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" MONITORING PUNCH FORCES AND PUNCH MOVEMENTS AS AN AID TO DEVELOPING ROBUST TABLET FORMULATIONS "

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Abstract

The benefits of commencing the pharmaceutical development program for a new drug entity as soon as practical are obvious. However, the ability to do so is controlled by many factors including limited availability of drug substance and very little information on pharmaceutically relevant properties. It is this data which the formulator must begin to collect as soon as any material becomes available. Establishing the physico-chemical characteristics (often referred to as 'preformulation') covers a wide range of attributes. This paper only considers those which can be investigated by use of instrumented compaction equipment.

The first experiments should include establishing the intrinsic compactibility of the compound by preparation of simple compacts of drug substance under controlled conditions and with essentially no additives except die wall lubrication. Irrespective of whether compacts are formed or not, the raw data collected from the instrumentation may be used to give an initial reading of this important property of the material.

On completion of these tests on drug substance, the development process then follows a pattern of making simple tablets and testing them for dissolution, strength, content uniformity, etc. Instrumentation can improve the efficiency of this process in several ways by providing information on predominant compaction mechanisms, a predictive capability of strength and maybe even dissolution. It will also create a data base of 'normal' results and a rapid, easy screen for variability.

If the work is being carried out on a sophisticated test instrument or simulator, the formulations may be subjected to high speed tabletting cycles in order to obtain a measure of the strain rate sensitivity. Several reports have now shown the effect of strain rate on properties such as tensile strength of tablets and their disintegration time.

As more drug substance becomes available a set of experiments designed to identify a commercializable formulation is carried out. This is also an appropriate point to transfer the processing to a rotary tablet press (if not already done), but the conditions must be controllable and precisely known. From these experiments a primary and at least one back-up formulation are identified, including processing conditions as well as composition.

The first clinical material, using the preferred formula and manufacturing instructions, can now be made. During the ensuing development phases the emphasis on utilisation of the instrumentation changes, but many of the measurements already referred to, are still useful. Much of the data resulting from the overall program described, can provide an impressive addition to the "Formulation Development" section of any submission!

1. INTRODUCTION

❑ Pharmaceutical development of oral solid dosage forms involves working toward the common goal of an approvable NDA and establishing technology to ensure compliance with it during the life of the product.

The benefits of commencing this development program as soon as practical are obvious, but are controlled by many factors including limited availability of drug substance. In addition, very little information on pharmaceutically relevant properties is generated during pharmacological screening and it is this data which the formulator must begin to collect.

Establishing the mechanical, physical and chemical characteristics (often referred to as 'pre-formulation') covers a wide range of attributes. In this paper we shall only consider those which can be investigated by use of instrumented compaction equipment.

❑ In terms of an approvable NDA we will be seeking to develop a product with attributes which include:-

- a reproducible, desired in vitro release pattern
- an appropriate physical and chemical stability profile
- market acceptability
- a commercializable process

❑ In terms of the development scientist this translates into:-

- developing robust formulations
- identifying critical properties
- minimising product variability
- ensuring the process is always under control and capable of validation

❑ It is essential to begin to establish a data base as soon as any material becomes available. At this point we face the following restrictions:-

- limited supply of possibly atypical lots of the compound
- unknown tabletting potential

- only a tentative dose regime
- unknown stability profile

So the first experiments must be carefully selected.

2. FIRST EXPERIMENTS

❑ The first steps should include establishing the '**intrinsic compactability**' of the compound by preparation of simple compacts of drug substance under controlled conditions and with essentially no additives except perhaps die wall lubrication.

These experiments may use either a single station press, an isolated punch and die assembly in a materials testing machine (such as an 'Instron'), or preferably a compaction simulator. Single ended compaction is adequate at this stage.

❑ Certain basic experimental ground rules may be specified for these tests:-

- use simple tool geometry, e.g. round flat faced
- compare constant true volumes of material, maybe even feed the die manually
- use degree of compression as end point, e.g. a specific porosity
- keep time frame realistic, e.g. less than 300 msec.
- control environmental conditions, say $20^{O}C \pm 5^{O}$, 45%RH $\pm$ 10%

The use of constant true volume is particularly important when comparing materials, since the response to punch movement (i.e. punch force) is a function of the volume of solid in the die and not its weight.

The raw data, collected with respect to time, should at least include:-

- applied compressional force
- force transmitted to lower punch
- movements of the two punches
- force to eject the compact

all with respect to accurately known time points.

❑ Since the compactability of the material is unknown, a workable compaction range of load (and porosity) should be qualitatively estimated by attempting to prepare compacts at say, three well spaced loading levels (maybe in a logarithmic ratio). This will generate data like that shown in Figure 1.

If acceptable compacts are not produced, a modified compactional force range can be tried, but preferably maintaining logarithmic ratios, (see Figure 1). If compacts can be made, then after their ejection the following parameters should be measured, weight, thickness, diameter and crushing strength (if any). In addition, appropriate tests could be carried out to detect any chemical degradation or polymorphic change in the drug substance, as a result of compaction.

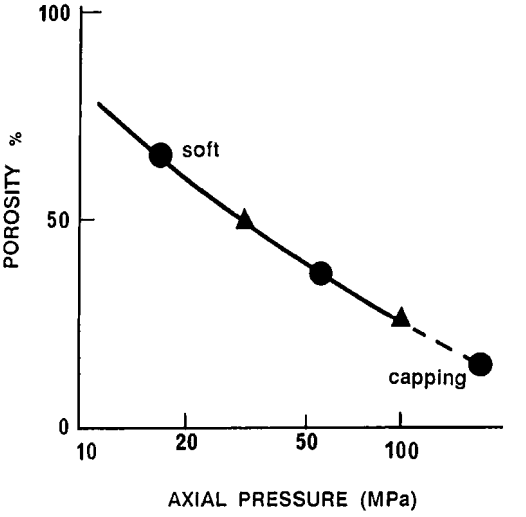

FIGURE 1.

Typical load versus porosity data from first experiments. ● points from first three test loads, ▲ points from additional load levels.

❑ Irrespective of whether compacts have been formed or not, the raw data collected from the instrumentation may be used to give an initial reading on the intrinsic compactability of the material. For example a '**consolidation potential**' (increase in mechanical strength of the bulk material) may be estimated by calculation of some work function from the area under the force versus displacement curves, as indicated in Figures 2 and 3.

