Breaking pharmaceutical tablets with a hole: Reevaluation of the stress concentration factor and influence of the hole size

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ABSTRACT

Mechanical strength is an important property for pharmaceutical tablets. Its study using the theory of linear elastic fracture mechanics has been introduced in the pharmaceutical field through the Brittle Fracture Index (BFI). This index is based on the stress concentration factor (SCF) and contradictory results have been published in the pharmaceutical literature about the value of the SCF during the diametral compression of a disc with a hole. In this work, thanks to the use of numerical simulations (FEM) and analytical results, the value of the SCF was proved to be equal to 6. The result was also applicable for the case of the flattened disc geometry that was introduced in a previous work. The value of the SCF is found to be nearly independent of the hole size if the ratio between the hole and the tablet diameters was lower than 0.1. Nevertheless, experimental results presented in this paper show that the load needed to break a compact varies with the hole size. This influence is due to the change in the stress distribution around the hole when the hole size is changing. Criteria such as the average stress criterion, which takes into account the stress distribution, made it possible to explain the influence of the hole on the breaking load.

Keywords:
Tablet
Pharmaceutics
Brazilian disc
Failure
FEM

1. Introduction

The tablet is the most common pharmaceutical form. As any pharmaceutical product, it must fulfill a number of requirements. Among them, the mechanical strength plays an important role. This property assures the integrity of the tablet during all the processes from the ejection from the tablet press to the dispensation to the patient (coating, blistering, etc.). Moreover, the mechanical strength is also linked with classical issues like capping, lamination or chipping that arise during manufacturing of the tablet. A good quantification of the mechanical behavior of a tablet is thus of great importance from an industrial perspective.

The classical approach in the pharmaceutical field for the characterization of the mechanical strength of tablets is the use of breaking tests. The common practice is to use the diametral compression test to calculate the tensile strength. As the tablet is made from a compression of powders, the final material is a porous solid which intrinsically contains structural defaults. It is known that a structure can fail at loads that are far below the value that would be necessary to break the same structure without defect [1–3]. As it is sometimes difficult to correctly quantify the defects in a structure, the common practice is to insert a defect of controlled size [4]. In that case, continuous mechanics can be assumed as well as the Linear Elastic Fracture Mechanics (LEFM) formalism. It leads to the concepts of stress concentration factors and to fracture toughness [5]. In all the following text, the Stress Concentration Factor (SCF) due to a defect will be denoted K_t and will be calculated as:

$$K_t = \frac{\sigma_H}{\sigma_0} \quad (1)$$

where σ_H is the maximum tensile stress near the hole and σ_0 is the stress which would prevail in the structure if no defects were present.

This approach was introduced in the pharmaceutical field by Hiestand et al. [6]. The purpose was to characterize the tendency of a compact to laminate. According to Hiestand et al., some materials with a "high propensity for brittle fracture may undergo brittle fracture from points of very high stress concentration such as the die edge". They classified the materials according to their propensity to relieve stress at sites of stress concentration (i.e. not to propagate cracks). This propensity can be estimated by inserting a well-defined defect in the structure of the compacts for which it is easy to calculate the stress concentration factor. They chose to insert a cylindrical hole, then they defined a Brittle Fracture Propensity or Brittle Fracture Index (BFI) for a product. This index was calculated by using the tensile strength of

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compacts with (σ_{T0}) and without (σ_T) a central hole using the following equation:

$$\mathrm{BFI} = \frac{1}{2}\left(\frac{\sigma_T}{\sigma_{T0}} - 1\right) \quad (2)$$

This equation is based on the assumption that the stress concentration factor around a hole is equal to 3, which is true for an infinite plate in tension [7]. It is also worth noting that σ_{T0} is an apparent tensile strength which is calculated with the same equation as σ_T. σ_{T0} is then not the real stress at the hole edge. For a perfectly brittle material, the SCF should thus take a value of 3, as σ_{T0} is 1/3 of the real value of the stress near the hole. In this case the BFI should thus take the value of 1. In their work Hiestand et al. used holed square compacts.

The Hiestand's approach was later applied to round compacts by Roberts and Rowe [8]. They confirmed that differences on the BFI can be observed depending on the products and on its known mechanical behavior. They still considered that the SCF was 3 even in the case of round compacts submitted to diametral compression.

