

Influence of Coating Parameters on Instant Release Coated Colored Tablets

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Objectives

Color coating systems have been developed to ensure a convenient and short film coating process thus facilitating cost savings. Coating systems are composed of the film forming polymer, pigments and further additives. For preparation of the coating suspension only water addition is necessary. Chemical and physical properties of the polymer influence the coating performance in the manufacturing process to a major degree. For the coating systems studied, the polymer used is Kollicoat® IR, a PEG-PVA grafted copolymer [1]. Compared to coating systems based on polyvinyl alcohol or hypromellose, the low viscosity of Kollicoat® IR solutions and polymer flexibility enables to reduce the process time in production scale by 30 – 40% [2, 3].

The goal of this study was to investigate the impact of coater type and process parameters on tablets with respect to surface and color using Kollicoat® IR coating systems. Kollicoat® IR White II, Kollicoat® IR Red and Kollicoat® IR Brilliant Blue representing titanium dioxide, iron oxide and aluminum lake based coating systems were used to determine the effect of solids content and suspension viscosity on the process time and appearance of coated tablets.

Methodology

Materials

Instant release coating systems Kollicoat® IR White II, Kollicoat® IR Red and Kollicoat® IR Brilliant Blue (BASF SE, Germany) containing titanium dioxide, iron oxide red and Brilliant Blue aluminum lake respectively were used in this study. Core formulation of the tablets was 99.5 % Ludipress® LCE (BASF SE, Germany) and 0.5 % magnesium stearate (Baerlocher GmbH, Germany).

Film Coating

The coating trials were carried out in an innovative fluid bed coater with a central rotating spraying nozzle (Ventilus IEV1, Innojet Herbert Huettlin, Germany) and in a side-vented pan coater (Manesty XL Lab 01, OYSTAR Manesty, England). The film coating suspensions were prepared by re-dispersion of the coating system in water.

Weight gain of tablets was set to 3.6 % weight gain (5.9 mg/cm²). The impact of the solids content of the film coating suspension on the tablet appearance was investigated using the process parameters displayed in table 1.

Parameter settings of the drum coater for different solids content of the coating suspension (Batch size 5 kg).

Solid content					
spraying suspension	[m/m]	15%	20%	25%	30%
Inlet air temperature	[°C]	55.0	55.0	55.0	55.0
Spraying rate	[g/min]	21.7 ± 1.2	28.3 ± 0.6	27.7 ± 1.5	25.7 ± 1.2
Spraying pressure	[bar]	2.4	2.8	3.2	3.2
Flat jet air pressure	[bar]	2.4	2.8	3.2	3.2
Temperature tablets	[°C]	38.7 ± 0.6	35.0 ± 0.0	37.3 ± 0.6	38.0 ± 1.0
Process time	[min]	56.7 ± 2.5	32.7 ± 0.6	27.0 ± 1.0	24.3 ± 1.2

Table 1

Analytical methods

The effect of coater type and coating suspension solids content on the tablet color uniformity was assessed by colorimetric evaluation (Datacolor 400, Datacolor, USA). Gloss values were determined using a Novocurve 400 gloss-meter (Gloss-Meters, USA). Surface roughness was evaluated by laser profilometry. The experimental setup for colorimetric evaluation was: aperture USAV, light source d65 and observer angle 10°. The colorimetric values were recorded as L*a*b* values of the CIELAB color space (see figure 1) and color deviation was calculated by determining the Delta E value as displayed in equation (1).

$$\Delta E = \sqrt{(L^*_1 - L^*_2)^2 + (a^*_1 - a^*_2)^2 + (b^*_1 - b^*_2)^2} \quad (1)$$

Schematic drawing of the CIE L*a*b* color space.

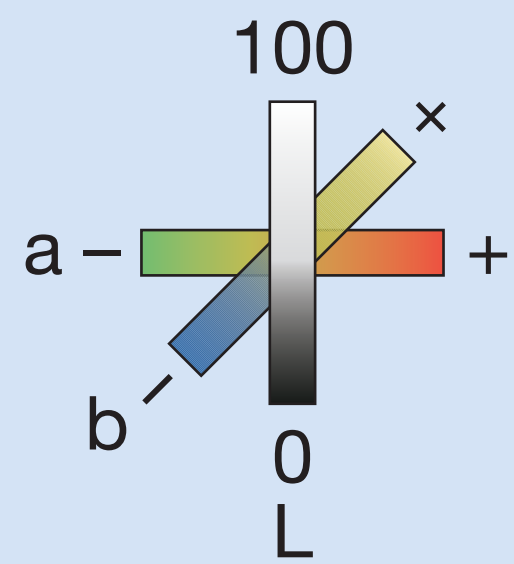


Figure 1

Results

Influence of coater type on tablet color

In comparison to the perforated drum coater, the fluid bed coater led to a rougher but glossier tablet surface. Color deviation resulting from the coater type was observed to a minor extent (see table 2).