❑ The hypothesis here is that some of the work supplied during tabletting is used to break bonds between particles, so that further compression (reduction in volume) can take place. A material which readily bonds and/or forms strong bonds, should therefore require more work to achieve a certain degree of compression, than a poorly bonding one. In other words, the slope of the porosity versus work plot should ideally be constant and shallow. See examples in Figure 3.

However, the ultimate strength of the finished tablet is not necessarily a direct function of the degree of strong bond formation, but more a reflection of those bonds that have survived the unloading and ejection parts of the cycle, as well as any relaxation subsequent to ejection.

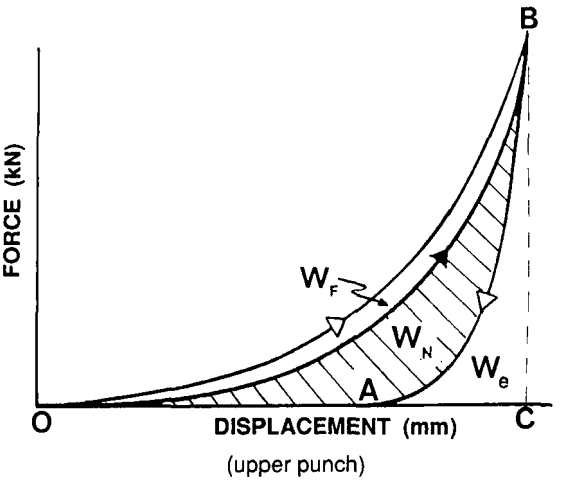

FIGURE 2.

Typical force-displacement curves. Area 'W_F' is a potential measure of the work done in overcoming die-wall friction, area 'W_e' corresponds to any work of elastic recovery and 'W_N' is a measure of the net work utilised in compaction of the tablet.

❑ The major mechanisms contributing to the compression of a powder or granule under load are repacking, elastic deformation, plastic deformation, visco-elastic deformation and brittle fracture.

Ways of estimating the contribution each mechanism makes during compression and unloading of a particular material have been widely studied, because massive elastic relaxation and brittle fracture during the unloading part of the cycle, may significantly reduce the number of surviving bonds.

❑ A qualitative estimate of the elastic deformation experienced by the compact material can be made from a simple measurement of the amount of elastic recovery 'ER' from:-

$$ER = 100 \cdot \frac{H_e - H_c}{H_c} \quad (1)$$

where 'H_c' and 'H_e' are the measured heights of the compact in the die (under load) and at a fixed time after ejection, respectively.

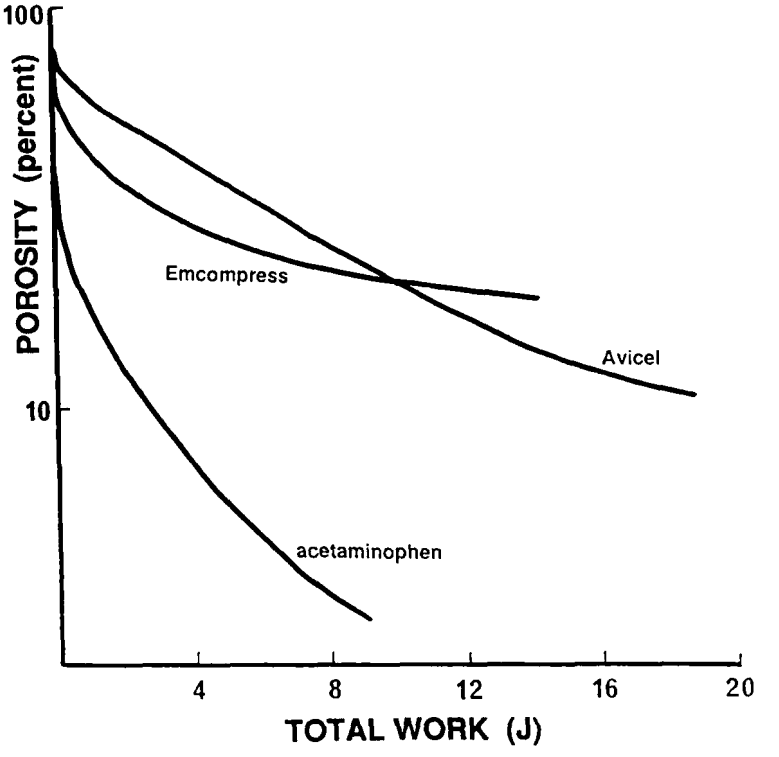

FIGURE 3.

Examples of the relationship between total work and porosity for two materials which form strong tablets (microcrystalline cellulose and Dicalcium Phosphate) and one which does not (acetaminophen).

Under certain circumstances, the area ABC in Figure 2. may give a second estimate of this property, since it can be a measure of the work transferred back to the punch during initial unloading. An extension of this approach is to compare the amount of work done with the degree of elastic recovery, as an indirect way of estimating surviving bonds, as illustrated in Figure 4. [1]

❑ Distinguishing brittle fracture propensity from visco-elastic and purely plastic effects is difficult from the measurements under review here. One of the more widely used approaches (but still controversial!) is application of the Athy-Heckel relationship [2]. This may be expressed in the form:-

$$\text{Log } E^{-1} = P.k_y + k_0 \qquad (2)$$

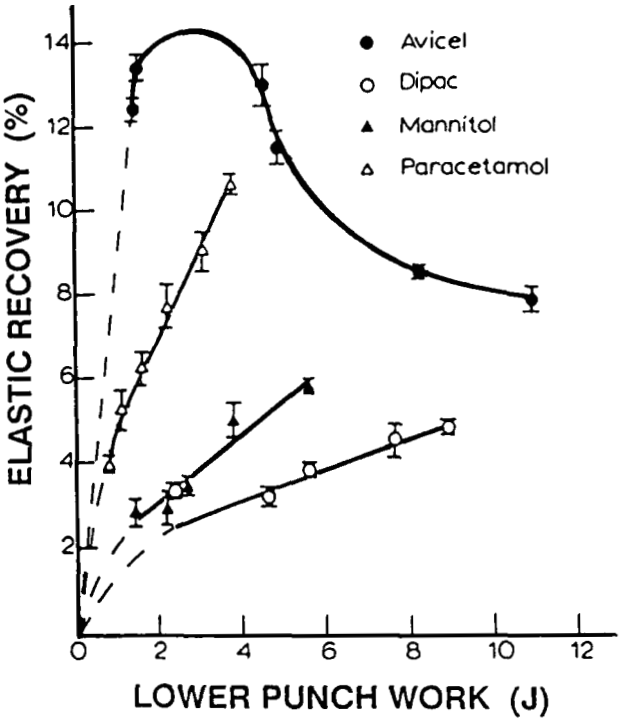

FIGURE 4.

