Probability of mechanical loosening of the femoral component in high flexion total knee arthroplasty can be reduced by rather simple surgical techniques

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Background: Some follow-up studies of high flexion total knee arthroplasties report disturbingly high incidences of femoral component loosening. Femoral implant fixation is dependant on two interfaces: the cement–implant and the cement–bone interface. The present finite-element model (FEM) is the first to analyse both the cement–implant interface and cement–bone interface. The cement–bone interface is divided into cement-cancellable and cement–cortical bone interfaces, each having their own strength values. The research questions were: (1) which of the two interfaces is more prone to failure? and (2) what is the effect of different surgical preparation techniques for cortical bone on the risk of early failure?

Methods: FEM was used in which the posterior-stabilized PFC Sigma RP-F (DePuy) TKA components were incorporated. A full weight-bearing squatting cycle was simulated (ROM = 50°–155°). An interface failure index (FI) was calculated for both interfaces.

Results: The cement-bone interface is more prone to failure than the cement implant interface. When drilling holes through the cortex behind the anterior flange instead of unprepared cortical bone, the area prone to early interface failure can be reduced from 31.3% to 2.6%.

Conclusion: The results clearly demonstrate high risk of early failure at the cement–bone interface. This risk can be reduced by some simple preparation techniques of the cortex behind the anterior flange.

Clinical relevance: High-flexion TKA is currently being introduced. Some reports show high failure rates. FEM can be helpful in understanding failure of implants.

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1. Introduction

With the introduction of high flexion total knee arthroplasty (TKA), at the beginning of this century, concerns have been raised regarding early aseptic loosening. In the “normal” flexion range TKA, aseptic loosening is the fourth reason for revision of all components after infection, instability and pain [1]. The revision rate for aseptic loosening in standard designs is less than 2% after 7 years [1]. Recent literature reports have shown that high-flexion designs sometimes show much higher revision rates due to femoral component loosening, ranging from 3.6% after 10.9 months up to 21% after 23 months [2–4]. It is thought that during high flexion excessive compressive forces are generated at the posterior femoral condyles, leading to distal shear and anterior tensile forces. This suggests that femoral implant fixation is a more apparent concern in high-flexion designs compared to the standard designs. Radiographs of loose femoral components show radiolucent lines behind the anterior flange. However, other studies report no difference in loosening between standard prosthetic designs and high-flexion designs [5,6].

A finite-element (FE) simulation by Zelle et al. [7], of the well performing Sigma RP-F (DePuy, Leeds) TKA, showed that the anterior flange was most at risk of failure, especially at high flexion angles. That study only simulated the cement–implant interface.

Obviously, in terms of prosthetic loosening, there are two interfaces to consider: the cement–bone interface and the cement–implant interface. Since the anterior flange covers both cancellous and cortical bone, the cement–bone interface can be divided in two; cement–cancellous and cement–cortical bone interfaces. More than 50% of the flange area can cover cortical bone, which has a relatively low interfacial strength [8]. This weak interface can be strengthened by relatively simple surgical preparation techniques such as removal of the periosteum, roughening the cortex and by drilling some small anchoring holes [8]. Strength values of the cement–cancellous bone interface are widely studied [9,10] and are much higher than those of the cement–cortical bone interface. In order to reduce long-term aseptic loosening of high flexion femoral components, the strength-to-stress ratios at both (cement–bone and cement–implant) interfaces.

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behind the anterior flange should be considered, since both interfaces need a different approach to increase their strength. The cement–implant interface can be strengthened by application of different surface finishing techniques [11], whereas the strength of the cement–bone interface can be influenced by the preparation technique of the cortical bone [8].

The goals of this biomechanical study were:

1. To determine if the cement–bone interface was more prone to early failure than the cement–prosthesis interface in high flexion TKA.
2. To determine whether improvement of the cement–bone interface strength, as proposed by van de Groes et al. [8], would reduce the potential for prosthetic loosening.

