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Opinion
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About Osseointegration Evaluation Criteria

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Opinion

When it comes to osseointegration of an implant, the constituent material and its shape must be studied separately. When the osseointegration step is reached, in principle, "in vitro" tests have been already carried out to evaluate the compatibility of the material with osteoblasts, elements driving bone progression. However, the commonly used method, consisting of the multiplication of cell layers achieved in a test tube over a short period, is not reliable to anticipate accurately the osseointegration quality of the material, and thus puts the patient at risk. The same applies to ongoing chemical studies of the implant/organic material junction zone.

This leads to the need for "*in vivo*" experimentations. Such "*in vivo*" experiments induce first selecting appropriate animals. The type of animals needs to be ethically available. The size of the animal must enable the latter to be robust enough to support the implant without weakening. In addition, its size must ensure that the bone volume surrounding the implant provides enough substrate. A 5–6-year-old sheep meets these criteria. Furthermore, they are easy to intubate, and are, in any case, generally sacrificed around this age, minimizing public sensitivity. However, other animals are used, but a reference animal should be defined.

Such "*in vivo*" experimentations induce secondly defining a relevant site for the implant in the animal, considering that vascularity varies from one site to another. For example, the metatarsus is less vascularized than the tibia. For this reason, as well as its easy surgical approach, most experimenters select the tibia.

Such "*in vivo*" experimentations induce thirdly deciding the number of animals to involve in the study as well as on the number of implants. The statistician will advise 5 animals but considering the amount of work and the cost of such a study, 3 can be considered as a correct number and may be sufficient for a first approach. And 4 to 5 implants per animal will reinforce the reliability of the results.

Such "*in vivo*" experimentations induce fourthly evaluating the length of time required for implant insertion before removal for osseointegration study. Most authors adopt a period of 8 weeks for several reasons [1]. Indeed, the time required before consolidation of a fracture of the upper limb, not requiring weight-bearing, is 6 weeks whereas the generally accepted period for the consolidation of a dental implant is 8 weeks. However, 12 weeks are required to consolidate a fracture of the lower limb. In fact, the duration depends on the quantity of bone to be reconstituted, and on the way the implant is inserted. If the bone cavity to be filled is large, 12 weeks are necessary. The same applies to implants inserted with too much pressure as this leads to local necrosis of the bone delaying the osseointegration process. Thus, a duration of 12 weeks is safer, even though more expensive to maintain the animals 4 more weeks in specialized premises.

For a long time, osseointegration study has relied on histology, i.e. the microscopic study of the tissues through paraffin embedding, followed by sectioning in blocks, then in thin layers using a "scrapper", a tool quite like those used to produce thin skin grafts. Layers of 20 to 30 µm thickness were obtained and examined under a microscope. However, this technique could not include metal, and the implant was deposited beforehand. A scaled design of the implant was used for superimposition. Consequently, the accepted uncertainty was initially very wide - 150 µm. Another approach was to section the bone and metal using a metallic wire cut technique. The results were more accurate, although approximate due to the damage caused by the metallic wire and local heating.

X-ray computed tomography (XCT), a non-invasive investigation technique, has opened up new possibilities. This technique provides a three-dimensional grey scale (from white i.e. air to black i.e. the denser material) image of the whole implant surrounded by the bone, image that can then be post-processed. But this progress in computerization of the evaluation process has masked the degradation of its precision! In order words, the size of the units - pixels for surfaces or voxels for volumes - making up the image, i.e. the image spatial resolution, was too high (at best 25 µm) to get a clear idea of the reality. And it remained the case for many years. Thus, this computerization has given rise to the idea of close bone/implant contact. The idea of a gradually transition zone, on the edge of the implant, was replaced by a Manichean conception of a direct transition from black to white. This approximation has led to "unsharpness" (to make a pun on tomography) in certain works, not always mentioning their resolution, particularly in the field of popularization or commercial promotion. Thus, for a long time, it was believed that there was a direct contact between the bone and the implant, and juxtaposition is consolidation!

The advent of microtomography (µCT) and synchrotron was a revolution in this domain as they enable a much lower image spatial resolution. For example, we performed µCT scans of metallic implants surrounded by bone with a voxel size up to 6.7 µm in our previous "in vivo" studies carried out with the BAM in Berlin [1,2]. Considering, the voxel size, a maximum gap of 6.7 µm is still possible when a "bone" pixel and a "metal" pixel are observed to be touching each other. Beyond that, one of the two pixels considered would fall into another grey value category. This gap between the bone and the implant corresponds to the BII, or Bone Interface Implant, a nowadays fundamental notion whose exploration requires considerable resources to be precise, and therefore considered. This gap, which thickness can vary along the edge of the implant, is occupied by osteoid tissue (woven bone).

How does this work in practice?

The material must be taken into consideration, but also the technique to manufacture the implant. A casting implant and an additive manufacturing implant will not necessarily have the same characteristics. Build cylinders and implant them into drilled holes in the animal bone, avoiding any heat generation. A "functional" approach is to test the pull-out force required to extrude the cylinder and relate it to the bone/implant contact surface, or to another material, positioned in the same way on the same animal. Then carry out the tomographic analysis on a sectional plane/straight cylinder intersection of sufficient length (in our study, 150 pixels) and repeat this analysis on several sections. Pixel characterization into several categories (eg. bone, material, osteoid tissue or "woven bone", pores) can be performed by artificial intelligence (AI). Count the number of bone/implant material pairs in contact and relate it to the number of pixels on a line. This percentage will give the BIC, Bone Implant Contact. And the size of the pixel will give the maximum thickness of the BII. BIC and BII are, at present, the two fundamental metrics, which should always be given, for quantifying osseointegration.

In addition, µCT can be used to test the impact of the implant on the drilled bone by defining a volume surrounding the implant and studying the percentage of each of the four categories: bone, osteoid tissue, material, and pore. A comparison between cylindrical and screw implants will show the impact of shape on results. Bone remodeling occurs in both cases, but screwing may create areas of hyper pressure, leading to localized necrosis. Microscopic study of the BII, using high-tech equipment, provides little predictive information on osseointegration, apart from this: the arrangement of connective fibers within the intermediate tissue. Parallel to the implant axis, they would indicate fibrous consolidation. Perpendicular to this surface, they augur well for future osseointegration.

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