Editorial

Looking for a new international standard for characterization, classification and identification of surfaces in implantable materials: the long march for the evaluation of dental implant surfaces has just begun

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1. Introduction

Implantable materials are largely used in daily clinical practice in many medical fields. In dentistry and orthopedics, many materials are placed at the direct contact with bone, and many new surfaces were developed to improve this implant/bone interface **[1]**. In the dental field, most companies are nowadays advertising their proprietary surfaces, and it is part of the commercial argument that is used to convince customers to use new products **[2]**. However, what most clinicians do not know, it is that there is in fact no real standard to define a minimum quality for a commercially available surface. In fact, there is not even a standard to define how to characterize and evaluate properly the dental implants surfaces.

This situation created many problems in the past. In the absence of common standard and definitions, many companies are using wrong statements (for example, many products are claimed to be nano-modified, while they clearly are not, whatever the definition you use)**[2,3]** or placing in the market products that clearly do not meet the minimum sanitary standards and present severe pollutions **[4]**. With the globalization of markets, implants are produced anywhere in the world without meeting any control and quality standard, and the number of low quality products available freely on the market is rising dramatically. Moreover, even the large and renowned companies faced significant problems with their products in the past years, but very little information was given to the many users of the defective surfaces **[5,6]**.

Facing this strange situation of almost absence of control for medical devices, the dental clinician is a victim that ignores himself. When placing a dental implant, the clinician is responsible - in most Law systems - of the material he selected and placed in the patient mouth. But the clinician often does not have the possibility to evaluate seriously what the company is selling him. In the best case, he can only recognize some specific families of surfaces (for example sand-blasted acid-etched, SLA type) to try to secure himself, but he has no access to a safe and standardized information to secure his choice of implantable material. In case of serious problems with some products, he is alone **[6,7]**.

The scientific international literature is also not helping so much to secure our choices. Most companies are sponsoring research to prove that their products are safe, and bad results are rarely published **[7]**. Even if disclosure of interest must always be notified in

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all articles, the way an article is written is too often biased by the source of the funding of the study. Moreover, most of the published data are very difficult to sort and interpret, even for the specialists, as no standard for the definitions really exists **[8,9]**. A few years ago, when a friend was talking with some implant surface specialists and complaining about the difficulty to understand the specialized scientific literature about surfaces (and the many interferences from the companies) for the clinicians using these products on a daily practice, one famous academic researcher just told him that the clinicians just have to use what we tell them to use. My friend was so shocked by this answer that he gave me this idea to develop a method to bring clear information to the clinicians by proposing a new ISO international standard for the description of implant surface characteristics. This dream may finally come true in a few years.

2. The ISO approach

The ISO (International Organization for Standardization) is the world largest organization for the development and publication of international standards. It is an independent non-governmental organization coordinated from a central secretariat in Geneva, Switzerland and built as a network of national standards entities representing their respective countries on the global scene (in France, this is the AFNOR entity for example). When ISO was created in 1947 with 25 member countries, the objective was to facilitate the international coordination and unification of industrial standards. Since these first steps, the organization regrouped national standard entities from 164 countries and published almost 20 000 international standards covering almost all aspects of technology, manufacturing and business. The same mechanisms of standardization are applied from medical devices and food safety to electronics, and help to secure the products and services of our daily life.

The general purpose of an international standard is to define the state of the art specifications for products, services and good practice. Standardization allows first industries to be more efficient and effective. In the globalized world we are living in, the international standards helped to secure the exchanges of products between countries with different organizational cultures and levels of control, but with similar objectives of security and efficiency. A standard is therefore both an instrument of safety and of simplification of international trade.

To reach such objectives, international standards are quite slow to produce, as they require global consensus. Each commission gathers representatives from all the actors of a field: representatives of the users (dentists or maxillofacial surgeons in the case of dental implants), representatives from the producers (implant companies in this case), researchers and academic experts. In this way, each commission gathers all the expertise required to elaborate a standard and a reference document. This composition allows to develop standards that reflect the practical reality and are applicable properly by producers and satisfying the needs of the users. The equilibrium of each commission is also very important, as users and producers may not perceive the interest of a standard in the same way, as a standard can impose more restrictions and expensive tests to the producers. This may explain why after so many years of intense development of dental implant surfaces, a standard on this important matter still does not exist. Behind each standard, there is the need to find the right equilibrium at the right moment, and it takes time.