2. Materials and methods

In this study FE techniques were used to assess the stress levels during high flexion at both interfaces (cement–implant and cement–bone interface). By comparing these stress levels to strength values as reported in earlier studies [7,8] we were able to assess the potential for mechanical failure at both interfaces and how this was affected by surgical preparation techniques of the cortical bone behind the flange.

2.1. FE knee model

The FE analysis performed in this study included two sub-models to improve computational efficiency: (1) a global FE knee model to determine the femoral loading during knee flexion and (2) a local femoral FE model to analyse the stress state at the cement–prosthesis and cement–bone interface (Fig. 1).

The global knee model has previously been described in detail [7] and consisted of a proximal tibia and fibula, high-flexion TKA components (posterior-stabilized PFC Sigma RP-F, rotating-platform TKA system, DePuy International, Leeds, UK), a quadriceps/patella tendon and a non-resurfaced patella. Knee flexion was achieved by application of the ground reaction force (= 350 N, to represent ½ bodyweight) to the ankle joint and releasing the fixed quadriceps tendon slightly per increment of flexion, comparable to cadaveric loading setups such as the Oxford knee testing rig [12]. A weight-bearing deep knee bend up to 155° was simulated. Thigh-calf contact, occurring during knee flexion beyond 130°, was integrated in the knee model to account for the joint relieving effect of posterior soft-tissue compression during high flexion [13]. The FE knee model was relatively unconstrained and free to seek its own kinematics.

Subsequently, the femoral loading conditions per node derived from the global FE knee model were applied to matching local femoral FE models. The local FE models included a femoral component, implant–cement interface elements, a 1 mm thick bone cement layer, cement–bone interface elements and a distal femur. The Young’s modulus of the bone was in the range of 26.3–14,500 MPa (based on bone mineral density (BMD) on CT-scan), bone cement 2,200 MPa and the femoral component 210,000 MPa. Except for the implant–cement and cement–bone interface, four-noded tetrahedral elements were used to generate the FE model. Cement pockets in the femoral component were neglected to avoid edge artefacts and simplify the interface analysis. The geometry of the distal femur was obtained from a femoral CT-scan of an 81 year old male (t-score = −1.9) using modelling software (Mimics 11.0, Materialise, Leuven, Belgium). The femur was CT-scanned using a calibration phantom and material properties were mapped to the femur using BMD information derived from the calibrated CT-scan according to Keyak and Falkinstein [14]. Bone cement was modelled as a linear elastic material. FE simulations were performed using MSC/MARC (MSC Software Corporation, Santa Ana, CA, USA).

2.2. Cement–bone and cement–implant interface

Zero-thickness six-noded cohesive elements were used to model the cement–bone and cement–implant interface, which were the regions of interest and indicated to be at risk during deep knee flexion [2]. Interface loading was expressed in terms of normal (σn) and shear stresses (τs). Since the analysis of the stress conditions and failure potential of the cement–bone interface compared to the implant–cement interface was the main objective of this study, actual debonding was not simulated and only linear elastic behavior was applied to the interface elements.

2.3. Cement–implant interface

The tensile (St = 2.09 MPa) and shear (Ss = 3.89 MPa) strengths of the cement–implant interface were based on the (arithmetic) average surface roughness of the femoral components (Rɑ = 1.593 μm) and experimental data of interface specimens with varying surface roughness [15]. The interface stiffness in tensile and shear direction (Kt = 57.3 MPa/mm; Ks = 151.4 MPa/mm) as well as the compressive

Fig. 1. The global FE knee model (left) utilized in this study to determine the femoral loading conditions during deep knee flexion and the local femoral FE model (right) to subsequently analyze the loading of the femoral fixation site. The global knee model contained osseous tissues (femur, tibia, fibula and patella), soft-tissues (quadriceps, patella tendon and PCL) and high-flexion TKA components. The boundary conditions applied to the FE models, such as the ground reaction force Fgrf and the thigh-calf contact force Ftc, are shown as well.
interface strength ($S_t = 70$ MPa) were estimated from literature [7,14,15]. The stiffness of the interface under compression was set at a relatively high value compared to the tension stiffness ($K_c = 100 \cdot K_t$).

