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A novel technique for the visualization of tablet punch surfaces: Characterization of surface modification, wear and sticking

Claudia Al-Karawi[a], Thomas Kaiser[b], Claudia S. Leopold[a,*]

[a] Division of Pharmaceutical Technology, University of Hamburg, Bundesstr. 45, 20146 Hamburg, Germany
[b] Center of Natural History (CeNak), University of Hamburg, Martin-Luther-King-Platz 3, 20146 Hamburg, Germany

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ABSTRACT

The surface quality of tablets is strongly related to the surface quality of the tablet punch. Therefore, regular control of the punch surfaces is needed to determine the surface properties, the wear status and sticking tendency of the punches. The aim of the present study was to develop and evaluate a new technique to visualize and evaluate tablet punch surfaces using high-resolution impression molding combined with 3D surface analysis. Standardized 3D surface texture parameters were analyzed by principal component analysis (PCA) to characterized differently surface-modified punches, punches with different wear status and the sticking pattern on the punch surfaces. It could be shown that the presented technique was precise enough to differentiate between differently coated and texturized punches, to evaluate the abrasive wear status of the investigated punches, and to visualize and assess punch tip sticking behavior. In conclusion, this novel technique may serve as a valuable tool for systematic punch surface characterization, wear status check-up and optimization of the punch surface quality e.g. for improvement of the anti-sticking behavior.

1. Introduction

The surface properties of the tablet tooling may significantly affect the quality of the produced tablets (Borzunov et al., 1967). An insufficient surface quality of the dies may cause unacceptable tablet ejection forces or may even lead to an increased risk of damaging the press or the tooling (Otz and Thoma, 2000). Moreover, the condition of the tablet punch surfaces has a direct influence on the appearance of the produced tablets (Gerhardt, 2009).

The quality of tablet punch surfaces decreases over time resulting from abrasive and corrosive wear (Alimov, 1975; Hyvärinen et al., 2000b). Swartz et al. observed that even newly obtained punches may show numerous imperfections regarding the homogeneity of the punch surfaces and an improper surface finish. They therefore suggested the initiation of a 100 % inspection program for new punches (Swartz et al., 1962). Tablet punch inspection may be conducted with a mechanical stylus, an optical stylus or a laser reflectometer (Hyvärinen, 2000; Hyvärinen et al., 2000a). However, it has been reported that these methods either have limitations regarding the inspection of concave punches or it is impossible to visualize the surface texture or to quantify it with the common surface parameters. Apart from these publications there appears to be a lack of systematic characterization of a punch surfaces and the changes caused by wear.

Another common problem resulting from poor punch surface properties is the occurrence of sticking (Wang et al., 2015). Sticking occurs if the tablet formulation adheres to the punch, which manifests itself in a layer of material on the punch surface and in roughened tablet surfaces (Toyoshima et al., 1988). Often, sticking problems become apparent at a late stage in the development of a tablet formulation, when the formulation is tableted for the first time (Wang et al., 2003).

Therefore, there has been an increased interest in identifying surface properties causing sticking problems to eventually develop optimized punch surfaces which are able to prevent this phenomenon. There was substantial effort to visualize sticking residue on punch surfaces for example using scanning electron microscopy (SEM) combined with energy dispersive X-ray spectroscopy (EDS) (McDermott et al., 2011; Neilly et al., 2009; Thomas, 2015). However, the sticking pattern on the punch surfaces after subsequent compaction runs has not been sufficiently investigated in these studies. In the master thesis by James V. Thomas, ibuprofen was used as a model drug for sticking

* Corresponding author.
E-mail address: claudia.leopold@uni-hamburg.de (C.S. Leopold).

