DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 14(7), 895-903 (1988)

THE TENSILE STRENGTH OF TABLETS OF BINARY MIXTURES LUBRICATED WITH MAGNESIUM STEARATE

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ABSTRACT

The influence of magnesium stearate on the tensile strength of tablets prepared from binary mixtures of materials lubricated with magnesium stearate have been studied. Mixtures of which both components (lactose and Emcompress) compact by fragmentation are largely unaffected. For a mixture of materials with dissimilar compaction mechanisms, (lactose and sodium chloride) magnesium stearate has a significant effect in that the originally high tensile strength of the sodium chloride is reduced to the level of lactose and the strengths of the mixtures and independent of the proportion of the components.

INTRODUCTION

Lubricants may seriously reduce the strength of tablets. In particular, magnesium stearate can, with prolonged mixing, completely coat the surface of particles preventing effective bonding from occurring on subsequent compression. This effect is especially noticeable with materials such as sodium chloride and Sta-Rx which undergo plastic deformation during compression. The magnesium stearate film is not disrupted and bonding is significantly reduced. Materials such as lactose and Emcompress which fragment on compression form uncontaminated surfaces and bonding is largely unaffected (1).

The compaction of mixtures of materials with dissimilar compaction characteristics (lactose and sodium chloride)(2), where sodium chloride forms much stronger tablets than lactose, leads to a rapid reduction in the strength of the tablets with the introduction of small quantities of lactose. This paper examines the influence of magnesium stearate on the tensile strength of tablets prepared from such mixtures and compares the results to those obtained from a mixture of materials compacting by a similar mechanism.

MATERIALS AND METHODS

The materials used were sodium chloride (B.D.H. Ltd, U.K.), lactose (D.M.V. Ltd, The Netherlands), and Emcompress (Forum

Chemicals, U.K.). All were sieved to give a 125-150μm size fraction. The materials were dried at 60°C and stored over silica gel until used.

Mixtures with a 0.1% magnesium stearate (Hopkin and Williams, U.K.) were prepared using a Turbula mixer at 60 r.p.m. (W.A.Bachhoven, Switzerland). Samples were taken at appropriate time intervals and 0.5g aliquots compressed at 77.4MN/m^2 using an Instron Physical Testing Instrument (Instron Ltd, U.K.) equipped with a conventional ½ inch flat faced punch and die operating at 0.1cm/min.(3). The tablets were stored over silica gel for 24 hrs and their tensile strengths measured using the Instron (3).

RESULTS

The influence of mixing time on the strength of the pure materials is in keeping with the results of earlier work (1). The tensile strength of sodium chloride is dramatically reduced whereas lactose and Emcompress are largely unaffected.

Figure 1 compares the tensile strength of sodium chloride/lactose mixtures with and without 0.1%, magnesium stearate after 60 min mixing. The strength of the tablets with magnesium stearate remains largely constant throughout the mixture range whereas the unlubricated tablets show a dramatic reduction in strength as the lactose concentration is increased.

