

Study of post-compressional parameters in the friction properties of maltodextrins

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Received 13 January 1997; received in revised form 1 May 1997; accepted 11 May 1997

Abstract

Maltrin® M510 and M150 have been evaluated with post-compressional parameters. M150 was selected due to its sticking and friction characteristics, and another variety provided by the same supplier, M510, was also studied. Three lubricants (magnesium stearate, PRUV® and PRECIROL®) were added at different concentrations and mixing times. Tablets were compressed at three applied pressures. According to maximum ejection values, the lubricants under study behaved differently for each maltodextrin, showing that excipient characteristics determined lubricant efficiency during the ejection phase. In the residual force, the results were similar for both excipients, so it seems that the lubricant properties are critical in this phase. A novel quantitative approach to ejection curves is proposed, the work ratio, defined as the ratio between corrected ejection work with the residual force and the ejection work. Magnesium stearate mixtures showed ejection curves with low residual forces similar to type I, while PRUV® and PRECIROL® showed curves more similar to type II. The increment of concentration and mixing time lead to characteristics of type I, with low residual force and a steady ejection force during the upward movement of the tablet. For residual force and work ratio, the sequence of lubricant efficiency was similar for both excipients, with magnesium stearate the best, followed by PRUV® and PRECIROL®. © 1997 Elsevier Science B.V.

Keywords: Maltodextrins; Lubrication; Magnesium stearate; Ejection; Post-compressional parameters

1. Introduction

Maltrin® is the registered trademark for a family of maltodextrins supplied from the Grain Pro-

cessing Corporation (GPC). They are composed of water-soluble glucose polymers obtained from the reaction of starch with acid and/or enzymes in the presence of water (Li and Peck, 1990a).

Li and Peck (1990a,b) stated that the method of granulation influenced the physical properties of maltodextrins and that the moisture content of

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the material exerted an effect on its compaction behaviour. Papadimitriou et al. (1992) evaluated Maltrin[®] as excipients for direct compression as well as their influence on the dissolution rate. Mollan and Çelik (1993, 1994, 1996) started with the characterization of five types of maltodextrins manufactured by different methods, and later evaluated their mixtures with different ratios of acetaminophen. Recently Mollan and Çelik (1995) studied the effects of humidity and storage time on the behaviour of maltodextrins for direct compression.

The grade M150 presents manufacturing problems due to high ejection and residual forces as well as its stickiness in comparison with other maltodextrins such as M510, QD M500 and QD M550 (Muñoz-Ruiz et al., 1993). Therefore, the use of lubricants is necessary in the formulation to reduce friction between the tablet and die wall and to prevent adhesion of the tablet material to the punches or die wall (Shah et al., 1986). However, there has been no research work focused on the ejection behaviour of these new excipients.

Although the physical and chemical characteristics of the materials are important in their behaviour, the instrumented tablet machines are considered the best tool to evaluate friction during tableting (Delacourte et al., 1987). However, there are several parameters that can evaluate this property either by comparison of the forces on the upper and lower punches or by measuring the forces on the lower punch immediately before ejection or during ejection as well as by graphical means (Hölzer and Sjögren, 1977).

The aim of this study was to evaluate the post-compressional behaviour of the M510 and M150 grades after the addition of lubricants under different conditions as well as to discuss the parameters available to measure this tableting phase.

2. Material and methods

In this study, two excipients for direct compression were used: Maltrin[®] M150, batch T0466 and Maltrin[®] M510, batch G0705 (Grain Processing Corporation, Muscatine, Iowa, USA).

Three lubricants were also used: magnesium stearate, batch 920844 (Lab. Dr Esteve, Barcelona, Spain); PRUV[®], sodium stearyl fumarate, batch 139-01 (Juliá-Parrera, Barcelona, Spain) and PRECIROL[®], glyceryl palmito-stearic ester, batch 18832 (Gattefossé, Saint-Priest Cedex, France). Magnesium stearate was sieved using a 450 micron screen to minimize agglomeration.

