Mechanical reliability of ceramic packages for active implantable medical devices - The IEC hammer test

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Abstract
Implantable neural prostheses have to fulfill manifold requirements, from the technological side as well as legally. One particular normative demand for active implantable medical devices (AIMDs) which are intended to be implanted in the skull, is withstanding a mechanical impact of 2.5 J, defined by BS EN 45502-2-3:2010 and IEC 60068-2-75:1997. This article shows two computational approaches based on finite element modeling to evaluate the influence of geometrical variations on a brain-computer interfaces' mechanical package stability and the likelihood of withstanding mechanical impact. The presence of a fillet at inner edges (>0.5 mm) as well as a minimum wall thickness of 1 mm could be identified as a mandatory design requirements for axially symmetric packages to avoid extensively high stress levels. Mechanical event simulation (MES) predicted a passing of the hammer test if additional protective material (silicone rubber) is used. This however is postulated by the EN 45502-2-3 standard. The computational findings could be confirmed in a laboratory setup of the impact test.

Key words
IEC pendulum hammer test, implantable device packaging, mechanical reliability, finite element modeling.

I. Introduction
The development of active implantable medical devices (AIMDs) implicates versatile challenges for an engineer. This combined with substantial normative legislations and linked to that further demands or restrictions, the development process becomes even more difficult. On the pure technological side, AIMDs are by definition electrically active, hence packages host sensitive electronic components which need to be protected from the harsh environment at their designated location - the human body. For long-term applications this can only be achieved by putting them into hermetic (gas-tight) packages which are either made of metal or ceramic. Only these materials fulfil the requirement of hermeticity satisfactorily [1]. For a wireless brain-computer-interface (BCI), named Braincon and developed in our laboratories [2], we chose ceramic package to enable infra-red (IR) data communication through the package wall. For the latest technological generation of Braincon, the packaging concept was reduced from a three-part to a two-part assembly, consisting of a lid and a screen-printed base substrate. Reasons for that were, amongst others, improved hermeticity, a better process reliability and miniaturization of the whole device [3].

Similarities to existing cochlear implants can be drawn due to the BCI's intended implantation site at the skull and because of comparable dimensions. Consistently, standards for implantable hearing aids such as BS EN 45502-2-3:2010 [4] can be applied for our BCI too. One particular section of this standard implies that the implant must not be harmed due to mechanical impacts under normal use. In detail, all recently developed devices have to withstand an impact energy of 2.5 J. A suggested test apparatus to apply this energy is the so called pendulum hammer test according to IEC 60068-2-75:1997 [5]. This is a tough challenge for an inherently brittle ceramic package.

In this paper we present two finite element modeling (FEM) strategies to assess the hammer test. Both allow us to predict whether a certain geometrical package design fails or not. The first method is based on a simplified approach to estimate an equivalent force representing the impact. This force is then centrally loaded to the packages' top surface. A rotational symmetric 2D model is set up where geometrical parameters, such as package diameter or wall thickness, can easily be modified without too much computational effort. The second modeling strategy is based on mechanical event simulation (MES); implementing a kinematic striking element (the hammer) which is actually hitting the package. The intention of this second method is an as accurate as possible reproduction of the hammer test. Eventually, to prove the predictability of the simulation models, the performance of two specific Braincon package designs are evaluated in a laboratory setup of the hammer test.

II. Materials, Methods and Modeling

A. IEC hammer test - Background

The cochlear implant standard BS EN 45502-2-3:2010 demands the hammer test for all implants likely to be exposed to mechanical impact. This definitely holds true for all AIMDs implanted in the skull. Specimen under test should be mounted in a test apparatus in accordance with IEC 60068-2-75:1997, Test Eha - the pendulum hammer test (cf. Fig 1). For implants developed after 2013, the impact energy is predefined to 2.5 J and the number of impacts set to one, hence restriking after rebound has to be avoided. The IEC standard defines dimensions for different striking elements and their corresponding height of fall to reach necessary impact energies. Since the closest matching geometry is the 5 J striking element, the height of fall needs to be divided in half, i.e.150 mm, for 2.5 J. The test specimen must be affixed firmly to the supporting surface of the mounting part of the apparatus. Proper mounting has to ensure that the surface which is likely to be exposed to mechanical forces under normal use (implanted) faces the striking element.

