



The “*Lucian Blaga*” University of Sibiu

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## **PhD. THESIS**

## **SUMMARY**

# **Contributions regarding the improvement of the dental implant conception and manufacturing**

**Coordinator:**

**Prof. Eng. Dan-Maniu Dușe, PhD**

**PhD. student:**

**Eng. Alexandru Pașa**

**Sibiu**

**– 2011 –**



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***„The energy of the mind represents the essence of life.”***

Aristotel (384 b.c.e.-322 b.c.e., Greek philosopher)

## **Foreword**

The loss of a limb, of a tooth...these are not new problems, and neither is the concern of replacing them. Prosthetics represents the replacement of a damaged or lost body part with a natural or synthetic material. Attempts in this direction have been made with 1000 years b.c.e., in spite of the technological limitations and scarce medical knowledge. The most complicated procedures were those where a foreign object was attempted to be inserted into the biological environment – implants.

The human organism tends to eliminate foreign objects, any structure not compatible with its biology generating inflammations and infections. As consequence, attempts have been made to suppress these reactions, through the usage of natural and synthetic materials. As such, rudimentary implantology was born.

The current paper is focused on dental implantological restorations, presenting their evolution, classification and characteristics, as well as the process of developing a new dental implant system. The thesis is at the same time a medical and technical guide, which presents the main aspects of dental implantology, combining clinical cases with technical specifications, therefore providing an interdisciplinary approach to the current theme. The importance of this type of restorations is the greater, in the measure in which dentition influences other body functions – directly of the digestive system, and indirectly, by the limitations generated by partial or total edentation, of the nervous system (the psyche).

The subjects addressed include the insertion procedures of screw-shaped dental implants, the dental implant market status in the context of the current economical crisis and forecasts on its evolution and a market survey which targets the analysis of over 200 dental implant systems, from both a technical and medical point of view.

The purpose of the current research is the development of an improved dental implant system through the utilization of the classic, computer aided and creative design methods. In the development of the current dental implant system, an important part was played by virtual engineering, because of time and cost saving considerations and the interconnectivity of the computer aided design processes, which allows their tracking and analysis.

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# Chapter I - The current state of dental implant development

## 1. Introduction to the bio-materials science

In order to have an overview on the environment which facilitated the development of implants, a short introduction to the bio-materials science, materials of which all medical implants are made, is required.

*Biomaterials* represent “any substance or substances combination, natural or synthetic, except for drugs, which can be used [...] as a whole or a part of a system which treats, accelerates regeneration or replaces a tissue, organ or function of the human body” [ Williams et al., 1992].

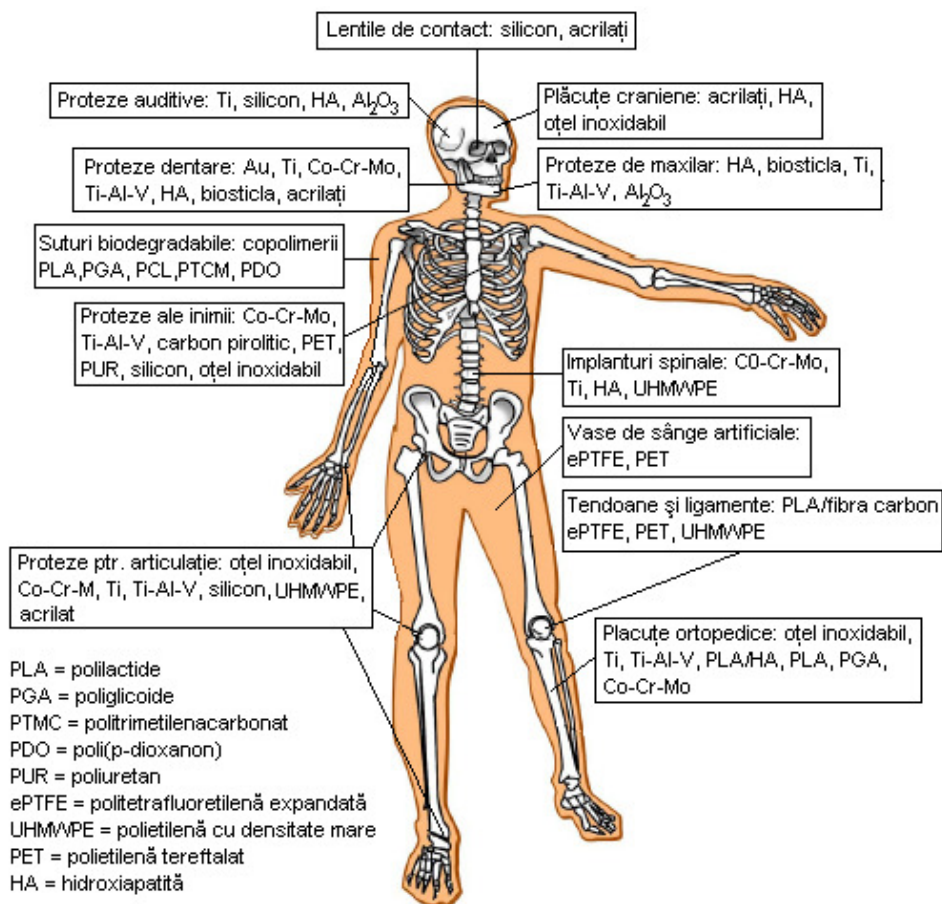


Figure 1.1.1. Biomaterials applications in medicine

The biomaterials science studies the physical, chemical and biological characteristics of materials, in the context of their interaction with the biological environment. [Demian , 2007]

According to this interaction type, biomaterials are classified in:

- bioinert materials;
- bioabsorbant materials;
- bioactive materials.

The biomaterials class sets itself apart from the other material classes through the *biocompatibility* criteria, which is defined as being the materials' property because of which, following their implantation into a live organism, do not cause adverse reactions and are accepted by the surrounding tissue.

Wintermatel and Mayer (1999) have extended the biocompatibility definition and came to splitting it into two sub-classes: *intrinsic biocompatibility* and *extrinsic biocompatibility* (functional). Intrinsic biocompatibility specifies that the implant surface must be compatible with the host tissue from a chemical, biological and physical point of view (including surface morphology). As far as extrinsic biocompatibility is concerned, this refers to the mechanical properties of the material, such as the elasticity modulus, deformation behaviour and stress transmission at the implant-tissue interface level.

At the European level, the ISO 10933(parts 1 to 18, from 2002-2007) regulates the implants' biocompatibility testing specifications [1]. In Romania, this standard series has been adopted under the name of SR EN ISO 10933 (parts 1 to 18, from 2002-2007), with the classification index CAN (Convertor Analogic Numeric) E32 „Instruments, devices and mechanical machines of medical use”. These standards contain both in-vitro, as well as in-vivo testing specifications.

## **2. Dental implants**

### **2.1. Introduction**

Dental implant are inert alloplastic materials, integrated in the maxilla and/or mandible, to be used in the event of tooth loss (prosthetic restorations) or for the restoration of orofacial structures, damaged/lost as a result of trauma, neoplasty or congenital defects [Pye, 2009]. In general, a dental implant system consists of the implant itself and the abutment. The restaorative prosthetic structure is typically fixed onto the abutment by one of the following means: cementing, with an occlusal screw or a bridge with pins (telescopes), which allows a mobile prosthesis fixture. The implant is the part inserted in the bone and the abutment is the part which supports and/or fixes the prosthetic structure [Misch, 1999].

The moust widely accepted and moust successful dental implant on the market is the Ti screw-shaped endosseous one, which is constructed based on the discovery of the Swedish professor Per-Ingvar Brånemark (1952), according to which titanium can be successfully integrated in a bone structure.

### **2.2. History**

It has been recorded that in the Maya civilization the first known endosseous implants were used (implants integrated in the bone structure), with 1350 years before the renowned Per-I. Brånemark started to experiment with titanium. During the excavation of Maya graveyards in Honduras in 1931, archaeologists discovered a fragment of a Mayan mandible, dating from the year 600 c.e. This mandible, considered to belong to a 20<sup>th</sup> year old woman, had three tooth-shaped seashell fragments fixed in the alveoli of three missing lower incisors. For forty years the archaeological world considered that these fragments were placed post-mortem, in the manner also observed in the ancient Egyptian culture. However, in 1970, professor dentist Amadeo Bobbio, of Brazil, studied the mandible fragments and took some x-rays. He observed compact bone structures around two of the “implants”, which led to the conclusion that the fragments were placed during that person’s life.



An Inca skull with all 32 individual teeth made of quartz and amethyst was also discovered to be dating from that same period.

Contemporary implantology begins between the 13<sup>th</sup> and 14<sup>th</sup> of July 1978, when the Harvard American Institute of Health Conference takes place. In 1980 three decisive factors assure the continuation of oral implantology:

- The results of the Harvard Conference in 1978;
- The scientific credibility of the Goeteborg studies (initiated in 1951) conducted by P. I. Bränemark;
- The expansion of scientific studies in the field of implantology.

In Romania, the field of implantology was explored in the '90s by professors Dan Teodorescu, A. Stanescu, E. Costa, P. Pârvu, V. Popescu a.o. [Mihai, 1995].

