# Re-evaluation of the diametral compression test as a rupture test for pharmaceutical tablet: insertion of flat ends and defects of controlled size

**B. CROQUELOIS[a], J. GIRARDOT[b], J-B. KOPP[c], P. TCHORELOFF[d], V. MAZEL[e]**

a. Univ. Bordeaux, CNRS, Bordeaux INP, Arts et Métiers ParisTech, I2M, UMR 5295, F-33000 Bordeaux, France, Benjamin.croquelois@u-bordeaux.fr
b. Arts et Métiers ParisTech, Univ. Bordeaux, Bordeaux INP, I2M, UMR 5295, F-33000 Bordeaux, France, jeremie.girardot@ensam.eu
c. Arts et Métiers ParisTech, Univ. Bordeaux, Bordeaux INP, I2M, UMR 5295, F-33000 Bordeaux, France, jean-benoit.kopp@ensam.eu
d. Univ. Bordeaux, CNRS, Bordeaux INP, Arts et Métiers ParisTech, I2M, UMR 5295, F-33000 Bordeaux, France, pierre.tchoreloff@u-bordeaux.fr
e. Univ. Bordeaux, CNRS, Bordeaux INP, Arts et Métiers ParisTech, I2M, UMR 5295, F-33000 Bordeaux, France, vincent.mazel@u-bordeaux.fr

## Abstract :

*Mechanical strength is an important property for pharmaceutical tablets. It is classically measured, in the pharmaceutical field, using the diametral compression test (Brazilian test). Nevertheless, in its classical form, due to small contact area between the tablet and the platens, the failure could occur in tension away from the center which would invalidate the test and the calculation of the tensile strength. In this study, the flattened disk geometry was used as an alternative to avoid contact problems. Both numerical simulation (FEM) and high speed video acquisitions during the test were used to confirm that the use of perfectly cylindrical tablets does not make it possible to initiate the crack at the center of the tablet, contrary to the flattened geometry.*

*As a pharmaceutical tablet is formed from powder compression, the final material is a porous solid which intrinsically contains structural defects which leads to the Stress Concentration Factor (SCF) concepts. These defects are difficult to characterize. In order to study the influence of the defects on the failure behavior, it's thus a common practice to insert defects larger in size than the defects intrinsically present in the material. The SCF was studied using numerical simulations (FEM) and analytical results. In the case of a disk containing a central hole and submitted to the Brazilian test, the value of the SCF was proved to be equal to 6. The result was also applicable for the case of the flattened disk geometry. The value of the SCF was found nearly independent of the hole size if the ratio between the hole and the tablet diameter 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. It was therefore decided to transpose to our problem, criteria taking into account the supposed capacity of the material to redistribute the local stress concentrations. These criteria commonly referred to as "point-stress" and "average-stress", defined in the literature about composite materials, have been successfully applied to the case of the breaking of the pharmaceutical tablet.*

**Keywords : Rupture, Pharmaceutical tablet, Brazilian test, Defects**

# 1 Introduction

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 properties is guarantying the integrity of the tablet from the ejection from the tablet press to the dispensation to the patient. Moreover, the mechanical strength is also linked with classical issues that arise during the manufacturing of tablet like capping, lamination or chipping. 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 (also known as Brazilian test) to calculate the tensile strength. This test was developed during the 40's to study the mechanical strength of concrete cylinders [2]. It measures the tensile strength in an indirect manner when direct tensile tests are difficult to perform due to the mechanical properties of the tested material. Firstly used for concrete or rocks, it was introduced, during the 60's for the characterization of pharmaceutical tablets [22, 23]. The cylindrical shape is indeed easy to obtain when performing die compression and the test is thus well suited for tablets. Nevertheless, as mentioned before, the diametral compression test is an indirect test. A cylindrical sample is submitted to a compressive force along its diameter by diametral compression between two flat platens. This promotes the development of tensile stresses at the center of the compact. These tensile stresses are supposed to cause the failure. Then, by supposing an elastic behavior of the compact and by using the elastic theory, in a 2D plane stress, it is possible to prove that the maximum tensile stress is located at the center of the compact and is given by:

$$\sigma = \frac{2F}{\pi D h} \qquad (1)$$

where $\sigma$ is the maximum tensile stress, F is the applied force and, D and h are respectively the diameter and thickness of the cylinder. Thus, considering a failure criteria based on the maximum principal stress, the tensile strength is calculated by substituting, in Eq. (1), the force that caused the failure. However the main problem of this test geometry is the contact in the loading area. The contact area between the platens and the cylinder is very small, and it promotes the development of high stresses. If the contact is too small, the failure could be caused by shear effects in this area, leading thus to incorrect failure pattern.

