



Success Story / **FEM analysis ceramic implants**

# Saving time and money in the FDA approval process

In silico simulation methods have the potential to revolutionize medical device approval by reliably replacing in vitro and in vivo testing. By moving to the virtual patient, there are numerous advantages for medical device manufacturers: early intervention in product development, safe testing and fitting, avoidance of time-consuming and costly human and animal trials. The innovative Swiss company SDS already benefits from the possibilities of FEM analysis in the approval process.



*„Simq's FEM analysis allowed us to answer the FDA's inquiries faster at a critical approval step of our product and minimize risk by reducing costly and time-consuming physical testing.“*

**Dr. Karl Ulrich Volz /**  
CEO / SDS SWISS DENTAL SOLUTIONS

## The task

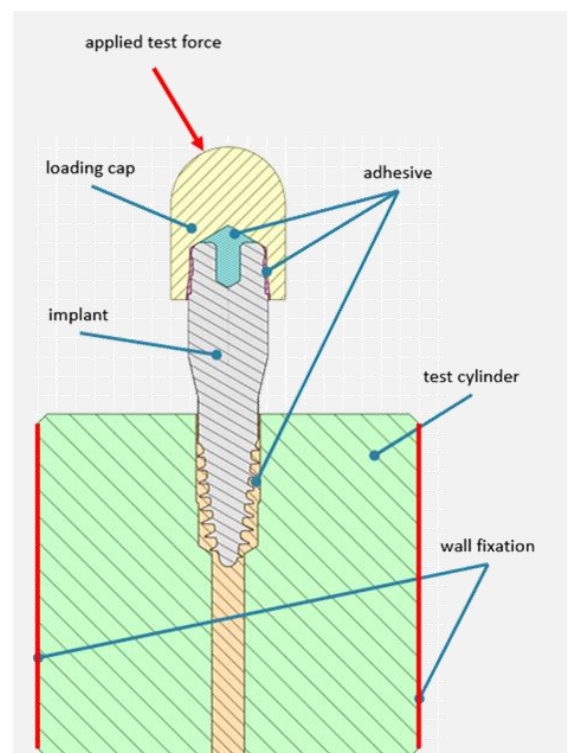
Response to an FDA request: The American Food and Drug Administration (FDA) requested proof that further variants of the ceramic implants already successfully tested by SDS - Swiss Dental Solution in a physical fatigue test (**Fig. 1**) do not exhibit higher loads. The response to this FDA request had to be given within 120 days. Simq's simulations were intended to prove that even ground implants could withstand the high loads, so that costly and time-consuming physical tests could be avoided.