### **3. The screw-shaped endosseous dental implant**

The most utilized dental implants on the market today are the screw-shaped endosseous ones because of their high stability at insertion and their bio-mimesis. As such, the current research will be focused on this group of dental implants.

#### **3.1. The base structure of a screw-shaped endosseous implant**

In order to present the structure of such an implant, a system which contains a high number of general characteristics will be analysed. In order to avoid an extensive analysis of the current dental implant systems, at this stage of the paper, the main system promoted by the market leader will be considered -- Nobel Active from Nobel Biocare.

A typical implant is formed by 3 main bodies:

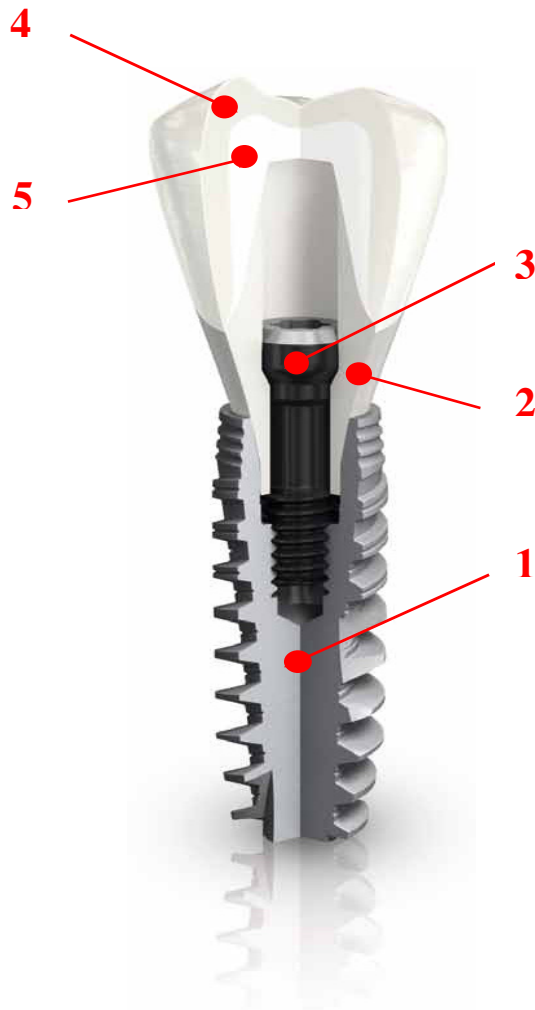
- 1- the implant body
- 2- the abutment
- 3- the abutment fixing screw

An implant based restorative structure also consists of a crown (bridge/prosthesis) and a superstructure fixing system (usually, for partial edentations, a cement is used, and for total edentations telescopic systems) (Figure 1.3.1).

4- dental crown

5- fixing system (here represented by a binder – cement)

The implant body is the structure inserted in the abutment is mounted on it in order to sustain the dental superstructure.



**Figure 1.3.1.** Components of an implant prosthetic structure

### 3.2. The implantation protocol of a screw-shaped endosseous dental implant

Each dental implant system has its own implant insertion toll-kit. Therefore, the tool set may differ according to the implantation protocol. The current tendency is that of simplifying the protocol and reducing the number of tools necessary. Such a tool-kit is presented in Figure 1.3.2.

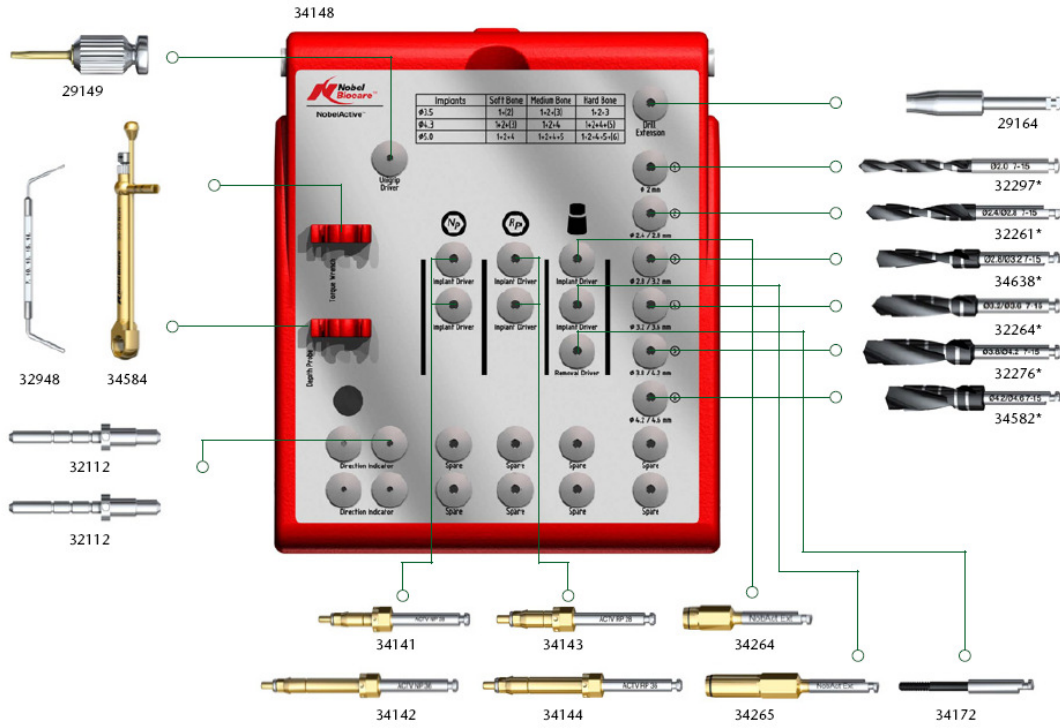


Figure 1.3.2 Implantology tool-kit example – NobelBiocare [8]

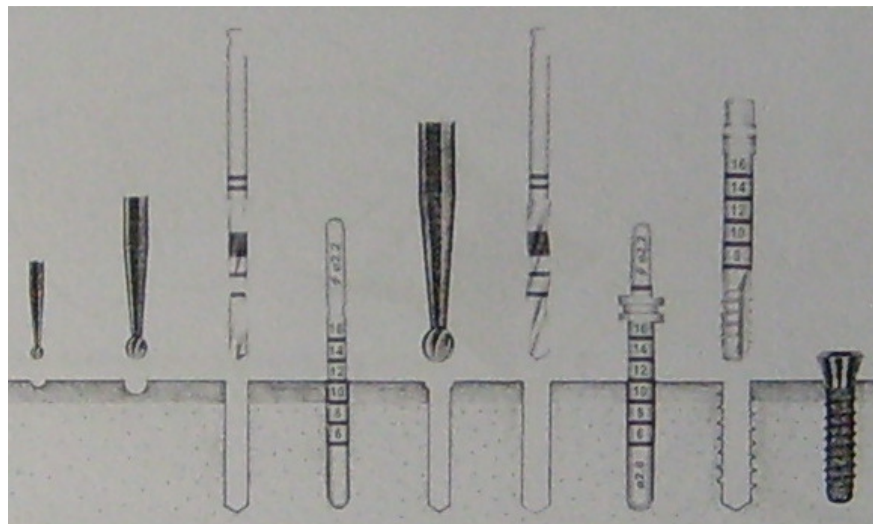


Figure 1.3.3 The general dental implant insertion protocol [Buser, 2007]

### **3.3. The success rate of screw-shaped endosseous dental implants**

The success rate of dental implants greatly depends on the medic's skills, the quality and quantity of the available bone mass in the insertion area, as well as on the patient's oral hygiene. According to various studies developed, the success rate of dental implants varies. According to [Dodson, 2006], the success rate of standard implants (D>3mm), after a 5 years survey, varies between 87,9% and 91,2%. Nobel Biocare developed a study on one of their implants (Mark III), according to which they claim a 99% success rate [Allen, 2008]. Another study developed in 2002 claims a success rate of 90,2% for the Bicon implants [Vehemente, 2002]. An American study, developed on a period of 13 years, the mean survival rate of dental implants is 93,7% for patients with no signs of parodontosis and 90,6% for those presenting such affections [Rosenberg, 2010]. Based on the presented studies, the author concludes that dental implants have a mean success rate of 91%.

Smokers present a considerably lower success rate [Balshe, 2009]. According to [Kan, 1999] this rate is approximately 65,3%.