Influence of coater type on color deviation (concentration of cating suspension: 15 %; optimal coating parameter settings were used)

	Fluid bed coating process, process time 18 min			Drum coating process, process time 1h			
Batch size	150 g			5 kg			
Colorimetirc data	L*	a*	b*	L*	a*	b*	Delta E
Kollicoat®IRWhiteII	97.48	-0.19	3.58	97.18	-0.18	3.28	0.42
Kollicoat®IRRed	45.66	31.31	21.79	45.96	31.29	22.56	0.83
Kollicoat®IRBrilliantBlue	42.24	-17.06	-30.97	42.09	-16.58	-32.10	1.24

Table 2

Influence of solid content on tablet appearance

A more detailed study of the drum coater process parameters enabled the determination of optimal process parameters for coating suspensions prepared with solids content between 15 % to 30 % (see table 1). By increasing the solid content from 15 % to 30 %, the process time was significantly reduced from 60 min to 30 min. The impact of coating suspension solids content on tablet appearance is shown exemplarily for Kollicoat® IR Red coated tablets in figure 2. All tablets had a smooth surface with slightly reduced gloss for higher concentrated coating suspension of 25 % and 30 %. Gloss value analysis revealed a correlation with the concentration of the film-coating suspension applied:

higher solids content resulted in reduced gloss values as shown in figure 3. A comparison of the different coating systems revealed that the surface shine was highest for Kollicoat® IR White II coated tablets, followed by Kollicoat® IR Brilliant Blue and Kollicoat® IR Red. The surface roughness of Kollicoat® IR Red coated tablets increased from 2.4 up to 4.2 µm by raising the solids content of the spray suspension from 15 % to 30 %, whereas the gloss was reduced from 3.9 to 2.1 (see figure 4).

To achieve a complete covering film coating a certain amount of coating suspension has to be sprayed onto the tablets. However, final color homogeneity may be affected by spray-pattern variations caused by the impact of solids content on the viscosity of the coating suspension. The effect of coating level on color development is displayed in figure 5. The largest decrease in color deviation was observed between 1.1 % and 1.6 %, which leveled off to a value of 0.5 to 0.8 as compared to the final coating weight gain of 3.6 %. Comparison of the different coating systems reveals a homogeneous color is reached fastest in the following order: Kollicoat® IR White II >> Kollicoat® IR Red > Kollicoat® IR Brilliant Blue. This can be attributed to the higher transparency of Brilliant Blue aluminum lake as compared to red iron oxide and titanium dioxide.

The solids content of the coating suspension had no impact on final tablet color. For Kollicoat® IR Red, at a coating level of 1.1 % higher color deviation correlated with increasing concentration of coating suspension.

Influence of the solids content [%] of Kollicoat® IR Red coating suspensions on tablet appearance (drum coater).



Figure 2

Influence of the solids content of the coating suspension on tablet gloss of different Kollicoat® IR Coating Systems (drum coater).