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because it exhibits a strong temperature-dependent sticking tendency caused by its low melting point of 75–78 °C (Saniocki et al., 2013). During compaction, ibuprofen undergoes mainly plastic and elastic deformation (Bateman, 1988; Nokhodchi et al., 1995). The predominating deformation mechanism depends on the tableting speed (Marshall et al., 1993). Additionally, ibuprofen

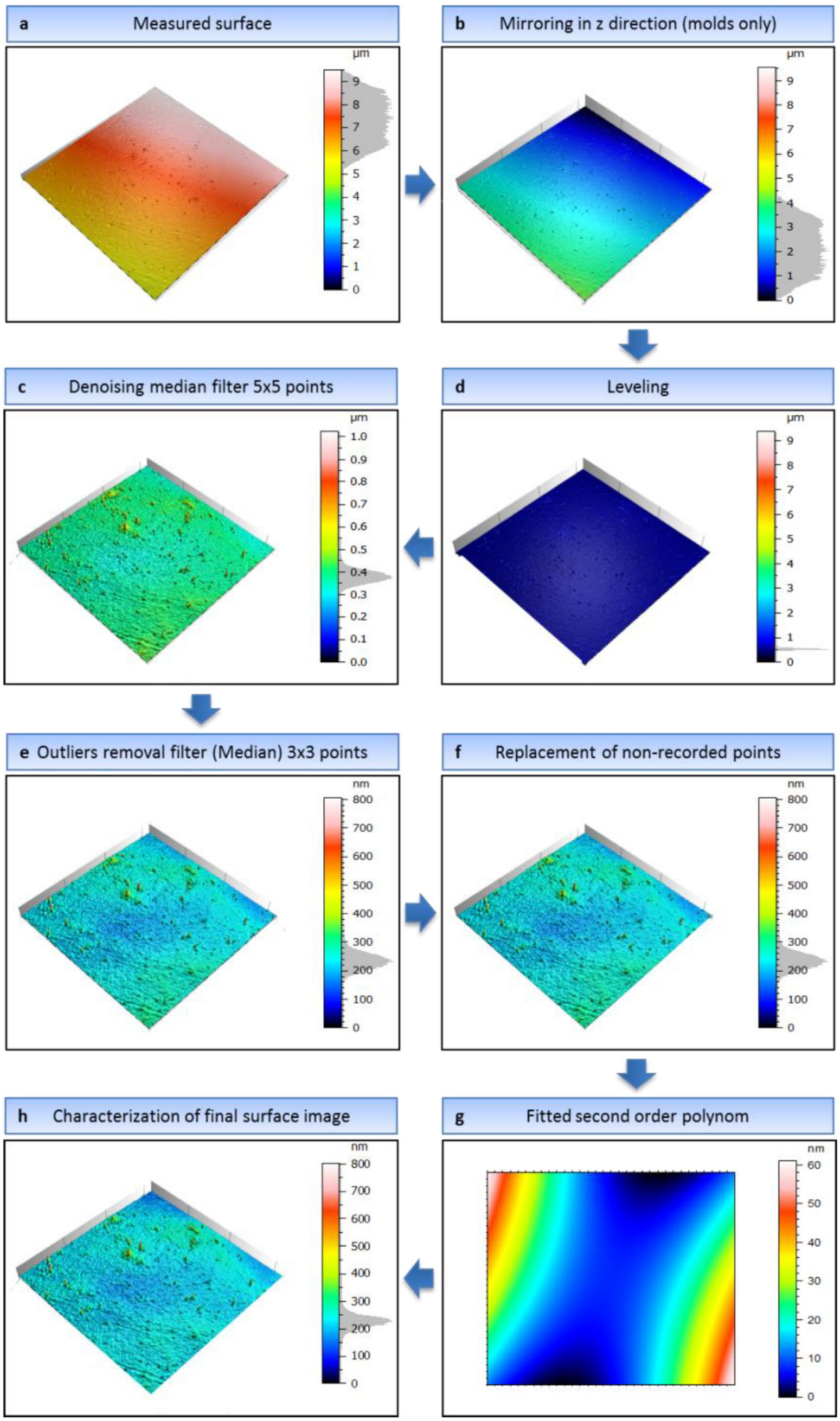

Fig. 1. Surface data processing. The image sizes were 160 µm × 160 µm and the height frequency distribution is depicted in grey.