Examples of the relationship between lower punch work and the degree of elastic recovery of the tablet, which may provide an indirect assessment of the level of surviving bonds. [after ref:(1)]

where 'k_y' is related to the reciprocal of the yield pressure of the material and 'k_o' is a function of the porosity at zero load. 'E' is the porosity of the compact at the applied pressure 'P'.

If plots of Log E^{-1} versus applied pressure are linear, a yield pressure may be calculated from the reciprocal of the slope. Lower yield pressures are said to be typical of more plastically deforming materials. The literature has many examples of non-linearity and exceptions to this generalisation.

It may be more informative to carry out experiments at two widely separated press speeds as shown by the examples in Figure 5.[3] This data shows the brittle nature of lactose and Emcompress [Mendell] (low slope, therefore high yield value) as

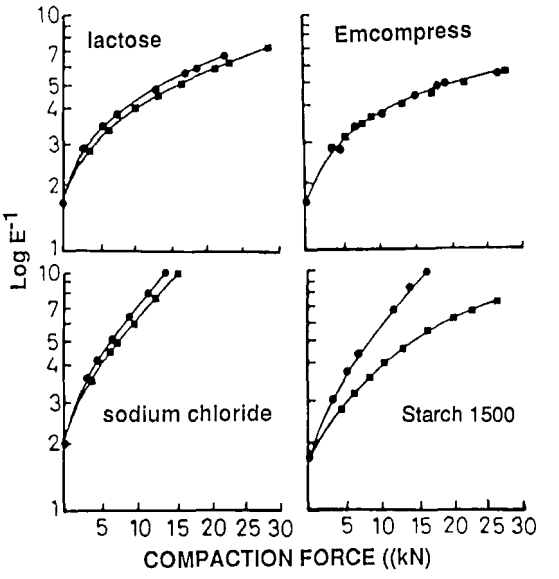

FIGURE 5.

Examples of Athy-Heckel plots obtained at two press speeds (● 10sec. contact time, ■ 0.17 sec. contact time). [after ref:(3)]

opposed to the high slope of plastically deforming materials sodium chloride and 'Starch 1500' [Colorcon]. Note that the rate of deformation of sodium chloride is high, therefore the effect of speed is minimal, but this is not the case with 'Starch 1500'.

One alternative suggestion [4] is that the area under the Athy-Heckel plots obtained at different rates of compaction is related to the degree of plastic deformation which has taken place. Large area being indicative of a highly plastic material.

❑ A useful additional experiment to provide information on the visco-elastic character of the drug substance, involves collecting constant strain data. This is accomplished by compressing the material to a fixed degree and then halting punch movements. The decay of the applied force, due to continuing visco-elastic and plastic deformation of the material, is then monitored. From such data plots like that shown in Figure 6 may be obtained [5].

The slope of these plots (k) is proportional to the ratio Y/ψ, where 'Y' (Youngs Modulus) represents the elastic component and 'ψ' the contribution of the viscous effect. High k values are indicative of more plastic flow and seem to correlate with tablet strength, see Table I.

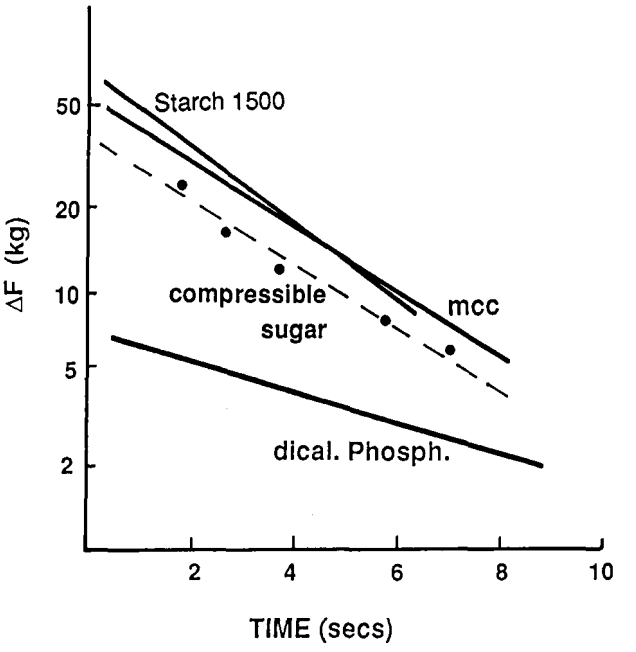

FIGURE 6.

Examples of constant strain data. [after ref:(5)]

TABLE I. EXAMPLES OF DATA FROM CONSTANT STRAIN TESTS

MATERIAL	k	ΔF (TOTAL)	TENSILE STRENGTH[a]
Starch '1500'	0.336	63	18.8
Avicel PH101	0.332	53	18.7
Compressible sugar	0.281	37	12.3
Dicalcium phosphate	0.182	7	-

(a) $kg.cm^{-2}$ [after ref:(5)]

Additional ways to obtain information on predominant compression mechanisms are illustrated in the section on formulation development.

3. INITIAL FORMULATION SCREENING

❑ The development process could now follow a pattern of making tablets and testing them for dissolution, strength, content uniformity, etc.
Instrumentation may be able to improve the efficiency of this process in several ways by providing:-

- information on predominant compaction mechanisms, hence assist in problem solving
- predictive capability of strength and may be even dissolution
- a rapid, easy screen for variability
- a data base of 'normal' results

❑ A possible approach is to use one of a number of 'standard' base formulations which have already been fully characterised. Choice is based upon the chemistry of the drug substance and likely interactions with the functional groups of specific excipients, plus knowledge of the compactional properties from the experiments just described.

