

João Geraldo Bugarin Júnior¹
Volnei Garrafa¹¹

Bioethics and biosafety: the use of biomaterials in dental practice

ABSTRACT

OBJECTIVE: To analyze the use of biomaterials in surgical procedures carried out by specialist dental surgeons, in light of the Principlist Bioethics Theory and the Individual and Collective Ethics of Responsibility.

METHODS: Dental surgeons (n=95), who were registered as specialists at the Regional Dentistry Council of Brasilia as of 2002, completed questionnaires regarding the use of biomaterials in their work. Data relating to sanitary control were collated, based on these dental surgeons' responses and research at relevant organizations.

RESULTS: All of the professionals in the survey used biomaterials on a regular basis; 45% believed their use to be risk-free for patients, and 48% did not classify biomaterials as drugs. About 70% of professionals trust the source of the biomaterials even though membranes and bones are the items most commonly bought from individual suppliers. Nonetheless, 96% of interviewees believed that government sanitation agencies should regulate more. More than half of the professionals (51%) pointed to little or no participation by the patient in the process of therapeutic choice. A copy of the informed consent form was provided by 12% of the dental surgeons interviewed produced.

CONCLUSIONS: The results showed that the professionals use biomaterials without knowing about related risks and adverse side effects, contrary to the principle of beneficence. Government agencies and professional bodies alike do not show evidence of observing public responsibility ethics. Informed consent is not yet integrated fully into professional practice and the doctor-patient relationship in dentistry remains markedly vertical.

KEYWORDS: Bioethics. Biosafety. Biomaterials. Dentistry.

INTRODUCTION

Significant advances in the use of biomaterials in clinical dentistry over the last decade mean that these materials are now used as powerful therapeutic tools in surgical procedures, particularly in the correction of bone defects.³ However, in spite of these proven benefits, the use of biomaterials requires the dental professional to take great care, both clinically and ethically, in analyzing the risks and benefits that may come with the use of biomaterials.

Anthropological and archeological studies show that primitive communities were concerned with dental prosthetics. A human jaw bone of Mayan origin dating from the 7th Century AD was found to contain three small fragments of coral that served as substitutes for the mandibular incisors. Using radiography exams, researchers found that compact bone had formed around these fragments. As a result, these were considered the world's oldest example of alloplastic implants successfully inserted into a living human being. This example shows that, for a very long time, materials have been inserted next to oral tissues

¹ Programa de Pós-graduação em Ciências da Saúde. Universidade de Brasília. Brasília, DF, Brasil

¹¹ Cátedra Unesco de Bioética. Universidade de Brasília. Brasília, DF, Brasil

Correspondence:

Cátedra UNESCO de Bioética
Universidade de Brasília – UnB
Caixa Postal 04451
70904-970 Brasília, DF, Brasil
E-mail: bioetica@unb.br

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as a replacement for lost teeth, without knowing the biological consequence. This empirical practice continued throughout the Middle and Modern Ages, when dentistry was considered to be essentially the work of craftsmen, without any scientific basis.

However, developments in biotechnology that began in the 1950s and have gathered speed in recent years have given rise to significant advances in dentistry and increased the scope of work of dental surgeons and reinforced the discipline as a science. At the same time, the responsibility of the dental professional has increased and he or she is now required to keep up to date with new areas of research.⁴

In today's globalized world, scientific discoveries are introduced and swiftly absorbed into clinical practice. In dentistry, new products are launched daily, most of which are used in dental surgery. When these products are used, they come into direct contact with living tissues, such as dentin, pulp, the alveolar bone and periodontal tissue, and sometimes stay in contact for prolonged periods.

Biomaterial is defined, in the broader sense, as any pharmacologically inert material that is capable of interacting with a living organism without causing adverse reactions either at the site of the implant or across the whole organism.⁹ The treatment with dental biomaterials of gum, mucosal and hard tissues, represents a therapeutic risk that can only be contained if the dental professional has knowledge of the qualities, strengths and properties of the products.

The use of biomaterials without any recognized criteria for biosafety not only causes clinical problems such as therapeutic failure, but also gives rise to ethically conflicting situations. This is because the patient may undergo treatment without knowing about the subsequent risks, either to himself or to the dental professional.⁴

Schramm* (1998) defines biosafety as "the series of actions aimed at preventing, minimizing or eliminating the risks involved in activities such as research, production, teaching, technological development and service provision, risks that could jeopardize good health, the environment or the quality of work under development". Both bioethics and biosafety are concerned with the probability of risks, with negative impacts on the quality of life of individuals and populations and with the adoption of new practices. However biosafety quantifies and measures risks and benefits, while bioethics analyses the rational arguments which justify or fail to justify such risks.