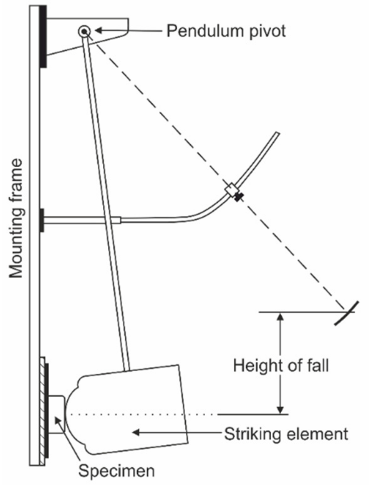

Figure 1: Simplified schematic of the test apparatus for impact tests according to IEC 60068-2-75:1997 [5].

A piece of silicone (3 mm x 100 mm x 100 mm) has to be placed evenly over the implants surface as protective material replacing the skin. For the experimental verification with a laboratory test setup, described at the end of this article, we utilized MED-4940 (Nusil, Carpinteria, CA, USA) which provided the necessary shore-A 40 hardness to manufacture the protective sheet.

B. Sample materials and dimensions

For the Braincon implant we considered Al_2O_3 (alumina) ceramic of 96 % purity for both parts of the package, lid and base substrate. Since lids were manufactured externally, the material specifications vary slightly depending on the manufacturer, as summarized in Table 1. Eventually we decided to have our lids produced by BCE Special Ceramics (Mannheim, Germany), whereas our substrates were bought from CeramTec (Marktredwitz, Germany).

Table 1: Mechanical material properties of some commercial 96% alumina ceramics which were considered for package fabrication.

	BCE A960	Kyocera A-476	CeramTec Rubalit® 708S
Density in g/cm³	3.7	3.7	3.78
Flexural strength in MPa	290	350	400
Vickers Hardness (HV1)	>1400	-	1620
Young's modulus in GPa	380	320	340
Poisson's ratio	0.23	0.23	0.23

Two Braincon packages were manufactured during different stages of our implant development to host different electronics and to fulfill surgical demands. The smaller Braincon was 30 mm in diameter (substrate) and 8 mm high, whereas the subsequently utilized, larger Braincon was 36 mm in diameter, but less elevated (height = 5 mm). The substrates were occupied with several functional screen-printed layers as described in [2]. For example, to obtain a metal frame on which the metalized bottom part of the lid could be soldered to. Wall thicknesses and fillet radius of the lid were 1 mm to provide enough space for the electronics.

Figure 2: Different substrate, lid and package designs for the Braincon implant. Top row: 36 mm screen-printed alumina substrate, lid (ø=27 mm, height h=5 mm, wall thickness d=1 mm, fillet R_f=1 mm) and fully-assembled package. Bottom row: 30 mm substrate, lid (ø=21 mm, h=8 mm, d=1 mm, R_f=1 mm) and corresponding assembly.

C. Structural mechanics modeling

For FEM tools such as Comsol Multiphysics™, the standard simulation environment available at our laboratory, a dynamic scenario, e.g. the impact of a moving object, is difficult to simulate and demands large computational resources. Accordingly, an entire dynamic reproduction of the hammer test including the protective silicone rubber (non-linear material) was not possible. Comsol however allows an easy implementation of parametric sweeps which was desired for comparing geometry variations of possible lid configurations. Because the IEC test only stated an energy of 2.5 J related to a dynamic impact of the striking element on the specimen, it was necessary to determine a suitable equivalent force. This in turn should be fed into static structural mechanics FEM models, which are easy to model in Comsol. For general estimations this equivalent force could be obtained by applying the very fundamentals for conservation of energy. The change in kinetic energy (1) equals the impact energy of 2.5 J since the hammer is accelerated from a resting position with an initial velocity v_i of zero.