### **3.4. The current development of the dental implant market**

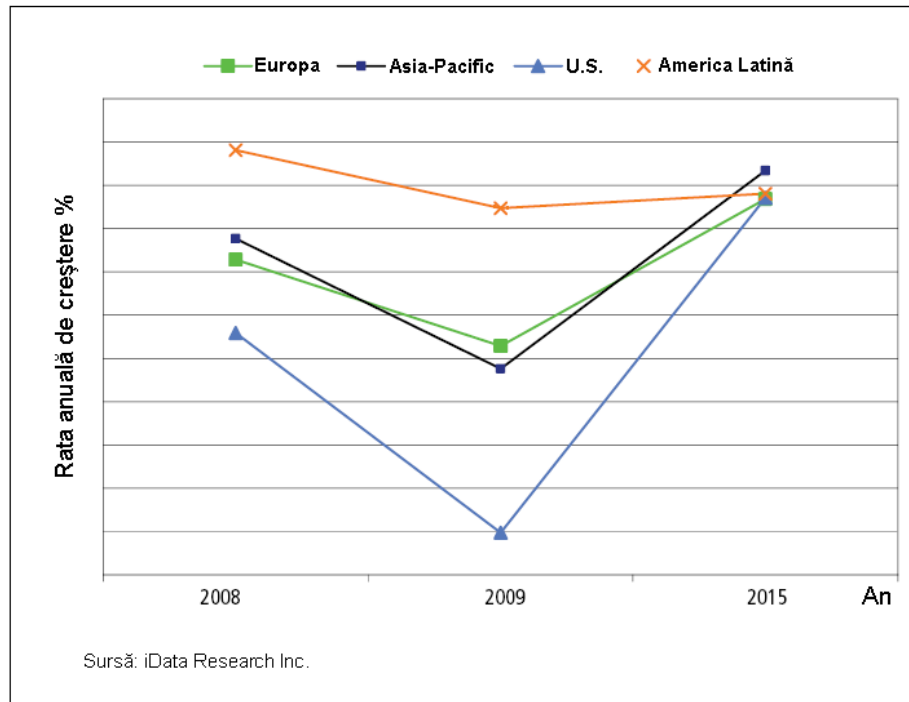
It is estimated that in the western world there are approximately 40 million people presenting full total edentations. These numbers are probably higher in Asia and Africa. In present, the dental implant market is worth over 2 billion euro world wide, and the prosthetic crowns and bridges one over 4 billion euro - Nobel Biocare Annual Report 2008.

Analyzing the dental implant market in the context of the current financial crisis, as shown in Figure 1.3.4, the lowest fall was suffered by the Latin America, and the highest the U.S.A.. However, it is forecasted that the Asia-pacific region will present the highest increase in the market by 2015.

Regardin prices, they differ from one region to the next, depending on the implant system used and the complexity of the implantation procedure – bone mass, helth issues, occlusion, etc.. Hence, in the U.S., the cost of an insetion procedure varies between \$1,250 and \$3,000 per tooth and can go as high as \$50,000 for the entire procedure, depending on its complexity [20].In Wester Europe, prices can go as high as 60.000 - 80.000 euro for total edentations which sufferd

major complications (implant loss, insufficient bone mass associated with health complications, etc.).

In Romania, the cost of a dental implant insertion starts at 500 euros, the medics here drastically reducing the procedure cost [22].



**Figura 1.3.4** Anlal growth comparison between Europe, the Asia-Pacific region, the U.S. and Latin America 2008-2015 [Paterson, 2009]

## 4. Conclusions

The analysis developed in this chapter represents a detailed approach of the constructive and functional characteristics of dental implants. The predominant dental implant model on today's market is the screw-shaped one.

From an economical point of view, as a result of the current climate study, the influence of the financial crisis on the dental implant market has been observed.

The dental implant market presents a continuous growth, especially in the Asia-Pacific region, price, notoriety and technical innovations (including implantation protocol) representing the determining competing factors.

## ***Chapter II – Research regarding the development of an improved dental implant system***

### **1. Scientific research methodologies**

A research is considered and accepted as scientific if and only if it is developed through a logic method, based on scientific thinking and course of action. [Rimouski, 2005]

The base postulates, according to [Sridhar, 2010] are:

1. It is based on empirical evidence;
2. Uses relevant concepts;
3. Engaged only in objective considerations;
4. Implies ethical neutrality;
5. Has as result probabilistical predictions;
6. The methodology is made public for its critical analysis and research repeatability;
7. Has as target the formulation of general theorems and axioms;
8. Encourages the impersonal and rigorous action mode, dictated by logical requirements and objective procedures.

Taking into consideration the current PhD. thematic and opting towards the individual informational fund described by Prof. Vitalie Belous, and taking into consideration the research methods presented by [Belous, 1992], [Oprean, 2006], [Du Plessis, 2003] and [Nichici, 2008], the following scientific research program is defined (Tabel 1.1).

**Tabel 1.1.** The scientific research development stages

<b>Nr. Crt.</b>	<b>The scientific research stages</b>	<b>Scientific research stages detailing, reported to the current research theme</b>
1	Defining the analysis domain	Bio-engineering
2	Defining analysis domain branch	Dental implants
3	Research team forming	The collaboration with specialists in the field (medics, engineers)
4	The initial defining of the research theme	Contributions in the field of dental implants

5	The study of the current development stage of the researched field	The study of the current development stage of dental implants
		5.1. The study of the dental implant history
		5.2. The study of the current classifications
		5.3. The generalized morphological and functional study of dental implants
		5.4. The study of the current main and auxiliary implantation procedures
		5.5. The study of the current dental implant market
6	The intermediary definition of the research theme	Contributions in the field of screw-shaped endosseous dental implants
7	The detailed morphological and functional analysis of the existing solutions	The detailed morphological and functional analysis of the current dental implant systems
		7.1. Research project stages planning.
		7.2. Research methods selection.
		7.3. Creation of informational funds
		7.4. The detailed morphological and functional analysis of the current dental implant systems
8	The final definition of the PhD. thesis	Contributions regarding the improvement of the conception and manufacturing of dental implants
9	The design / system/solution improvement made based on the previous analysis	The design of an improved dental implant system
		9.1. The system design and improvement from a topological point of view
		9.2. The system design and improvement from the parts' material point of view
		9.3. The system design and improvement from the surface covering and texturing point of view (interaction with the biological environment)
		9.4. The system design and improvement from the production methods point of view

10	Testing the designed solutions	The in-vitro and in-vivo (if possible) testing of the designed solutions
		10.1. The production of the prototypes
		10.2. The testing of the prototypes
		10.3. Interpretation of the results
		10.4. System optimization (if necessary)
11	The publishing / patenting / presentation of the results	The publishing / patenting / presentation of the results

## **2. The morphological and functional detailed analysis of the current endosseous dental implant systems**

At the base of the research is situated the international collaboration with stomatologists, implantologists, orthodontists and dental technicians from Sibiu, Austria and Germany and with dental implant parts producers from Germany. In the scientific research process were integrated both creative research methods - brain storming, consonant association, morphological matrix, comparison etc. – and empirical research methods – the physical and virtual testing of dental implants and the quantitative analysis of the results.

The dental implant systems' analysis has been performed both theoretical, as well as practical, the main purpose of this research stage being the determining of the analyzed specimens' physical and bio-chemical properties, serving as means to the enrichment of the project informational data base. The forming of the informational fund is a continuous process and is integrated in all the steps of the project.

### **2.1. The deeper understanding of the dental implant concept**

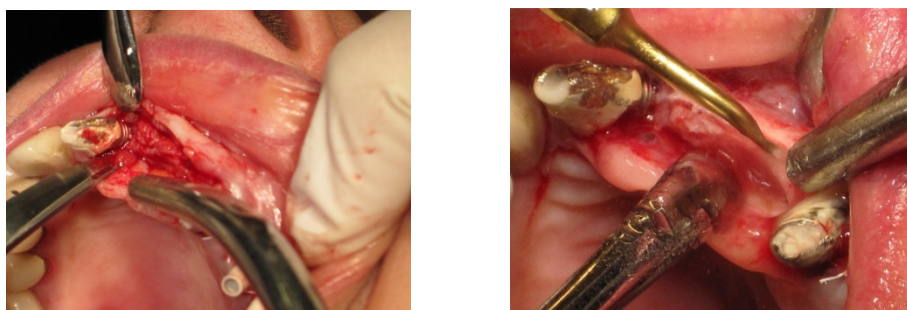
This stage consists in a one week internship at Prof. Med. Bernhard Broos, PhD. implantologist, Peraustraße 28, 9500 Villach, Austria, between the 06<sup>th</sup> and 12<sup>th</sup> December 2009.



The purpose of the program was the collecting, validation and exchange of information in the field of dental implantology and the deeper understanding of the implant-biological environment interaction.



**Figura 2.2.1.** Prof. Broos' praxis – general presentation



**Figura 2.2.2.** The bone splitting method of preparation of the implantation site

As a result of the collaboration with Dr. Broos, information regarding the following subjects was obtained:

- tools / surgical instruments used in implantology;
- dental implants design rules; functional and physiological;
- dental implants insertion rules;
- complications which may appear in oral implantology, from the implant insertion and functioning point of view; traumatology notions;
- the stresses to which dental implants are subjected;
- approximately 60 dental implant systems.

## 2.2. The analysis of the current dental implant market

The current study aims at creating a detailed analysis of as many screw-shaped dental implants as possible from the current market.

From the analysis criteria point of view, they will be selected from both the medical and technical field. The criteria selection will be made based on the ones already used in literature and on the author's own considerations, depending on their relevance for the implantologist, the patient and for third parties which would like to get information about dental implants (students, technicians, engineers, PhD. students, professors, etc.). Each criterion will receive between 1 and 5 points (1 being the lowest score and 5 the highest), and its selection will be justified.

Because what primes in the analysis is the patient's health, and the third parties have a lower influence on it than that of the medic's, the number of points which can be awarded by the third parties will be limited to maximum 3.