The experiments should be carried out with different concentrations of drug substance and under precise conditions which include:-

- compensation for changes in composition, so that the true volume of material in the die is constant
- precisely reproducible compaction cycle, including a realistic fixed time parameter
- compensation for tooling distortion (due to load), so that accurate die cavity geometry data is collected throughout the cycle
- accurate measurement of the various forces throughout the compaction cycle

If due attention is paid to these factors, the data collected during the tabletting cycle should be highly reproducible and a minimum number, as low as 5 tablets for each set of conditions, may be adequate. Obviously if material is available, then preparation of more tablets will facilitate a larger number of post-compaction tests, but these more usually occur at the next stage.

❑ These initial tests provide information on:-

- potential for drug loading
- parameters for experimental design of formulation screen
- potential incompatibilities

❑ The following examples illustrate the type of information which may be obtained at this preliminary stage. The first relationship to try and establish is one between tablet "strength" and some parameter measured during the cycle, e.g. applied force or work of compaction. The example given in Figure 7 illustrates this principle. Emphasis is on what can be deduced from a monitored compaction cycle itself, with a minimum of post-compaction testing.

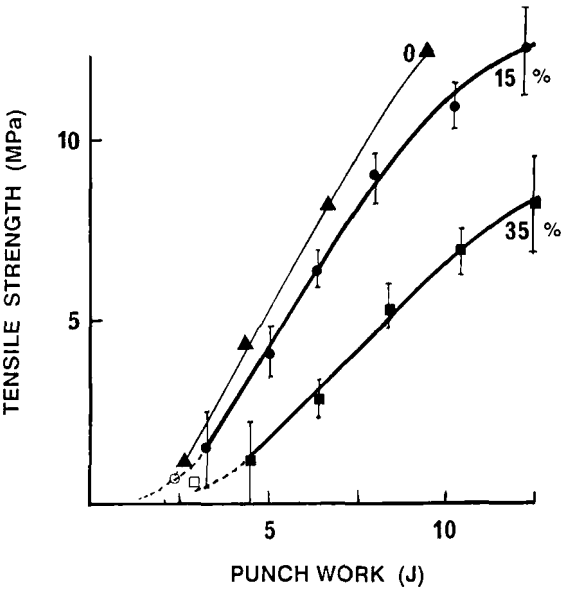

FIGURE 7.

Tensile strength versus punch work plots of a lactose base formulation to which different amounts of an experimental drug have been added. ▲ 0%, ● 15% and ■ 35%.

Note that the base formulation exhibits a linear relationship between tablet strength and punch work for most of the useful range, but that the drug in this example significantly weakens the tablets when present at a level of 35%.

Having established a connection with tablet strength it is then possible to look at the influence of important variables.

1. **Compaction Force**- It is important to appreciate that the parameter which will affect other attributes most significantly, is likely to be the applied pressure (P) or force (F). It is essential that this pressure or force is accurately known and the sensitivity of each component to changes in it, is known. The data in Figure 8 illustrates this by showing the effect of 'F' on the tablet crushing strength of some common excipients. Note in particular the high sensitivity of some excipients, such as microcrystalline cellulose, to applied force which will make greater demands on controlling this parameter in say a production environment.

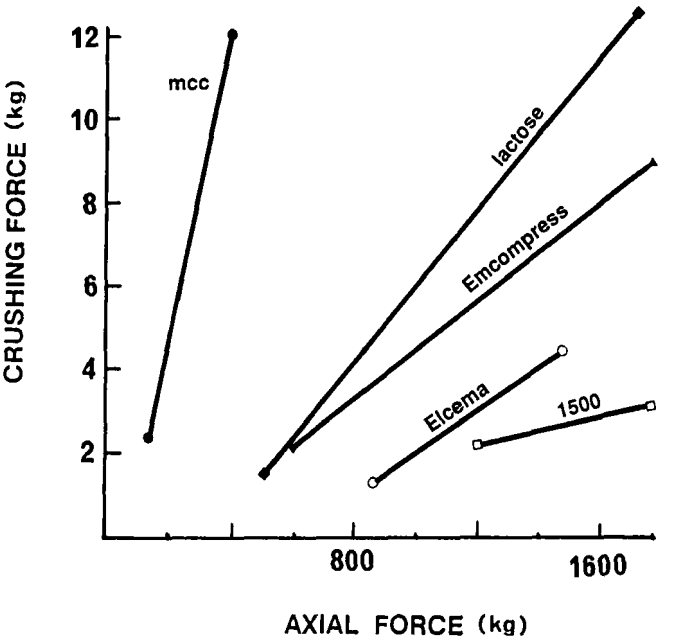

FIGURE 8.

The effect of compactional force level on the crushing strength of certain excipients. [after Shangraw: unpublished data]

2. **Selection of Excipients, e.g. Binder-** If a relationship like that shown in Figure 7 can be established, work data collected during the tabletting event can be substituted for actual strength measurements. A further example of this approach is seen in Figure 9.

Accepting the hypothesis that more bonding and hence stronger tablets, can be inferred from net work, means that the latter parameter can be used to compare binders. This relationship was confirmed and used in the selection of starch, gelatin or methyl cellulose for a sulphonamide tablet as shown in Figure 9. [6]

Note in particular that when using starch paste, higher compactional forces do not result in an increase in net work (tablet strength), so presumably the work associated with the additional force level is being recovered during elastic relaxation, which might result in weakening of the tablet structure.

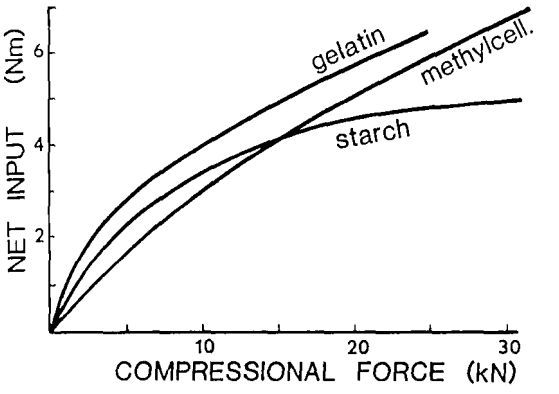

FIGURE 9.