Among the solutions to increase this contact, the flattened Brazilian disk was proposed for rocks. It consists in introducing two flat ends to the disk [19]. This technique has the advantage of introducing a well-defined and quantified contact area between the platens and the tablet. By choosing the correct contact surface, it should thus be possible to suppress the problem of shear. In the case of pharmaceutical tablets, by designing tools with the proper shape, it is easy to produce flattened tablets.

In addition, the pharmaceutical tablet is formed from powder compression. The final material is therefore a porous solid which intrinsically contains structural defects. It is well known that the presence of defects leads to a weakening of the structure [1, 3], due to stress concentrations at the local level. Since it is sometimes difficult to correctly quantify defects in a structure, it is common practice to insert defects larger in size than the defects intrinsically present in the material [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), denoted Kt, due to a defect will be calculated as:

$$K_t = \frac{\sigma_H}{\sigma_0} \qquad (2)$$

where $\sigma_H$ is the maximum tensile stress at the hole neighborhood and $\sigma_0$ is the stress which prevailed in the structure without defect submitted to the same mechanical action.

This approach was introduced in the pharmaceutical field by Hiestand and al.[6]. The reason was the characterization of the tendency of a compact to lamination. 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 compacts with ($\sigma_{T0}$) and without ($\sigma_T$) a central hole using the following equation:

$$BFI = \frac{1}{2}\left(\frac{\sigma_T}{\sigma_{T0}} - 1\right) \qquad (3)$$

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 $\sigma_{T0}$ is an apparent tensile strength which is calculated with the same equation than $\sigma_T$. $\sigma_{T0}$ is then not the real stress at hole edge. For a perfectly brittle material, the SCF should thus take a value of 3, as $\sigma_{T0}$ 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 only requirement for the hole size that is mentioned in the pharmaceutical literature is that the dimensions of the hole should be small enough compared to the dimension of the tablet [6]. No influence of the hole size seems expected if the hole size is small enough and 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 [12]. To our knowledge, only one article in the pharmaceutical field tried to compare BFI obtained with different hole sizes [13] . In this study, no influence of the hole size was found, but the values of the BFI were always very low (<0.17). On the contrary, articles published in other fields indicates that the hole size always influence on the load necessary to break a sample [14].

In the first part of this study first part the Brazilian test was studied to understand the influence of the contact area between the sample and the platens. FEM studies were performed to compare the stress and strain distributions inside the compact during the diametral compression for both geometries. Afterwards, a high speed camera was used to locate the crack initiation during the test on both geometries.

In a second part, 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 influence of the hole size was then further studied and discussed.

# 2 Material and methods

## 2.1 Powders

Three different powders were used to produce compacts: anhydrous calcium phosphate (aCP) (Anhydrous Emcompress®, JRS Pharma, Rosenberg, Germany), spray-dried lactose monohydrate (SDLac) (Flowlac® 90, Meggle, Wasserburg, Germany) and granulated lactose monohydrate (GLac) (Tablettose1 80, Meggle, Wasserburg, Germany). To perform the compaction experiments, the products were mixed with 1% (w/w) of magnesium stearate (Cooper, Melun, France) to minimize the frictions in the die. The blending was performed at 50 rpm for 5 min using a turbula mixer (Type T2C, Willy A Bachofen, Muttenz, Switzerland).

## 2.2 Compression

All the compacts were produced using a compaction simulator Styl'one® (Medelpharm, Bourg-en-Bresse, France). This tableting press is a single station press. It is equipped with force sensor (accuracy 10 N) and the displacements of the punches are monitored with an accuracy of 0.01 mm. Two different sets of flat-faced euro B punches were used (ACM, Avilly-Saint-Leonard, France). The first set was round with a diameter of 11 mm and made it possible to obtain round tablets (fig. 1a). The second set was made of punches especially designed to obtain flattened disks (fig. 1b). All the compacts were obtained using the same compaction kinematic (total compression time of about 100 ms).

