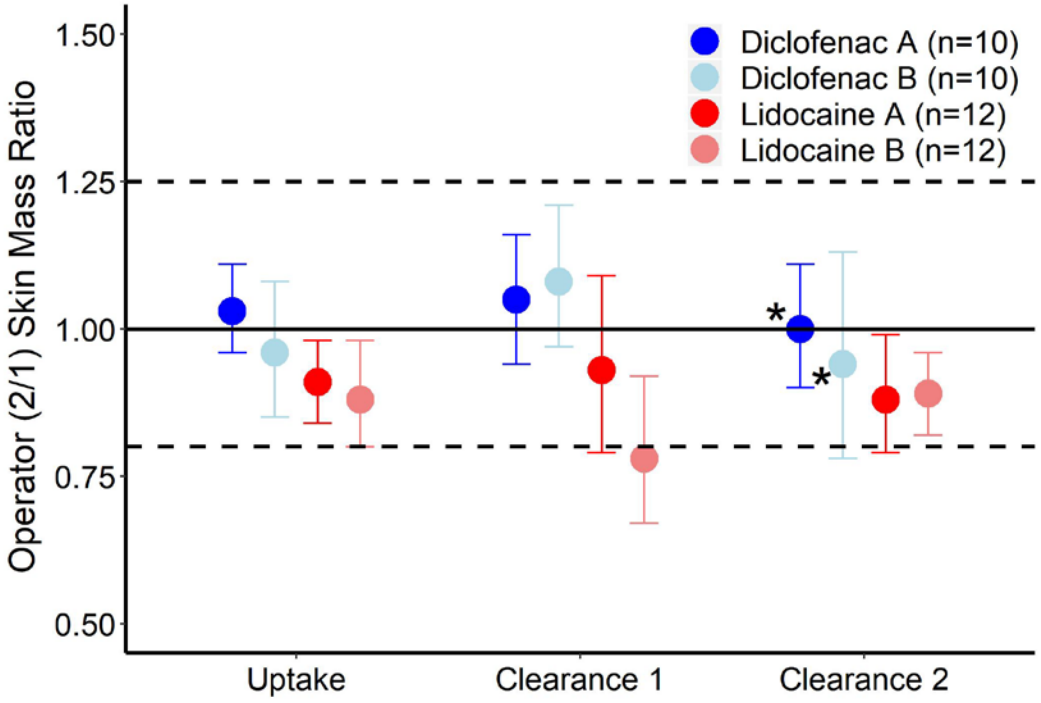
Clinical Study Design



Skin Mass Ratio



* n = 9

Figure 5. Operator ratio for skin mass from tape strips (geometric mean and 90% confidence interval) for lidocaine and diclofenac clinical study

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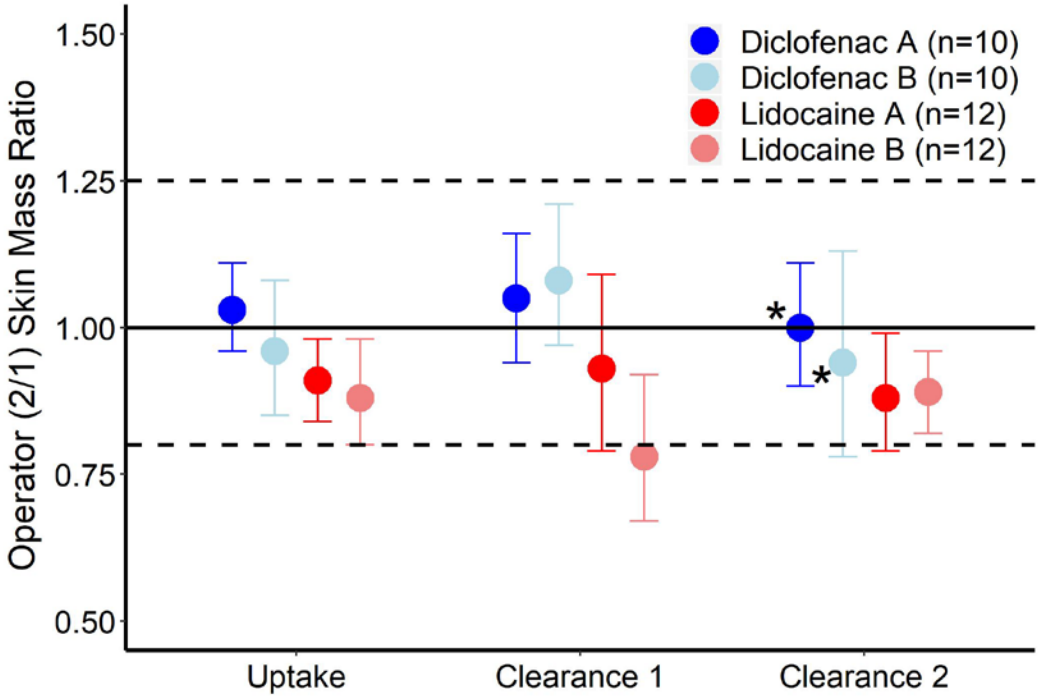
Number of Tape Strips needed