**Table 2.2.1** . The criteria according to which the dental implants' analysis will be conducted

Crt. No.	Manufacturer name and logo	Country of origin	System name	Implant image	System part no.	Ø implant [mm]	l implant [mm]	Body shape	Thread dimen.	Thread shape
Implant material	Implant surface	Surface texturing method	Apex geometry	Implant collar	Implant-abutment connexion (i/e)	Implant-abutment indexing geometry	Bone type for which the implant is recommended	Notes		

The original elements brought to the already existing criteria are:

- Manufacturer logo;
- Manufacturer country of origin;
- The optimisation of the minimum and maximum implant length and diameter presentation;
- Thread dimensions (whether they are constant or variable);
- The type of bone best suited for the implantation of the implant system;
- The detailing of the implant-abutment connexion;

- Notes – section which compensates the lack of any other classification criterion.

Compared to the other classifications made on this theme, the current study presents a more detailed approach from both the criteria number and relevance points of view.

As a result of the bibliographical study developed, the base characteristics of the new implant system can be defined. Because the osseointegration level of the implant depends on the bone quality in which it is inserted [Truhlar et.al.,1997 ], and in the bone types III and IV an implant loss up to 35% has been documented [Jaffin & Berman, 1991], the developed implant system will be for the soft bone (types III and IV), on the market already existing numerous implants dedicated to the hard bone (types I and II).

The one piece dental implant is not a viable option from either traumatological or practical considerations.

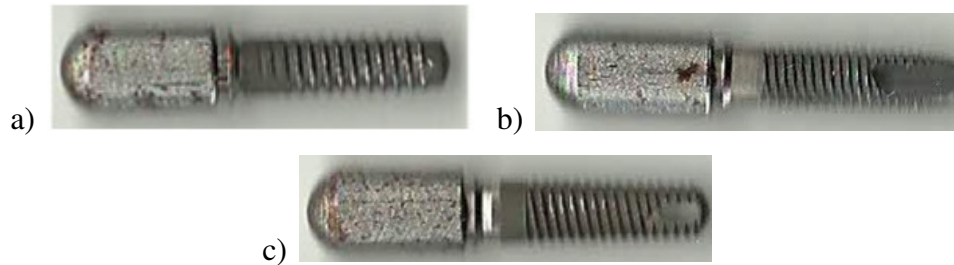
Because the developed implant is dedicated to the soft bone, initial stability of the system body is a defining factor and is generally achieved through bone condensation. From this point of view, a threaded implant is strictly superior to a non-threaded one.

To conclude, the type of implant being developed will be a screw-shaped one. For this purpose, further on, the mechanical analysis of 3 of the best sold dental implants on the market will be conducted.

## **2.3. The mechanical analysis of the representative dental implants of the market's leaders**

### **2.3.1. Physical compression testing**

Between 29.03.2010 and 01.07.2010 I had the opportunity to supervise the research project developed by the Lucian Blaga University, in partnership with the national institute for mechatronics and measuring techniques INCDMTM, Bucharest (Institutul Național de Cercetare Dezvoltare pentru Mecatronică și Tehnica Măsurării –București). The project consisted in the physical testing of abutments according to ISO 14801:2007 for NT-Trading GmbH, Karlsruhe, Germany. The implant systems used in the investigations are presented in Figure 2.2.3. They will be henceforth named System A, System B and System C. The testing equipment specifications are presented in Table 2.2.3.



**Figure 2.2.3.** Specimens which endured the fatigue requirements(5mil. cycles)

a) System A; b) System B; c) System C

The systems' parts specifications can be observed in Table 2.2.2. The worst case scenario was analysed for each of the three implant systems, meaning minimum implant diameter and maximum length, the specimen mounting being done with the collar's thinnest cross-section in the loading direction, according to ISO 14801:2007.

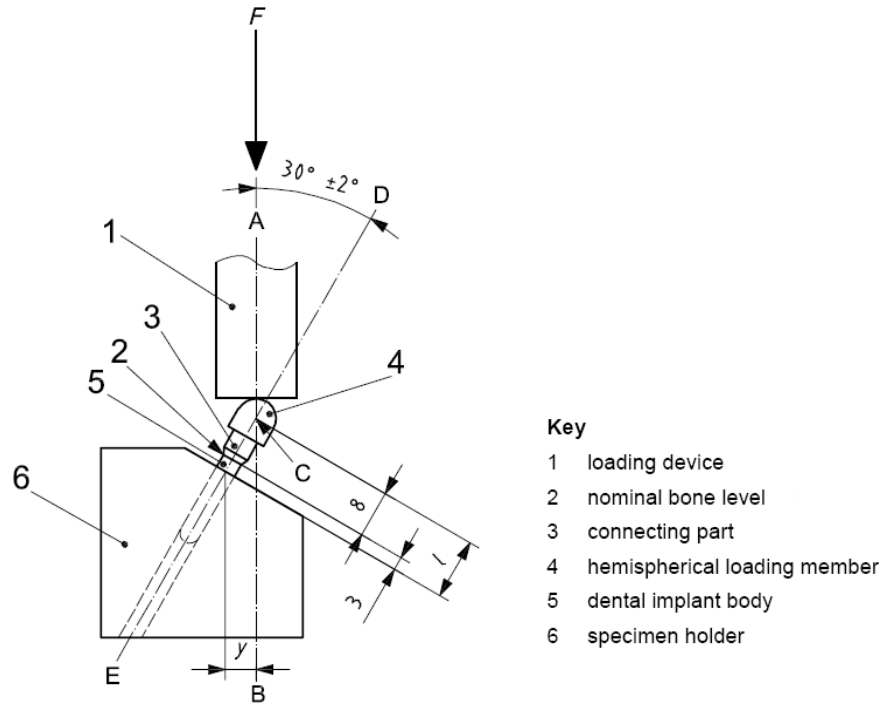
**Table 2.2.2.** The used assemblies' specifications

Implant system	Implant material	Implant diameter [mm]	Implant length [mm]	NT-Trading abutment	Abutment material	Fixing screw torque [Ncm]
System A	Ti Grade4 CP	3,5	13	E800	Ti Grade5 CP	35
System B	Ti Grade4 CP	3,3	12	L800	Ti Grade5 CP	35
System C	Ti Grade5 CP	3,7	13	R800	Ti Grade5 CP	30

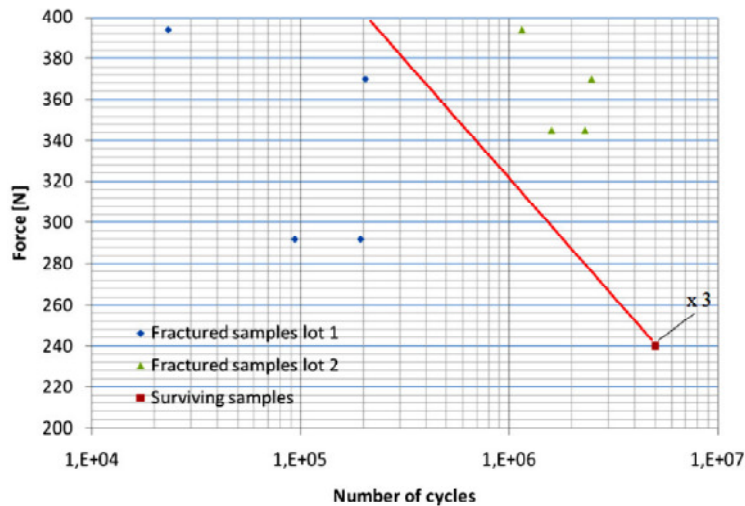
**Table 2.2.3.** Installations used for the tests according to ISO 14801:2007

<p>Static loading equipment HOUNSFIELD H10KT</p>	<p>Universal loading equipment INSTRON 8872</p>

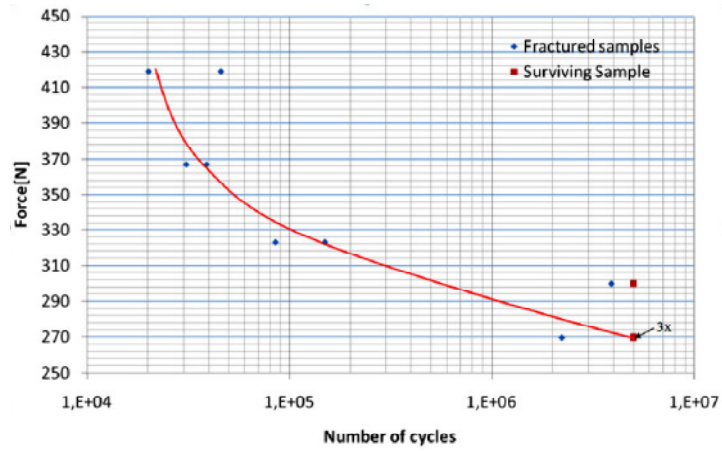
The first stage of testing, described by the standard, is the determination of the static breaking load of the specimens. The second stage consisted in the determination of the fatigue limit of the systems. For both testing steps the same loading layout was used (Figure 2.2.4).