The Principlist theory of bioethics, proffered by Beauchamp & Childress¹ (2001) in "Principles of Biomedical Ethics", has become the prime theoretical basis for the new field of biomedical ethics. It applies a system of principles – autonomy, beneficence, non-maleficence and justice – to the area of medical care in everyday situations involving professional-patient relations.

The speed of medical and technological advances means that the work of health care professionals involved in the area of new biomedical discoveries requires more careful ethical consideration.⁶ It is in this context that bioethics appears as a new field of study and reflection in morals and ethics, involving different developments and subjects. Its focus is on the conduct of the health professional, in relation to citizenship and human rights, in contexts of time and space where people find themselves vulnerable, both in terms of their access to and search for health care.

Muñoz & Fortes** (1998) argue that the patient has the moral right to be given explanations about the nature and objectives of procedures, be they diagnostic, preventive or therapeutic. In the same way, the patient should be informed about the invasiveness, length of treatment, benefits, likely discomfort and potential physical, psychic, economic and social risks that could be involved. The health care professional should offer possible alternatives to treatment, where available. The person needs to be informed about the presumed effectiveness of the proposed course of action, and the probability of any changes in levels of pain, suffering and pathological conditions. In other words, he or she should be clearly supplied with the information required to make informed decisions.

Graham & Harel-Raviv⁶ (1997) explain that informed consent is a fundamental instrument in the process of communication between the patient and health professional. With this in mind, the present article sets out to analyze the use of biomaterials in dentistry with respect to criteria such as use, risks, origins, commercialization, sanitary control and participation of the patient in therapeutic choice.

METHODS

The use of biomaterials by dental surgeons was analyzed, in relation to biosafety measures and in light of the Principlist Theory of Bioethics (Beauchamp & Childress¹ 2001) and the Ethics of Individual and Collective Responsibility (Jonas⁷ 1990; Garrafa⁵ 1995).

* Schramm FR. Bioética e biossegurança. In: Costa SIF, Garrafa V, Oselka G. (orgs.). Iniciação à Bioética, Conselho Federal de Medicina, Brasília, 1998, p.217-230.

** Muñoz DR, Fortes PAC. O princípio da autonomia e o consentimento livre e esclarecido. In: Costa SIF, Garrafa V, Oselka G. (orgs.). Iniciação à Bioética. Brasília, Conselho Federal de Medicina, Brasília, 1998, p. 99-110.

The specializations in which biomaterials are most used in professional practice were chosen. It was decided that the study would include all specialists who work in these areas and who have registered as specialists at the Regional Dentistry Council of the Federal District (CRO-DF in the Portuguese) as of 2002.

Once the study group had been determined, criteria for inclusion were established, as follows: participants should be specialists in periodontology, dental implants and buco-maxillofacial surgery and traumatology, and agree to partake independently in the research by signing the terms of informed consent.

Of the original 123 dental surgeons working in the aforementioned specializations and included in the official list provided by CRO-DF, 28 professionals were excluded from the study for one or more of the following reasons: their place of residence was not Brasilia, their current address was not available through the CRO-DF, or they did not agree to participate in the research. Therefore the total number of participants was 95 professionals, which equates to 77.2% of the total study sample.

To gather data, an interview questionnaire was drawn up, containing 13 questions, of which nine were closed and four open.

The aim of the first set of questions was to gather information on the profile of the professional involved in the research, with regard to sex, age, length of education, specialization and period of time operating as a registered specialist. Other questions included: information about the patient's participation in therapeutic planning, by means of use of the terms of consent; notions of risk and biological effects in the use of these materials on patients; and details about the biomaterials most used in their professional practice.

The questionnaire was designed to gather data on the degree of concern displayed by the professional in relation to the origin, quality, regulation and source of the biomaterials. To close, the final question sought to examine once gain the notion of risk in the use of biomaterials, by means of an open question, so that the professional could freely express his or her opinion.