**Figure 1:** SDS1.2 Ceramic implants

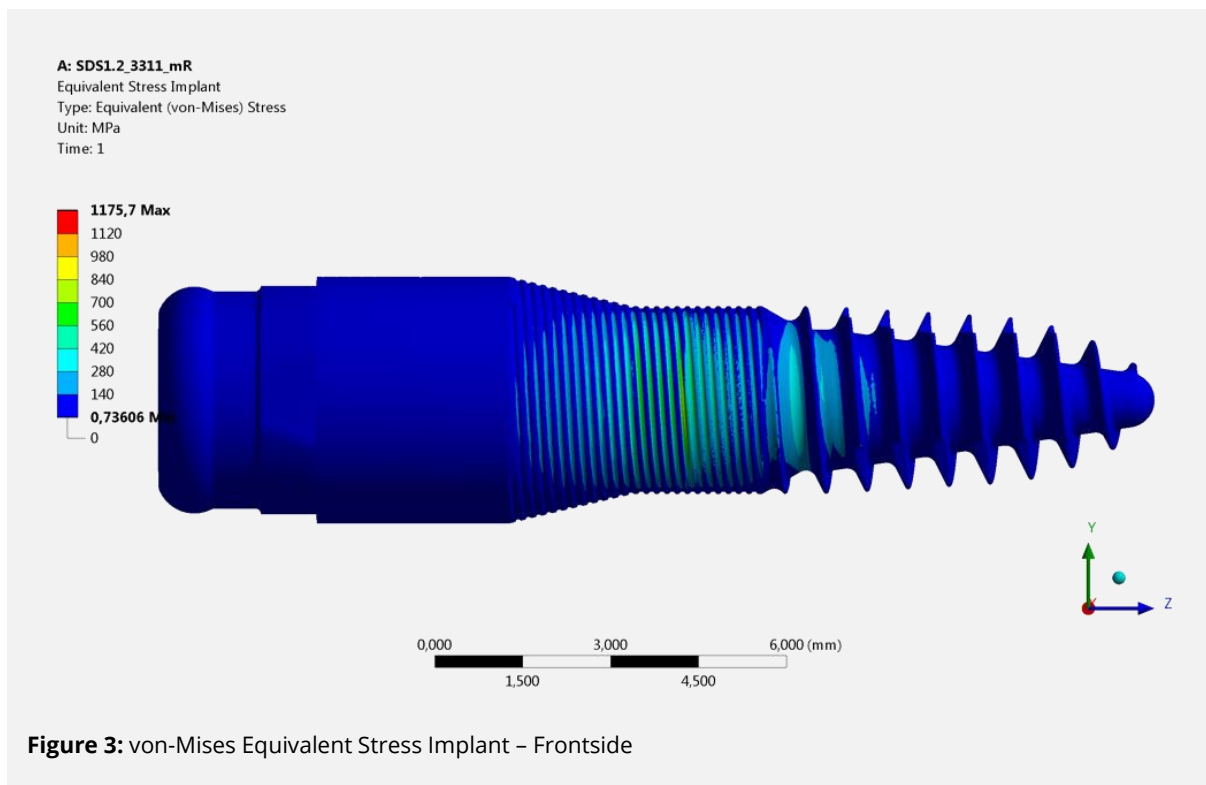
## The solution

The finite element analysis of the fatigue behavior according to EN ISO 14801 of the variants and the already successfully physically tested zirconium oxide implants made it possible to perform a comparative analysis. The test setup already carried out is reproduced in the FEA with the same implant geometry and the same embedding parts (test cylinder and hemispherical loading cap) (**Fig. 2**).



**Figure 2:** Test setup

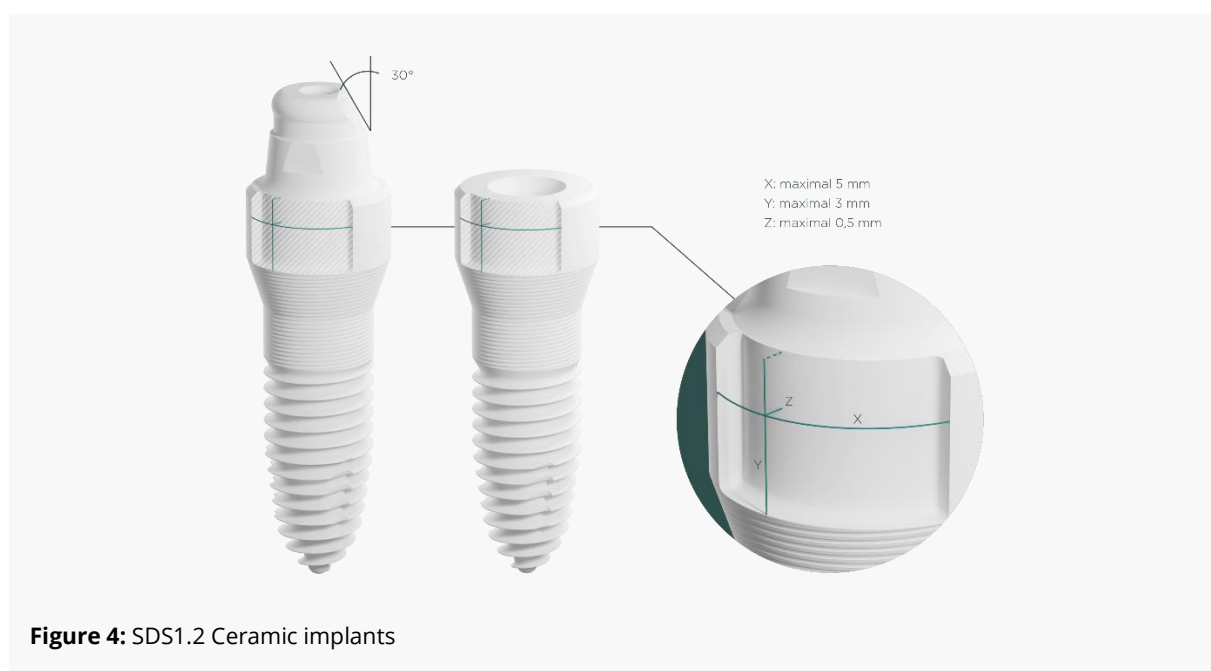
Subsequently, the variants with different abutment heights and the maximum milled depths of the grindable implants were compared. Based on the calculated parameters, such as the equivalent stress (von Mises), the maximum principal stress and the normal stress in the Z-direction (the bending direction) and others, the effects of the variation can be evaluated (**Fig. 3**).



## The result

The stress distribution and the magnitude of the maximum values are lower and not significantly different from the worst-case variants already physically tested. SDS SWISS DENTAL SOLUTIONS proves by means of the FEM analysis of Simq that for one-piece SDS1.2 implants (**Fig. 4**) with 4mm abutment height the values of the

permanent stress do not change and it does not lead to a reduced lifetime if these ceramic implants are ground within the framework of the grinding protocol approved by SDS SWISS DENTAL SOLUTIONS. Simq's FEM analyses were able to demonstrate that the variants already physically tested represent the worst-case variants.



## Your contact



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### About the customer

Founded by ceramic pioneer and implantologist Dr. Ulrich Volz, Swiss Dental Solutions offers a comprehensive treatment concept for biological medical implant solutions with ceramic implants.

**SDS** SWISS DENTAL  
SOLUTIONS

### About Simq

The company was founded in 2014 and is part of the CADFEM Group. Simq's products and services enable medical device manufacturers, clinicians and medical staff to practically apply numerical simulation and use it for more effective and safer patient care.

Simq is committed to the standardization and broader application of in silico medicine as part of the Avicenna Alliance, thereby ensuring safe, affordable and cost-effective healthcare.



Simq is a certified simulation service provider and software manufacturer in the field of medicine and medical technology and is one of the pioneers of in silico medicine.