$$\Delta E_{kin} = \frac{1}{2}mv_e^2 - \frac{1}{2}mv_i^2 = 2.5J \qquad (1)$$

The mass of the striking element m was listed in the IEC standard and accordingly the velocity at impact v_e could be calculated to *1.7 m/*s. In an impact, kinetic energy is converted to work. The work W, i.e. ΔE_{kin}, necessary to slow down the striking element once it has hit the object is expressed as (2):

$$W = \Delta E_{kin} = F_{im} s \qquad (2)$$

The critical aspect in this consideration was the distance s, which described the necessary path length for the striking element to come to rest during impact. For brittle materials with almost no plastic deformation, but rapid crack formation, s was not easily determined. As an assumption s was chosen to *1.6 mm,* which represents an interim value between a stack of two and a stack of three substrate ceramics (thickness of one substrate equals 0.635 µm). Preliminary impact tests showed that a stack of two was destroyed while only both top substrates cracked for a stack of three. Accordingly the equivalent force F_{im} was calculated to *~1.5 kN*.

For the structural mechanics FEM, a rotational symmetric 2D model was set up according to the schematic in Fig. 3. The lids' radius R (10.5 -13.5 mm), wall thickness d (0.5 - 2.5 mm), height h (5 - 8 mm) and inner fillet R_f (0.01 - 2.0 mm) were parameterized. Material specifications (BCE A960) were taken from Table 1.

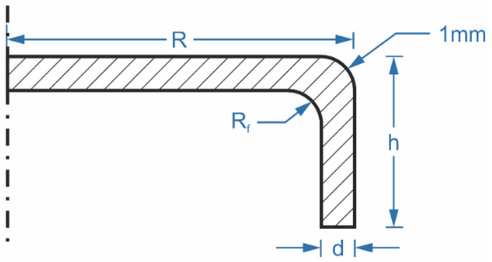

Figure 3: Schematic half section of the lid design incl. adjustable geometry parameters for the FEM. To obtain a three dimensional lid, the structure was rotated around its center line.

The model was meshed with free triangles sized between 0.25 µm and 100 µm. The resolution of the mesh was higher in curvatures and narrow regions.

D. Mechanical event simulation

In contrast to static structural mechanics modeling, an advantage of mechanical event simulation (MES) is the little number of assumptions which have to be made to investigate a specific problem. This is because comprehensive dynamic processes can be implemented and there is no limitation to static phenomena. For the hammer test shown here, the whole dynamic impact could be simulated, while the part of estimating an equivalent force could be omitted. However, the impact between multiple 3D objects increased the computational effort, especially if non-linear materials such as the silicone rubber are involved. The two Braincon designs, small and large, were implemented in a MES, which was conducted using the Software Autodesk Mechanical 2014. 3D CAD models for both Braincon lids and for the 5 J-striking element were designed in Solidworks 2013. The dimensions for the latter were taken from [5]. ASTM steel A572 was chosen for the hammer as specified in the standard. Lid material was again BCE A960. The silicone rubber protective material demanded a non-linear material model such as Neo-Hook, which considered hyperelasticity. The utilized parameters were C_{10} = 0.375 MPa and bulk modulus K = 375 MPa. The density of MED-4940 silicone was 1.12 g/cm³, taken from the material datasheet.

The striking hammer was implemented as a purely kinematic element with a coarse mesh of 5 mm. As the software performs no calculations for kinematic objects, the overall solving time could be reduced by this measure. The brick type mesh of the lid had an average mesh size of 0.6 mm. The protective silicone was also coarsely meshed (element size: 6 mm). The lid was locked with fixed constraints in all spatial directions. The striking element was placed 150 mm above the impact surface and restricted to vertical movement towards the lid only. Subsequently, acceleration was set to gravity for all objects for 300 ms, long enough to cover one impact. The temporal resolution was 10 ms.