More recently, Podczeck and Newton [9] published an article in which they criticized the two previous studies. They raised two main criticisms. First they stated: "The use of the same equation to derive the tensile strength of a compact with or without a central hole is fundamentally incorrect, as the stress distributions in the two systems are not the same". To our point of view, this criticism misses the point of the BFI equation. In fact, Hiestand et al. included the stress concentration factor in the BFI, and assumed, as explained above, that σ_{T0} is only an apparent tensile strength and not the real value of the stress at the neighborhood of the hole. Using the real value of the tensile stress taking into account the SCF in the BFI is missing the point of the equation.

Their second criticism is based on the fact that, in the case of cylindrical tablets, there are analytical solutions proposed in the literature and that were not used by Roberts and Rowe. According to these solutions, the SCF for a cylindrical disc under compression is not 3. Podczeck and Newton presented in their paper the results from Durelli and Lin [10]. Unfortunately, they inverted the values of the maximum compressive and tensile stresses near the hole. They considered that the maximum tensile stress is at $\theta = 90°$ (Fig. 1a) instead of $\theta = 0°$. As a consequence, the stress concentration factor is found equal to 10, which is, as we will see later, incorrect.

This brief review of the pharmaceutical literature on the breaking of compacts with a hole clearly indicates that further clarification is needed. Furthermore, several studies indicate that the interpretation of the results of the Brazilian test are not always straightforward [11,12]. In a previous study, we demonstrated that the use of cylindrical tablets did not make it possible to ensure a central failure during the diametral compression test [13]. The use of a flattened geometry (Fig. 1b) was proposed to measure more accurately the tensile strength of tablets. As the tensile strength of a tablet without a hole is needed for the calculation of the BFI, it would be interesting to see if the flattened tablet geometry could be used in this kind of approach.

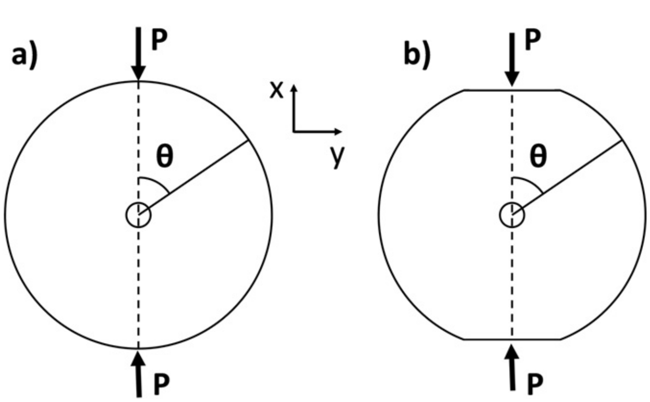

Fig. 1. Schematic representation of the compression of tablets with a hole. P represents the applied load: (a) standard geometry; (b) flattened geometry.

Finally, the only requirement for the hole size mentioned in the previously cited works, is that the dimension of the hole should be small enough compared to the dimension of the tablet [6]. No influence of the hole size is expected if the hole size is small enough. Several values of the ratio between the radius of the hole and the radius of the tablet can be found in the pharmaceutical literature, e.g. 0.067 [8], 0.088 [9] or 0.15 [14]. To our knowledge, only one article in the pharmaceutical field tried to compare BFI obtained with different hole sizes [15]. In this study, no influence of the hole size was found, but the values of the BFI were always very low (lower than 0.17). On the contrary, articles published in other fields indicate that the hole size always influences the load necessary to break a sample [16].

In this study, a reevaluation of the SCF in the case of cylindrical and flattened tablets was performed. It was based on the analytical results of the literature and on FEM simulations. For different products, the effect of the hole size was then further studied and discussed.

2. Material and methods

2.1. Powders

Two different powders were used to produce compacts: anhydrous calcium phosphate (aCP) (Anhydrous Emcompress®, JRS Pharma, Rosenberg, Germany) and spray-dried lactose monohydrate (SDLac) (Flowlac® 90, Meggle, Wasserburg, Germany). To perform the compaction experiments, the products were mixed with 1% (*w*/*w*) of magnesium stearate (Cooper, Melun, France) to minimize friction in the die. The blending was performed at 50 rpm for 5 min using a turbula mixer (Type T2C, Willy A Bachofen, Muttenz, Switzerland). These two products were chosen because they do not show significant plastic deformation during the diametral compression test. Plastic deformation during the diametral compression can make the results difficult to interpret [12].