The excipients were mixed for two mixing times (2 and 10 min) with three different concentrations (0.5, 1 and 2%) of magnesium stearate, PRUV[®] and PRECIROL[®], in an asymmetric double-cone mixer (Retsch, Haan, Germany) at 50 rev/min.

The friction parameters of the mixtures were investigated using an instrumented single-punch tablet machine (Bonals, model AMT 300, Barcelona, Spain) fitted with strain gauges (HBM YL6) attached to dynamic amplifiers (NEC San-ei 6M81, Tokyo, Japan), inductive displacement transducers (HBM TS50, Darmstadt, Germany), digital amplifiers (HBM AB 12 with channels M55, Darmstadt, Germany), and via an analogue-to-digital converter (Metrabyte DAS-16G1, Metrabyte, MA, USA). Displacements were corrected with punch deformation (Muñoz-Ruiz et al., 1995). Our own software (Muñoz-Ruiz et al., 1995) was used for data acquisition and reduction. An exact amount of powder to produce tablets with a thickness of 4 mm at zero porosity was manually filled into the die (12 mm). Cleaning was accomplished by manually treating punches and die wall with a cotton swab. Flat compacts were prepared at three different applied pressures (50, 100 and 200 MPa). All the results are the average of three tablets.

The nomenclature used to identify the conditions is: A (0.5%, 2 min); B (0.5%, 10 min); C (1%, 2 min); D (1%, 10 min); E (2%, 2 min) and F (2%, 10 min). The tablet batches elaborated at different applied pressures are distinguished as follows: 1 (200 MPa); 2 (100 MPa) and 3 (50 MPa). Experiments were randomized grouping the whole design in one block.

Data were analyzed using a Student's *t*-test and an analysis of variance (ANOVA) according to the design of the experimental conditions chosen.

Table 1

Results of maximum ejection force (MEF in N), residual force (RF in N) and work ratio (WR dimensionless) for mixtures of Maltrin[®] M150 and M510 with magnesium stearate (average of three tablets and S.D.)

Conditions	M150			M510		
	MEF (N)	RF (N)	WR	MEF (N)	RF (N)	WR
A1	161.3 (2.7)	74.4 (13.5)	0.424 (0.06)	182.1 (17.7)	80.8 (1.2)	0.511 (0.01)
A2	209.9 (5.3)	115.7 (6.6)	0.468 (0.02)	217.9 (2.2)	96.9 (2.6)	0.566 (0.01)
A3	186.5 (1.5)	79.2 (4.5)	0.569 (0.01)	194.7 (7.6)	102.6 (3.1)	0.497 (0.01)
B1	140.1 (3.2)	69.2 (1.9)	0.426 (0.02)	140.6 (3.2)	38.9 (3.2)	0.674 (0.01)
B2	218.8 (3.0)	111.6 (23.5)	0.524 (0.08)	177.3 (4.1)	85.4 (3.6)	0.554 (0.01)
B3	208.3 (11.1)	124.8 (1.9)	0.425 (0.01)	147.5 (0.8)	71.6 (0.2)	0.529 (0.01)
C1	195.1 (11.4)	102.4 (14.1)	0.397 (0.03)	162.4 (12.2)	59.5 (6.6)	0.549 (0.04)
C2	221.4 (2.9)	112.3 (7.22)	0.537 (0.02)	200.9 (2.5)	99.5 (8.7)	0.500 (0.02)
C3	200.1 (3.6)	81.2 (4.7)	0.586 (0.01)	171.9 (7.7)	87.2 (5.5)	0.464 (0.02)
D1	202.9 (13.7)	79.2 (13.7)	0.530 (0.05)	129.4 (14.6)	33.2 (11.1)	0.709 (0.07)
D2	246.5 (9.57)	134.2 (6.5)	0.500 (0.02)	181.7 (3.5)	85.0 (4.4)	0.549 (0.02)
D3	203.3 (11.2)	104.5 (4.2)	0.498 (0.01)	159.6 (5.8)	77.2 (2.2)	0.524 (0.01)
E1	195.1 (9.6)	72.35 (2.1)	0.530 (0.01)	144.2 (4.7)	37.9 (3.9)	0.695 (0.02)
E2	187.6 (3.93)	70.99 (9.0)	0.641 (0.03)	198.4 (6.6)	78.5 (3.3)	0.605 (0.01)
E3	168.8 (5.3)	63.6 (3.6)	0.630 (0.01)	161.9 (7.5)	69.0 (5.4)	0.563 (0.03)
F1	186.5 (10.1)	75.9 (6.5)	0.525 (0.02)	159.1 (11.4)	53.2 (8.9)	0.649 (0.03)
F2	204.3 (5.4)	76.8 (3.2)	0.630 (0.01)	160.7 (1.8)	70.9 (1.5)	0.549 (0.01)
F3	171.9 (2.9)	63.9 (4.4)	0.650 (0.02)	98.8 (4.9)	26.3 (3.3)	0.685 (0.03)