Comparison of three binders by means of the effect of compactional force on the net work utilised in making tablets from them. [after ref:(6)]

3. **Frictional Effects**- The level of lubrication in most formulations is usually more than adequate to overcome die wall friction effects during ejection. In fact there is a tendency to overlubricate. Monitoring of lower to upper punch force (or pressure) ratios ('R' values) which tend to approach unity under these conditions, then becomes an insensitive measurement. However, data similar to that given in Figure 10 of 'effective ejection pressure' against maximum applied pressure, can provide a guide to optimising the lubricant level [7]. Note the high frictional forces of pure lactose, but the dramatic reduction resulting from even low levels of a lubricant. Alternatively, the approach illustrated by the data in Table II, where net work is used to assess lubrication effects, may be a more sensitive method. [8]

4. **Dissolution Rate**- It is asking a great deal for the type of data under review to provide predictive information about dissolution. However, information on porosity is available and in many cases it has been shown that there is a relationship between it and dissolution, see Figure 11 [9]. It follows that monitoring porosity versus punch movements is a useful exercise and could be particularly important for say a matrix type modified release dosage form.

A more complex rationale (this author's), concerns studies with a new drug in a simple base formulation of lactose, Primogel [Mendell] and magnesium stearate.[10] In the hypothesis using this example, dissolution time plotted against compressional force gave the curve shown in Figure 12a. The shape of the curve is easy to explain from consideration of the plot of tablet hardness versus compactional force (Figure 12b), where the shape is similar.

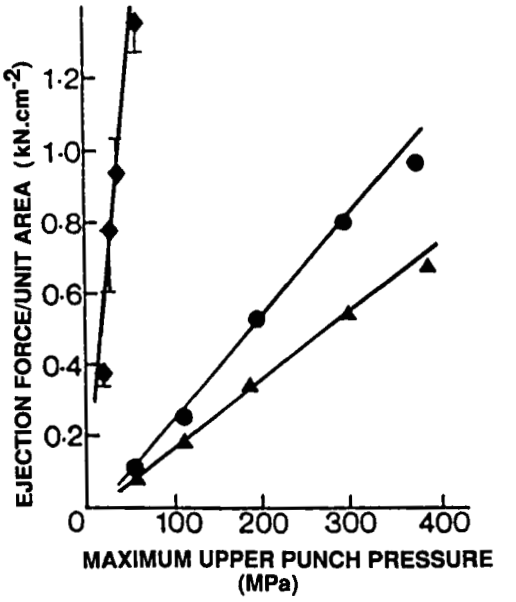

FIGURE 10.

The relationship between the maximum applied pressure and the effective ejection pressure for unlubricated and lubricated lactose tablets. ◆ 0%, ● 0.1% and ▲ 0.75% magnesium stearate. [after ref:(7)]

TABLE II. COMPARISON OF 'R' VALUES WITH NET WORK AS A MEANS OF EVALUATING LUBRICATION

	UNLUBRICATED	DIE WALL LUBRICATED	GRANULATION LUBRICATED
'R' value	0.84	0.98	0.98
Net work of Compaction (N.m)	5.6	4.4	3.4
Residual Lower Punch Pressure (MPa)	32	2.5	2.5

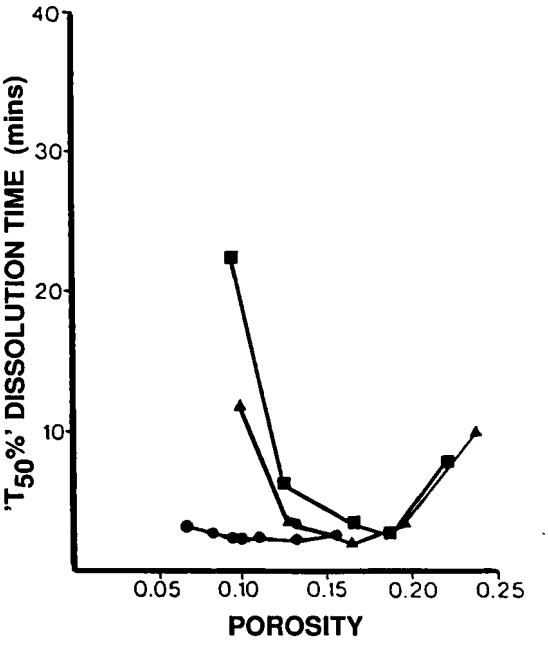

FIGURE 11.

The effect of granulation method and tablet porosity on dissolution time. ▲ spray dried, ■ wet massed and ● roller compacted. [after ref:(9)]

It is also possible to demonstrate a linear relationship between tablet hardness and net work of compaction for this system, as shown in Figure 12c. Could we then predict dissolution time for this formulation from net work data obtained during the compaction cycle?

Figure 12d shows the correlation obtained by abstracting data from the other curves, but this is not to necessarily imply wider applicability.

❑ Compacts made at this stage also provide the means for compatibility screening and should be set down on some appropriate accelerated stability test protocol. This approach is probably preferable to simply making intimate mixes of powdered ingredients and is certainly more efficient than testing mixes of drug substance with a range of individual excipients.

❑ Another advantage of using a punch and die assembly in a materials test instrument, or use of a simulator, is the ability to do constant stress measurements, i.e.