E. Experimental verification

A bench-top version of the pendulum hammer test suitable for 2.5 J impact testing was constructed. For approval of specific Braincon designs, the package under test was affixed to the mounting panel (cf. Fig. 1) with adhesive tape. The protective material (silicone rubber) was placed evenly on top of the lid and also fixed to the mounting panel with adhesive tape. As mentioned earlier the protective material was made of Nusil MED-4940, a Shore-A40 two-component silicone which could be injection molded to the desired shape (3 mm x 100 mm x 100 mm). The striking element was moved to its starting position, i.e. height of fall (150 mm) and released. After impact the pendulum was manually held, to avoid rebound. According to the cochlear implant standard, every package and protective material under test was used only once.

III. Results and Discussion

A. Structural mechanics - Geometry variations

The first geometrical configuration which was investigated corresponded to the small Braincon design, since this type of lid was intended to be used for actual implant prototypes. Changing the wall thickness *d* of the lid showed the unsuitability of thin-walled packages. A factor four in stress reduction was found if *d* was doubled (Fig. 4).

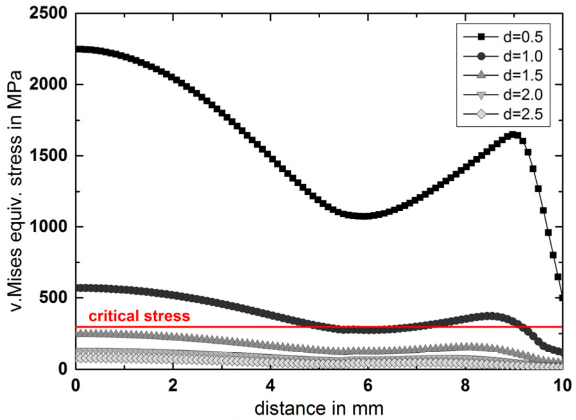

Figure 4: Structural mechanics FEM simulation for the von Mises stress distributed over the lid surface. The wall thickness d of the lid was varied, remaining geometries corresponded to the small Braincon lid design (ø=21 mm). The critical stress threshold (red) marks the flexural strength of the utilized alumina, i.e. 290 MPa.

The maximum stress, localized at the lids' center could be described by an inverse proportional characteristic to the wall thickness. Compared to the flexural strength of A960 alumina, lids of ø21 mm had to have at least walls of 1.5 mm thickness, if this value is considered as a threshold for a breakage. Because of the assumptions which had to be made linked to the FEM, relative changes between individual configurations have to be preferred over the hard numbers.

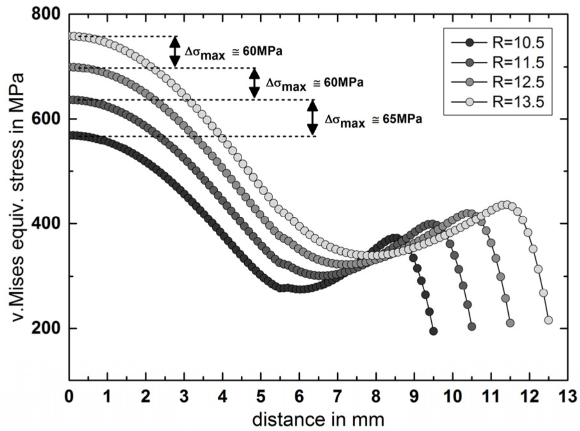

Figure 5: Structural mechanics FEM simulation for the von Mises stress distributed over the lid surface. The radius R of the lid was increased. Wall thickness d was constantly kept to 1 mm, height was 8 mm.

Increasing the radius of the lid from 10.5 mm to 13.5 mm in steps of 1 mm revealed a linear correlation between maximal stress and radius (Fig. 5). The lid was modified to approximate the dimensions of the large Braincon design, except for the height which was kept at 8 mm. For the next calculation, the lids' height *h* was decreased to 5 mm and found to have no noteworthy influence on the overall stress distribution. It was hence kept constant for subsequent analyses. A diminishment of the fillet R_f which is located at the inner top edge showed the creation of stress maxima at the same. For the large Braincon design, a fillet of at least 0.5 mm was found to mark the threshold, where the stress intensity on the top surface exceeded the maximum stress in the fillet (Fig. 6).