3. Results and discussion

Tables 1–3 show the results of the post-compressional parameters for the mixtures of M150 and M510 with the three lubricants.

The grade M150 cannot be compressed without lubricants under these conditions of applied pres-

sure due to the high friction, as shown previously (Muñoz-Ruiz et al., 1993). After the addition of any of the three lubricants, M150 mixtures were tableted, but they show higher friction and adhesion than M510 mixtures. So the maximum ejection force was significantly higher for M150 ($t = 9.05$, $p < 0.05$) as was the residual force ($t = 7.43$, $p < 0.05$).

Table 2

Results of maximum ejection force (MEF in N), residual force (RF in N) and work ratio (WR dimensionless) for mixtures of Maltrin[®] M150 and M510 with PRUV[®] (average of three tablets and S.D.)

Conditions	M150			M510		
	MEF (N)	RF (N)	WR	MEF (N)	RF (N)	WR
A1	214.4 (16.8)	193.5 (15.9)	0.219 (0.02)	125.0 (4.8)	54.2 (4.5)	0.422 (0.02)
A2	295.7 (9.16)	262.7 (22.0)	0.226 (0.03)	169.6 (6.7)	73.4 (5.9)	0.551 (0.01)
A3	231.5 (25.5)	101.3 (22.1)	0.582 (0.05)	160.8 (7.8)	78.6 (2.5)	0.503 (0.01)
B1	224.0 (5.5)	153.4 (2.2)	0.289 (0.01)	98.6 (10.8)	57.3 (6.0)	0.337 (0.05)
B2	312.7 (30.5)	256.1 (5.9)	0.247 (0.01)	194.5 (5.6)	101.1 (4.2)	0.453 (0.01)
B3	303.2 (17.1)	267.5 (10.1)	0.182 (0.01)	161.0 (1.9)	80.6 (1.7)	0.49 (0.02)
C1	203.9 (14.3)	90.4 (5.0)	0.477 (0.04)	120.3 (14.1)	43.4 (6.9)	0.556 (0.05)
C2	224.2 (25.2)	140.8 (6.6)	0.427 (0.02)	156.6 (4.3)	78.6 (1.1)	0.507 (0.01)
C3	207.3 (14.6)	155.9 (7.7)	0.306 (0.01)	146.9 (0.5)	72.1 (1.4)	0.530 (0.01)
D1	201.4 (16.2)	105.7 (7.2)	0.438 (0.01)	131.0 (8.3)	53.6 (4.5)	0.508 (0.02)
D2	222.6 (12.9)	120.6 (3.45)	0.499 (0.01)	150.7 (3.8)	76.7 (0.8)	0.518 (0.01)
D3	167.7 (1.2)	71.3 (2.9)	0.559 (0.01)	131.6 (7.6)	63.5 (1.6)	0.569 (0.01)
E1	195.1 (8.2)	62.0 (4.1)	0.591 (0.02)	136.2 (10.1)	63.9 (1.6)	0.552 (0.01)
E2	205.5 (12.8)	95.7 (6.1)	0.539 (0.02)	166.7 (0.7)	73.7 (9.1)	0.599 (0.04)
E3	154.8 (16.4)	67.9 (4.4)	0.581 (0.01)	153.1 (9.4)	69.3 (6.1)	0.512 (0.03)
F1	161.2 (15.7)	61.0 (0.7)	0.536 (0.01)	151.7 (21.9)	64.7 (13.2)	0.542 (0.05)
F2	189.9 (2.9)	86.9 (6.6)	0.549 (0.02)	166.3 (5.8)	88.4 (7.5)	0.491 (0.02)
F3	148.2 (1.7)	69.4 (6.6)	0.536 (0.03)	160.5 (7.9)	79.3 (3.1)	0.500 (0.02)