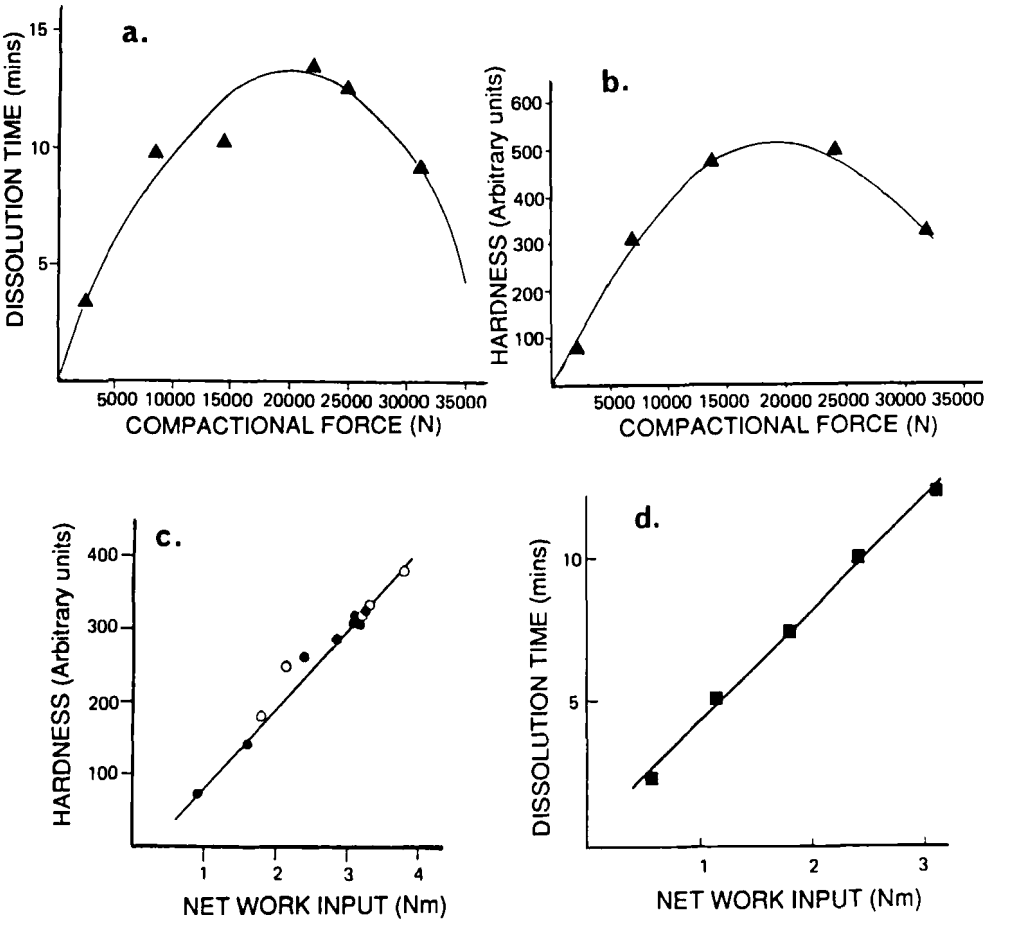

FIGURE 12.

Data indicating a possible relationship between dissolution time and work of compaction. [12 a,b,c, after ref:(10)]

loading material to a given point and maintaining the load for a fixed period before release. This facilitates determination of the comparative plastic and visco-elastic deformation induced during the fixed time period, as illustrated by the data in Figure 13. [11]

Note that in this example the highly plastic materials 'Starch 1500' and 'Avicel' [FMC Corp.] can relieve stress by plastic flow, whereas acetaminophen and

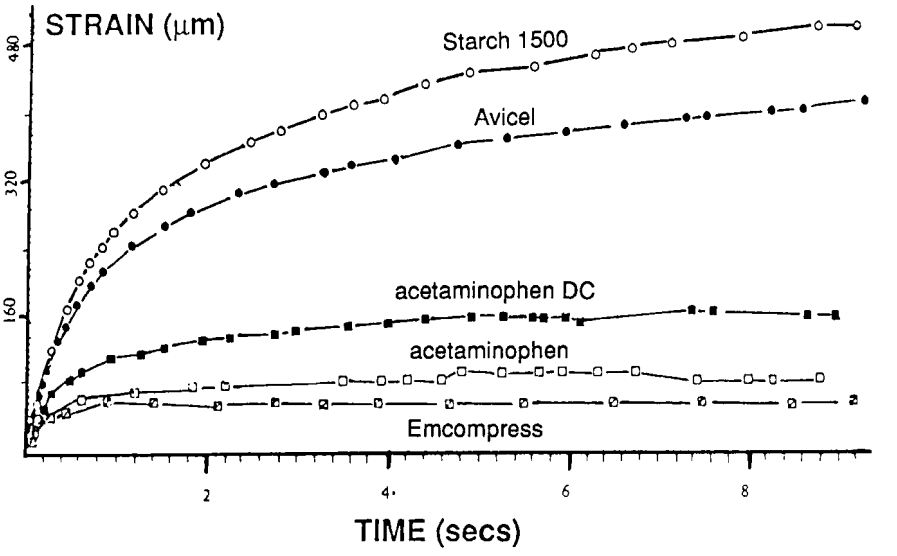

FIGURE 13.

Examples of strain versus time data obtained under constant stress conditions. [after ref:(11)]

'Emcompress' show little plasticity. In addition acetaminophen is elastic and so combined with a weak bonding tendency, readily fails during unloading due to the recovery strains.

❑ If the height of the compact is noted at the beginning and end of the constant stress period (H_c and H_m, respectively), then a measure of the compression due to plastic and visco-elastic deformation (PD) can be obtained from:-

$$PD = \frac{H_c - H_m}{H_c} \times 100 \quad (3)$$

We have already mentioned one estimate of elastic recovery 'ER' (equation 1.), but some authors [12] have suggested a better expression would be:-

$$ER = \frac{H_e - H_m}{H_m} \times 100 \quad (4)$$

They then proposed that the ratio ER/PD was inversely proportional to the tensile strength, as illustrated by the data in Figure 14.

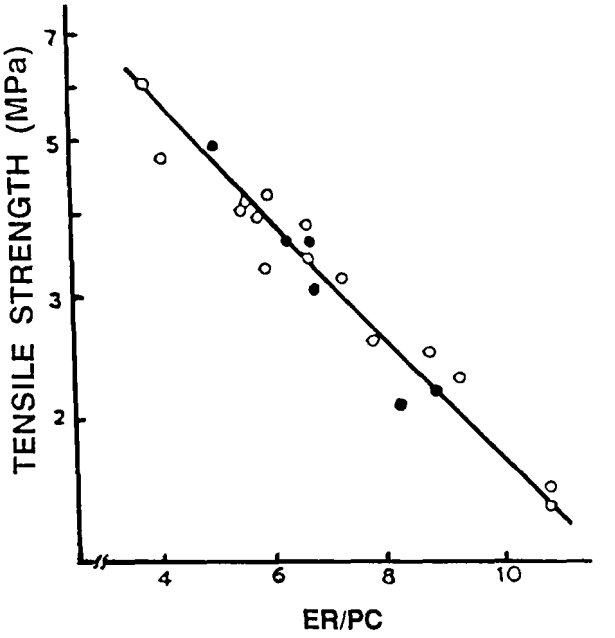

FIGURE 14.

