Biocompatibility testing of titanium dental implants in the pelvic model in sheep: comparison of two implant surface modifications on implants with an identical shape and geometry

INTRODUCTION:
In recent years many different implant surfaces have been brought to the market, which claim a faster osseointegration. The performance of dental implants is often judged of how long they are securely anchored in the patient’s bone. However the initial speed of osseointegration might enlarge the scope of the treatment concepts. A comparison of the osseointegration surfaces produced by different implant suppliers is hindered by the different design features of the implants. Therefore it is virtually impossible to discriminate between the influence of the surface and the implant design. Goal of this study is to compare two different commercial implant surfaces in one uniform design in order to focus on the osseointegration capacity of the surface only. Specific goals are to study bone formation and/or resorption and possible formation of a fibrous interface membrane at the different titanium surfaces after different time points.

METHODS:
Six mature female swiss white alpine sheep between 2 and 5 years were randomly allocated to two groups. Group 1 SLActive (SLA) had implants (n=36) with a hydrophilic, sand-blasted, large grit and acid-etched surface (Straumann AG, Basel, Switzerland) and group 2 (NB) consisted of implants (n=36) with a highly crystalline and phosphate-enriched anodized titanium oxide surface (Nobel Biocare, Göteborg, Sweden). All dental implants (diameter 4.1mm/length 10 mm) were placed in the iliac bones of the pelvis (total n=72). NB implants were custom modified with the SLA implant design. Conventional implant site preparation was performed according to the implant manufacturer’s recommendations and drilling protocol using standard rotating pilot and twist drills in ascending order (diameter). Implants of each type were randomized over the implantation sites. Six implants were placed in each side of the pelvis (total 12 per sheep). The study design aimed to achieve a statistical sample size of 6 implants each for either a semiquantitative histological assessment of the bone-to-implant contact (BIC) or biomechanical removal torque testing of the different osseointegration techniques after 0, 2, 4 and 8 weeks. BIC measurements were performed separately and were differentiated between a cortical and trabecular evaluation. Intravitral fluorochrome staining by subcutaneous injection was performed at 2 (Calcein-Green) 4 (Xylenol-Orange) and 8 (Oxytetracyclin) weeks after surgery. The implant stability quotient (ISQ) was measured after 0, 2, 4 and 8 weeks (Ostell Mentor). All experiments were conducted according to the Swiss regulations of animal welfare and were authorized by the local federal authorities.

RESULTS SECTION:
All implants (n=72) could be placed without complications and with good primary stability. Radiographs in two directions demonstrated n=72 implants to be right in place. Implants of both groups had a direct contact with the host bone after 2, 4 and 8 weeks. Qualitative microscopic evaluation demonstrated new bone formation in all of the samples. New bone matrix, visible as dark-bluish stain, was obvious in the cortical as well as the cancellous parts adjacent to the implant surface after 4 weeks. From a qualitative aspect implants were surrounded by loose woven bone with a relatively low mineral density and irregular microarchitecture. BIC values in both groups revealed a steady rise in the trabecular bone after 2 (SLA: 56.2±8.6; NB: 55.6±10.3) 4 (SLA: 73.0±4.5; NB: 73.4±3.4) and 8 weeks (SLA: 81.0±5.6; NB: 78.3±9.3) weeks. In the 2 to 4 time interval in the NB group (p=0.005) as well as in the SLA group (p<0.01) a statistically significant increase could be observed. At the 4 to 8 weeks time ranges no statistically significant differences in the trabecular bone could be detected (post hoc test Bonferroni). In both groups BIC values after 8 weeks were significantly higher than after 2 weeks (p≤0.05). Differences between both groups at corresponding time points at 2, 4 and 8 weeks were not statistically different. BIC analysis in the cortical bone showed no statistically significant differences (p≥0.05) between the SLA and NB groups at individual time points. Fluorescent dyes matched exactly with dark blue stained structures (new bone matrix) of corresponding ground sections. Cancellous bone was subjected to strong remodelling after 4 weeks, often accompanied by remnants of bony debris in implant channels. Almost no active bone remodelling occurred in cortical bone after 2 weeks in both groups, but primary cortical bone remodelling could be observed after 4 weeks (xylbenol orange). Torque tests confirmed values found for BIC, where the higher the BIC the better the torque removal tests. A steady and significant rise (p<0.05) from 2 weeks (SLA: 1022.3±260.7; NB: 706.5±219.9) to 4 weeks (SLA: 1598.2±471.3; NB: 1123.1±115.2) and 8 weeks (SLA: 1783.6±120.6; NB: 1844.5±247.6) could be measured in both groups. For one implant of the 4 weeks SLA group and four implants of the 8 weeks SLA group, no definite torque values could be determined as the connecting device between implant and testing machine broke before the bone to implant contact failed. Post hoc analysis revealed significantly lower values for the NB group of 4 weeks in comparison to the SLA group of 4 weeks (p = 0.001). After 2 and 8 weeks there were no statistical differences between the corresponding groups. The ISQ values showed for both implant surfaces an initial increase between 0 and 2 weeks, followed by a drop after 4 weeks and finally the ISQ regained its original level after 8 weeks of implantation. There wer no significant differences between the two surfaces.

DISCUSSION:
It was the aim of this animal study in sheep to compare a hydrophilic, sand-blasted, large grit and acid-etched surface to a highly crystalline and phosphate-enriched titanium oxide surface at 2, 4, 8 weeks after implantation of dental implants with an identical shape and geometry. Overall the histological as well as the biomechanical evaluation revealed no striking differences of the two surface modifications concerning a successful osseointegration. As the macro-design of both implant types was identical the direct influence of individual surface characteristics on the osseointegration process could be scrutinized. Thereby only after 4 weeks the hydrophilic SLA surface disclosed a statistically significant higher torque value than the dry NB surface. One of the claimed advantages of the hydrophilic SLA surface is the enhanced osseointegration process in the early wound healing phase. Even though this issue could be partially confirmed biomechanically in our study, the histological evaluation (BIC value) in trabecular and cortical bone and the implant stability measurements (ISQ) did not support these findings. Further histomorphometrical and scanning electron microscopy evaluations will provide more comprehensive insight into the bone-to-implant-interface. Thus a final conclusion concerning the early osseointegration process can not be drawn at the moment. However, after 8 weeks both surfaces revealed comparable results with a high new bone formation and no formation of a fibrous encapsulation.

As an experimental setup for this analysis a pelvic model in sheep was used. Due to commensurate bone metabolism rates as well as adequate biomechanics the iliac shaft of sheep provide a sound basis for the analysis of periimplant endosseous healing respecting the different healing patterns in cortical and trabecular bone.