Title: Optical Measurements of the Skin Surface to Infer Distinctions in Myofascial Tissue Stiffness

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Statistical Design and Power

Aim 1. We will evaluate the sensitivity of a suite of mechanical biomarkers. Using the imaging approach, we will create an optimal set of biomarkers which is the best classifier of myofascial pain state. In order to select the best suite of complementary metrics, which are most effective in predicting pain state, and which are simplest to accurate we will develop a classification strategy, we will perform multi-dimensional cluster analysis based on measured biomarkers. By using the biomarkers as predictors, data points representing different stimulus sets will be clustered into certain distinct groups based on the minimized average deviation (Jenks natural breaks classification method, 1-dimensional) and the minimized distance to the centroid (k-Means clustering, 2,3-dimensional). The match rate between clustered groups and ground-truth stimulus sets will determine the utility of unique biomarkers.

Aim 2. We will refine the requirements of the imaging deployment by evaluating tradeoffs in the array of ink speckles on the skin, in particular their density and heterogeneity requirements, to determine to what extent the density can be reduced yet still achieve similar imaging accuracy. We will perform ANOVA and t-tests with p values set at 0.5.

Sample size justification and power. Aim 1 will enroll 15 individuals. We will have a >80% power to identify biomarkers that have a moderate/strong rank correlation (e.g., Spearman's correlation ≥0.57) with pain. Aim 2 will enroll 6 individuals. These participants will be evaluated in refining requirements for imaging deployment, data collection, and data analysis.