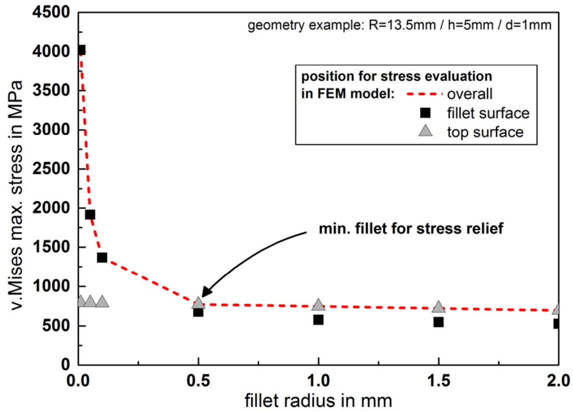

Figure 6: Influence of the inner fillet R_f to the von Mises stress maximum. Distribution on the top surface of the lid is compared to the fillets surface. The geometries correspond to the large Braincon package (cf. Figure 2).

A larger R_f could not significantly reduce the local stress even further, however a fillet of 1 mm showed a higher margin to the surfaces' stress distribution. The influence of the wall thickness for the large Braincon design showed the necessity of at least 2 mm to stay safely below the flexural strength of A960 (Fig. 7).

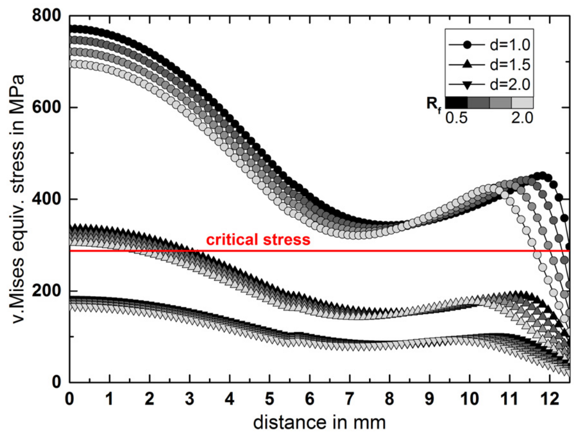

Figure 7: FEM analysis for the large Braincon design. Wall thickness d and fillet Rf were varied. The critical stress threshold (red) again marks the flexural strength (290 MPa) of the utilized alumina A960.

Fig. 8 summarizes two important findings of the geometrical analysis for the large Braincon design. Thin-walled packages (d<2 mm) exhibited too high internal stresses (Fig. 8 - a) and were found unsuitable for passing the hammer test. At least if considered as blank ceramic lids without any impact-cushioning protection. However *d*=2 mm reduces the internal package volume in such a way that complex electronics for neural implants cannot be fit within the available space (Fig. 8 - b). This at least holds true for circuitry realized with discrete electronic components. State of the art ASICs could resolve this issue by increasing the integration density and by providing on-chip solutions for functional demands.

The second important conclusion was the necessity of an internal fillet of at least 0.5 mm. Otherwise the package cracks. Regardless of the wall thickness (Fig. 8 - c).

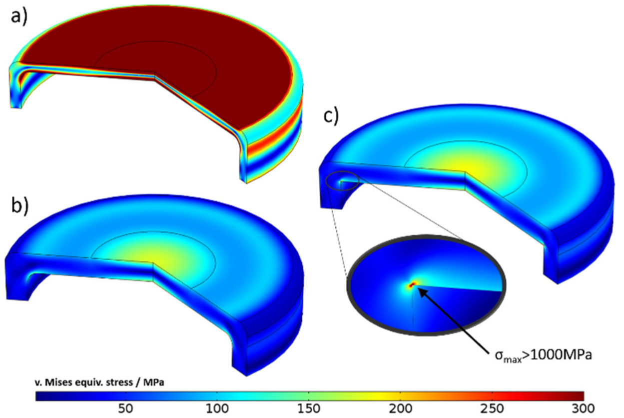

Figure 8: Comparison of the stress distribution for different lid geometries. Dark red indicates an exceeded critical stress. a) Braincon large b) Braincon large, wall thickness doubled (d=2 mm) c) Dimensions as in b) but very small fillet which produces a critical stress peak.