The relationship between the 'ER/PD' and tablet tensile strength for some microcystalline cellulose/lactose mixtures (●) and some other materials (o). [after ref:(12)]

❑ If the work is being carried out on a sophisticated test instrument or simulator, one further series of tests can be carried out before proceeding to the next development phase. This involves challenging the formulations to high speed tabletting cycles in order to obtain a measure of the strain rate sensitivity. Several reports have now shown the effect of strain rate on properties such as tensile strength of tablets and their disintegration time. The example in figure 15 illustrates this type of data. [13]

This shows that in the case of lactose, the yield point for the initiation of plastic flow is dependent upon particle size and compressional speed. Avicel on the other hand is not so dependent on particle size, but is more sensitive to press speed, i.e. the yield pressure increases by 45% over this range of speed, whereas lactose yield pressure only increases by 20%.

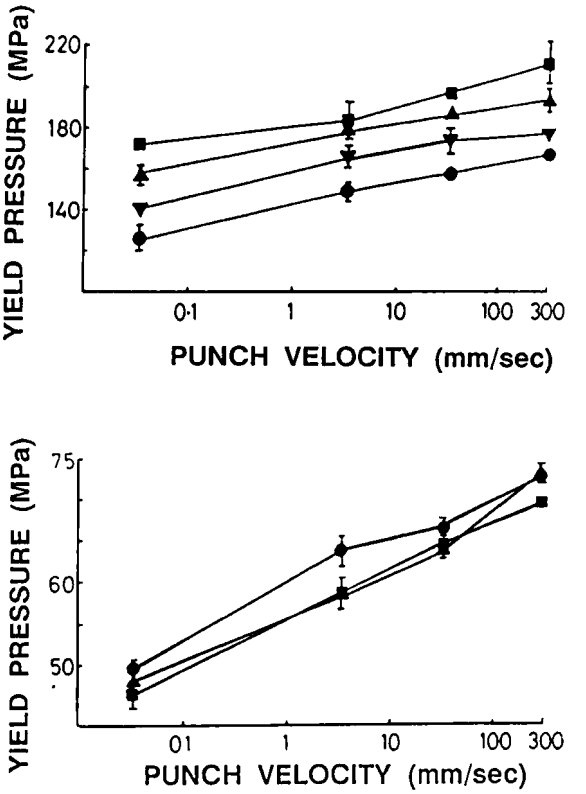

FIGURE 15.

The effect of particle size and speed of compaction on yield pressure. [after ref:(13)]

Lactose: ● grade 50, ▼ regular, ▲ grade 170 and ■ grade 170 after fluid energy milling

Avicel: ● PH 102, ■ PH 101 and ▲ PH 105.

4. DEVELOPMENT OF PRIMARY FORMULATION/FIRST CLINICAL TABLETS

❑ As more drug substance becomes available, it is possible to embark on a set of experiments designed to identify a robust primary formulation and at least one back-up formula. The data from the initial formulation screen should facilitate design of a statistical set of experiments requiring a reasonably modest amount of drug substance.

This is also an appropriate point to transfer the processing to a multi-station tablet press (if not already done), but the conditions must be controllable and precisely known. At the very least the press must be equipped with accurate applied force measuring transducers.

One practical complication is that measurement of punch displacements on a multi-station tablet machine is not easy unless radio-telemetry is employed to retrieve signals from the rotating turret. Alternatively, the vertical punch displacements 'D' may be calculated from time data if the critical geometry of the press is known. For example the equation proposed by Rippie [14] has been used in our laboratory, i.e.:-

$$D = [\,(r_1 + r_2)^2 - (r_3.\sin \omega.t - x)^2\,]^{0.5} \qquad (5)$$

where D is the vertical displacement of the punch at time t; r_1 and r_2 are the radii of the compression rolls and punch head OD respectively; r_3 is the pitch circle of the press; x is the horizontal distance between the center of the punch and the center of the vertical curvature of the punch head rim and ω is the turret angular velocity.

From such experiments a primary and at least one back-up formulation are identified, including processing conditions as well as composition. The formulation screen will also have indicated the most significant variables and these should receive particular attention in the next phase.

❑ The first clinical material, using the preferred formula and manufacturing instructions, can now be made. Data from the instrumentation on the press used, should at least facilitate monitoring of the identified significant variables and provide information for comparison of this lot with the compaction characteristics of the experimental phase tablets. Deviations need to be quantified in terms of their impact on the desired attributes of the tablets and if significant, provide recommendations for modifications to future lots.

5. LATE DEVELOPMENT PHASE

❑ The emphasis now changes, since most of the major intrinsic compaction problems (if any) should have been resolved! Concern is now for the effect of changes to the developed clinical product arising from unintentional small variations when compared to the data base on 'normal' lots of the product and intentional changes resulting from on going fine tuning of the formulation and/or process.

The development program may continue in two ways:-

- small scale experiments on a 'non-multistation' press
- data from a multi-station press while manufacturing clinical supplies

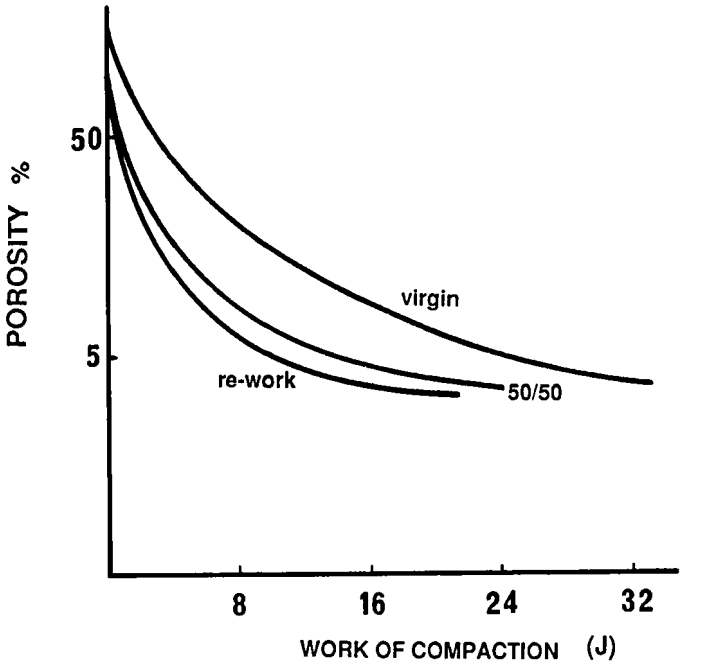

FIGURE 16.