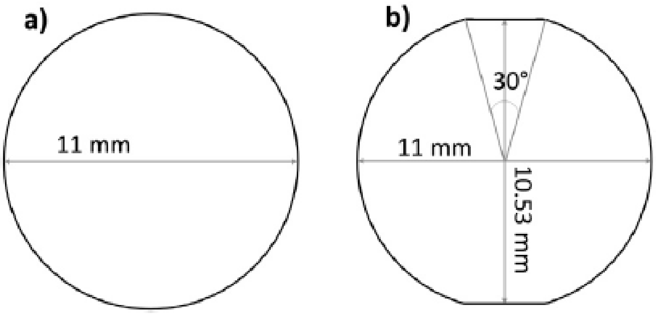

**Figure 1:** Projection of the active surface of the punches for the standard (a) and flattened (b) geometries.

## 2.3 Tablet machining

In the pharmaceutical field, two techniques were be used to insert holes in the compacts: using specially designed punches[6, 8, 9, 12] or making holes using a drill [13]. 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 experiment.

## 2.4 FEM simulation

For all the simulations the compact was considered as an elastic material. The value of Young's modulus and Poisson's ratio for the simulation were chosen depending on the compact. Their determination was done as described elsewhere [15]. The deformation of the platens during the experiment was neglected and the platens were modelled as rigid analytic surfaces. The two opposite forces were obtained by moving the rigid analytic surfaces. The contact between the disk and the rigid analytic surfaces were managed by a penalty law.

For the simulations about the influence of the introduction of flat ends on the compact during diametral compression, 3D simulations were used. Using the symmetry of the system, only an eighth of the compact was modelled.

For simulation on the reevaluation of the stress concentration factor and hole size influence during diametral compression, a 2D-Shell model was used. The numerical simulations were conducted over a quarter of the geometry for symmetry reasons to gain of computation time. In the simulations, the ratio between the inner and the outer radius 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 Influence of the introduction of flats on the compact in a Brazilian test

The first step of this study [11] was to understand the consequence of flattening a compact on the stress and strain distributions during the diametral test by using FEM simulation. The thickness was set to 3.8 mm and the diameter to 11.03 mm to match experimental compacts that were produced and that were used for the following section. The results of the simulations are presented in Figure 2. The displacement was set to obtain an applied force of 100 N on the compact. The results obtained on the standard geometry (Figure 2a and b) are comparable to those presented by Li and Wong [17]. The highest tensile strains are located slightly under the contact point. The maximum tensile stress is located on the surface of the compact and is not centered. The case of the flattened disk is presented in Figure 2c and d. The stress and strain distributions are completely different from those obtained in the standard geometry. Both maximum stresses and strains are now located on the central axis of the compact.

The simulations presented in Figure 2 indicate that the use of a flattened disk is favorable to obtain a crack initiation at the center of the compact as, at this location, both stresses and strains are maximum. On the contrary, for the case of the standard geometry, neither the maximum tensile stress nor the maximum tensile strain is located at the center. The possibility of a fracture initiation away from the center of the compact must be regarded as a possibility. And in this case, the use of Eq. (1) would lead to an under estimation of the tensile strength of the compact.