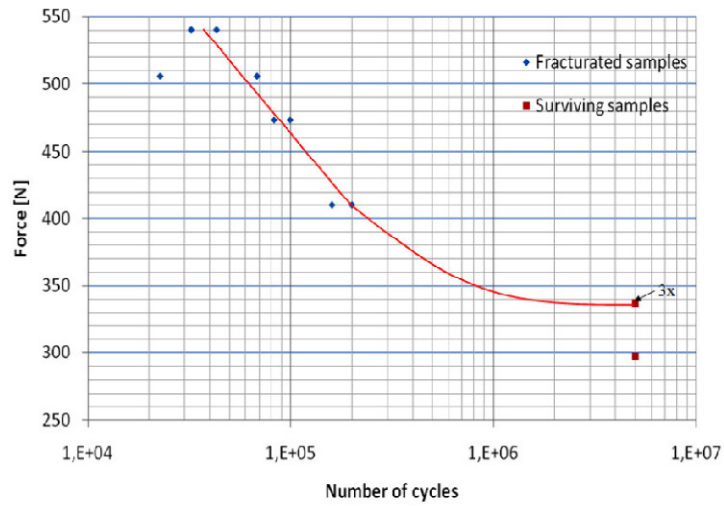
**Figure 2.2.4.** Loading layout of implant systems with straight abutments – ISO 14801:2007 extras



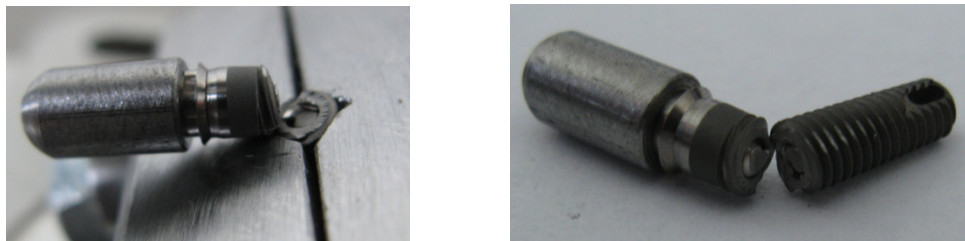
**Figure 2.2.5.** System A Wöhler curve



**Figure 2.2.6.** System B Wöhler curve



**Figure 2.2.7.** System C Wöhler curve



**Figure 2.2.8.** Specimens broken during the fatigue testing

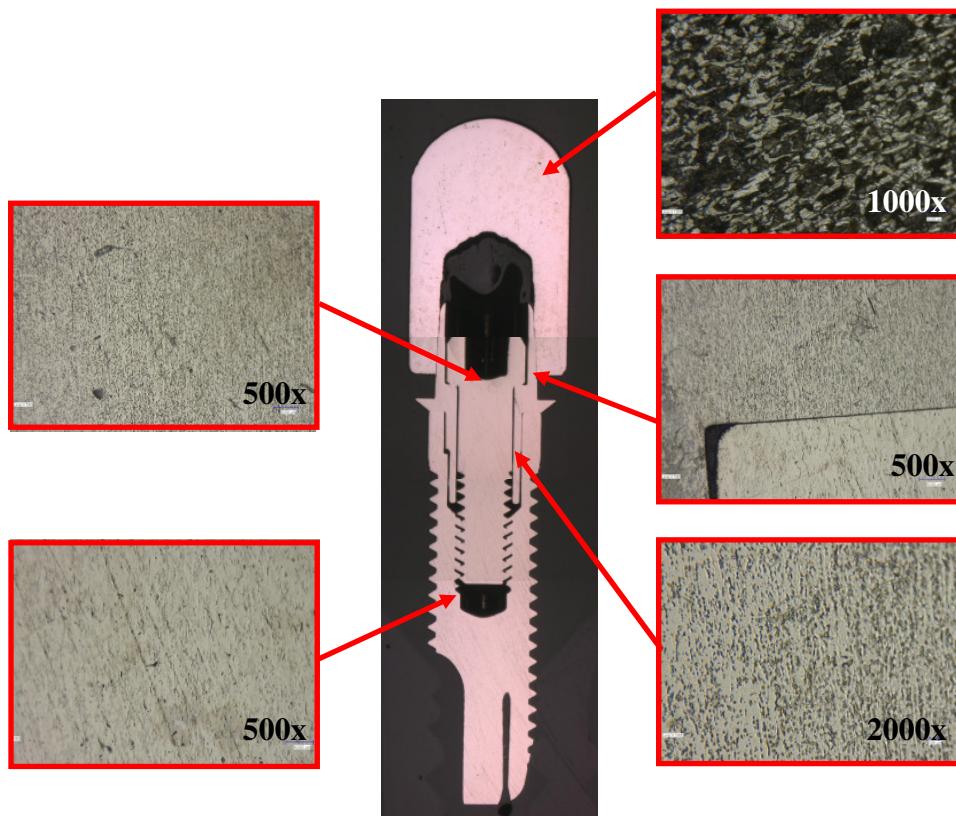
During the tests the elements which broke were the implant bodies, either at the collar minimum thickness cross-section or at the fixing device level.



**Table 2.2.4.** Analyses' results comparison

Tested system name	Static breaking load (FEA) [N]	Static breaking load (physical) [N]	Fatigue limit (FEA) [N]	Fatigue limit (physical) [N]	$\frac{F_{static}}{F_{fatigue}} \cdot 100$	$\frac{F_{static}}{F_{fatigue}} \cdot 100$
					FEA [%]	physical [%]
System A	534	492,5	332	240	62,17	48,73
System B	694	524	363	270	52,31	51,53
System C	613	675	337	337	54,98	49,93

In order to confirm the tested specimens' material and to analyse the geometrical aspects of the implant systems, a specimen which held for 5 mil. cycles, of each implant system, was metallographically prepared and observed under the microscope [Gammon, 2004], [Leyens, 2003], [Peters et.al, 1983], [Albrecht, 2000], [Lütjering&Williams, 2003].



**Figure 2.2.9.** Metallographical study of the System A specimen

## 2.4. Conclusions

As a result of the morphological and functional critical analysis of over 200 of the current dental implant systems on the market, the physical testing of 38 specimens belonging to three of the best sold dental implant systems in the world and of the microscopical observations made on three metallographically prepared specimens which held for 5mil. cycles according to ISO14801:2007, the following conclusions are drawn:

- a) The conical implant-abutment connexion is superior to the planar one, from the abutment positioning and load transmission points of view;
- b) The fatigue limit for screw-shaped, rigid implants with straight abutments made of Ti Grade4 or Grade5 and tested according to ISO 14801:2007, is approximately 50% of the static breaking load.
- c) The finite element analysis is an approximate analysis tool and its results should be confirmed by physical testing.

Also, according to the results of the conducted analyses, three main common characteristics of the studied systems stand out:

- a) *The rigidity of osteointegrated systems* – the chewing forces are directly sent into the maxilla / mandible bone, generating in all known clinical cases bone resorption. Moreover, the antagonist tooth of the implant structure is overloaded due to the dental implant's rigidity.
- b) *The lack of an effective implant-abutment sealing solution* – in the author's opinion, a metal to metal sealing is not effective in terms of long term sealing (years), for a multi-directional loading case;
- c) *The lack of an effective solution of adhesion of the gum to the prosthetic structure* – due to a partial adhesion of the gum to the prosthetic structure, bacteria penetrate the space between the abutment and the gum, the implant requiring periodical professional cleaning. Research in this direction has been made, but none of the developed methods (Ta, Au, Pt coverings) can ensure the 100% adhesion of the gum.

The current research direction aims at improving the implant rigidity problem from the force dampening point of view and of the implant-abutment sealing issue.



### **3. The design of an improved screw-shaped endosseous dental implant**

#### **3.1. First steps of the design**

In order to begin the product development, the main dimensions need to be established (length and diameter). Because the testing standard requires only the analysis of the longest and thinnest implant, after the defining of all of the implants in the system's dimensions, the one developed will be only the one corresponding to ISO 14801:2007's requirements. According to the previous investigations developed in this paper, it is concluded that most systems use a 3,5mm diameter and a maximum length between 13 and 15mm. The specified dimensions have been most probably determined statistically by the producers. Therefore, the developed implant main dimensions are  $\varnothing 3,5\text{mm}$  and  $l=15\text{mm}$ . The applicability in practice of an implant of these dimensions is confirmed by Prof. Dr. Med. Broos, of The Ludwig Maximilian University of München, Germany, by Prof. Dr. Med. Eisenburger, of the MHH (Medizinische Hochschule Hannover) of Hanover, Germany and by Prof. Dr. Med. Nicolae and Boboc of The Lucian Blaga Universitatea of Sibiu, Romania.

#### **3.2. The mandatory practice period according to the POS\_DRU contract**

“Association, defined by Alex Osborn “The fundamental process for the generation of ideas”, represents a function of the human intellect which *establishes links between imagination and memory*. Association is strongly developed at people with a high imaginative energy doubled by a high amount of knowledge.” [Belous, 1992] Using this creative design method, named consonant association, the functionality of a natural tooth has been identified with the one of a pneumatic car suspension. As such, between 31.01.2011 and 06.05.2011, the mandatory practice period has been performed at Continental AG, Stoecken, Hannover, within the pneumatic suspensions department. The purpose of this practice was to analyse the pneumatic suspensions and try to implement their functional concepts into the development of the dental implant system.