Study	Lidocaine (n=12)		Diclofenac (n=10)	
Operator	**1**	**2**	**1**	**2**
Number of Tapes used, Mean (SD)				
Product A (%)				
Uptake	22.5 (6.6)	19.1 (6.3)	20.2 (5.9)	17.9 (6.7)
Clearance 1	24.2 (5.1)	23.3 (6.2)	25.0 (5.8)	21.5 (4.7)
Clearance 2	24.2 (5.1)	23.1 (7.2)	25.6 (5.3)*	23.9 (7.4)*
Product B (%)				
Uptake	17.3 (5.2)	15.6 (5.4)	23.0 (6.7)	22.5 (7.2)
Clearance 1	26.7 (4.9)	23.3 (6.9)	21.0 (3.9)	18.5 (4.7)
Clearance 2	26.7 (5.4)	22.9 (6.9)	24.4 (5.3)*	22.8 (6.2)*

* n = 9

Operator 1 consistently used a greater number of tapes on average compared to operator 2 for all products and tape stripping time points

Skin Mass Ratio



* n = 9

- The skin mass removed does not correlate with the number of tapes used by each operator.
- The TEWL value helps correct for operator differences.

Drug Amount Ratio

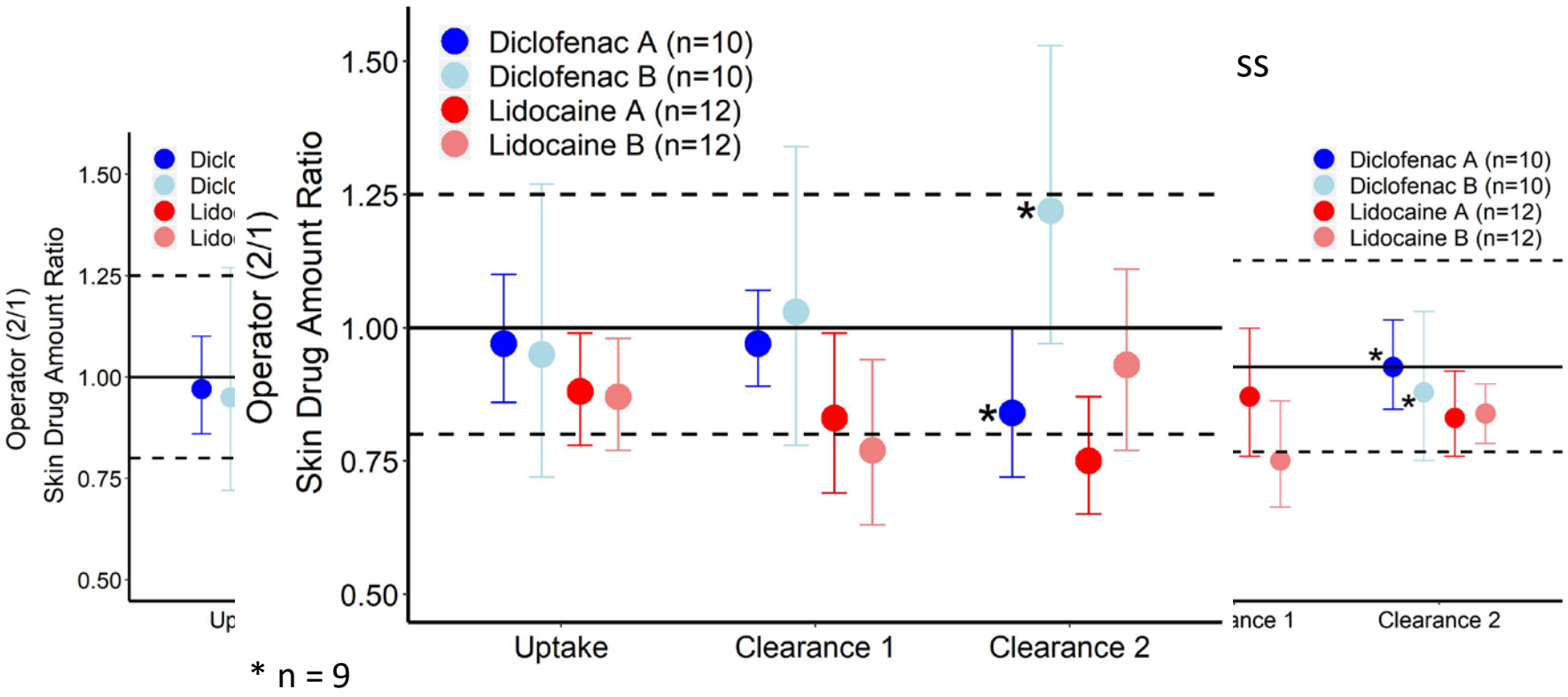


Figure 6. Operator ratio for skin drug amount from tape strips (geometric mean and 90% confidence interval) for lidocaine and diclofenac clinical study