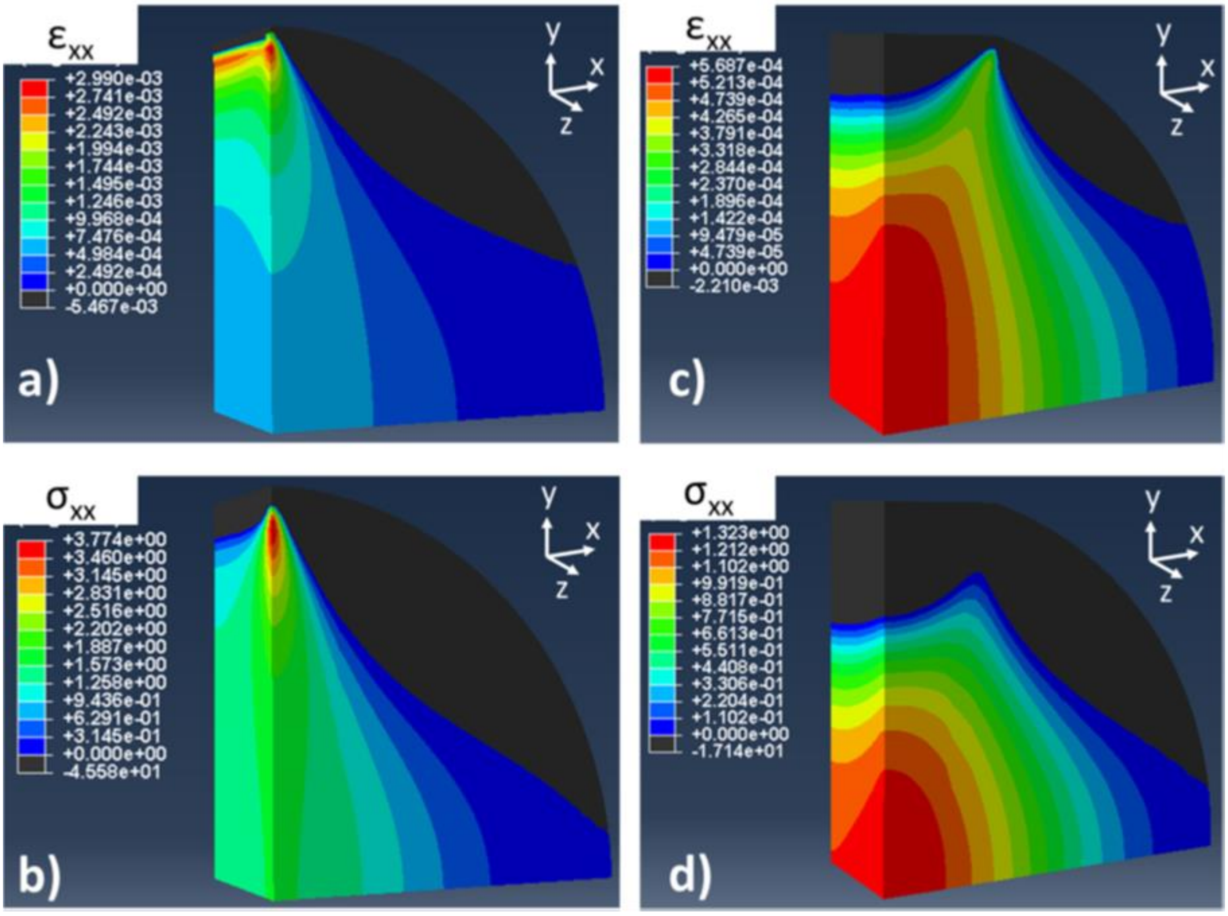

**Figure 2**: FEM simulation of the diametral compression test for the standard (a and b) and the flattened (c and d) geometry. Color scale represents the strain $\varepsilon_{xx}$ (a and c) or the stress $\sigma_{xx}$ (b and d) (in MPa).

The second step of this study was to performed diametral compression tests with high speed video camera. For each product, compacts that corresponded to an apparent tensile strength of 2 MPa using the standard geometry were used. At least four compacts for each geometry were broken and the video was then analysed to detect the crack initiation. For SDLac and Glac, it was possible for both geometry to detect correctly the crack initiation. For aCP, the resolution of the camera at the frame speed used was not enough to be able to locate the initiation properly, especially in the case of the flattened geometry. Figure 3 presents representative examples of crack initiation and propagation for SDLac and GLac for both geometries. For the standard geometry the failure initiates away from the center in the direction of one of the platen before propagating through the whole sample. On the contrary for the flattened geometry, the failure is located at the center at the same distance from each platen. The videos confirm all the results presented above. The crack initiation is away from the center for the standard geometry as predicted by FEM simulation. On the contrary, for the flattened geometry, the failure starts at the center were the stress and strain are maximum. Using the standard geometry to perform the diametral compression of pharmaceutical tablet does thus not make it possible to calculate correctly the tensile strength of the tablet [11].

