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Newly developed surface modification punches treated with alloying techniques reduce sticking during the manufacture of ibuprofen tablets

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ABSTRACT

Sticking is a serious problem during the manufacturing process of tablets. In order to prevent this, we used alloying techniques to prepare metal hardening (MH) and electron beam processing infinite product (EIP) punches with rougher asperity of surfaces than a hard chrome plated (HCr) punch. This study evaluated the anti-sticking properties of the MH and EIP punches compared to the HCr punch, using quantitative scraper force measurements and visual observation, for the manufacture of ibuprofen (Ibu) tablets. The anti-sticking property mechanism of the MH and EIP punches was also confirmed. The amount of Ibu adhering to the punch surface was 66% lower for the MH and EIP punches than for the HCr punch, suggesting a superior anti-sticking property of the MH and EIP punches. The scraper force of the HCr punch was 2.60–4.28 N, while that for the MH and EIP punches was 0.54–1.64 N and 0.42–1.33 N, respectively. The result of X-ray photoelectron spectroscopy suggested that the anti-sticking property of the EIP punch was attributed by the rough asperity as well as existence of low friction substance carbon fluoride on the punch surface. In conclusion, this study provides new evidence for the mechanisms behind the superior anti-sticking property of the MH and EIP punches.

1. Introduction

Sticking is one of the most serious problems to occur during the tablet manufacturing process because it induces roughness or cracks on the tablet surface, resulting in deterioration in tablet productivity and appearance. Sticking can be caused by an excess of water in the granules or powder (Danjo et al., 1997), a lack of lubricant (Roberts et al., 2004a), or punch surface conditions (Roberts et al., 2004b). In order to prevent sticking, several approaches have been attempted including increasing the mixing time or the amount of lubricant in the formulation (Mitrevej and Augsbuger, 1982; Waimer et al., 1999), making changes to the tableting compression (Roberts et al., 2004b; Waimer et al., 1999), cleaning and polishing the punch surface (Waimer et al., 1999), and adding a hard chrome plating (HCr) or other coating to the punch surface (Roberts et al., 2003; Schumann and Searle, 1992; Watanabe et al., 1998). After the countermeasures are treated, tableting with no sticking problems can be performed temporarily; however, sticking will occur again. Therefore, these countermeasures do not solve the sticking problem fundamentally. In addition, the coating method may be insufficient or leave a risk of peeling during the compression process. Hence, an alternative method to prevent sticking in the tableting process is required.

Previously, we designed two types of punches, the metal hardening (MH) punch and the electron beam processing infinite product (EIP) punch, which both have their surfaces modified by alloying techniques. Fig. 1 shows a schematic diagram of the surface treatment and laser microscopy images of the punch surfaces. Generally, the surface of an HCr punch is flat and smooth, while that of the MH punch made from a discharge of tungsten carbide (alloying process), is rough, with an asperity range of 0.5–5.0 μm (Fig. 1a and b). This roughness can be controlled at the time of the discharge alloying process by varying the pulsed electrical current (Uemura et al., 2007). The EIP punch is made by the molten alloying of a metal with a low friction property such as calcium fluoride (Fig. 1c). Thus, various types of EIP punches can be prepared based on the characteristics of the metal itself and/or combinations without an electrode. Although the surface is still irregular and rough, it is slightly smoother than that of the MH punch (Fig. 1d).

Previously, Uemura et al. (2007) reported that tablet sticking on a rotary tablet machine was prevented for the MH punch

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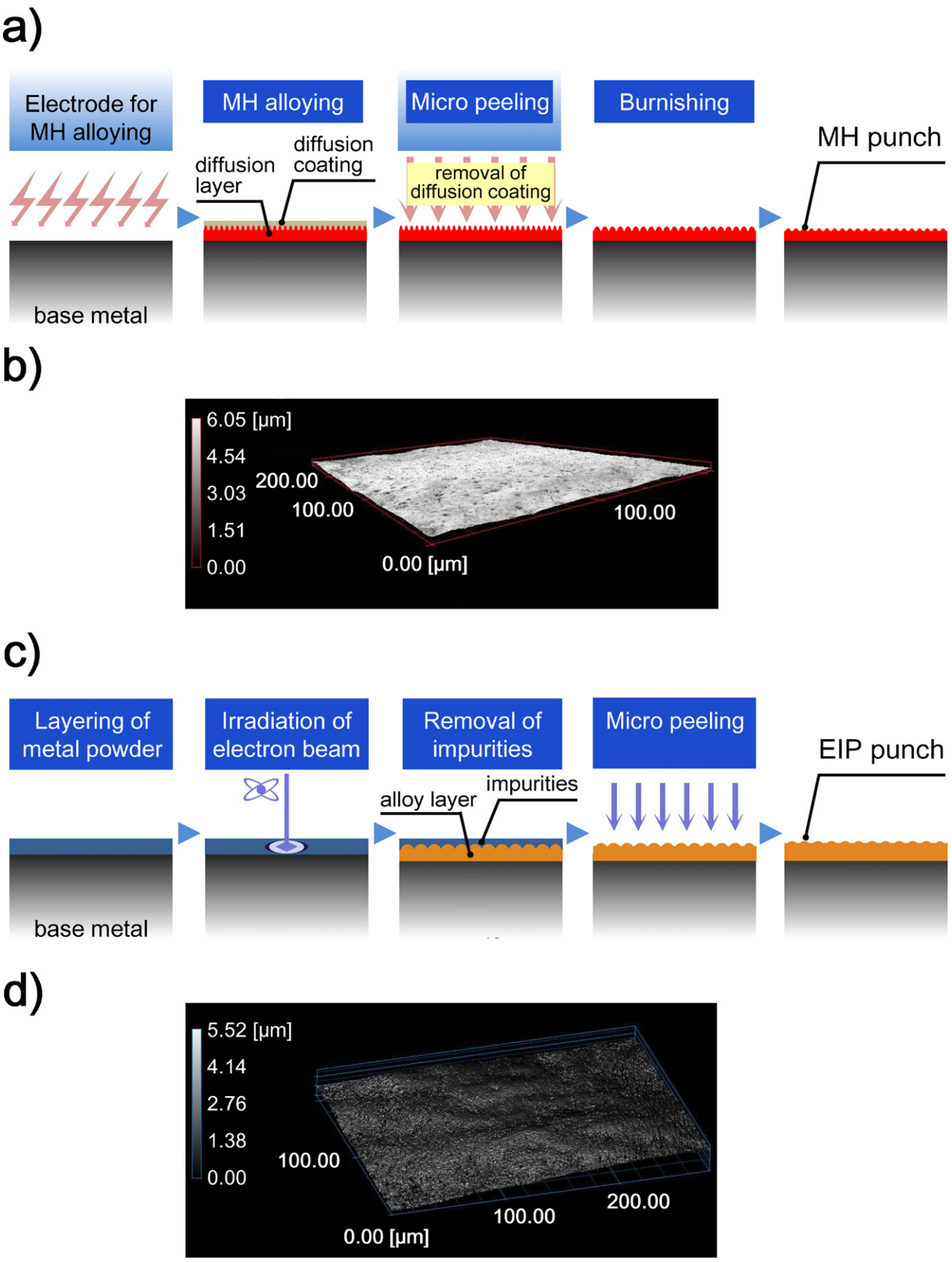

Fig. 1. Schematic diagrams and photographs of punch surface treatments. (a) Surface treatment schematic of MH punch. (b) MH punch photograph. (c) Surface treatment schematic of EIP punch. (d) EIP punch photograph.