2.2. Compression

All the compacts were produced using a compaction simulator Styl'one® Evolution (Medelpharm, Bourg-en-Bresse, France). This tableting press is a single station press. It is equipped with force sensors (accuracy 10 N) and the displacements of the punches are monitored with an accuracy of 0.01 mm. In our case symmetrical compaction was used. Two different sets of flat-faced euro B punches were used (ACM, Avilly-Saint-Leonard, France) as already described elsewhere [13]. The first set was round with a diameter of 11 mm. The second set was designed to produce flattened discs (Fig. 1). All the compacts were produced using the same compaction speed (total compression time of about 100 ms). One compression pressure was chosen for each product based on our experience on the products. For SDLac a pressure of 110 MPa was chosen. This corresponds to tablets with a good cohesion but that are still breakable on our device. For aCP a pressure of 150 MPa was used. This pressure gives tablets with a lower cohesion than in the case of SDLac but it also avoids chipping problems at the ejection of the tablet. To avoid any effect due to the thickness (variation of density distribution, etc.), all the compacts manufactured had similar thicknesses around 3.0 mm. The tablet density was calculated using the weight and dimensions of the compacts. The relative densities of the tablets were 0.83 for SDLac and 0.61 for aCP.

2.3. Tablet machining

In the pharmaceutical field, two techniques were used to insert holes in the compacts, either using specially designed punches [6,8,9,14] or making holes using a drill [15]. In the present study, the last method was used. A conventional lathe LM 450 (LEFEBVRE-MARTIN, Moulins, France) was used at a speed of 1600 rpm. Three drill diameters (0.5, 0.8 and 1 mm) were used to make the holes. The tablets were maintained using a specially designed polymeric holder obtained by 3D printing. Furthermore a polytetrafluoroethylene sheet was used to limit friction between the tablet and the piece holder. To avoid defects at the back of the tablet during machining holes, two tablets were placed together and only the upper one was finally used for the experiment.

After the machining process, the tablets were carefully observed under a Scanning Electron Microscope (SEM) TM3000 (Hitachi, Tokyo, Japan). Examples of SEM images are presented in Fig. 2. Observations did not highlight crack initiation neither around the hole nor on the internal surface of the hole. This technique was thus considered suitable for the present study.

2.4. Mechanical characterization

The diametral compression test was performed using a TA.HDplus texture analyzer (Stable Micro Systems, Surrey, United Kingdom). Compacts were compressed between two flat surfaces at a constant speed of 0.1 $mm \cdot s^{-1}$ with an acquisition frequency of 500 Hz. For each tablet set, ten compacts were broken.

2.5. FEM simulation

For the simulation of the diametral compression, a 2D-Shell model was used and the compact was considered as an elastic material. The value of Young's modulus ($\boldsymbol{E}$) and Poisson's ratio ($\boldsymbol{\nu}$) for the simulation were chosen depending on the compact. Their determination for each set of tablets (SDLac at a relative density of 0.83 and aCP at a relative density of 0.61) was done as described elsewhere [17]. The values taken were $\boldsymbol{E} = 4.4$ GPa and $\boldsymbol{\nu} = 0.25$ for SDLac and $\boldsymbol{E} = 3.7$ GPa and $\boldsymbol{\nu} = 0.23$ for aCP. The deformation of the platens during the experiment was neglected and the platens were modeled as rigid analytic surfaces. The two opposite forces were obtained by moving the rigid analytic surfaces. The contact between the disc and the rigid analytic surfaces were managed by a penalty law. The numerical simulations were conducted over a quarter of the geometry for symmetry reasons to reduce computation time. In the simulations, the ratio between the inner and the outer radii ranged from 0.045 to 0.55. The same modeling procedure was applied to both geometries. The FEM modeling was performed using Abaqus® Standard software 6.13 (Dassault Systèmes, Vélizy-Villacoublay, France).

3. Results and discussion

3.1. Finite element analysis of the SCF during diametral compression

The stress concentration factor (SCF) K_t, as already defined in the Introduction, depends on the stress field in the structure, i.e. on the stress conditions and on the geometry. The aim of this part is thus to define, based on the literature and on FEM simulations, which value of K_t should be used for the diametral compression of a sample containing a cylindrical hole.

The case of the infinite plate submitted to uniform tension is already well known. If a small circular hole is positioned in the plane, the SCF will take the value of three. This was the value considered by Hiestand et al. [6]. In the same paper, the influence of another stress superimposed in the perpendicular direction was also discussed. It was shown that additional stress led to a slight increase of the SCF which can reach values up to 4 depending on the stress state.