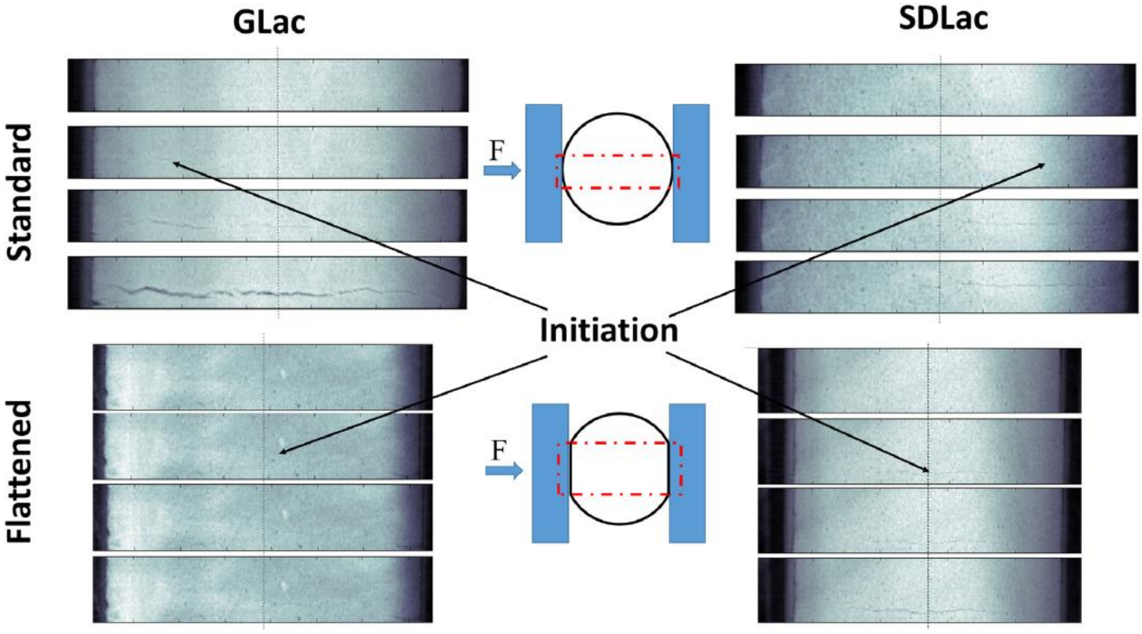

**Figure 3:** High speed video results for GLac (a and c) and SDLac (b and d). a and b represent tests made with the standard geometry and c and d tests performed on the flattened geometry. On each serie of photos, time evolution goes from the top to the bottom.

## 3.2 Reevaluation of the stress concentration factor and influence of the hole size

The stress concentration factor (SCF) Kt was already defined in the introduction. Its value depends on the stress field in the structure, i.e. on the stress conditions and on the geometry. The aim of this part was thus to define, based on the literature and on FEM simulation, which value of Kt 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 in traduced in the plane, the SFC will take the value of three. This value was considered by Hiestand et al [6]. Several articles gives the solution in the case of a circular disk in 2D plane stress [10, 16-18]. The distributions given by Batista and Usenik [16] were considered in the present study.

The comparison between the results obtained by FEM simulation and the analytical results [16] can be found in Figure 4. A very good agreement between the two methods was obtained. For small values (<0.1) of the ratio between the inner and the outer radius, the SCF was approximately constant and equal to 6. When the ratio increased, the SCF then also increased which was due to the fact the size of the hole was no more negligible compared to the size of the tablet. Moreover, as it can be seen in Figure 4, the introduction of flat parts in the disk had no significant effect on the SCF for a ratio of inner and outer radius between 0 and 0.4. This geometry is thus suitable to calculate the SCF. Finally, the value which must be considered for the SCF in the case of the diametral compression of a cylindrical tablets is 6 and not 3 as taken by Roberts and Rowe [8] or 10 as given by Podzceck and Newton [9]. This value is nearly independent of the hole size if this size is small enough compared to the dimension of the tablet, a ratio between the radius of the hole and the radius of the tablet below 0.1 can be taken as criterion. This value was also true for the flattened ring geometry used in this study.

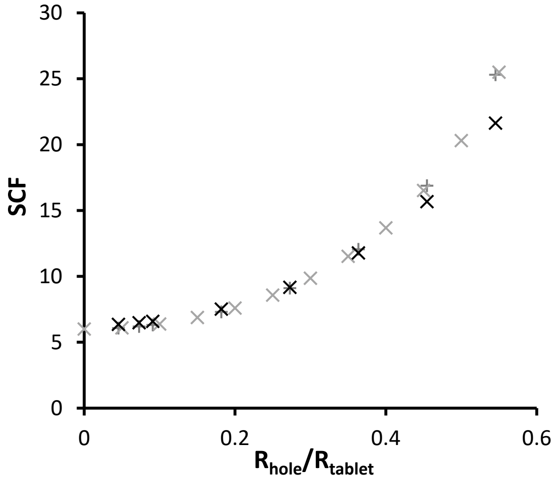

**Figure 4:** SCF as a function of the ratio between the hole radius ($R_{hole}$) and the tablet radius ($R_{tablet}$): analytical results (X) and FEM results for the standard (+) and flattened (**X**) geometry

As a consequence, the value of the maximum tensile stress at the edge of the hole will be the same whatever the hole size. So one might expect that, in this case, the hole size would 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 Figure 5. For each product, all the samples used had the same size (diameter and thickness). It is thus possible to compare directly the forces needed to break the compact. Several comments can be made on this results.