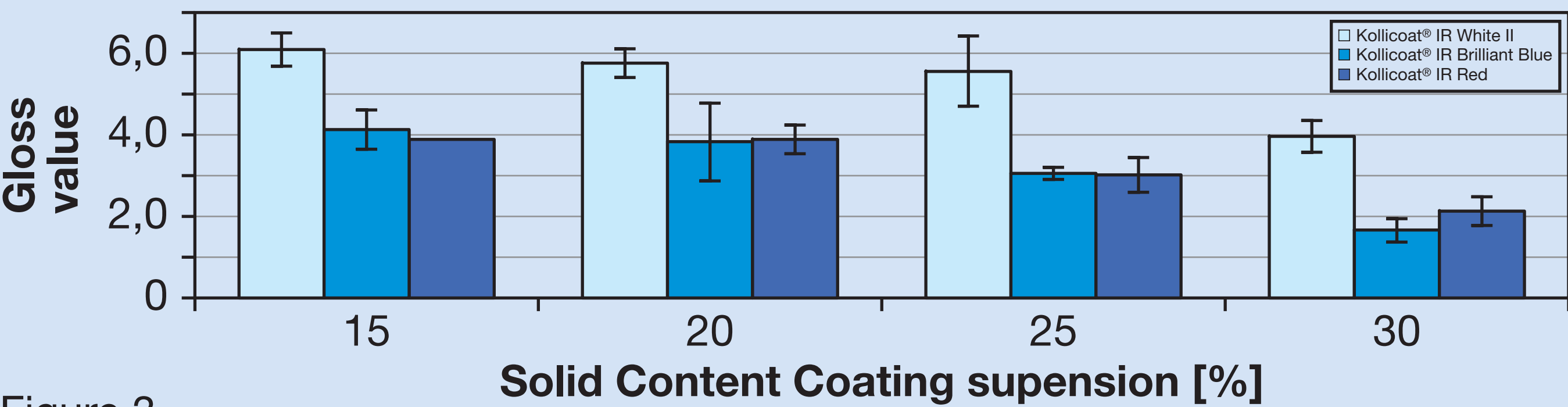


Figure 3

Influence of the solids content of the coating suspension on surface roughness of Kollicoat® IR Red coated tablets (drum coater).

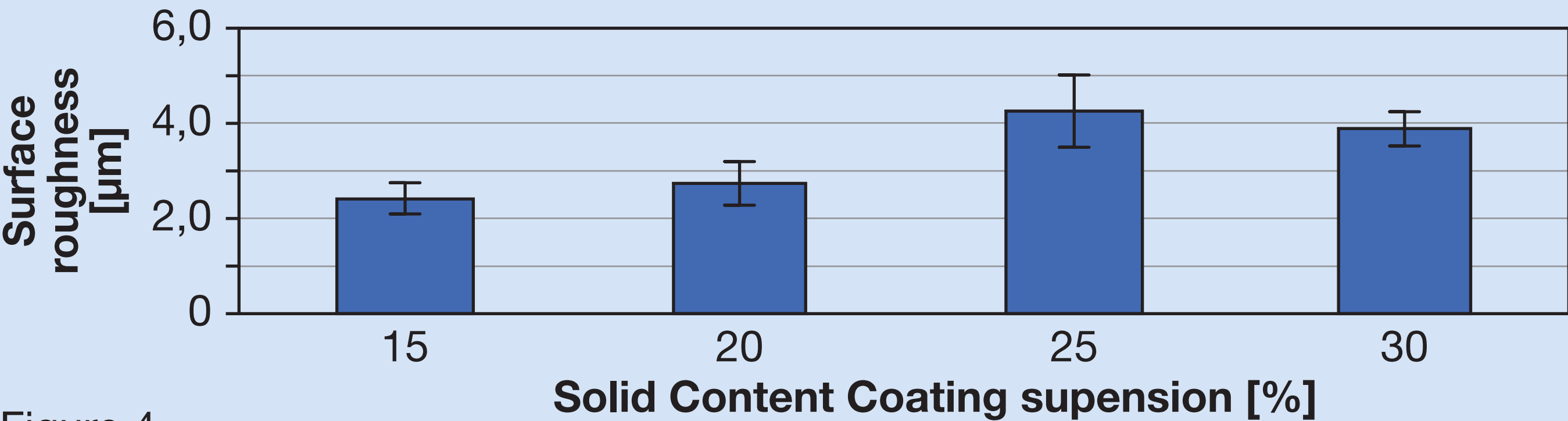


Figure 4

Color deviation of tablets as a function of the amount of applied Kollicoat® IR coating system compared to tablets with a 3.6 % film coating.