The maximum ejection force, which is the maximum force exerted on the lower punch during the ejection of the tablet, is probably the most widely used measure of tablet friction (Sadjady et al., 1993), i.e. in the case of rotary tablet presses working with double-sided tablet compression profiles. In this case, it is only pos-

sible to evaluate friction during tableting from the ejection phase. Several authors (Juslin and Krogerus, 1971; Hölzer and Sjögren, 1979; Mitrevej and Augsburg, 1982) have used this parameter to evaluate lubricants as it corresponds more directly to actual tablet production.

Table 3

Results of maximum ejection force (MEF in N), residual force (RF in N) and work ratio (WR dimensionless) for mixtures of Maltrin[®] M150 and M510 with PRECIROL[®] (average of three tablets and S.D.)

Conditions	M150			M510		
	MEF (N)	RF (N)	WR	MEF (N)	RF (N)	WR
A1	232.2 (21.3)	193.9 (4.1)	0.190 (0.01)	142.9 (14.1)	112.0 (6.9)	0.209 (0.03)
A2	242.4 (22.0)	216.9 (4.9)	0.269 (0.01)	179.4 (14.9)	61.3 (0.5)	0.664 (0.01)
A3	305.8 (7.5)	267.6 (17.8)	0.147 (0.01)	162.9 (23.7)	62.9 (30.5)	0.585 (0.14)
B1	297.9 (8.6)	315.0 (10.7)	0.174 (0.01)	123.6 (10.3)	52.6 (8.9)	0.319 (0.02)
B2	323.4 (9.4)	288.9 (6.72)	0.136 (0.01)	185.3 (5.5)	110.0 (7.7)	0.453 (0.04)
B3	311.4 (4.8)	237.6 (66.7)	0.268 (0.15)	194.1 (14.7)	103.0 (1.1)	0.541 (0.01)
C1	152.7 (2.4)	70.5 (20.2)	0.361 (0.11)	174.9 (8.8)	61.2 (7.1)	0.409 (0.01)
C2	170.9 (10.7)	88.8 (2.3)	0.358 (0.11)	165.3 (7.1)	62.9 (3.3)	0.611 (0.01)
C3	104.2 (0.9)	91.4 (1.8)	0.133 (0.02)	150.8 (9.6)	94.1 (3.8)	0.342 (0.02)
D1	146.8 (11.4)	39.8 (31.6)	0.665 (0.32)	129.7 (6.6)	55.3 (8.8)	0.307 (0.06)
D2	155.4 (5.7)	93.2 (0.6)	0.416 (0.01)	140.2 (0.6)	51.2 (3.1)	0.611 (0.01)
D3	127.4 (7.6)	66.3 (6.7)	0.498 (0.03)	136.9 (9.1)	58.9 (3.5)	0.574 (0.02)
E1	130.0 (13.8)	36.3 (15.8)	0.670 (0.14)	124.6 (21.2)	54.9 (12.5)	0.451 (0.07)
E2	155.3 (6.5)	90.3 (2.6)	0.394 (0.04)	151.5 (4.3)	71.0 (2.2)	0.484 (0.01)
E3	127.2 (6.6)	37.7 (28.8)	0.670 (0.24)	143.1 (24.1)	66.9 (29.9)	0.556 (0.10)
F1	159.0 (4.6)	39.4 (4.6)	0.681 (0.03)	183.4 (17.6)	89.5 (11.8)	0.536 (0.02)
F2	151.9 (10.3)	36.6 (6.4)	0.736 (0.05)	141.9 (13.6)	56.7 (11.3)	0.6 (0.02)
F3	116.7 (11.3)	22.9 (11.7)	0.791 (0.09)	156.4 (10.4)	78.5 (11.5)	0.566 (0.05)