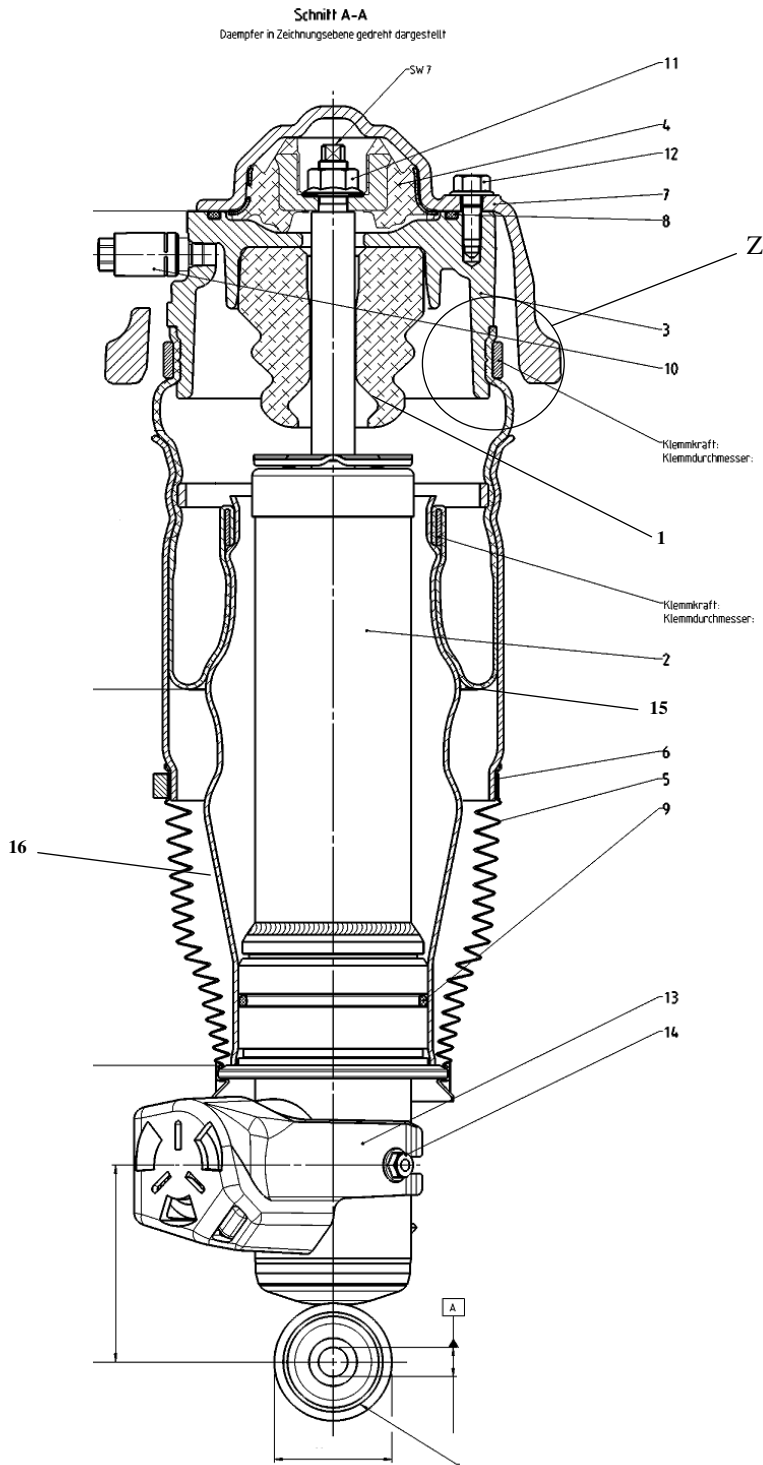
A pneumatic suspension consists of two main parts: the pneumatic spring and the damper, which can be mounted coaxially or in parallel. The suspension type studied has the two

elements mounted coaxially. The detail level of the presented suspension is limited by the copyright European law *D.2001/29/EC*. The pneumatic suspension presents functional characteristics similar to the natural tooth, both entities being subjected to high forces, compared to their dimensions, and presenting relative movement relative to their fixing surfaces – the maxilla bone, as far as the tooth is concerned and the wheel axis in the suspension's case.

The limitations of the current study are obviously of dimensional nature, a cost effective biocompatible pneumatic system being unable to be incorporated in a dental implant. As a result, the analysed parts of the suspension were the elastic, sealing and fixing elements.



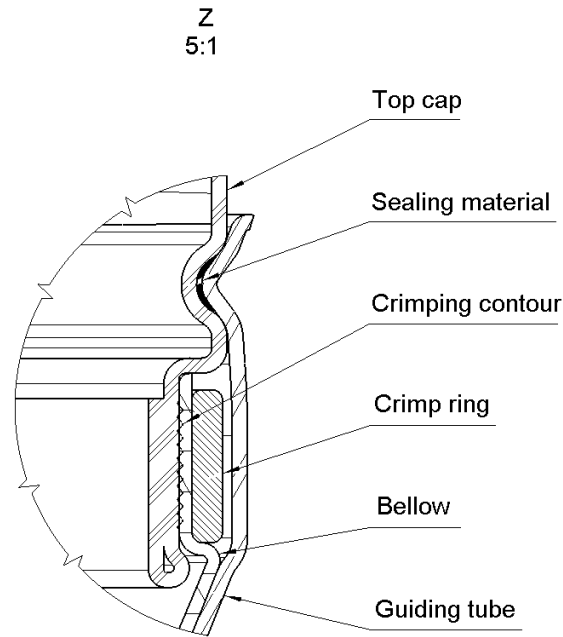
**Figure 2.3.1.** Continental AG developed pneumatic suspension (VW Touareg / Porsche Cayenne)



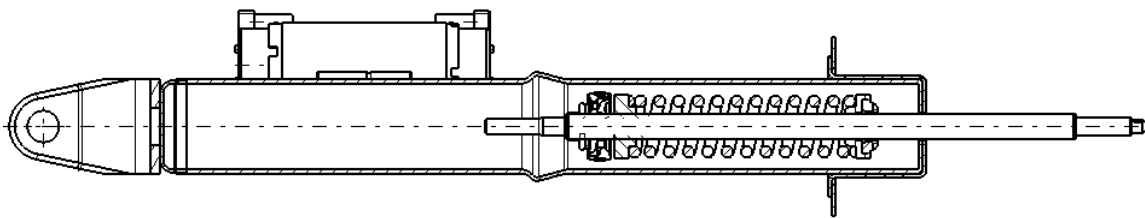
**Table of contents of the “Pneumatic suspension” assembly**

- 1 - Jounce bumper
- 2 - Damper
- 3 - Top cap
- 4 - Damper bearing
- 5 - Gaiter
- 6 - Ear clamp
- 7 - Top cap protection carcass
- 8 - O-ring
- 9 - O-ring
- 10 - Pressure retaining valve
- 11 - Nut
- 12 - Screw
- 13 - Electronic Control Unit
- 14 - ECU nut
- 15 - Bellow
- 16 - Piston

**Figure 2.3.2.** A Continental AG developed suspension assembly drawing  
(VW Touareg / Porsche Cayenne)



**Figure 2.3.3.** Guiding tube-Top cap detail of the suspension analysed during the practice period



**Figure 2.3.4.** Cross-section through the current damper of the analysed suspension

### 3.2.1. Conclusions and proposals

The position 1 functional principle (Figure 2.3.2) may be implemented as a dampening element between the abutment and the implant. However, because the abutment fixing screw, the part of the implant in which it is screwed-in and the abutment must form a rigid assembly in order to prevent the fixing screw from unscrewing, this constructive solution is not recommended.

Position 4 (Figure 2.3.2) may present a variant to chewing load dampening, if mounted above the abutment shoulder.

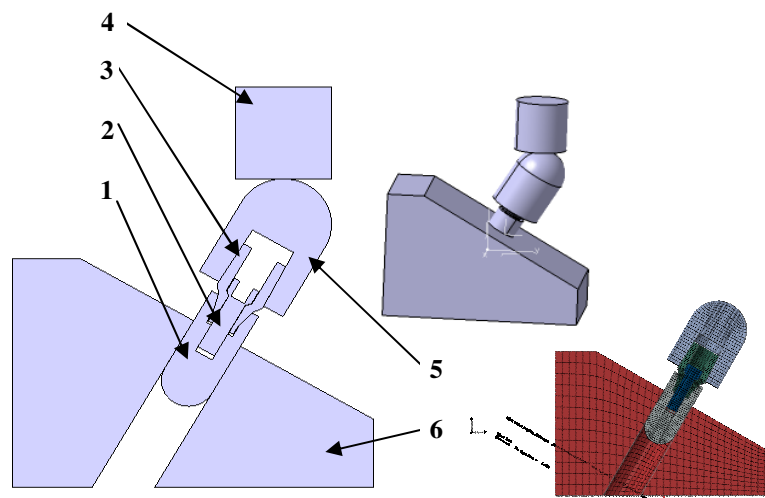
Position 2 (Figure 2.3.2) has the same applicability as position 1, with the difference that a helical metal spring is stiff enough to limit the abutment travel. However the available space problem remains for an implant of the current dimensions.