The difference in the porosity versus compaction work profile for virgin and reworked tablets

❑ The former will include any or all of the parameters already reviewed and will probably be designed to confirm "profiles" such as:-

- porosity v. work for bonding
- Athy-Heckel curve area, ER/PD ratios, 'k' values from constant strain data, all for deformation mechanism assessment
- strain rate sensitivity checks for potential high speed production

Monitoring the manufacture of subsequent clinical lots of tablets, also provides a valuable source of reference when handling a whole range of continuing activities, including:-

-establishing specifications
-process validation
-change in batch size
-equipment/process changes
-'development to production' transfer
-change in manufacturing location

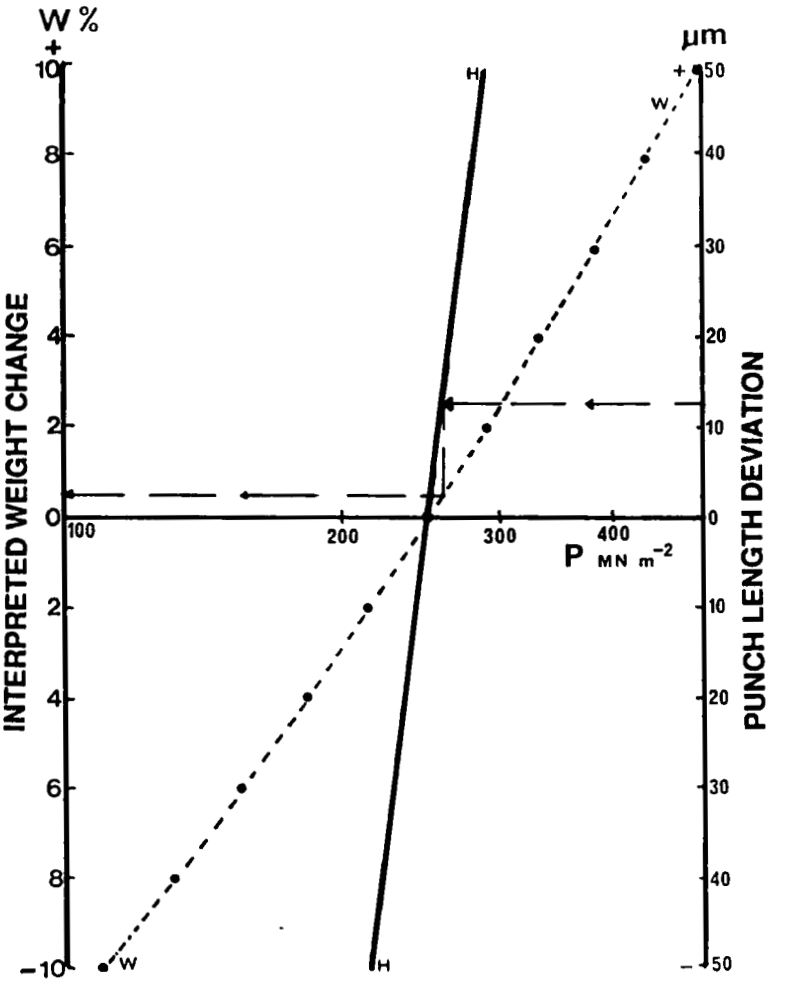

FIGURE 17.

Nomogram to illustrate how variations in tooling dimensions would be interpreted as weight changes by a typical weight monitoring system. (See text for explanation)

TABLE III. RELATIONSHIP BETWEEN PRESS TOLERANCES AND WEIGHT MONITORING RESPONSES

	Approximate Equivalent Percentage Weight
Maximum punch tolerances (± 12.7 μm)	1.00
Maximum die bore tolerance (± 12.7 μm)	0.50
Maximum pressure roll/axle tolerance (± 19.0 μm)	0.75
Total possible tolerance (worst case)	2.25

From such data a limiting resolution in the ability of the system to monitor weight variations can be assessed.

The two examples which follow serve to illustrate the continuing contribution that press instrumentation can make at the R & D/Manufacturing interface.

❑ **Re-work-** Figure 16 is an example of an exercise concerned with re-work procedures. It shows the sensitivity of the formulation to the milling and re-compaction of tablet cores. The work of compaction was calculated from a knowledge of the force versus time profile, not from displacement data.

In this formulation reworking results in a signicant reduction in the amount of work needed to compress to a given degree, because bonding is poorer and this effect was reflected in much weaker tablets, which tended to laminate.

❑ **Tablet Weight Monitoring-** Most contemporary production presses have provision for monitoring , and in some cases controlling, tablet weight variation. This is achieved from measurement of the maximum applied force reached during the compaction of individual tablets.
The equating of tablet weight with compaction force in a multi-station press involves several important assumptions which include:-

- constant die cavity volume between stations
- constant density of feed material
- constant relationship between applied force and absolute volume of solid in the die
- no extraneous signals

Since weight 'M' is obtained from the product of true density 'ρ' and true volume 'V' and

$V = A . H$ (tablet cross-sectional area . height)

we need to establish the equation relating the applied pressure 'P' to 'V'.

The example given in Figure 17 was for a material obeying the "Walker" equation:-

$$1/(1 - E) = k_1.\text{Log } P - k_2 \quad (6)$$

In Figure 17 is shown the effect of changes in punch length on the interpretation of the resultant force, by the instrumentation. The right hand ordinate scale is the deviation (in μm) of the tooling from a nominal value. In the example illustrated by the arrowed lines, a deviation of 12.7 μm in punch length (the maximum allowed) results in a change of force response (abscissa) of 'x' from the nominal of 250 MPa. When converted by the Walker equation (dotted line) it is interpreted by the instrumentation (left hand ordinate) as a weight change of 0.5%.

In a worst case scenario where the length of both punches, the bore of the die and the compression roll diameter are all at their upper limit, this would be interpreted by the instrumentation as a 2.25% weight change (see Table III). This emphasises the importance of maintaining press and tooling in good condition when using such instrumentation.

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