As mentioned by Podczeck and Newton [9], several articles give the solution of this problem in 2D plane stress [10,18–20]. The distributions given by Batista and Usenik [18] were considered in the present study. They calculated a SCF, for different values of the ratio between the radius of the hole and the radius of the disc using the following equation:

$$K_t' = \frac{\sigma_{\theta\theta}}{\left(\frac{2F}{\pi b}\right)} \tag{3}$$

where $\sigma_{\theta\theta}$ is the orthoradial stress, F is the applied force per unit of thickness and b is the disc radius. This equation differs from Eq. (1), because the equation for calculating the stress that prevails in the disc without the hole is [21]:

$$\sigma_0 = \frac{2F'}{\pi D t} \tag{4}$$

where F' is the applied load, t is the thickness of the disc and D its diameter. It can thus be found that:

$$K_t' = \frac{K_t}{2} \tag{5}$$

Consequently, for all the comparisons, the results of Batista and Usenik [18] were multiplied by two to compare the values of K_t properly.

The comparison between the analytical results [18] and those obtained by FEM simulation can be found in Fig. 3. A very good agreement between the two methods was obtained. For small values (<0.1) of the ratio between the inner and the outer radii, the SCF was approximately constant and equal to 6. When the ratio increased, the SCF then also increased which was due to the fact that the size of the hole was no longer negligible compared to the size of the tablet.

In a previous article [13] the use of a flattened tablet to measure the tensile strength was introduced. Numerical simulations on the flattened geometry were thus also performed to see the influence of the flat parts on the SCF. As it can be seen in Fig. 3, the introduction of flat parts in the disc had no significant effect on the SCF for a ratio between the inner and the outer radii between 0 and 0.4. This geometry is thus suitable to calculate the SCF.

As a conclusion for this part, the value which must be considered for the SCF in the case of the diametral compression of cylindrical tablets is 6. It is neither 3 as taken by Roberts and Rowe [8] nor 10 as given by

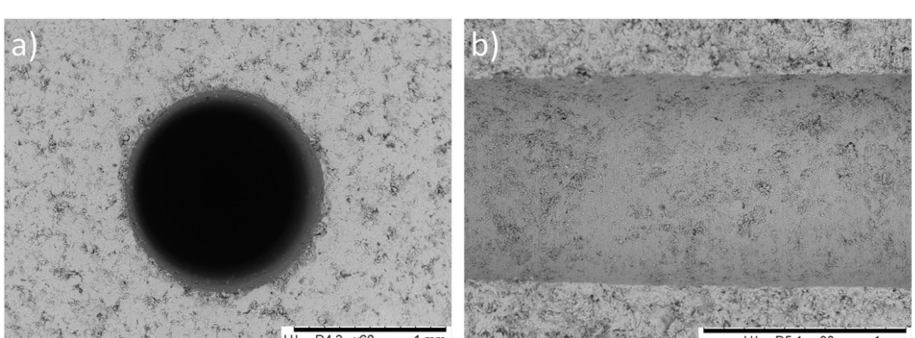

Fig. 2. SEM photograph of a tablet after machining: (a) surface of the tablet and (b) hole internal surface after the breakage of the tablet.

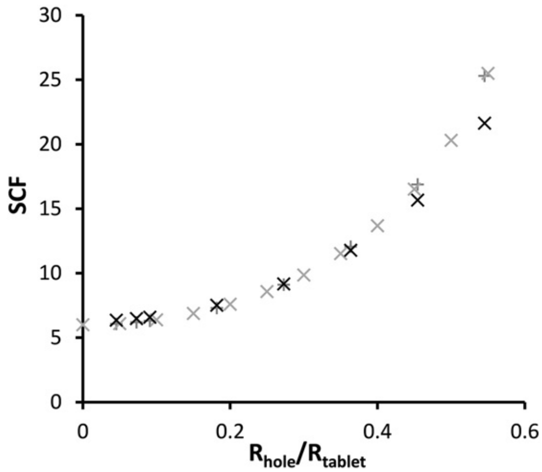

Fig. 3. SCF as a function of the ratio between the hole radius (R_{hole}) and the tablet radius (R_{tablet}): analytical results (×) and FEM results for the standard (+) and flattened (×) geometry.

