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Objective:
Within the field of pen needle development, most research on needle design revolves around mechanical tensile testing and patient statements. Only little has been published on the actual biological skin response to needle insertions. The objective of this study was to develop a computational method to quantify tissue trauma based on skin bleeding and immune response.

Method:
Two common sized pen needles of 28G (0.36mm) and 32G (0.23mm) were inserted into skin of sedated LYD pigs prior to termination. Four pigs were included and a total of 32 randomized needle insertions were conducted. The affected tissue was removed and fixated in formalin following tissue preparation for histology. Standard immunohistochemical staining procedure was applied with CD-45 and anti-hemoglobin primary antibodies to stain immune cells and red blood cells, respectively. The stained tissue slides were subsequently digitized using 200X magnification. Based on thresholding, morphological masks and blob detection, segmentation of the histology was performed to locate tissue bleeding and immune response. Image-to-image registration was used on images originating from the same tissue, and a quantitative measure of tissue trauma was obtained for each needle insertion.

Result:
Bleeding and immune response were seen for all tested needles. Positive correlation was seen between the needle diameter and the size of the bleeding. The quantitative measure reveal a trend that tissue trauma decreases with decreasing needle diameter.

Conclusion:
A computational and quantitative method has been developed to assess tissue trauma following insulin pen needle insertions. Application of the method is tested by conduction of a needle diameter study. The obtained quantitative measures of tissue trauma correlate positively to needle diameter.