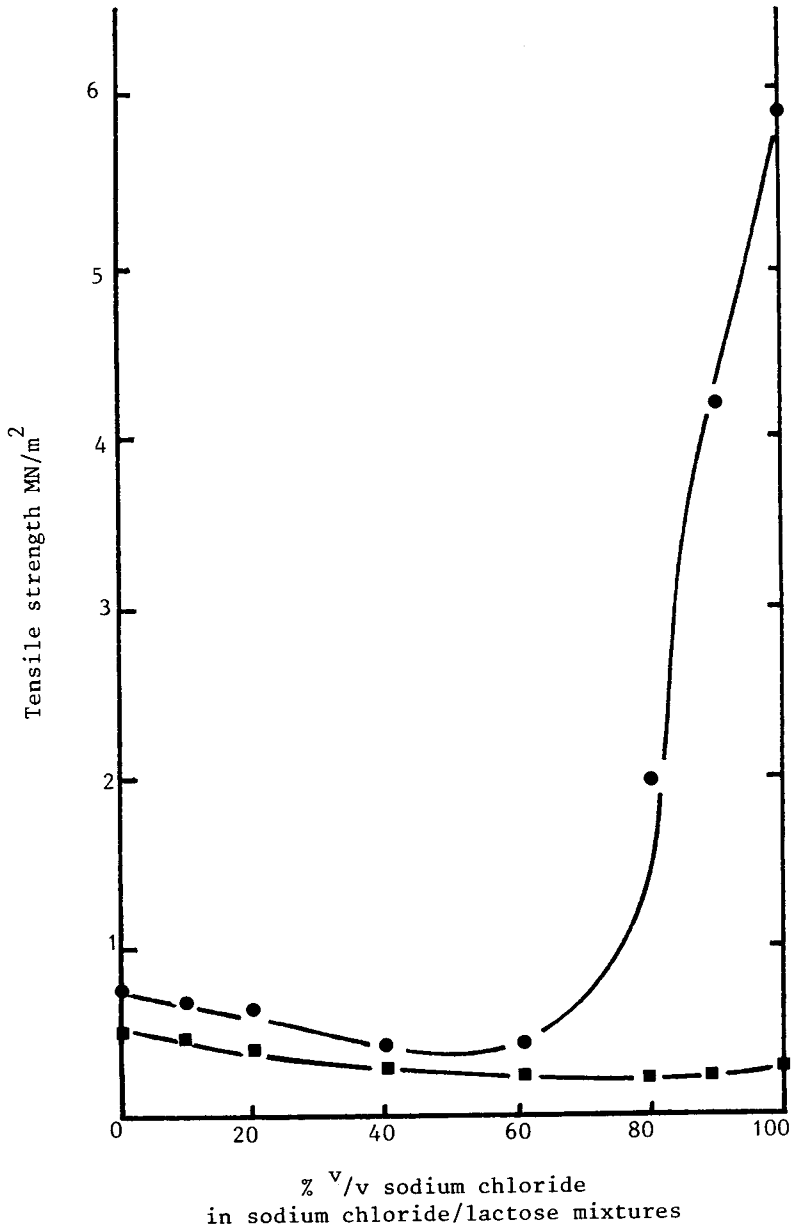

FIGURE 1

The relationship between tensile strength and mixture composition ● = lactose/sodium chloride alone ■ = lactose/sodium chloride with 0.1% magnesium stearate.

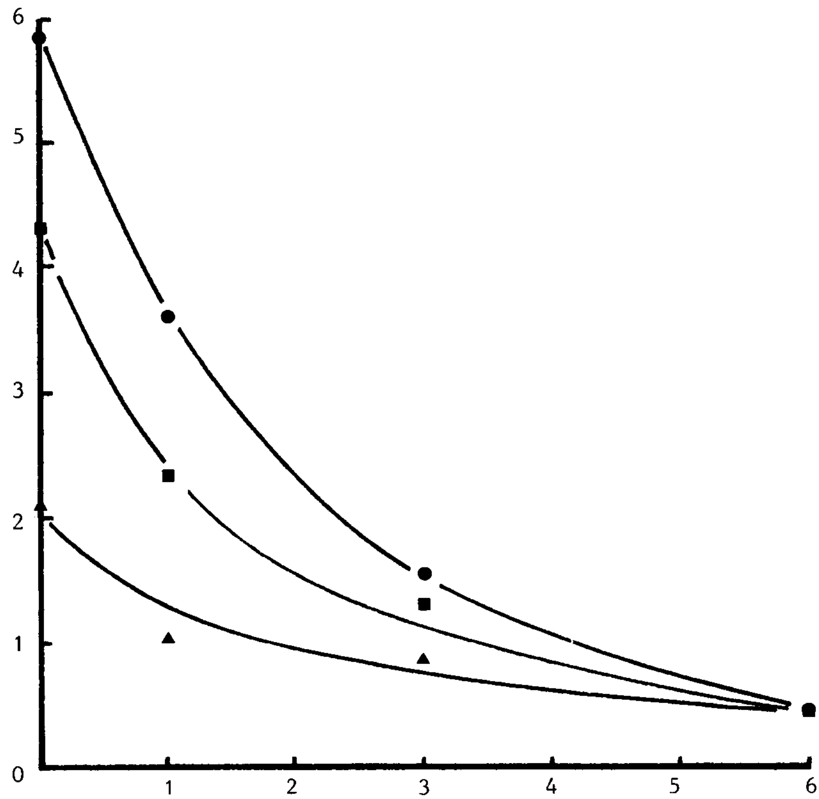

FIGURE 2

The relationship between tensile strength and mixing time for sodium chloride/lactose mixtures with 0.1% magnesium stearate
● = 100% sodium chloride, ■ = 90% $^{v}/v$ sodium chloride,
▲ = 80% $^{v}/v$ sodium chloride.

Figure 2 shows the influence of mixing time on the tensile strength of lactose/sodium chloride tablets containing 0.1% magnesium stearate. For concentrations lower than 60% and for mixing times over 6 min the tensile strength remains the same.