### 2.4. Cement–bone interface

The cement–bone interface was divided into two areas. During the creation of the model, a femoral component was fitted to the model of the femur with $3^\circ$ external rotation. The size 3 femoral component was sized to generate a perfect fit in antero-posterior direction. Accurate positioning of the component over the distal femur created cuts, representing the cuts during intra-operative placement of a prosthesis, which automatically divided the surface area behind the anterior flange in exposed cortical and cancellous bone (see Fig. 2). A total of 68.5% of the anterior flange covered cancellous bone and the other 31.5% covered cortical bone, this is in concordance with actual measurements we performed in theatre. The tensile and shear strengths of the cement–cortical bone, with three different preparation techniques, and cement–cancellous bone interface were experimentally measured and published by van de Groes et al. [8]:

1. Unprepared cortical bone with periost still attached ($S_t = 0.06$ MPa and $S_c = 0.05$ MPa) (cortical, unprepared)
2. Periost removed and cortical bone roughened with a file ($S_t = 0.22$ MPa and $S_c = 1.12$) (cortical, roughened)
3. Periost removed and three ø 3.2 mm holes drilled through the cortex ($S_t = 1.15$ MPa and $S_c = 1.77$ MPa) (cortical with holes)
4. Cancellous bone ($S_t = 1.79$ MPa and $S_c = 3.85$ MPa)

Since van de Groes et al. [8] did not determine interface stiffness, these were taken from literature ($K_c = 37.4$ MPa/mm and $K_t = 38.4$ MPa/mm) [7]. The compressive strength was kept equal to the strength of the cement–implant interface since this is likely to represent the strength of the cement. Similarly to the cement–implant interface, the stiffness of the interface under compression was set relatively high compared to tension ($K_c = 100 \cdot K_t$).

### 2.5. Failure criterion

Obviously a mixed-mode stress condition (consisting of normal and shear stresses) is generated at both interfaces. To represent this complex stress condition a failure index (FI) was defined [7,8]. A higher FI corresponds to a higher risk of failure. The multi-axial Hoffman failure criterion [16] was used to determine the locations of femoral cement–implant interface debonding, based on the local normal and shear stresses (Fig. 3a). The Hoffman criterion uses the FI to describe the risk of interface failure when exposed to a certain stress state based on a quadratic relation between the interface strength in pure normal and shear direction. Static interface debonding is expected to occur in case $FI \geq 1$. Since Zelle et al. [7] demonstrated that the strength of the implant–cement interface under mixed-mode tensile and shear loading conditions does not comply with the traditional quadratic Hoffman failure formulation [17], the Hoffmann criterion was modified for normal loading conditions (Eqs. (1) and (2)):

**Normal tensile stress:**

$$\sigma_n \geq 0 \rightarrow FI = \frac{1}{S_t} \sigma_n + \frac{1}{S_c} \sigma_n = 1$$

(1)

**Normal compressive stress:**

$$\sigma_n < 0 \rightarrow FI = \frac{1}{S_t} \sigma_n^2 + \left(\frac{1}{S_t} + \frac{1}{S_c}\right) \sigma_n + \frac{1}{S_c} \sigma_n^2 = 1$$

(2)

The Hoffman failure criterion is not known for the cement–bone interface. Some literature [9] suggests an elliptical relation between tensile and shear strength for the cement–cancellous bone interface. Other literature [10] showed a clear linear relation between strength and loading angle. Since a linear Hoffmann failure criterion was found for the cement–implant interface, and no mixed-mode interface strengths are known for the cement–cortical bone interface, the same linear Hoffmann failure criterion was used for all interfaces in this study.

### 2.6. Femoral fixation analysis

The anterior, posterior and distal areas of the femoral implant–cement interface (Fig. 3b) were selected as separate regions of interest in order to assess which part of the interface would be more prone to failure. For these interface regions, the risk of interface failure was quantified per integration point by determining the FI from the local stress state (Eqs. (1) and (2)).