The residual force is the force remaining on the lower punch following compression and prior to ejection (Sadjady et al., 1993). Although the residual force should be measured in the die wall, as radial and axial forces are related by the Poisson's ratio (Sadjady et al., 1993), the residual force recorded from the lower punch can also evaluate

this phase of the tableting production. According to Hölzer and Sjögren (1978), the use of the residual force as a measure of friction is not recommended as it is dependent not only on friction at the die wall but also largely on expansion of the tablet and machine parts. Hölzer and Sjögren (1977) also suggested that the maximum

ejection force gives a better prediction of the adhesional problems in tableting. On the other hand, Shah et al. (1986) used the residual force measurements to obtain the tendency for picking and sticking.

Ejection properties evaluated by the maximum ejection force gave a different sequence in efficiency for lubricants for the maltodextrins under study. For M150, the higher ejection force media was obtained for PRUV[®] (LSD, $F = 44.95$, $p < 0.05$), while in M510 the lower value was for PRUV[®] (LSD, $F = 24.88$, $p < 0.05$). The lack of particle–particle interactions between the filler and this lubricant is attributed to physical properties of the sodium stearyl fumarate (Chowhan and Chi, 1986). In the other cases, magnesium stearate and PRECIROL[®], a particle–particle interaction resulted in lamination and flaking of the lubricants, and can be influenced by the stickiness. In M150, possibly due to its stickiness and poor flowability (Muñoz-Ruiz et al., 1993), lubricants that do not act by particle interaction, such as PRUV[®], are more efficient. Both maltodextrins fulfilled the requirements proposed by Bolhuis and Lerk (1973) in most of the batches, because their values were lower than 750 N (Tables 1–3). According to these results, lubricant efficiency and mechanism depend not only on the lubricant properties but also on the excipients' characteristics.

On the other hand, the following sequence from minimum to maximum was found for both maltodextrins in relation to the residual force: magnesium stearate, followed by PRUV[®] and PRECIROL[®]. So, in relation to adhesion efficiency, lubricant properties are the critical factor in its behaviour. While residual force evaluates not only the stickiness of the tablet but also the stress transmission through the whole tablet, maximum ejection force is only due to friction between die wall and tablet surface. The statistical results are also important because they were only significant for M150 (LSD, M150: $F = 84.43$, $p < 0.05$; M510: $F = 1.34$, $p > 0.01$). Probably, the antiadhesion efficiency of lubricants is more difficult to evaluate when the materials admixed show low friction and adhesion, as occurs in M510. In both maltodextrins, magnesium stearate was the best antiadherent (Shah et al., 1986).

In this sense, our results support the finding of Waring et al. (1987), who found that the residual force (static component) is more suitable for comparing the efficiency of different lubricants, while the maximum ejection force (dynamic component) is more appropriate for the optimization of lubricant concentrations.

Increasing concentrations of PRUV[®] (Schmidt and Brögmann, 1989), PRECIROL[®] and magnesium stearate displayed improved lubrication properties during ejection for M150 tablets, according to maximum ejection force values. For M510, the lowest value of this parameter was found in tablets containing the maximum magnesium stearate concentration (2%), while for the other two lubricants it was achieved in 1% (Hölzer and Sjögren, 1979; Schmidt and Brögmann, 1989; Delacourte et al., 1993b).

Regarding mixing time, it was significant for all M510 mixtures, whereas in M150 with PRUV[®] and PRECIROL[®] mixtures the effect was not significant. These results show less sensitivity of M150 to lubricant due to its poor flow properties, low density and size that produce less shear stress during the mixing phase, and for this reason less coverage of excipient particles (Doelker, 1993). These results are also due to the different laminar structure of the lubricants, magnesium stearate being more capable of spreading over the surface of filler particles (Chowhan and Chi, 1986; Rowe, 1988).