The sealing principle presented in Figure 2.3.3 (“Sealing material”), may be used to seal the implant-abutment junction if the utilized material is bio-compatible (for an unlimited period of time), non resorbable, non degradable in the oral cavity, preferably bacteriostatic, semi-elastic (to compensate the micro-movements of the abutment) and non irritating to the gingiva.

### 3.3. Dimensional optimization of the implant system

Taking as basis the results of the physical tests performed, next possible implant-abutment shapes will be investigated, on the principle of contact area increase. The analysis will be made from both topological and dimensional points of view.

The geometrical optimization is done by varying the profile shape, based on manufacturing possibilities, sealing capability during functioning and estimative costs.



**Key**

- |                |                                |
|----------------|--------------------------------|
| 1-implant      | 4-loading device               |
| 2-fixing screw | 5-hemispherical loading member |
| 3-abutment     | 6-specimen fixing device       |

**Figure 2.3.5.** Testing setup

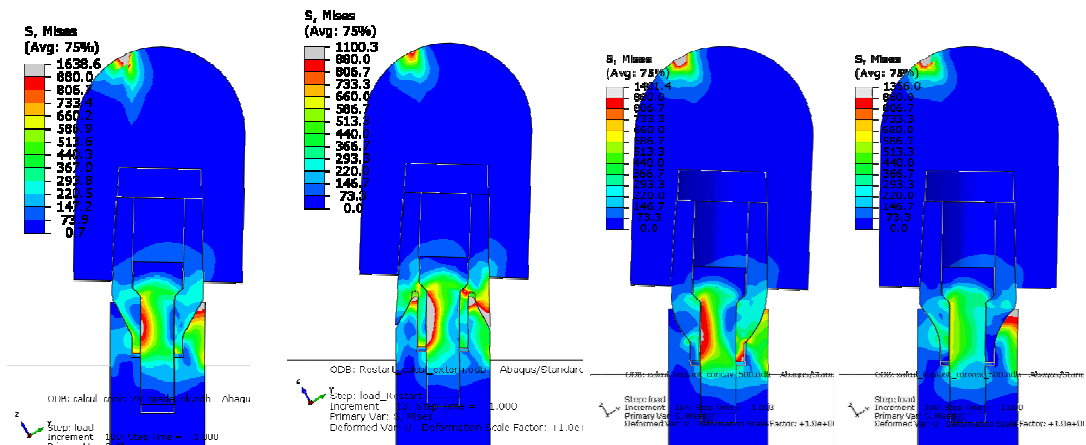


Figure 2.3.6. Stress distribution in the conical (int.-ext.), concave and convex assemblies

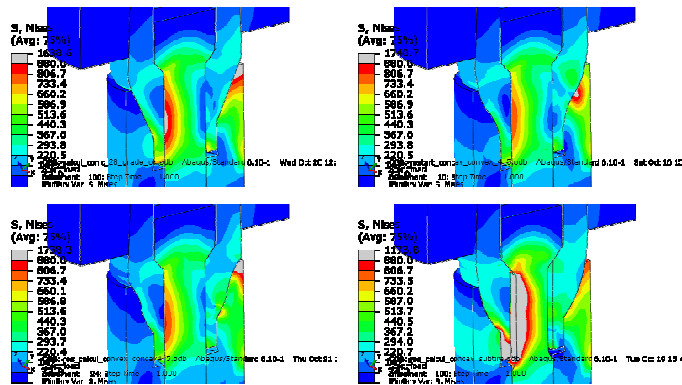


Figure 2.3.7. Stress distribution in the conical, concave (modified fixing screw), concave-convex and convex-concave assemblies

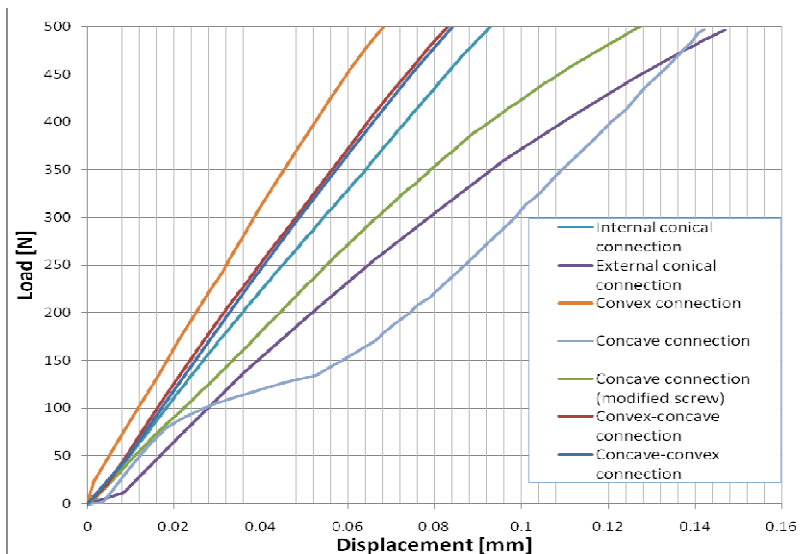
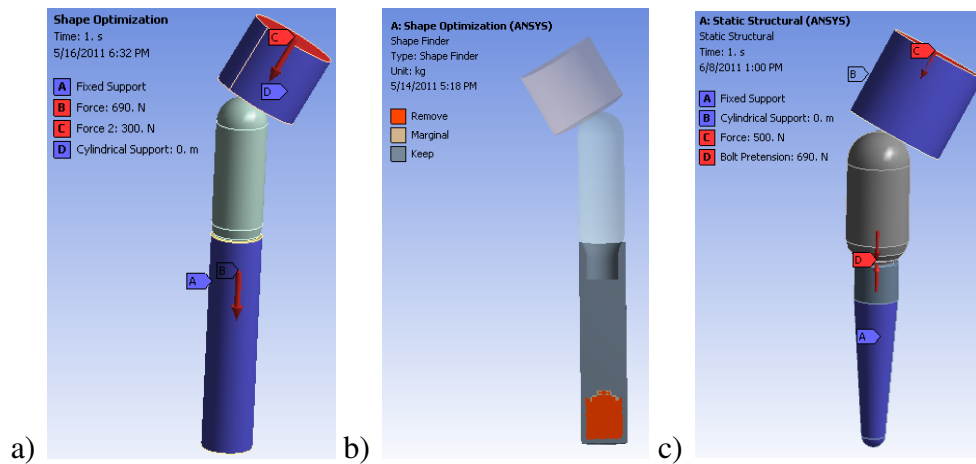


Figure 2.3.8. Load-displacement curves of all analysed models

Figure 2.3.8 presents the load-displacement curves of all analysed models, in this research step. Taking also into account the manufacturing possibilities and the sealing provided by each of the presented connections, the shapes which will be further analysed from a dimensional point of view are the conical and convex ones.

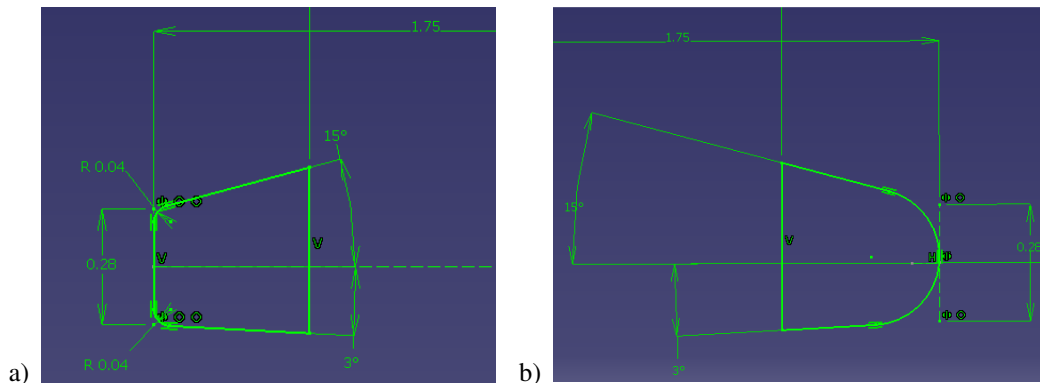
Next, in order to determine the optimal dental implant body shape, the “Shape finder” optimization module, belonging to the ANSYS software will be utilized. The material properties and loading schematics correspond to the specifications of the previous analyses and of the ISO 14801:2007 standard (Figure 2.3.9).



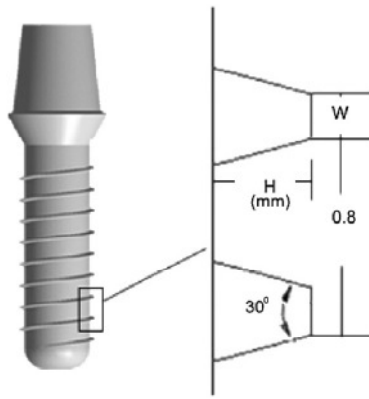
**Figure 2.3.9.** The implant body shape finding analysis results

a) Initial conditions; b) analysis result; c) implant approximated shape

The thread was designed with the help of the same “Shape finder” module and based on the research of [Ao et al., 2010] (Figure 2.3.11).