Firstly, there was the good reproducibility of the breaking force values for the tablet with a hole. This is an important proof 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. Thirdly, contrary to what could have been expected considering the SCF, 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.

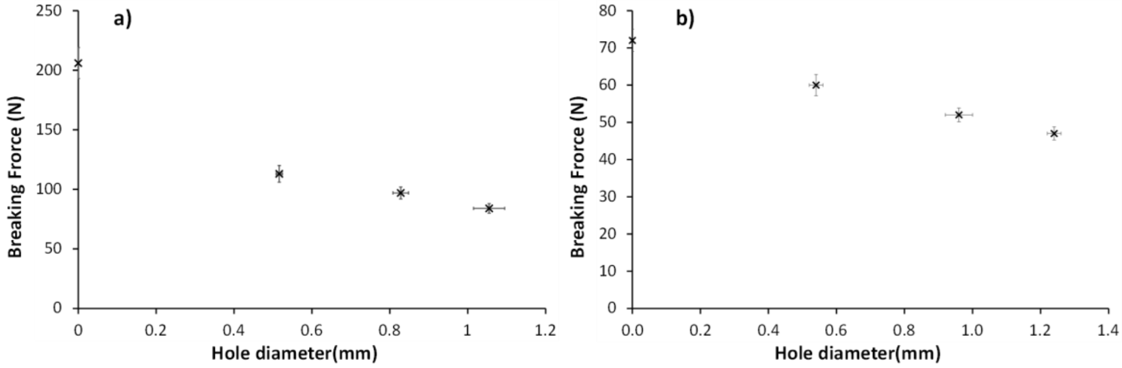

**Figure 5**: Breaking force in the diametral compression test, as a function of the hole size: (a) SDLac and (b) aCP.

The value of the maximum tensile stress is thus not sufficient to predict the failure of the compact. Although the SCF is the same at the edge of the hole for small values (<0.1) of the ratio of inner and outer radius, around a value of six, the stress concentration is much more localized for smallest radius hole [14, 20, 21]. These stress distributions can be easily obtained using FEM simulation. Intuitively, one might expect the sample containing the larger hole to have a lower residual strength than the sample containing the smaller hole. In fact, a larger volume of material is subjected to a high stress in the case of the sample containing the larger hole, the probability of having a large flaw in the highly stressed region is thus greater, resulting in a lower average strength for this sample. In addition, the sample containing the smaller hole has more capability to redistribute the stress, leading to higher average strength than a sample with a larger hole [1, 14]. According to Whitney and Nuismer [14], “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.

Based on these general considerations, these authors proposed a first criterion that is classically called the point-stress criterion [14]. 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:

$$\sigma_y(a + d_0\,, 0) = \sigma_0 \qquad (4)$$

where $\boldsymbol{\sigma_y}$ is the normal stress along the x-axis (Figure 6), $\boldsymbol{\sigma_0}$ is the unnotched plate strength and $\boldsymbol{a}$ is the hole radius. They have use Timoshenko solution [7], for 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. This solution is no more useable in the case of the flattened ring. The study of Battista and Usenik [16] showed also that, in the problem of the ring, the analytical solution is complex. The problem in the present study is also slightly different from the one of Battista and Usenik as the ring is flattened. So, instead of using theoretical equations, the stress distribution obtained by a finite element analysis were used. The distributions were interpolated using the equation:

$$f\left(\frac{a}{x}\right) = b_0 + b_1\left(\frac{\mathrm{a}}{\mathrm{x}}\right)^4 + b_2\left(\frac{a}{x}\right)^5 = \frac{\sigma_y}{\bar{\sigma}} \qquad (5)$$

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

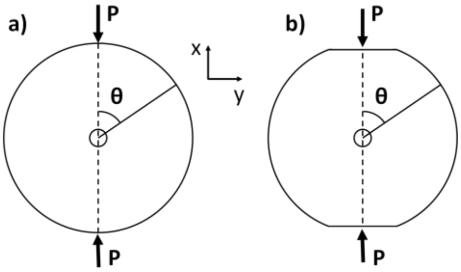

**Figure 6:** Schematic representation of the compression of tablets with a hole. P represents the applied load: (a) standard geometry; (b) flattened geometry.

