

## MOSAIC: Monitoring of Scratch via Accelerometry in Children with Atopic Dermatitis

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Atopic Dermatitis (AD) is the most common skin disease in children, with greater than 15% of all children being affected. The 3 top symptoms that AD patients report are itching, red inflamed skin and sleep disturbances. The terms itch and scratch are often used interchangeably, however it is the action of scratching that can lead to additional lesion formation. The interplay between itch, scratch, lesion/rash, and sleep disruptions creates a vicious cycle that can result in a reduction in the quality of life for both the child and caregivers. In children, passively and quantitatively measuring night-time sleep and scratching continuously in a home environment would provide great insight into the condition and is something that is currently not captured with current evaluation paradigms. We hypothesized that using a wrist-worn accelerometry device and night-time scratch and sleep detection algorithms would help fill that gap; however, we must fully understand the wearability, accuracy, sensitivity, and specificity of the endpoints measured.

**Methods:** Participants (N=41; aged 2-11 years) with AD (as determined by the investigator's static global assessment [ISGA]), that were "itchy" [as determined by patient reported outcomes (PRO)] spent 2 nights in a sleep clinic, wore wrist worn accelerometers (one on each wrist), and answered PRO surveys. In addition, thermal videography (forward-looking infrared camera; FLIR) was used as ground truth measures for quantifying scratching, and polysomnography (PSG) was used to obtain sleep metrics. Upon completion of the clinic portion, participants continued to wear the accelerometry devices in their home for 2 nights. The accelerometry data was processed via newly developed algorithms we call "SleepPy" and "ScratchPy," to evaluate night-time scratching and sleep quantity. These values were compared to the video scratch annotation and the PSG determined sleep measures.

**Results:** Forty-one children, including 18 males and 23 females with a mean age of  $5.7 \pm 2.9$  years of age, were enrolled in the study. The participants were classified with the ISGA as having Mild (n=19), Moderate (n=17) and Severe (n=4) AD, with a mean body surface area of  $10.57 \pm 7.15$  % of AD. The mean observer itch assessment at screening (scale of 0-10; ages 2-5; n=22) was  $6.2 \pm 2.05$  and the pruritus assessment at screening (scale of 1-5; ages 6-11; n=19) was  $2.6 \pm 0.90$ . The SleepPy algorithm evaluating sleep quantity results significantly correlated with the PSG determined sleep summaries, e.g. total sleep time (TST) ( $p < 0.001$ ). The ScratchPy algorithm was able to detect the motion of scratch, as compared to other movements with an accuracy of 70.2 %, Sensitivity of 62 % and a Specificity of 80 % with the area under the ROC curve of 0.78. When ScratchPy-derived scratch measures were compared to the scratch annotations obtained from FLIR videography (ground truth), the scratch duration and scratch events during the total sleep opportunity (TSO) were highly correlated with both the number of scratch events and scratch duration ( $p < 0.05$ ). Lastly, the participants felt the accelerometry devices were comfortable (97 %), were likely to wear continuously (84 %), and found the sensor locations (one on each wrist) also comfortable (92 %).

**Conclusions:** In conclusion, wrist-worn accelerometers were well-tolerated in these clinical studies and night-time scratch and sleep can be measured a quantitatively, accurately, and objectively in children with AD. Moreover, these endpoints measure meaningful aspects of AD in children with the additional advantage of being able to be deployed longitudinally at home.