The maximum ejection force increased between 50 and 100 MPa, followed by a decrease at 200 MPa. Similar results were found for the residual force of the mixtures of the three lubricants (Tables 1–3); the lower values occurred at the higher applied pressure (200 MPa). Even though materials usually show increasing residual force with an increase in applied force, a decrease in the residual force was observed for maltodextrins. This behaviour, differing from other materials (Hölzer and Sjögren, 1977; Sadjady et al., 1993), can also be explained by a reduced stickiness associated with a diminishing real contact surface area (Stamm and Mathis, 1975). This process is probably due to the deformation properties of these materials, which demonstrated a limit for plastic deformation around 100–180 MPa (Mollan and

Çelik, 1993). This limit or critical value was noted by Shah et al. (1986) for several pharmaceutical materials—above a certain compaction force no picking or sticking was observed. Therefore, in order to study the modification of friction with the applied pressure, the measurement of tablet friction should be performed at different pressures within the range of interest (Hölzer and Sjögren, 1977).

Fig. 1 shows the ejection curves of maltodextrins tablets under different conditions. The ejection curve can be considered a useful means for the evaluation of effectiveness of lubricants, mainly because its pattern is modified according to the conditions. Delacourte et al. (1993a, 1995) described two different types (I and II) of ejection curve. Type I behaviour shows a small ejection force followed by a steady ejection force value, whereas type II behaviour is characterized by a sharp ejection peak and an immediate decrease in force. In PRUV[®] and PRECIROL[®] mixtures, a high residual force similar to ejection force can be observed (Tables 2 and 3). For this reason, the behaviour of these two lubricants is more like type II. However, in agreement with Delacourte et al. (1993a, 1995), magnesium stearate shows the same behaviour under any of the conditions with

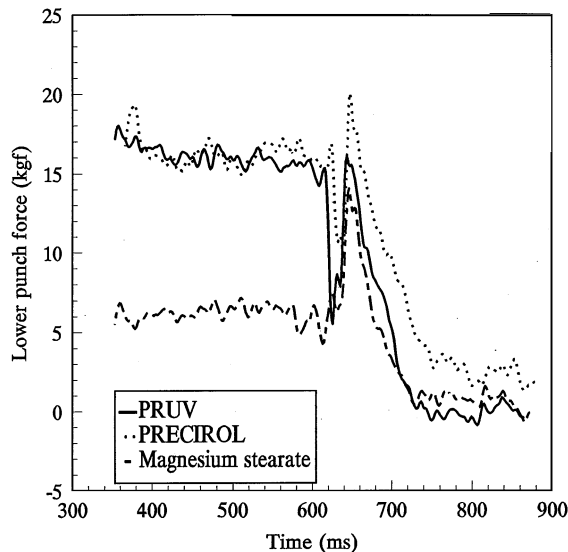


Fig. 1. Ejection force versus time in Maltrin[®] M150 with 0.5% of the three lubricants under study mixed over 2 min.

a low residual force, similar to type I for both diluents, as a result of its capacity to distribute the stresses during compression and ejection phases due to its ability to spread over maltodextrin particles (Table 1).

Delacourte et al. (1993a, 1995) proposed the lubrication index as the product between ejection peak value and ejection-time area. However, as force-time profiles show more time dependence (Sadjady et al., 1993), this parameter is dependent on ejection speed. In this sense, Sadjady et al. (1993) evaluated maximum ejection force and residual area at three different ejection speeds, showing that these parameters are also time-dependent.

In this paper, we propose a novel parameter 'work ratio' defined as the ratio between the corrected ejection work and the ejection work, the corrected ejection work being an area under the lower force-displacement curve during the ejection phase, using the ejection force minus the residual force (from the phase previous to the lower punch force baseline after compression and before ejection). This parameter comprises the static (residual) and the dynamic (ejection) force. The measurement of this work ratio gives a complete evaluation of the lubricant behaviour. The smaller the difference between the maximum ejection force and residual force, the closer the ratio is to 1. The work ratio constitutes a more informative approach to the lubricant efficacy because the ratio between the two works which increase simultaneously with time yields an independent time parameter (Mollan and Çelik, 1995).