Podzceck and Newton [9]. This value is nearly independent of the hole size if the hole is small enough compared to the dimension of the tablet. Considering the stresses calculated in Fig. 3, a ratio between the radius of the hole and the radius of the tablet below 0.1 can be taken as criterion. Moreover, this value of the SCF is also usable in the case of flattened tablets.

3.2. Experimental results: diametral compression of flattened discs with and without a hole

For small values of the ratio between the inner and the outer radii (<0.1), the SCF is approximately the same, around a value of six. Hence the value of the maximum tensile stress at the edge of the hole will be the same whatever the hole size is. If we consider a failure criterion based on the maximum tensile stress (i.e. the tablet breaks when the maximum tensile stress reaches the tensile strength) the hole size should not influence the load necessary to break the compact.

The results of the breaking force as a function of the size of the hole for the two sets of compacts studied (SDLac and aCP) can be found in Fig. 4. For each plot, all the tablets used had the same size (diameter = 11 mm and thickness = 3 mm). It is thus possible to compare directly the forces needed to break the compact. Several comments can be made on these results.

Firstly, there was a good reproducibility of the breaking force values for the tablet with a hole. This is another important sign that using a drill to make the hole in the tablets was a good technique that did not damage the tablets.

Secondly, the force necessary to break the compact with a hole was lower than the force needed to break the compact without a hole. As expected, the introduction of a defect in the structure had a weakening effect which is explained by the SCF. If this result can be considered as obvious, it is worth noting that in their study, Podzceck and Newton [9] strangely found for Lactose monohydrate, that the load to break a tablet with a hole was superior to the one to break an intact tablet. As a consequence, they obtained negative BFI values (see Tables 1 and 3 in their publication).

Thirdly, the force needed to break the compact was dependent on the hole size, even when the ratio between the hole radius and the tablet radius was lower than 0.1. As a consequence if the BFI is calculated according to Eq. (2), different values are found for each hole size (Table 1).

The value of the maximum tensile stress is thus not sufficient to predict the failure of the compact. This aspect is already well known in the literature outside the pharmaceutical field and is discussed in the following sections.

4. Discussion

4.1. Hole size effects on the stress distribution

As previously seen in Fig. 3, for small values (<0.1) of the ratio between the inner and the outer radii, the SCF is approximately constant, around a value of six, and hence the value of the maximum orthoradial stress $\sigma_{\theta\theta}^{max}$ on the edge of the hole does not depend on the hole size. Nevertheless, even if $\sigma_{\theta\theta}^{max}$ is the same, the hole size has an impact on the stress distribution [16,22,23]. These stress distributions can be easily obtained using FEM simulation. They are presented, in the case of the flattened disc with a hole, in Fig. 5. The external diameter of the flattened disc was 11 mm and three hole diameters were studied: 0.5 mm, 0.8 mm and 1 mm. The applied force P, on the rigid analytic surface was set to 100 N (which is a typical value for this kind of experiments, see Fig. 4). As expected by the linear elastic theory, the values of Young's modulus and Poisson's ratio have no significant effect on these distributions [7]. The case of the flattened disc without a hole was also modeled. The results are presented in Fig. 5. Two comments can be made about these results.