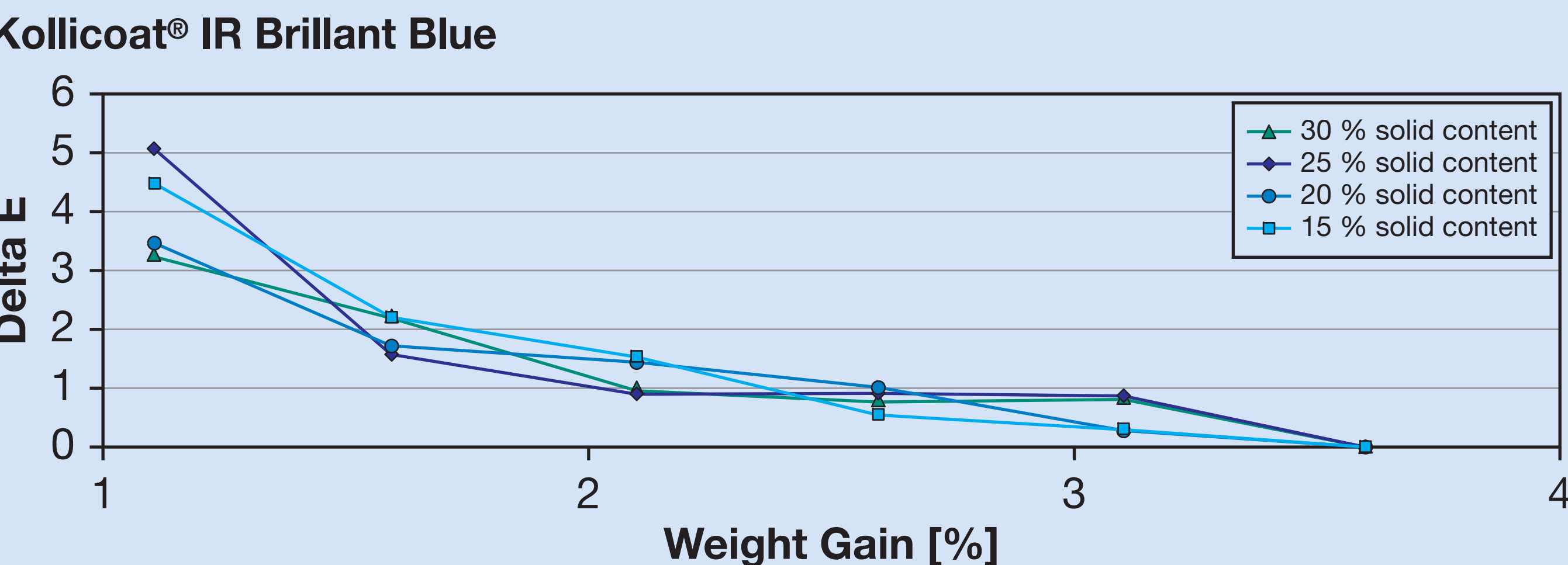
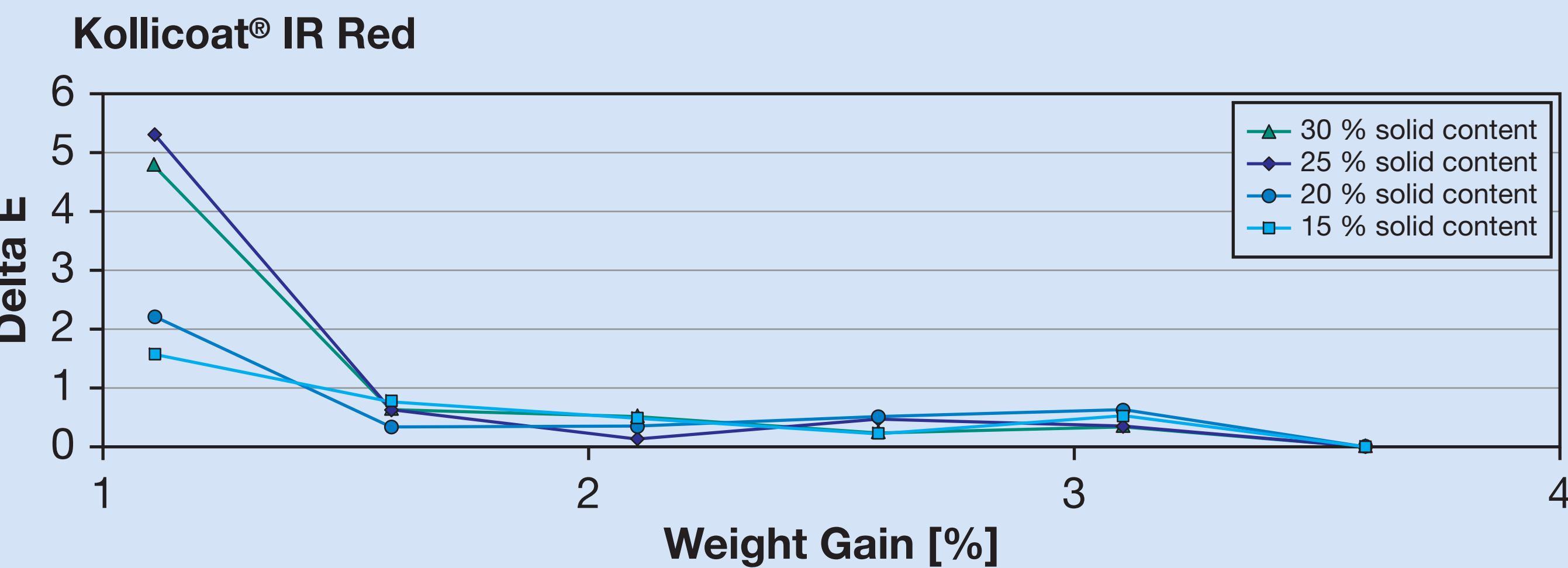
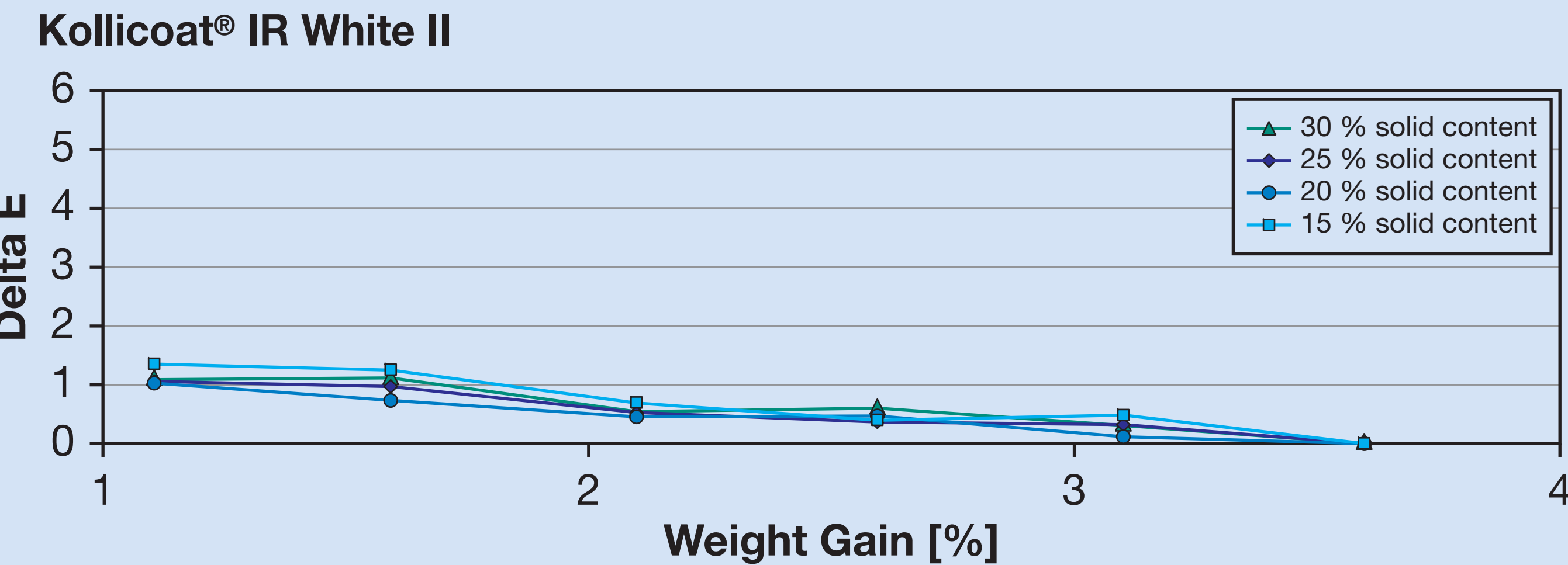


Figure 5

Conclusions

The type of coating machine and the solids content of the coating suspension affected the resulting color to a minor extent.

By increasing the solids content of the coating suspension

- Process time can be reduced from 60 min to 30 min.
- Gloss is slightly reduced and the surface roughness increased.
- Tablet color is not affected at a coating level of 3.6 %.

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