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Technical Paper

Good Practices in the Manufacture of Osseointegrated Implants: A Technical Note

Sabrina Batista Venancio[1], Gabriela Maia Barrenha[2], Marcia Ribeiro de Alcantara-Nascimento[3], Mary Lucia Maia Lima[4], Marcelo do Lago Pimentel Maia[5] and Irineu Gregnanin Pedron[6]*

[1]*Undergraduate Student, Universidade Brasil, São Paulo, Brazil*

[2]*Undergraduate Student, Universidade Cruzeiro do Sul, São Paulo, Brazil*

[3]*Private practice, São Paulo, Brazil*

[4]*Postgraduate Student, Department of Oral Implantology, Marcelo Yoshimoto Institute, São Paulo, Brazil*

[5]*Professor, Department of Oral Implantology, Marcelo Yoshimoto Institute, São Paulo, Brazil*

[6]*Professor, Department of Periodontology, Implantology, Stomatology, Integrated Clinic, Laser and Therapeutics, Universidade Brasil, São Paulo, Brazil*

***Corresponding Author:** Irineu Gregnanin Pedron, Department of Periodontology, Implantology, Stomatology, Integrated Clinic, Laser and Therapeutics, Universidade Brasil, São Paulo, Brazil*

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Introduction and Background

The replacement of lost teeth with analogs dates back to ancient times. In the phase that preceded the discovery of osseointegration, several types and designs of implants were created and used, such as needled tips, juxtaosseous and subperiosteal implants. However, over the years, rehabilitations on implants presented failures and unsuccess, determining a short longevity of the rehabilitations. With the advent of osseointegration, this desire has become accessible and present today. Several techniques and types of implants have been developed for the purpose of implantoprosthetic rehabilitation of partially or totally edentulous patients[1-5].

Evolution has reached not only new surgical techniques, but also the biomechanics of implants and components. The development of external and internal hexagons and currently morse tapers have increased this close relationship between implants and connections, favoring the maintenance and longevity of implant prosthetic rehabilitations. A wide variety of brands, implant body formats, lengths, diameters, platforms, thread patterns and surface topography, all to meet the market needs in many, if not all, countries in the world. Additionally, several types of implant surface treatment have been developed to improve the implant-bone union. Currently, the most used surface is the titanium blasting process and acid subtraction[1-6].

It is important to highlight that, in view of hundreds of brands existing all over the world, and the quantity of types of implants and components, it is necessary and important the establishment of technical norms and guidelines for the manufacturing of these components. The compliance to these guidelines determines the quality, standardization and traceability of the products offered and used in patients, reflecting in the follow-up and success of the implantoprosthetic rehabilitations[1,4,5].

In the United States, the Food and Drug Administration regulates the manufacture of all implants on the US market. Initially, implants are classified as class III, a category of medical devices, which requires approval before sales. However, the stringent requirements include pre-clinical and clinical controlled studies. Thus, implants have been included in a pre-market notification submission, which is much less stringent. For approval, the manufacturer must specify the intended use; provide a detailed report of design features, including diagrams, material specifications and tolerances; provide sterilisation information and labelling details; submit results of static and fatigue tests in compression and shear, along with corrosion tests; and toxicology tests when the material is new[1].

The Good Manufacturing Practice - Quality System Regulations manual is a quality control system on the design, production and distribution of products and medical devices[1].

The American Dental Association also has an acceptance programme for professional implant products. This program, although well intentioned, presents less stringent criteria for a modest level of clinical validation. However, most manufacturers do not present their products for endorsement, as it is in the best interest of the dental profession and consumer. Apparently, most dental surgeons consume products according to marketing rather than clinical and scientific documentation[1].

In recent years, manufacturers have shown interest in conforming to International Organization for Standardization (ISO) Standards. The purpose of the ISO Standards is to promote the international unification of standards. The ISO 9001 and ISO 9002 Standards are models for quality assurance in design, development and production, installation and service to customers and suppliers. The standards are generic across all types of industries for quality and assurance, but are not specific to operating procedures. Specifically for medical device manufacturing, there are EN46001 and EN46002. In Europe, the CE mark indicates conformity in the manufacturing process[1].

Few brands have well-documented longevity clinical studies. Several commercial brands have success rates above 90% for more than 10 years. In addition, significant refinement in the process of technological improvements in the manufacture of implants and components has favoured the increase of this success rate[1,5,6].