B. Mechanical event simulation

The MES allowed the implementation of the non-linear silicone rubber sheet as protective material, as well as a more accurate description of the whole scenario since the dynamic impact could be fully re-enacted (Fig. 9). Residual stress distributions (Fig. 9 - b, d) were attributable to the surface-surface contact definition between lid and protective material. The peak stresses for both Braincon designs (small and large) were considered uncritical, i.e. safely below the ceramics' flexural strength at the moment of impact (cf. Fig. 9 - c and Table 2) when the protective material was present. A close-up of the stress distribution for Braincon (large design) between blank and rubber protected lid, shown in Fig. 10 - a) and b), respectively, emphasized this finding.

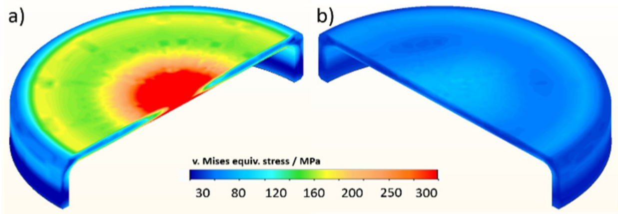

Figure 9: MES simulation. Close-up of the von Mises stress distribution for the large Braincon design. a) Impact on blank ceramic lid. b) Impact on lid protected by silicone skin dummy. For improved visualization, the striking element and silicone dummy are hidden.

Table 2: Influence of the presence of the skin dummy on maximum stress amplitude and position for different lid geometries.

	ceramic lid		ceramic + silicone	
	σ_{max}/ MPa	Position	σ_{max}/ MPa	Position
Braincon lid small	1700	surface / center	35	surface / center
Braincon lid large	2800	surface / center	70	surface / center

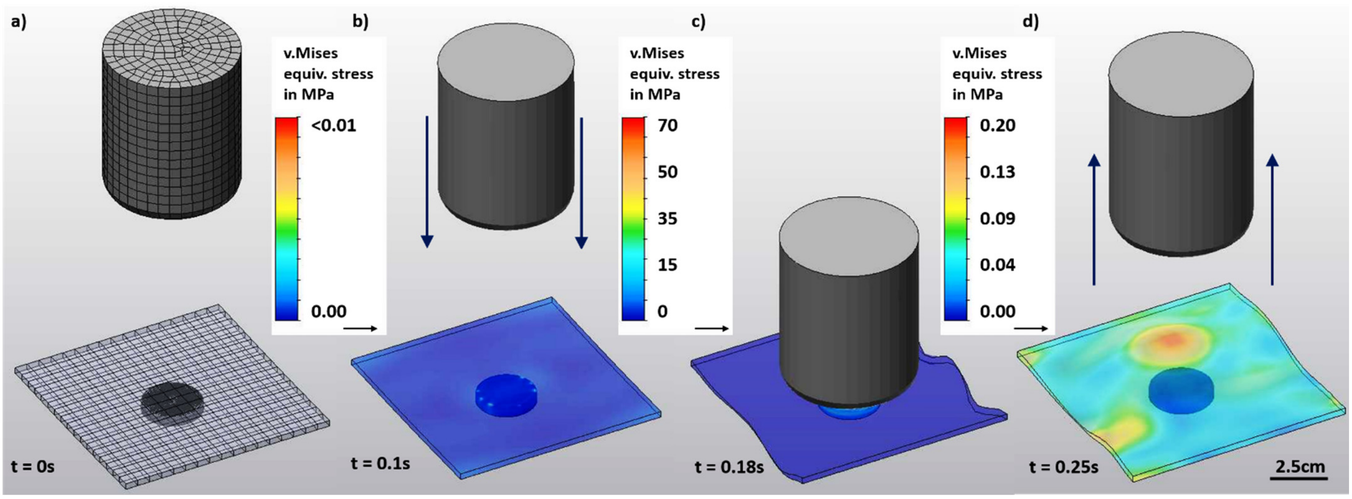

Figure 10: Mechanical event simulation (MES) of the hammer test according to the IEC standard. Example depicting the large Braincon design protected by a 3 mm silicone rubber skin dummy and the resulting von Mises stress distribution. a) Geometrical meshing. b) Condition after one third of the simulation time, i.e. striking element falling towards the lid due to gravity. c) Impact and resulting peak intensities in the lid. d) Rebound of the striking element. Small residual stresses in the silicone due to post-impact movement.