To apply the criterion, the methodology presented by Whitney and Nuismer [14] was used. Comparison between theoretical results and experimental data for two products (SDLac and aCP) is shown in Figure 7 for several values of $d_0$. The obtained comparison is clearly similar to the results showed by Whitney and Nuismer in their study [14]. For SDLac, $d_0 = 0.13$ mm is correct for the small hole data $d_0 = 0.18$ 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.

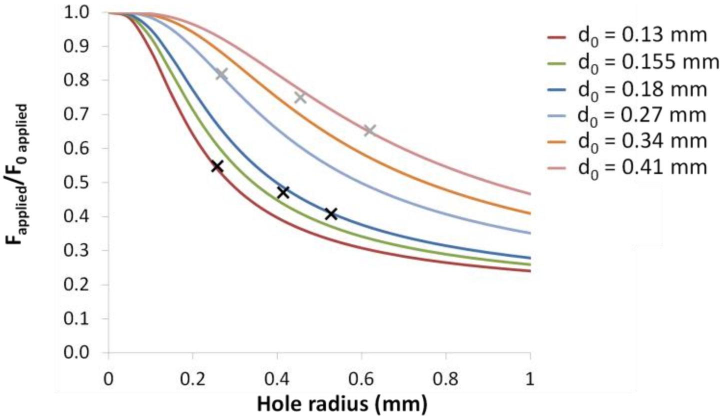

**Figure 7:** Application of the point stress criterion. The graph represents the ratio between the force needed to break a compact with a hole and the force needed to break a compact without a hole as a function of the hole radius. Marks represent the experimental values: (**x**) SDLac and (x) aCP.

Nuismer et al. developed a second criterion called the average stress criterion [14, 20, 21]. In this approach they assumed “that failure occurs when the average stress over some distance, $a_0$, equals the unnotched laminate strength”[14]. 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 [14], $a_0$ 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:

$$\sigma_0 = \frac{1}{a_0} \int_{a}^{a+a_0} \sigma_y(x\,,0)\mathrm{dx} \qquad (6)$$

To apply this criterion, the same kind of approach presented above for the point-stress criterion was used. Figure 8 shows the 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 [14], the average stress criterion is better suited than the point stress criterion to predict the influence of the hole size on the strength of a pharmaceutical tablets.

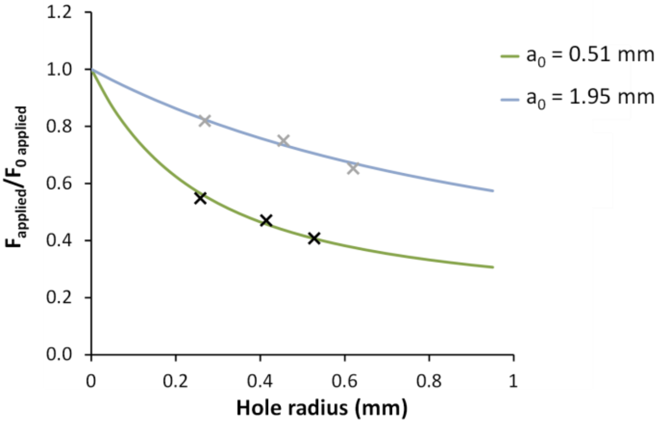

**Figure 8:** Application of the average stress criterion. The graph represents the ratio between the force needed to break a compact with a hole and the force needed to break a compact without a hole as a function of the hole radius. Marks represent the experimental values: (**x**) SDLac and (x) aCP.

# 4 Conclusion

FEM analysis made it possible to emphasize that, when performing the diametral test using the standard geometry, neither the maximum tensile strain nor the maximum tensile stress is located at the center of the compact. Out of center crack initiation must thus be considered as a possibility. On the contrary, when the flattened geometry is used both the maximum tensile stress and strain are located at the center. This geometry is thus more favorable to measure the tensile strength. High speed video experiments made it possible to localize the crack initiation during the tests. It confirmed what was foreseen in the simulations: for the standard geometry, the crack initiation is away from the center whereas centered fracture is obtained for the flattened tablets.

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. Using 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 equal to 6. This value was also true for the flattened disk geometry used in this study. 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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