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Conclusion

- The TEWL value can play a crucial role in reducing the impact of operator variability.
- From the results, it appears that the majority of the 90% confidence intervals for skin mass ratios are close to 1.0 indicating good reproducibility on the amount of skin removed following tape stripping.
- These results are only from 10 or 12 volunteers and it is likely that with additional volunteers it may be possible to move the mean ratio closer to 1.0 to get a tighter 90% confidence interval.
- These are promising results and show it is possible to perform tape stripping with multiple operators without increasing variability.

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Supplemental Material

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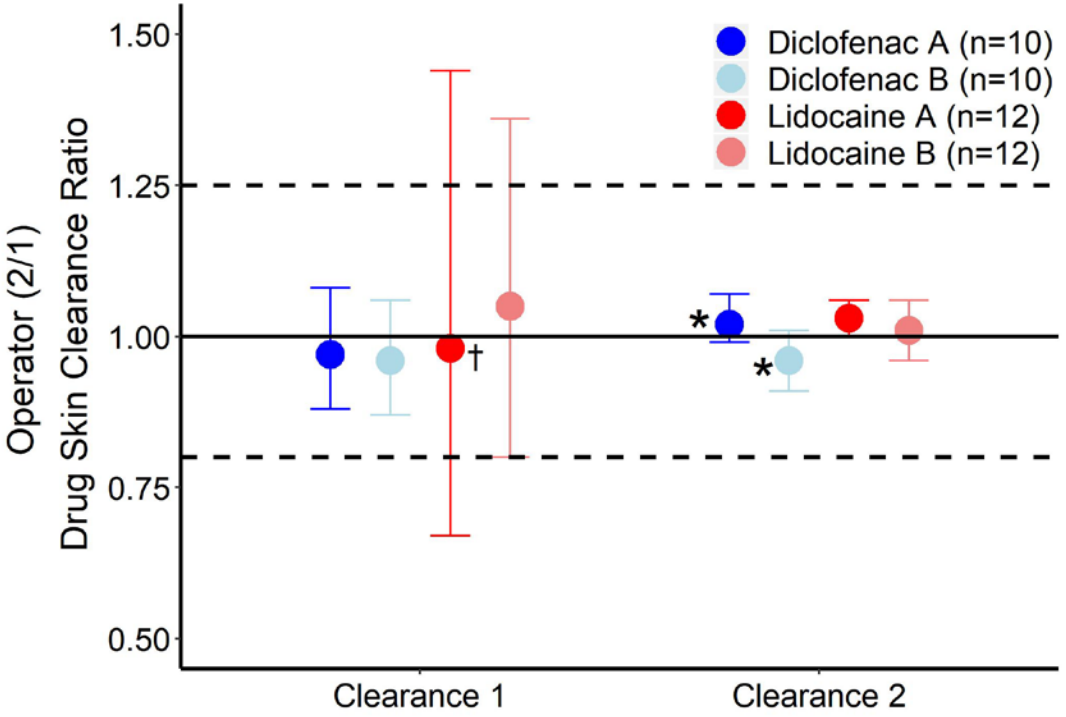
Drug Skin Clearance Ratio



* n = 9

† n = 10

Figure 7. Operator ratio for drug skin clearance from tape strips (geometric mean and 90% confidence interval) for lidocaine and diclofenac clinical study.