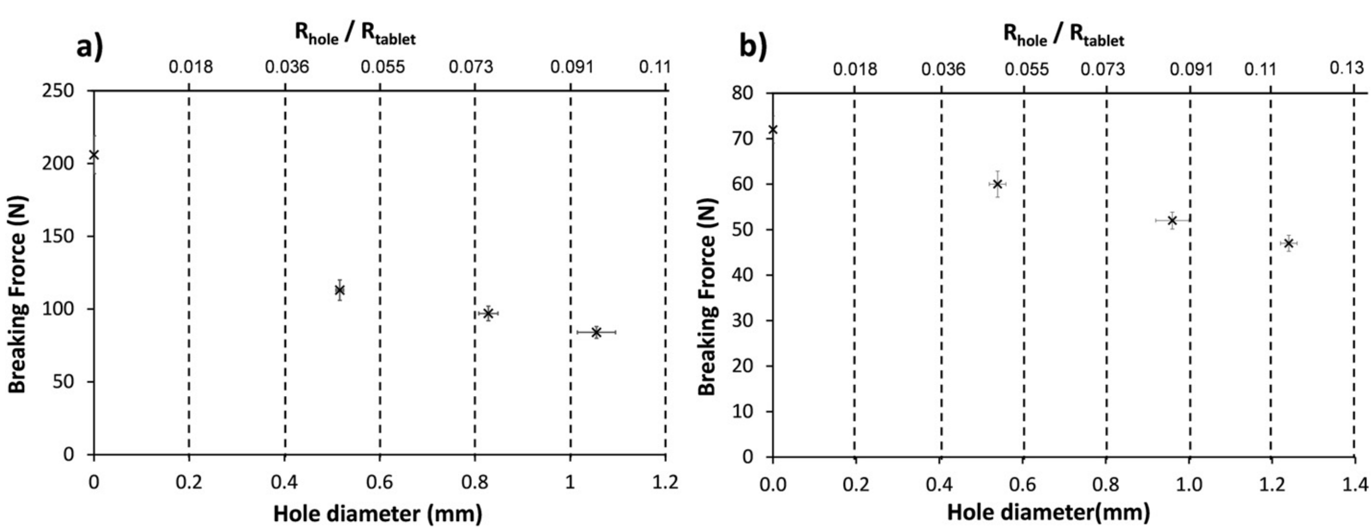

Fig. 4. Breaking force in the diametral compression test, as a function of the hole size: (a) SDLac and (b) aCP. The upper axis represents the ratio between the hole radius (R_{hole}) and the tablet radius (R_{tablet}).

Table 1
Values of the BFI for different hole sizes.

Drill diameter	BFI for aCP	BFI for SDLac
0.5	0.10 ± 0.01	0.41 ± 0.04
0.8	0.19 ± 0.01	0.56 ± 0.05
1	0.27 ± 0.02	0.72 ± 0.06

First, sufficiently far from the hole, the stress state in the disc with a hole is the same as the stress state in the disc without a hole. The differences in distribution are only significant in the first 800 μm from the hole edge. Secondly, although the SCF is the same at the edge of the hole for all hole sizes, the stress distribution width increases with the hole size. This difference in distribution is responsible for the influence of the hole size on the breaking load of the tablet. To take this effect into account, the failure criterion must not be only based on the value of the maximal stress but also on the stress distribution.

4.2. Failure criterions based on stress distribution

According to Whitney and Nuismer [16], "the concept of determining the strength of a brittle material from the maximum stress at a single point is questionable, especially when the maximum stress is highly localized". They have therefore proposed two related approaches for predicting the strength of laminated composites containing discontinuities, which take into account the hole size effect on the stress distribution. In fact, if a larger volume of material is subjected to a high stress in the case of the plate containing the larger hole, the probability of having a large flaw in the highly stressed region is greater, resulting in a lower average strength for this plate [1,16].

4.2.1. Point stress criterion

Based on these general considerations, Whitney and Nuismer proposed a first criterion that is classically called the point stress criterion [16]. They assumed that "failure occurs when the stress over some distance away from the discontinuity is equal to or greater than the strength of the unnotched material". They further assumed that this characteristic distance, d_o, should be a material property independent of stress distribution. This dimension represents the distance over which the material must be critically stressed in order to find a sufficient flaw size to initiate failure. The so-called point-stress criterion is given by:

$$\sigma_{yy}(a + d_0, 0) = \sigma_0 \qquad (6)$$

where $\sigma_{yy}(x,y)$ is the normal stress parallel to the y-axis (Fig. 1), σ_0 is the unnotched plate strength and a is the hole radius. According to Timoshenko [7], the stress distribution around the hole in an infinite plate with the origin of an x-y axes system at the center of the hole is given by:

$$\frac{\sigma_{yy}}{\overline{\sigma}} = 1 + \frac{1}{2}\left(\frac{a}{x}\right)^2 + \frac{3}{2}\left(\frac{a}{x}\right)^4 \qquad (7)$$

where $\overline{\sigma}$ is a uniform tensile stress applied parallel to the y axis at infinity and a and σ_{yy} are as defined above. Using this equation, the point stress criterion can be written as:

$$\frac{\sigma_N}{\sigma_0} = \frac{2}{\left(2 + \xi^2 + 3\xi^4\right)} \qquad (8)$$

where σ_N is the plate notched strength and

$$\xi = \frac{a}{a + d_0} \qquad (9)$$

Eq. (7) is no more useable in the case of the flattened holed disc. The study of Battista and Usenik [18] showed also that, in the problem of the holed disc, the analytical solution is complex. The problem in the present study is also slightly different from the one of Battista and Usenik as the disc is flattened. So, instead of using theoretical equations, the stress distribution obtained by a finite element analysis was used. The distributions were fit to the equation:

$$f\left(\frac{a}{x}\right) = b_0 + b_1\left(\frac{a}{x}\right)^4 + b_2\left(\frac{a}{x}\right)^5 = \frac{\sigma_{yy}}{\overline{\sigma}} \qquad (10)$$

with $b_0 = 0.145$, $b_1 = 0.28482$ and $b_2 = 0.52228$.