According to work ratio values for M150 and M510 respectively, magnesium stearate mixtures got closer to 1 ($0.5273 < 0.5766$) while PRUV[®] ($0.4324 < 0.5079$) and PRECIROL[®] ($0.4231 < 0.4875$) gave lower results. For M510 tablets, due to its less abrasive nature, the work ratio is close to 1 (Muñoz-Ruiz et al., 1993). The results obtained for PRUV[®] and PRECIROL[®] are due to the high residual force of these two lubricants, which are very similar to the maximum ejection force, as observed in Fig. 1. On the other hand, Fig. 1 provides a typical record for magnesium stearate, with a low residual force, followed by a higher ejection peak. A quantitative appreciation

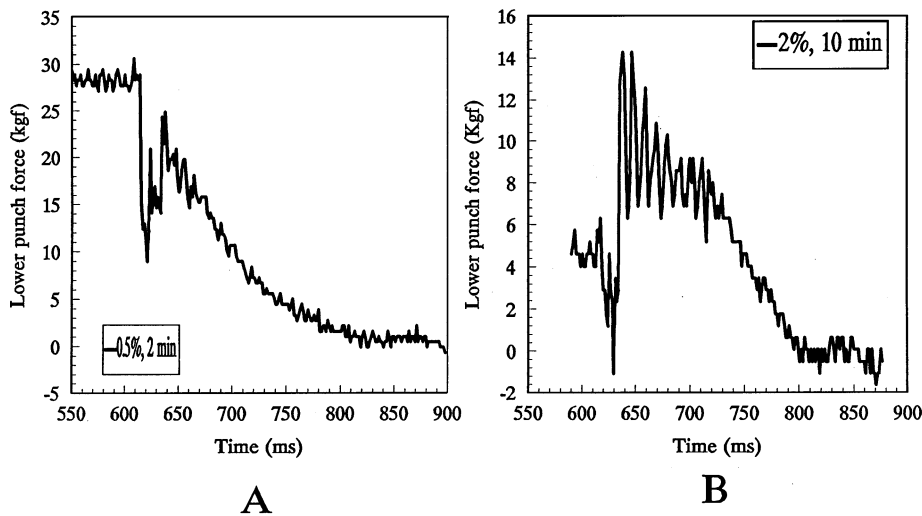


Fig. 2. Ejection force versus time in Maltrin[®] M150 with PRECIROL[®]. (A) 0.5%, 2 min; (B) 2%, 10 min.

of the types of behaviour can be obtained assisted by the work ratio. In this sense, the behaviour of magnesium stearate as type I described by Delacourte et al. (1993a, 1995) can be identified to a work ratio close to 1, with a significantly higher value (LSD, $F=31.11$ for M150 and $F=12.44$ for M510; $p < 0.01$) than PRECIROL[®] and PRUV[®], which corresponds to a type II behaviour. The effect of concentration is significant for the three lubricants: magnesium stearate, PRUV[®] and PRECIROL[®]. In all the cases, increasing the concentrations of lubricants, resulted in an increase in the work ratio. The mixing time was only significant for the PRECIROL[®] mixtures (LSD, $F=13.82$, $p < 0.01$). Also, an increase in concentration and mixing time leads to a response corresponding to type I, because a better coverage is achieved. These effects can also be observed in ejection curves (Fig. 2), where the ejection behaviour moves from type II to I, showing with the higher concentration and mixing time, a lower residual force and a steady phase after the maximum ejection force. This last phase corresponds to a steady resistance exerted by the tablet that will lead to a smooth appearance of the tablet without signs of indentation, because the tablet recovers the compression stress by pushing uniformly on the die wall (Delacourte et al., 1993a, 1995).

According to our results, no relation exists between applied pressure and work ratio. So the work ratio was independent of applied pressure and probably of compression speed. Hence, it seems possible that the work ratio is a valuable parameter in evaluating lubrication under any condition.

Acknowledgements

The authors wish to thank to Grain Processing Corporation for their supply of Maltrin[®] M510 and M150.

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