C. *Experimental verification*

The necessity of a silicone rubber protective material, which was discovered in MES, could be verified with our work-bench assembly of the pendulum hammer test. Both Braincon package configurations were crushed by a central 2.5 J impact. The presence of the 3 mm silicone sheet left them unharmed. This fact was confirmed by submersing the packages in water after impact testing. The lack of bubble formation was taken as an indicator for no leaks. The IEC standard demands central impact testing as well as another impact at the packages' weakest spot. As this both positions coincided for an axial symmetric design, the second testing could be omitted.

Recordings of the impact sequence demonstrated failure (Fig. 11) and success (Fig. 12) for passing the hammer test. However the recording was performed with 60fps, hence the moment of impact could not be captured without blurring. A high-speed camera setup was not available at the time of submission of this paper.

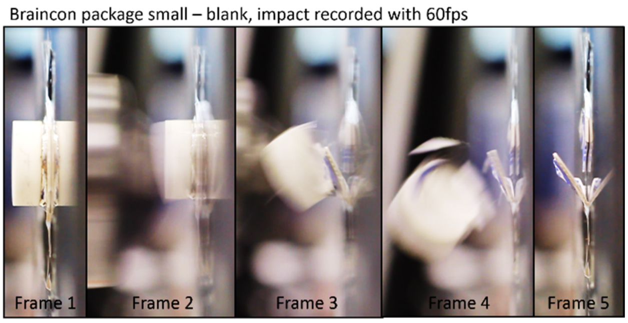

Figure 11: Single frames of a lateral recording of the hammer test for the small Braincon package. No silicone rubber dummy was used.

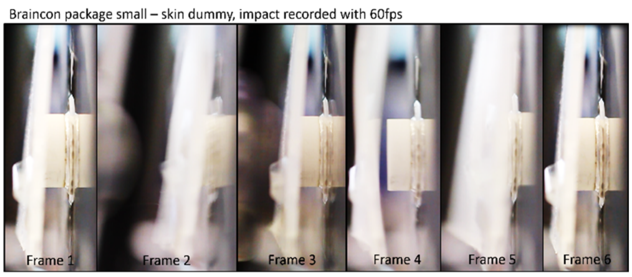

Figure 12: Lateral recording frames of the hammer test for the small Braincon package with silicone rubber dummy between striking element and ceramic.

Tests with the larger Braincon package behaved consistently to the small design and were hence not further illustrated.

IV. Conclusion

Structural mechanics FEM provides an adequate toolbox for investigating the influence of geometrical variations on the mechanical stability and reliability of ceramic implant packages. Important aspects, such as the presence of a fillet at edges or a minimal wall thickness (for our design 1 mm), can be identified beforehand to avoid critical design faults. However, the dynamic scenario of the IEC hammer test cannot be modeled in a way that results obtained from the static models are transferable to decide whether the test can be passed or not. For this decision, FEM combined with MES provides a comprehensive prediction of the whole dynamic impact test. Furthermore, all materials as demanded by the test, such as the protective silicone rubber sheet, can be implemented more easily. Results acquired by MES were hence comparable to experiments conducted in the laboratory, at least for the IEC hammer test. Nevertheless, simulations always represent an approximation of real-world scenarios. How close they actually match depends on the effort of an engineer to what depth a problem will be modeled and on the necessity for a highly complex model. If ceramics with possible material imperfections, varying grain boundaries etc. would be implemented in the model for such a test, the efficiency of the whole effort would be doubtful.

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