In the first instance, the questionnaire was applied to a pilot sample of ten professionals, chosen at random from the entire sample, in order to analyze the applicability, clarity and appropriateness of the proposed objectives. Since no changes to the questionnaire were subsequently necessary, the pilot sample was used in the final study. A group of ten dental students received training and guidance on the use of the questionnaires for the rest of the group under study, with supervision provided by the researcher at all times.

Measures for regulation, standardization or surveillance of the use of biomaterials on the part of governmental authorities or professional-level councils, were evaluated by searching for information in the publications of these organizations and on the web-sites of each institution.

The elements relating to safety and regulation of these materials were evaluated by means of an analysis of the responses given by interviewees in the questionnaire.

The project was submitted to the Committee on Research Ethics at the Faculdade de Ciências da Saúde of the Universidade de Brasilia, so as to assess the ethics and the technical and scientific content of the research, with approval subsequently being granted. Participants in the study signed informed consent forms.

RESULTS

There was a predominance of male specialists (75%), with the majority aged between 29 and 39, and holding between 11 and 20 years of experience (52%). The largest group was of periodontists (45%), with between 6 and 10 years of experience as specialists (36%).

The majority (51%) of dental surgeons reported using the terms of consent with the patient in their consultations. Of these, only 12% produced copies of this document, when asked.

Table 1. Numbers and Proportions of specialists who consider biomaterials to be a medicine. Federal District, Brazil, 2002.

Response	N	%
Yes	41	43
No	45	47
Do not know	7	8
Blank	2	2
Total	95	100

Table 2. List of materials most frequently cited by specialists. Federal District, Brazil, 2002.

Material	N
Reabsorbable membrane	42
Implants	38
Lyophilized bone	36
Non-reabsorbable membrane	30
Bovine bone	29
Hydroxyapatite	27
Human bone	26
Membranes	24
Autogenous bone	20
Capset (calcium sulfate)	18

Table 3. Total number of materials most frequently purchased from independent suppliers by dental surgeons. Federal District, Brazil, 2002.

Material	N
Reabsorbable membrane	8
Lyophilized bone	6
Membranes	5
Bovine bone	4
Non-reabsorbable membrane	3
Human bone	3
Autogenous bone	3
Capset (calcium sulfate)	3
Alloderm	3

Table 4. Total numbers and proportion of specialists, according to level of patient participation in the choice of materials. Federal District, Brazil, 2002.

Patient participates in choice	N	%
Always	22	23
Usually	21	22
Occasionally	27	29
Never	21	22
Blank	4	4
Total	95	100

Nearly 47% of those interviewed did not consider biomaterials to be a form of medication.

The 10 most commonly used materials are presented, in descending order, in Table 2. The most frequently cited were membranes, implants and lyophilized bone graft material.

The materials most frequently purchased by dental practices and bought directly from independent suppliers were membranes and bones; those purchased from import companies were implants and bones (Table 3). Implants are the material most commonly purchased directly from the factory, particularly from domestic suppliers; of materials purchased abroad, titanium screws and plates were most commonly mentioned. Seventy percent of professionals said that they trusted the source of these materials.

When asked about regulation of biomaterials, almost all professionals (96%) replied that there should be more controls. The Brazilian Ministry of Health was most commonly proposed (by 50% of interviewees) as the agency best suited to perform this function.

The results show that the professional practice of these specialists is essentially paternalistic: more than half (51%) pointed to little or no participation on the part of the patient in the process of therapeutic choice (Table 4).

In relation to the notion of risk to the patient in the use of these biomaterials, 55% of dental surgeons believed there to be some form of risk to the patient. The most frequently mentioned were: infection, contamination, transmission of disease, rejection, incorrect manipulation, allergic reactions, inefficiency and manufacturing defects.

DISCUSSION

Analysis of the results allowed for further reflection about the use of biomaterials by specialists.

The origins of the materials are diverse, primarily due to the fact that a large variety of membranes and lyophilized bone of bovine origin are available on the Brazilian market. Among the animal biomaterials are bone morphogenetic protein and lyophilized bone; among the synthetic biomaterials are hydroxyapatite and calcium sulfate. The use of biomaterials that are of animal and synthetic origin can largely be attributed to the fact that the Brazilian Constitution* forbids the sale and use of materials of human origin. Furthermore, Law 9434 of 4 February, 1997, which relates to the donation of organs and accompanying procedures, establishes penalties and fines for any kind of sale of human organs or tissues in Brazil.

