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Review Article

Do you know how Osseointegrated Implants are Manufactured?

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Abstract

The osseointegrated implants market is very wide, represented by various commercial brands and models. The choice of commercial brands should preferably be based on scientific research. The scientific and technological evolution allowed, along the years, the manufacturing of better products. The manufacture of the implant involves several stages and processes that must be known by the dental surgeon. This knowledge also allows the professional to choose better products. The traceability of these products increases the safety of use and subsequently the offer of quality to the final consumer (patient). We, dental surgeons with exclusively clinical activities, know little about the manufacturing process of osseointegrated implants. In this perspective, the purpose of this article is to present the step-by-step process of fabrication of osseointegrated implants.

Keywords: *Osseointegrated Implants; Scientific Research; Better Products*

Introduction and Background

The need to replace lost natural teeth with artificial analogs is remote. Since ancient times, mankind has used shells, bone fragments, wood, porcelain and metals (gold, silver, platinum, tin) as dental substitutes in the most archaic dental prostheses. In the Contemporary Age, as from the 1930s, needled, endo-osseous and subperiosteal implants were developed and widely used. However, these implants presented failures and a short useful life. After discovery of osseointegration by Branemark, implant dentistry became more popular and became more accessible to the partially or totally edentulous population [1-6].

Since then, new technologies have been developed and improved, including surgical techniques, rehabilitation and especially the biomechanics of implants and components. Currently, the morse taper, in view of its advantages, dominates the osseointegrated implant market. However, the development acquired in the past on external and internal hexagons led to the current knowledge. In the current world market, several brands, lengths, diameters, implant body shapes, platforms, thread patterns and surface treatments can be found [1-7].

It is important to emphasize that, considering the hundreds of commercial brands existing all over the world, it is essential to establish technical norms for the manufacturing of implants, for their correct indexation and standardization. Additionally, compliance with these technical standards offers quality and traceability of the products, inhibiting piracy of these articles [1,2,5,6].

The Food and Drug Administration regulates the manufacture of the implants on the US market. Implants are classified as medical devices (class III). Preclinical and clinical controlled studies are

required for approval before marketing. However, in view of these stringent requirements, implant companies issue a pre-market notification, which is less stringent. Only information such as design characteristics, indications for use, material specifications, tolerances, toxicological tests, sterilization and results of static, compressive and shear fatigue and corrosion tests are required [1,2].

The American Dental Association also presents an acceptance programme for implants. However, although well-intentioned, it proposes lenient criteria for a modest level of clinical validation. Unfortunately, most manufacturers do not certify their products for this endorsement. And, presumably, dental surgeons consume the products based on marketing rather than on scientific support [2].

In Europe, the CE label indicates adequacy of the manufacturing process [2].

In Brazil, the manual of Good Manufacturing Practices - Quality System Regulations, of the National Health Surveillance Agency of the Ministry of Health, is proposed for quality control in the design, manufacture and distribution of medical products and devices [2].

In recent years, there has been a growing interest among manufacturers to adapt to the standards of the International Organization for Standardization (ISO). The ISO Standards are intended to unify international standards. ISO 9001 and ISO 9002 are guidelines for quality assurance in design, development and production, installation and customer service. The standards are generic and applicable across all types of industries. For the manufacture of medical devices, there are specifically EN46001 and EN46002.

We, dental surgeons with exclusively clinical activities, know little about the manufacturing process of osseointegrated implants. In this perspective, the purpose of this article is to present the step-by-step process of fabrication of osseointegrated implants. This article was written based on Brazilian government guidelines and represented by a Brazilian implant company.

Phases of manufacturing

The manufacture of the osseointegrated implants is submitted to processes that certify the standardization of the products and their homogeneity. The phases mentioned below are generic, and may vary according to the commercial brands and types of implants. The compliance of all the phases, from the acquisition of raw materials of origin, until the delivery to the final consumer, guarantees the quality, standardization and traceability of the products, aiming at the excellence of the implantoprosthetic rehabilitation.

Raw material acquisition

The material is acquired from previously registered suppliers, according to the specification determined in the product design and development. The acquisition of raw materials must be made upon delivery of the metallographic analysis certificate. Upon receipt of the material, the report of supplier is checked, with the specifications referring to the chemical and physical/mechanical characteristics. The storage of these titanium alloy bars must be performed in dry places, with identification containing certificate, product description, measure and supplier.

Requisition the products

By means of a computerised system, based on production needs, the machines are prepared and programmed in accordance with the design and specifications of the product (Figure 1).