In the case of an unnotched plate, the stress in the plate has the same value as the applied stress. This is no longer true for the present geometry. Nevertheless, contrary to the case of the conventional disc, for the flattened disc, the load is applied on a flat surface with a known surface area. It is thus possible to calculate the applied stress $\sigma_{applied}$. This stress is linked with the maximal tensile stress in the tablet σ through the following relation:

$$\sigma = \gamma\,\sigma_{applied} \qquad (11)$$

where γ is a constant. This constant was calculated using the FEM simulations. In the case of the notched compact, this coefficient γ is close to 1, whatever the size of the hole and in the case of unnotched compacts the value was 0.145.

So Eq. (8) becomes:

$$\frac{\sigma_{applied}}{\sigma_{0\ applied}} = \frac{0.145}{f\left(\frac{a}{a + d_0}\right)} = \frac{F_{applied}}{F_{0\ applied}} \qquad (12)$$

with $F_{applied}$ the force to break the compact with a hole and $F_{0\ applied}$ the force to break the tablet without a hole.

To apply the criterion, the methodology presented by Whitney and Nuismer [16] was used, i.e. drawing the force ratio from Eq. (12) as a function of the radius of the hole for different values of d_0. Comparison between theoretical results determined from Eq. (12) and experimental data for two products (SDLac and aCP) is shown in Fig. 6 for several values of d_0. The obtained comparison is clearly similar to the results shown by Whitney and Nuismer in their study [16]. For SDLac, $d_0 = 0.13$ mm is correct for the small hole data and $d_0 = 0.18$ mm is better suited for the large hole data. Finally, $d_0 = 0.155$ mm represents all hole sizes reasonably well. The same logic can be applied to aCP and a mean value of 0.34 mm gives a correct representation for all the hole sizes.

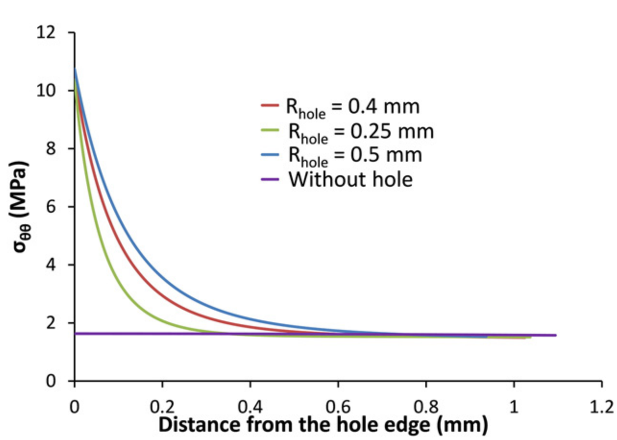

Fig. 5. Numerical modeling (FEM) of the orthoradial stress along the loading diameter for various hole sizes.

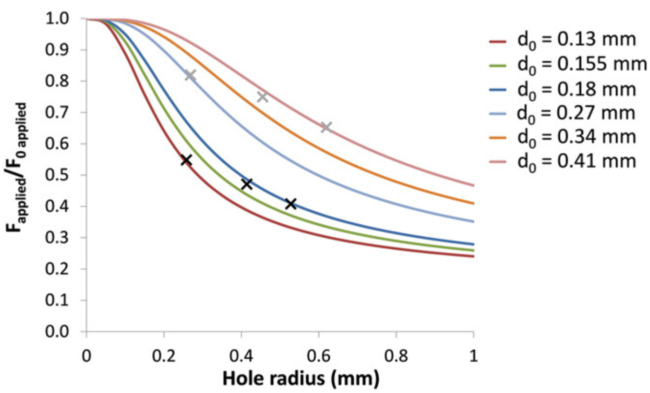

Fig. 6. Application of the point stress criterion. The graph represents the ratio between the force needed to break a compact with a hole and the force needed to break a compact without a hole as a function of the hole radius. Continuous lines are obtained according to Eq. (12) for several values of d_0. Marks represent the experimental values: (×) SDLac and (×) aCP.