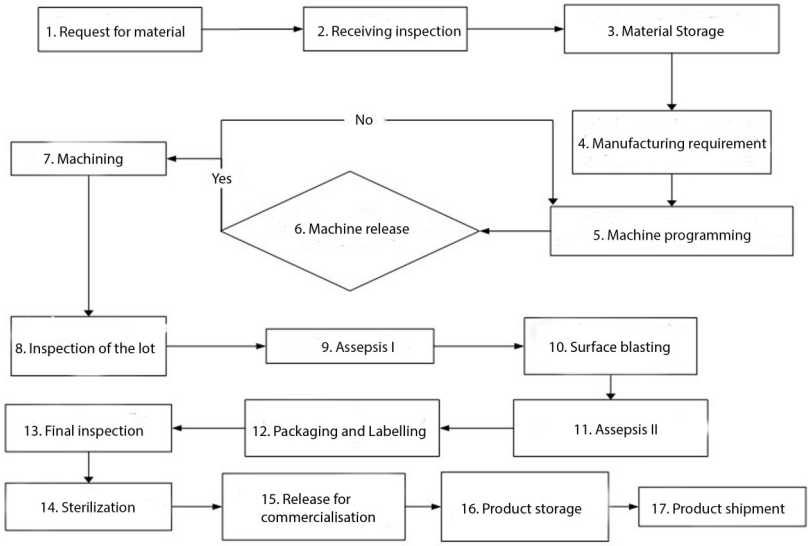
Manufacturing Process

The manufacturing process of osseointegrated implants generally involves the use of equipment that guarantees the homogeneity and standardization of the products in all its details. The steps reported here are generalized and may vary according to the various commercial brands and different types of implants.

The manufacture of the parts is based on an integrated set of procedures, operation routines, methodologies and technical and mechanical considerations, which covers from the procurement of raw materials to the delivery of the product to the customer.

The descriptions of the manufacturing process stages are summarised in Figure 1 and are listed below:

Figure 1: Stages of the manufacturing process of osseointegrated implants.



1. Material Request

The material is requested by a computerised system, acquired from previously qualified suppliers, in accordance with the purchase specification determined in the product design and development. To monitor the qualification of the supplier and the raw material, the metallographic analysis certificate is requested.

2. Reception Inspection

Upon receipt, the material is checked against the invoice, the report of supplier and the purchase specification regarding its chemical, physical and/or mechanical characteristics. If the product is in conformity, it is stored and the documentation relating to that batch is filed.

3. Material Storage

The product is identified with a label containing the product description, measure, supplier, certificate or note number and stored.

4. Survey of the Needs to be Manufactured

With the survey of stock and estimated production and according to the procedure established in the Quality Management System, it is determined the products that will be manufactured, their quantities and priority and then with these data are generated in the Manufacturing Orders Computer System.

5. Programming and Machine Preparation

With the manufacturing order in hand, the product drawing containing the process and its specifications, the machine programmer enters and checks the product programming on the sliding headstock lathe (Computerised Numeric Command).

6. Machine Release

After programming and preparation of the machine, the professional machines the piece and it is sent to Quality Control that will inspect all the characteristics of the product, verifying if they are in conformity with the specifications contained in the product design. The inspection is carried out with duly calibrated measuring instruments and with certificates traceable to the Brazilian Calibration Network.

After approval of this inspection, the scheduler is released to start machining the rest of the lot.

7. Machining

During machining, the parts are checked by a sampling process in accordance with the NBR ISO 5430 and NBR ISO 5429 standards, to ensure that the parts are being manufactured within specifications.

8. Lot Inspection

After the machining of the whole lot, the parts are sent to Quality Control for inspection of the product characteristics by random sampling.

9. Asepsis I

After approval of the batch by Quality Control, the parts are sent for removal of the oil and other contaminants, in accordance with NBR ISO 14233, in a class 8 controlled room, in accordance with ISO 14644-1:2005.

10. Surface blasting

The implants are blasted with titanium oxide, which ensures that the product has a porous surface, helping to anchor the implant.

11. Asepsis II

The product is then washed again and subsequently submitted to acid subtraction, in accordance with NBR ISO 14233.

12. Packaging and Labelling

The clean and dry parts are packed and labelled, keeping the product without deterioration and properly identified.

13. Sterilization

After being packed and labelled, the pieces are sent to the outsourced and qualified company for sterilisation (by gamma rays), where the process is also controlled and presents a new record for traceability.

The sterilisation process is validated according to the requirements of RDC16 and NBR ISO 11137 and is described in the procedures of the outsourced company. This company is also controlled annually by periodic audits of its quality system, as well as being authorized by the competent institutions to perform this type of service.

14. Final Inspection

At the end of the steps mentioned here, the product is inspected by comparing the product data and the Product History Record (records filled in all the product manufacturing stages), ensuring its traceability. The constituent components of the product, presentation form, registration number, description and lot are verified

15. Product Release for Commercialisation

After the end of the production process, the Technical Manager analyses the Product Historic Record. Only after analysis, approval and release of the Technical Manager at this stage that the parts will be stocked to be marketed.

16. Storage

The products are stored in properly identified drawers, avoiding exchange, damage or deterioration.

17. Expedition

According to the order entered into the computerised system, the products are separated, checked together with the invoice containing the product description, lot number, quantity and the details of the purchaser.

Conclusions

The dental surgeon must know the manufacturing process of the implant used. Knowledge of the manufacturing process is fundamental and allows the dental surgeon to opt for better products and with greater traceability, thus increasing the care of the patients who will receive the osseointegrated implants. It is also important to stress that the option for commercial brands and implant systems must be based on scientific research, further enhancing the choice of the implant brand. Preferably, evidence-based treatment requires scientific documentation before clinical use.

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