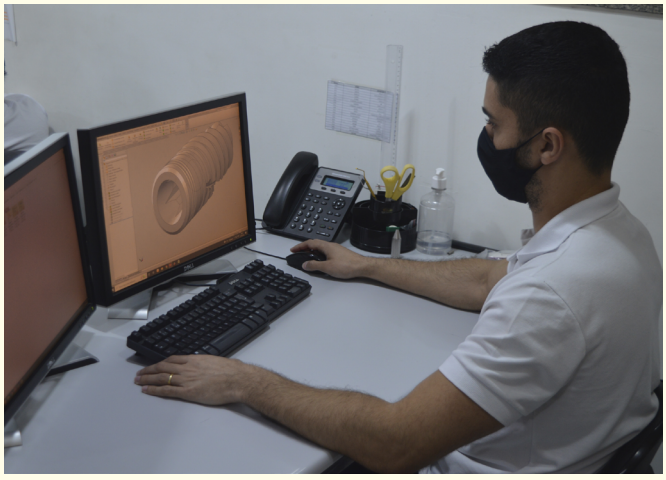

Figure 1: *Survey of production needs.*

Machining

From the programming and release of the lathe, the implant is machined by milling the titanium alloy bar (Figure 2). The newly manufactured implant is submitted to the Quality Control evaluation. The physical characteristics will be inspected and checked

Figure 2: *Machining of the implant.*

for conformity with the specifications contained in the project. It is important to point out that the inspection is carried out with duly calibrated and certified measuring instruments (Figure 3 and 4). Once the inspection has been approved, the rest of the lot is released for machining by the programmer responsible for the lathe. During the entire machining process, the parts are checked by sampling to ensure manufacturing within specifications. These guidelines follow the NBR ISO 5430 and NBR ISO 5429 standards. At the end of the machining of the whole lot, the inspection of the characteristics is performed by Quality Control, by random sampling.

Figure 3: *Macroscopic evaluation of the newly manufactured implant by the Quality Control.*

Figure 4: *Evaluation of implant characteristics by means of profilometry.*

First asepsis

In accordance with NBR ISO 14233 and ISO 14644-1:2005, which determines the use of a class 8 controlled room, the first asepsis is carried out to remove the oil and other contaminants (Figure 5).

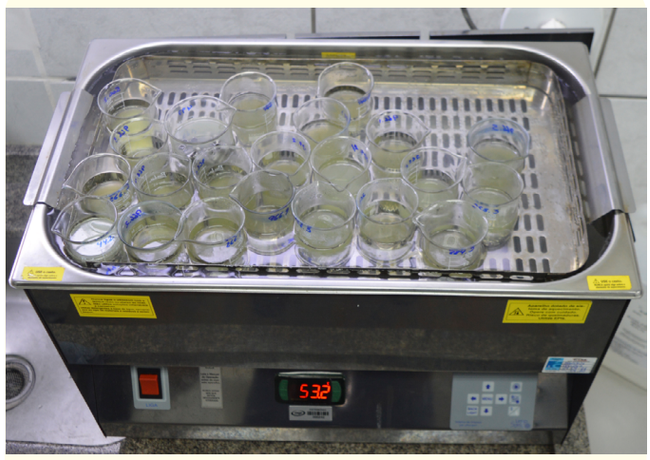

Figure 5: *Implants under the first asepsis (ultrasonic tank).*

Surface treatment

The implants are blasted with titanium oxide, increasing the porous surface of the implant and subsequently allowing greater microscopic intermingling between implant and bone.

Second asepsis

According to NBR ISO 14233, the product is again submitted to washing to remove contaminants. Subsequently, the implant is submitted to acid subtraction, also to increase the microscopic adhesion area at the bone-implant interface. Subsequently, the implants are dried and packed, followed by labeling, keeping the original identification of the product.

Sterilization

Sterilization is performed by gamma rays, after the implants are individually packed and labelled. This process is validated by the RDC16 and NBR ISO 11137 standards. It is also controlled and has a new traceability register.

Final inspection

Finally, the implant is inspected, verifying the components of product, form of presentation, description and lot, determined by the registration number. This registration ensures its traceability. From then on, the implant is stored, avoiding exchange, damage or deterioration, and released for commercialization (Figure 6).

Figure 6: *Implant packed and identified, ready for sale.*

Conclusion

The choice of commercial brands should preferably be based on scientific research. The scientific and technological evolution allowed, along the years, the manufacturing of better products. The manufacture of the implant involves several stages and processes that must be known by the dental surgeon. This knowledge also allows the professional to choose better products. The traceability of these products increases the safety of use and subsequently the offer of quality to the final consumer (patient).

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