For Berlinguer & Garrafa² (2001), in future there will be a shift away from the use of human biomaterials towards xenograft, as a result of shortages in the global supply of human bones. However, there remain many doubts about the relationship between cells from different species. Much polemic surrounded the proposal to use the organs of animals that had been genetically treated, due to long-term effects, principally in the field of immunology.²

The biomaterials most commonly referenced by import companies are implants manufactured in other countries and lyophilized human bone. The lack of a bank of human bones for commercial purposes in Brazil, similar to those that already exist in the United States, Singapore, Hong Kong and elsewhere, has meant that there has been a growth in the number of companies importing lyophilized human bone.

Among the materials that dental surgeons most frequently purchase from independent suppliers, are also reabsorbable membranes and lyophilized bone

* Federal Constitution of Brazil, Title VIII – on Social Order – Ch.II – section II – on health – article 100 – clause 4.

(Table 4). This finding gives cause for concern since of all possible sources, independent suppliers are indeed the least likely to control the quality of the origin of such materials.⁴ Many of the biomaterials and equipment that have North-American patents are produced in developing countries, such as Taiwan, Korea, Indonesia and others, where a large proportion of the labor force is cheap and unqualified. Outside of the USA, without regulation of the hygiene of their sources, these materials are not covered by the strict controls established by the Food and Drugs Administration (FDA).⁴ The risks inherent in the use of biomaterials are minimized by means of biological processing during their preparation.⁹ If the professional uses biomaterials of doubtful origin or those that are sourced locally without hygiene controls, the biological risks to the patient increase and the procedure risks falling short of the principle of beneficence. Above all, protection of the patient is the primary objective both of bioethics, through the principles of beneficence and non-maleficence, and of biosecurity with a view to prevent and avoid risks. Nonetheless, quality control of materials becomes fundamental.

From the perspective of the Principlist Theory of Bioethics, one notes that the principle of patient autonomy is frequently ignored. Most interviewees stated that the patient rarely or never participated in the decision about treatment. The use of terms of informed consent has not yet been incorporated into professional practice. The lack of patient participation was also noted in recent research that assessed the records of dental implant specialists in São Paulo and found that 50% of interviewees did not consider it important to pass on information about treatment to their patients.⁸ These findings show that the patient's autonomy is not respected, and that the use of informed consent forms has not yet been incorporated into professional practice, suggesting that the professional-patient relationship in dentistry is still excessively vertical.

Findings showed that dental professionals are not aware of the risks and benefits of biomaterials, nor of their biological origins, with 45% believing that there was no risk at all for the patient, and 56% do not consider biomaterials to be a medicine. However, even if the biomaterials are thought to be inert, they will come into contact with the oral cavity and be subjected to

the mechanical process of chewing, which may result in biological interactions.

This lack of knowledge on the part of dental surgeons calls for a review of professional conduct. By using materials without appropriate knowledge or by not following the biosafety principles inherent in their use, the dental surgeon goes against the principle of beneficence. Furthermore, he or she possibly fails to abide by the principle of non-maleficence (*primum non nocere* – above all, do no harm).

For Jonas⁷ (1990), it is necessary for ethical reasoning to advance at the same pace as scientific and technological progress. The freedom to generate and use new knowledge must show a direct relationship with responsibility – both individual and public – in the process of scientific discovery and its consequences.

By pointing to a compromise in the ethics of public responsibility, the lack of appropriate controls has been highlighted. This is because the review of the abovementioned biomaterials for the purposes of registration is purely a formality, and does not involve biological tests. In addition, this ethical compromise was not referred to by professional bodies such as the dentistry councils, whose legal role it is to promote, using all available means, the highest technical and moral standards in dentistry. Dental professionals are not provided with any guidance or norms for the use of biomaterials in Brazil.

The results show that 96% of dental surgeons recognize the need for regulation in the use of these materials. This leads to the conclusion that professionals do not feel secure about the control and regulation of these products in Brazil, or that they are unaware of the actions of the Brazilian Ministry of Health, through the Agência Nacional de Vigilância Sanitária (Anvisa – National Agency for Health Surveillance). Although some materials are registered at Anvisa, no measures or guidelines for their use were found within the federal and regional dental councils.

For this reason, the monitoring of their sale, use and scope by professionals, authorities and of all society is fundamental, as is, most importantly, the creation of a robust policy for health surveillance of these products.

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