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3. The road to a new standard is open

The ISO TC106/SC8/WG1 commission for dental implants (dental medicine, implantable material) is in charge of the various standards related to dental implants on the international scene, and we hope that a new work item proposal will be launched soon on this important topic, and that this standard will exist in the near future to help implant users to have a clear and safe information about the product they are using.

In the last years, the international scientific literature about implant surfaces grew exponentially and is very difficult to interpret, even for experts **[10]**. In many cases, it is difficult to define what characteristics of an implant surface would be better or worst for a clinician, as the literature about *in vitro* and *in vivo* results is often sponsored by companies and some surfaces that were recently retrieved from the markets because of mixed results were presented with excellent experimental results a few years earlier in the literature **[5]**. Even without the commercial bias, the optimal characteristics for an implant surface diverge depending on the School of researchers: some insist mostly on the chemical (or sometimes biochemical) modification of the surface (concept of bone/implant chemical interlocking)**[11]**, some insist mostly on the microtopographical modification of the surface (concept of bone/implant biomechanical interlocking)**[12]**, while some others even insist on the modifications at the nanoscale of implant surfaces **[13]**. The general consensus is that all these characteristics are important **[10]**. The main issue remains that many companies do not even characterize and define properly the characteristics of their products **[4]**.

In a recent series of articles, some authors proposed a new characterization and classification system for dental implant surfaces **[10,13,14]**. This system attracted our attention, as it does not give judgment of quality or clinical efficiency (often debatable and sometimes biased), but it defines very accurately scientific terms, instruments and protocols to evaluate the chemical and topographical characteristics of any implant surface **[15]**. The scientific method is relatively easy to calibrate to offer stable and reproducible results, and can therefore be performed by independent certification laboratories if needed **[4]**. These data can be given in a complex extended form or in a simple reader-friendly format (termed implant surface ID identification card). The given information is simple to read and to understand both for engineers, researchers and dental clinicians **[4]**.

This protocol is useful and may even be considered as a standard in many ways:

- as an industrial standard, this is a very complete method for implant companies to control the characteristics of their products and detect problems of calibration or pollutions in their production lines,

- as a research standard, this method allows to characterize extensively implant surfaces before *in vitro* or *in vivo* testing (what is unfortunately not so frequent at this time), and therefore to make the data published in the literature easier to sort and interpret,

- as a commercial standard, the ID cards obtained by the use of this method are a reader-friendly support of certification and communication for the final users about the exact characteristics of the implants they are using,

- as a public health policy standard, the control of production series with this method also allows to imagine a real traceability of implant lots, and improve the materiovigilance policies towards dental implants.

In this issue of the POSEIDO journal, the international group that started this work a few years ago **[4,10]** has regrouped data from 62 different implant surfaces in a series of articles. These data are given in a reader-friendly updated format, the implant surface ID

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card, following the characterization and codification system termed ISIS (Implant Surface Identification Standard). Even if it is impossible to know now what will be the final form of the ISO standard our commission will develop in the coming years, these articles are a mile stone to support our endeavor and a strong basis to define the expected technical standard for characterization and definition of implant surfaces. It is also an important basis for the future standards of evaluation of implant corrosion and ionic releases which are under discussion since many years.

The International Organization for Standardization is termed ISO whatever the language (while the acronym should in fact change depending on the language). The reason is that ISO referred also to the Greek *isos*, meaning equal. With this new standard, we hope that all clinicians may have access to a clear, complete and reader-friendly information concerning the products they implant and are responsible of. What better purpose could have an international standard than allowing all users worldwide to be equal in front of knowledge and information?

Disclosure of interests

The author has no conflict of interest to report.

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