### 3. Results

#### 3.1. Joint forces and interface stresses

The peak compressive joint force was 4.1xBW and shear force 0.9xBW at 140° of flexion, see Fig. 4. Highest shear stresses were found at the cement–implant interface (peak shear stress of 3.24 MPa at 145° of flexion). Highest tensile stresses were found at the cement–bone interface (peak tensile stress of 1.28 MPa at 145° of flexion). The FI was highest at the cement–bone interface. In Table 1 tensile and shear stresses, with the FI at different angles of flexion are given. Overall, the highest stresses were found at the proximo-medial part beneath the anterior flank of the femoral component, leading to the highest FI in this region (see also Fig. 5). Fig. 5a is showing the cement–implant interface. At this interface the FI does not exceed 1.0, so no early failure is expected at this interface. As previously described, the cement–bone interface is divided into the cement–cancellous bone interface and the cement–cortical bone interface (Fig. 2). Fig. 5b, c, and d show the FI at the cement–bone interface, for different preparation techniques of the cortical bone area. In Fig. 5b, the cement–cortical bone...
interface which is in contact with cortical bone, will fail at 145° of flexion. Since the cortical surface area is 31.5% of the total surface area, 31.3% of the total surface area behind the anterior flange will fail. Fig. 5c shows that the area subject to direct failure can be reduced to 76.1% (equals 24.0% of total interface) by removing all periost and roughening of the cortex. If further strengthening of the cement–cortical bone interface (periost removed and three ø 3.2 mm holes drilled through the cortex) was simulated, the area subject to direct failure was reduced to 8.3% (equals 2.6% of total interface); see Fig. 5d. When looking at the normal range of motion (up to 120°) the failed surface area is 3.0% (equals 0.9% of total interface) when the cortex is drilled with holes and 98.3% (equals 31.0% of total interface) when the cortical surface is left untreated.

In the ideal situation when the anterior flange is only covering cancellous bone, 0.4% of the cement–bone interface behind the anterior flange will fail.

### 3.2. Interface stress state per region of interest

Plotting the interface stress state per integration point at the interface, using the modified Hoffman failure criterion, confirmed that the posterior and distal areas remained clearly in the safe zone, for both the cement–bone interface which is unprepared and the cement–cortical bone interface (periost removed and three ø 3.2 mm holes drilled through the cortex) was simulated, the area subject to direct failure was reduced to 8.3% (equals 2.6% of total interface); see Fig. 5d. When looking at the normal range of motion (up to 120°) the failed surface area is 3.0% (equals 0.9% of total interface) when the cortex is drilled with holes and 98.3% (equals 31.0% of total interface) when the cortical surface is left untreated.

In the ideal situation when the anterior flange is only covering cancellous bone, 0.4% of the cement–bone interface behind the anterior flange will fail.

### 4. Discussion

Patients achieving high flexion may have a higher femoral failure risk than standard replacements as deep knee flexion puts higher demands on knee implants [18]. The objective of the present study was to evaluate the stresses and chance of failure of the cement–bone interface in relation to the cement–implant interface.

The first research question was to determine if the cement–bone interface was more prone to early failure than the cement–prosthesis interface in high flexion TKA. The present FE study showed that the FI was much higher at the cement–bone interface than at the cement–implant interface. Especially the cement–cortical bone interface is prone to failure. The highest tensile stresses (1.30 MPa) were found

### Table 1

Summary of tensile and shear stresses and failure index for different interfaces and flexion angles. Cement–cortical is the interface at the cut bone surface; cement–cortical I is unprepared cortical bone; cement–cortical II is cortical bone with removed periost and roughened with a file and cement–cortical III is cortical bone with removed periost and holes drilled through the cortex.