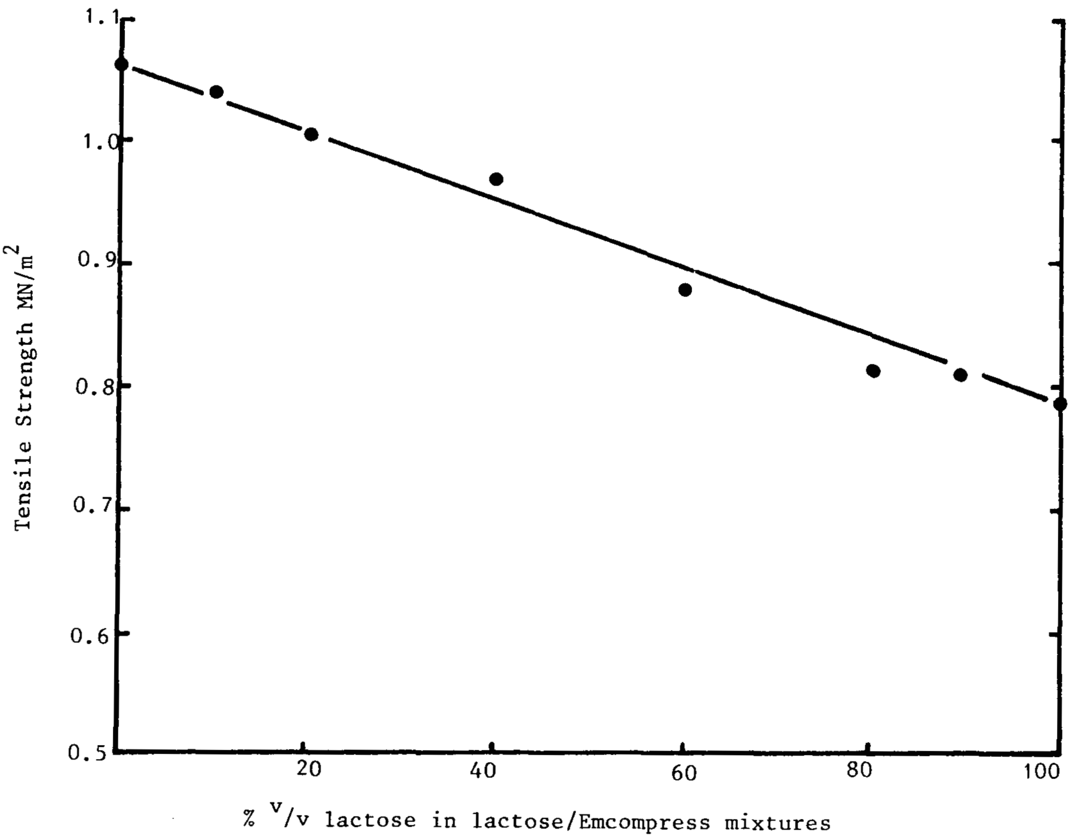

FIGURE 3

The relationship between tensile strength and mixture composition for lactose/Emcompress mixtures with and without 0.1% magnesium stearate.

Figure 3 shows the relation between tensile strength and mixtures composition for lactose/Emcompress mixtures. The results are average of samples taken at 7 mixing times up to 60 minutes as mixing time had no effect on the tensile strength of the tablets.