4.2.2. Average stress criterion

Nuismer et al. developed a second criterion called the average stress criterion [16,22,23]. In this approach, they assumed "that failure occurs when the average stress over some distance, a_0, equals the unnotched laminate strength" [16]. Again, the critical distance is assumed to be a material property independent of stress distribution. The physical argument for their approach is "in the assumed ability of the material to redistribute local stress concentrations". Thus according to Whitney and Nuismer [16], a_0 could be considered as a first order approximation to the distance ahead of the discontinuity across which failure has taken place. The so-called average-stress criterion takes the form:

$$\sigma_0 = \frac{1}{a_0} \int_a^{a+a_0} \sigma_{yy}(x,0)dx \tag{13}$$

Considering Eqs. (10) and (13), Eq. (12) becomes:

$$\frac{\sigma_{applied}}{\sigma_{0\ applied}} = \frac{0.145}{\frac{1}{a_0}\int_a^{a+a_0} f\left(\frac{a}{x}\right) dx} = \frac{F_{applied}}{F_{0\ applied}} \tag{14}$$

To apply this criterion, the same kind of approach presented above for the point-stress criterion was used. Fig. 7 shows the theoretical results as determined from Eq. (14) and the experimental results for both products. A value of $a_0 = 0.51$ mm was suitable to explain the experimental values obtained for SDLac. For aCP, $a_0 = 1.95$ mm was found. In each case, the experimental points for the different hole sizes nicely follow the curves. As found by Whitney and Nuismer in the original study [16], the average stress criterion is better suited than the point stress criterion to predict the influence of the hole size on the strength of pharmaceutical tablets.

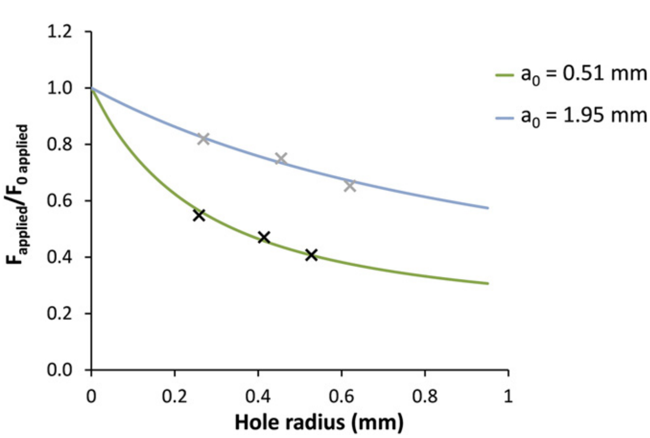

Fig. 7. Application of the average stress criterion. The graph represents the ratio between the force needed to break a compact with a hole and the force needed to break a compact without a hole as a function of the hole radius. Continuous lines are obtained according to Eq. (14) for several values of a_0. Marks represent the experimental values: (×) SDLac and (×) aCP.

5. Conclusion

As explained in the Introduction, the use of pharmaceutical tablets with a hole was first introduced by Hiestand et al. to characterize the brittle propensity of tablets using the BFI [6]. The main drawback of the approach was the use of a stress concentration factor of 3, which is no longer valid in the case of a disc submitted to a diametral compression. Using the theoretical calculations from the literature along with numerical simulations, we saw that, if the ratio between the hole size and tablet size is lower than 0.1, the stress concentration factor was in fact equal to 6. This value was also true for the flattened disc geometry used in this study. The main consequence is that, using the classical equation of the BFI (Eq. (2)), the upper limit is no longer 1 but 2.5. Nevertheless, this does not change fundamentally the philosophy of the use of the BFI which could thus still be used to compare products either in its original formulation or corrected by a factor 2.5.

Nevertheless, the hole size has an influence on the stress needed to break the tablet, even if it is small and if the SCF is constant. This means that the stress value cannot be considered alone and that the stress distribution must be taken into account. It was demonstrated that the average stress criterion, which takes into account the stress distribution, was well suited to represent the weakening of the tablet when the hole size increased.

This size effect cannot be neglected and to be accurately compared, the results of strength of pharmaceutical tablets with a hole must be performed with constant hole size to tablet size ratios.

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