<table>
<thead>
<tr>
<th>Angle</th>
<th>Interface</th>
<th>Peak tensile stress (MPa)</th>
<th>Peak shear stress (MPa)</th>
<th>Failure index</th>
<th>Surface area with FI ≥ 1.0 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90°</td>
<td>Cement–implant</td>
<td>0.63</td>
<td>1.85</td>
<td>0.52</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Cement–cancellous</td>
<td>0.43</td>
<td>1.35</td>
<td>0.50</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical I</td>
<td>0.66</td>
<td>1.31</td>
<td>3.91</td>
<td>54.7</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical II</td>
<td>0.66</td>
<td>1.31</td>
<td>1.20</td>
<td>1.4</td>
</tr>
<tr>
<td>120°</td>
<td>Cement–implant</td>
<td>0.66</td>
<td>2.43</td>
<td>0.55</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Cement–cancellous</td>
<td>0.48</td>
<td>1.78</td>
<td>0.68</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical I</td>
<td>0.94</td>
<td>1.76</td>
<td>42.86</td>
<td>98.5</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical II</td>
<td>0.94</td>
<td>1.76</td>
<td>5.26</td>
<td>66.8</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical III</td>
<td>0.94</td>
<td>1.76</td>
<td>1.54</td>
<td>3.0</td>
</tr>
<tr>
<td>145°</td>
<td>Cement–implant</td>
<td>0.68</td>
<td>3.24</td>
<td>0.73</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
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<td>2.41</td>
<td>0.91</td>
<td>0.0</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical I</td>
<td>1.26</td>
<td>2.36</td>
<td>57.84</td>
<td>99.3</td>
</tr>
<tr>
<td></td>
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<td>1.26</td>
<td>2.36</td>
<td>7.05</td>
<td>76.1</td>
</tr>
<tr>
<td></td>
<td>Cement–cortical III</td>
<td>1.26</td>
<td>2.36</td>
<td>2.07</td>
<td>8.3</td>
</tr>
<tr>
<td>155°</td>
<td>Cement–implant</td>
<td>0.72</td>
<td>2.90</td>
<td>0.82</td>
<td>0.0</td>
</tr>
<tr>
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<td>2.20</td>
<td>0.91</td>
<td>0.0</td>
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<tr>
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<tr>
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<td>69.7</td>
</tr>
<tr>
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<td>1.21</td>
<td>2.14</td>
<td>2.00</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Fig. 3. (a) Modified Hoffman failure criterion used to determine whether a local interface stress state would lead to interface debonding together with (b) the anterior, posterior and distal interface regions analyzed in this study. For a given interface stress state (P1) the failure index was determined by relating the stress condition to the Hoffman failure curve as shown in the figure. Static interface failure is expected to occur in case FI ≥ 1.0.
at the cement–cortical bone interface and the highest shear stresses (3.33 MPa) were found at the cement–implant interface. Since, the interface strength of the cement–bone interface is lower than the strength of the cement–implant interface, the FI is higher at the cement–bone interface. In all cases, no failure at the distal and posterior areas was found for neither the cement–implant nor cement–bone interface. Hence, this fits with the clinical observation that loosening of the femoral component is a rather rare event.

The second research question was to determine what the effect of different preparation techniques, as proposed by van de Groes et al. [8], was on the percentage of interface area prone to failure. This study suggests that the percentage of interface area prone to failure is different for the preparation techniques proposed by van de Groes et al. [8]. In all cases, no failure at the distal and posterior areas was found for neither the cement–implant nor cement–bone interface. Hence, this fits with the clinical observation that loosening of the femoral component is a rather rare event.

The present study was limited by the fact that progressive interfacial failure was not considered. Earlier studies focusing on the cement–bone interface [9,10] have demonstrated that such interface failure consists of a nearly linear elastic phase followed by a non-linear plastic or softening phase. Since we were primarily interested in the stress state at the femoral fixation site and the subsequent failure potential, debonding was not simulated and the interface elements all remained in the elastic phase. One should be aware that inclusion of the softening phase of the interfaces may lead to changes in the interface stresses calculated and therefore we mainly focused on qualitative trends rather than on consequences of partial debonding. The interface stiffness values used in this FE study were derived from literature [9,15] and led to virtually no immediate interface failure up to 120° of flexion at the cement–implant and cement–cancellous bone interface, which seems reasonable as clinically the components do not typically fail in this flexion range.