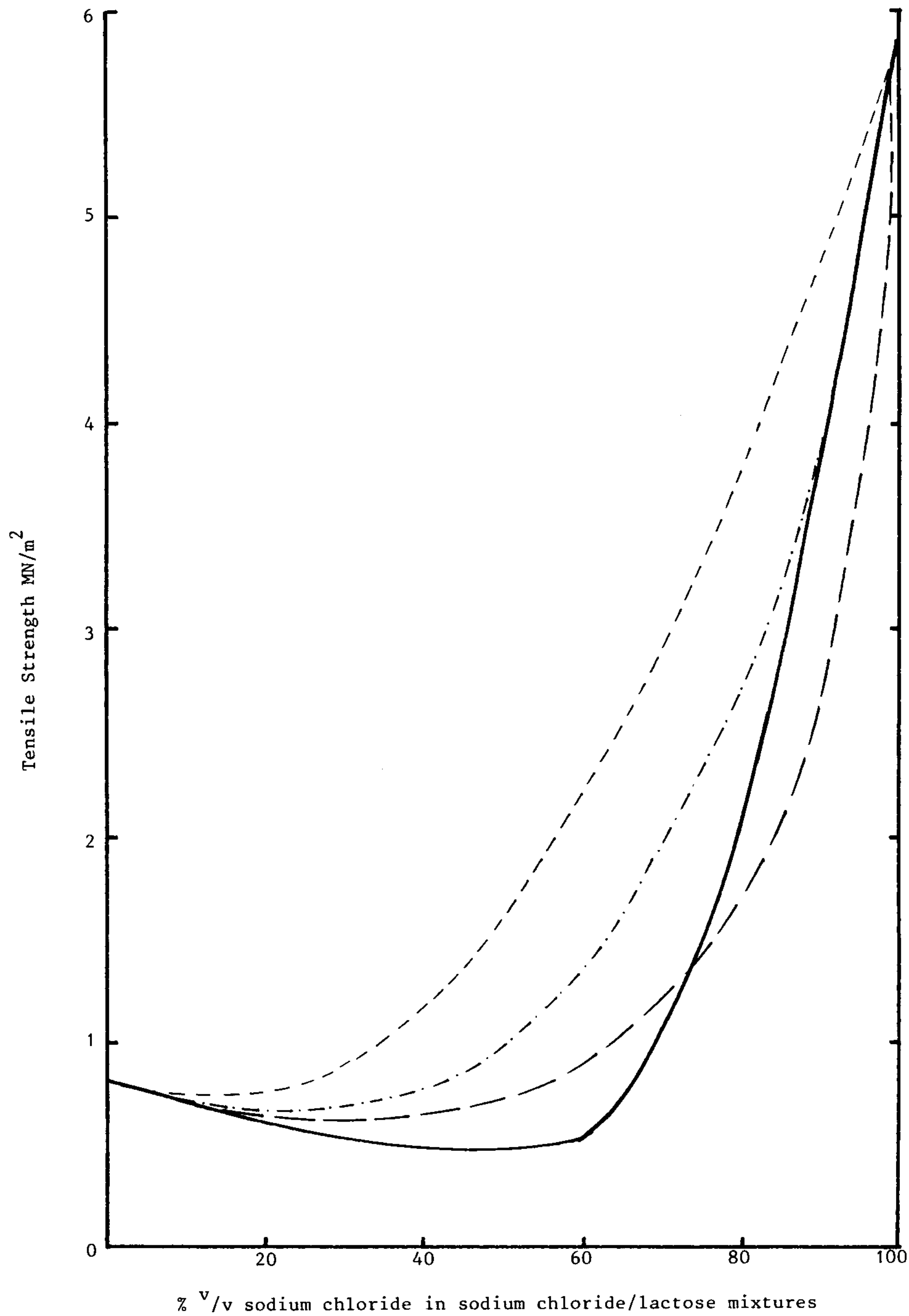

FIGURE 4

Actual and predicted values of tensile strength for sodium chloride/lactose mixtures. — — — — = no fragmentation —·—·—·= lactose fragments x2, ——— ———= lactose fragments x4.

DISCUSSION

The tensile strength of tablets formed from binary mixtures of components A and B will be as a result of three types of bonds, A-B, B-B and A-B. In the simplest possible case, the proportion of these bonds will be A-A=x^2; B-B=$(1-x)^2$ and A-B=$2x(1-x)$ where x is the fraction of component A. If the tensile strength of the mixture arises from a proportional contribution of the components then the strength of the mixtures could be predicted if the contribution of the bonding of A to B is known. In the particular case of lactose and sodium chloride this contribution can be assumed to be almost zero (2). Figure 4 shows the experimental and calculated values of the tensile strength based on the above assumptions. Lactose fragments during compaction, however, and hence the proportion of lactose/lactose bonds will be greater than that predicted from the original volume fraction. Figure 4 also shows the calculated values of tensile strength assuming that the lactose on fragmenting produces more bonds than originally predicted. Reasonable agreement can be obtained, but even the basic assumption produces a pattern similar to that found experimentally.

When magnesium stearate is included in the mixture, the lactose-lactose bonds are largely unaffected but the bonding of the sodium chloride is markedly reduced to the level of the lactose. Hence, the tensile strength of these tablets is almost unchanged with component proportion. This effect is time dependent as shown in Fig.2. The formation of the magnesium stearate film appears to be completed under the experimental conditions used after six minutes. Mixing times longer than this do not affect the results.

When two materials which fragment are used, magnesium stearate has no influence on the tensile strength as the films created on mixing are destroyed during compression.

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