The stiffness of the cement–cortical bone interface is not known in literature, we therefore took the same stiffness as for the cement–cancellous bone interface. In reality the stiffness is probably higher, which might lead to altered stresses at the cement–bone interface. The stiffness may be of great influence on calculated stresses. However, the expected stiffness of the cement–cortical bone is not higher than the stiffness of the cement–implant interface. When calculating stresses with a stiffness of the cement–cortical bone interface equal to that of the cement–implant interface, the peak shear stress at the cement–bone interface increased only 0.01 MPa. Hence, the results appeared not to be very sensitive to the exact value of the interface stiffness.

In contrast to the study of Zelle et al. [7], the present study showed no direct failure of the cement–implant interface. This is due to the lower stiffness at the added cement–bone interface, which was not incorporated in the model of Zelle et al. [7]. The Hoffman failure criterion is also a point of debate. A linear criterion was used in the combined tension and shear range. Some literature suggest an elliptical relation between shear and tension for the cement–cancellous bone interface [9], others suggest a linear relation [10]. The Hoffman failure criterion for the cement–implant interface is proven to be linear in combined shear and tensile stresses [15]. Since cortical bone is stiffer than cancellous bone, the Hoffman failure criterion for the cement–cortical bone interface is probably more like the cement–implant interface. The cement–cortical bone interface was the most important interface to fail, so we believe is probably reasonable to use the same linear Hoffman failure criterion in all interfaces.

Validation of the current FE-model is not performed by testing the actual cadaver bone in vitro, therefore one can argue that the model is not a resemblance of the in vivo situation. However, the forces generated in the model are similar to those measured in vivo as we discussed earlier [19]. Strength values of the interface were experimentally measured and reported earlier [8,15]. Further validation of the model is difficult as force measurements are only available for the tibia plateau [20] and the translation of these forces to the femoral component is hampered by the absence of knowledge about the force patterns at the patella–femoral joint. Hence, the findings of the study should be interpreted with these limitations in mind. Despite these limitations, the generated joint forces with the current model are similar to the forces measured in vivo by D’Lima et al. [20] and Kutzner et al. [21]. They found compressive forces of about 3xBW at 90° of flexion. Unfortunately, as far as we are aware of, no in vivo measurements are available for high flexion angles above 130° of
Fig. 6. Interface stresses at 145° of flexion at (a) the cement–implant interface, (b) the cement–cancellous bone interface at the cut surface (indicated in pink in Fig. 3) and (c) the cement–cortical bone interface, with Hoffman failure criterion for different preparation technique.

flexion. The current profile of compressive and shear forces generated with the present model during normal range of motion is comparable to literature [20,21] and therefore we expect the model to be adequate in higher flexion angles as well. Although, the failure mode resembles that reported by Han et al. [2], it is not reported for the PFC Sigma RP-F used in the present study. This might be related to the roughness of the prosthesis. Further research is planned to assess the influence of this.

The FE analysis performed in this paper may contribute to the general understanding of the loosening of the femoral component during deep knee flexion. It should be realized that the current study focuses on the prediction of stress patterns and subsequent FIs, it does not predict how loosening of one interface will affect progression of failure at other sites. To simulate progression, a dynamic simulation is required with multiple loading cycles. The FE framework defined in this study may be used in future fixation analyses of knee implants to study interface fatigue during multiple flexion cycles and effects of different implant designs.

In conclusion, it can be stated that the cement–bone interface is more prone to failure than the cement–implant interface (assuming for the metal an Ra = 1.593 μm). Failure occurs especially at the cement–cortical bone interface behind the anterior flange of the femoral component. The risk for early failure at the cement–bone interface can greatly be reduced by removing all perist and roughening of the cortical bone, ideally holes are drilled through the cortex to prevent early failure of the cement–cortical bone interface. However, since loosening at the anterior flange seems to occur, the rest of the interfaces remain intact. Therefore, the failure modes presented in this article may only influence long-term survival (>10 years), which is presented in current clinical studies.

5. Conflict of interest statement

The authors declare that they have no conflicting interests.

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