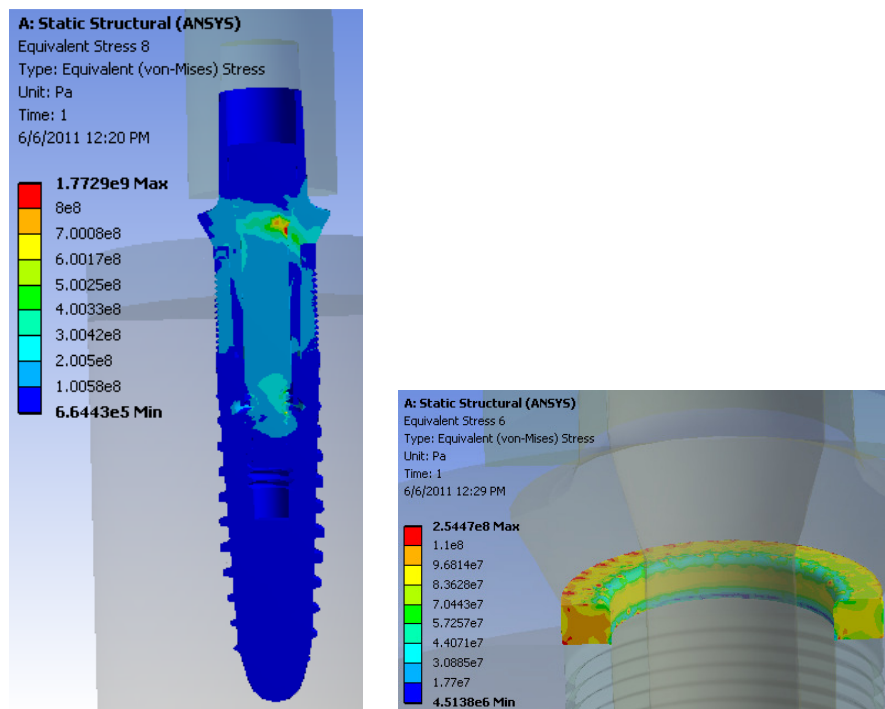


**Figure 2.3.10.** Thread shape optimization a) implant body threads; b) first threads under the implant body collar



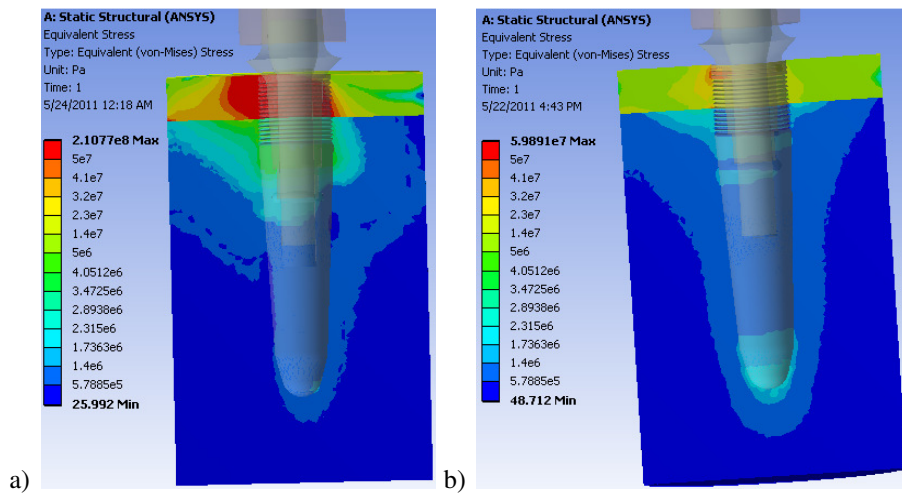
**Figure 2.3.11.** The [Ao et al., 2010] study parameters

As a result of the developed studies, it has been determined that the insertion of a pretensioning element between the implant body and abutment lowers the maxilla bone stresses. (Figure 2.3.13). However the available space does not allow the installation of a metallic elastic element (spring, washer).



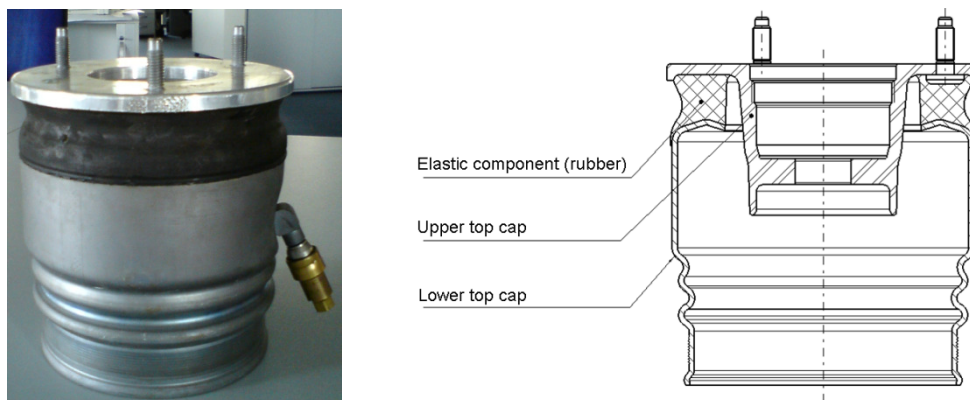
**Figure 2.3.12.** Stresses in the implant's parts and in the elastic pretensioning element (approximated with polyethylene) for a torque of the fixing screw of 25Ncm and a pretensioning force of 180N



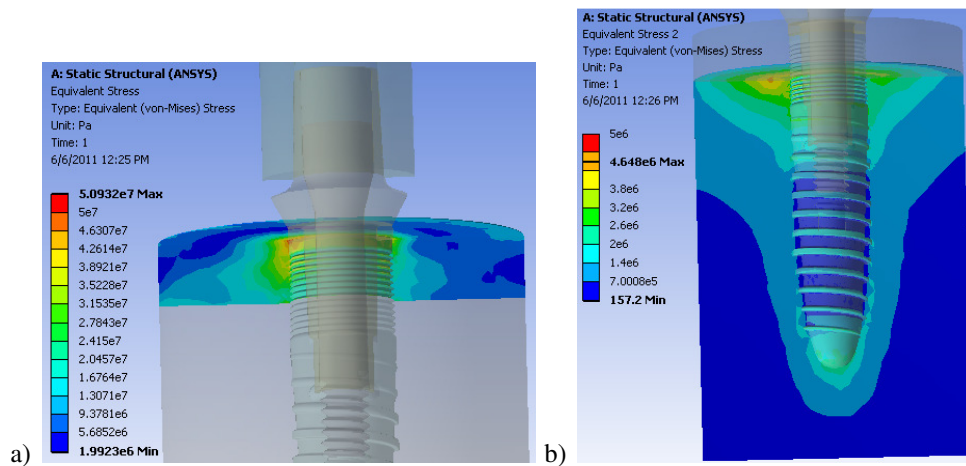


**Figure 2.3.13.** Approximated comparative analysis between  
a) not pretensioned implant and b) implant pretensioned with 220N

As a result of the FEA tests conducted, according to the creative design methodologies named “brain storming” (the Osborn method) and combination (method detailed by the same Alex Osborn [Osborn, 1957]), an elastic washer is fused with an o-ring, resulting in an elastic element with the purpose of pretensioning the abutment and sealing the implant-abutment junction. This concept, under the name of “comfort bearing”, is used by Continental AG to dampen the suspension’s vibrations during functioning, having at the same time a sealing purpose (Figure 2.3.14). The utilized material is rubber with a hardness of Shore70A, vulcanized to the two components of the top cap.

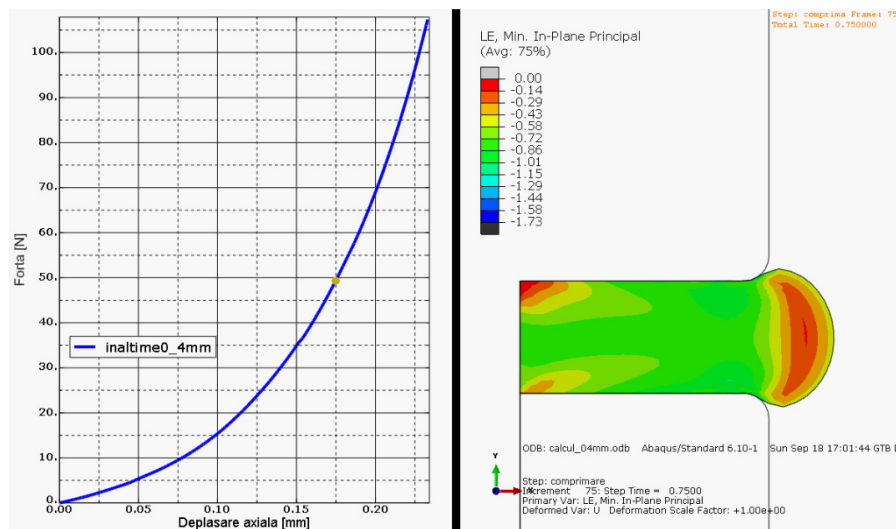


**Figure 2.3.14.** Comfort bearing

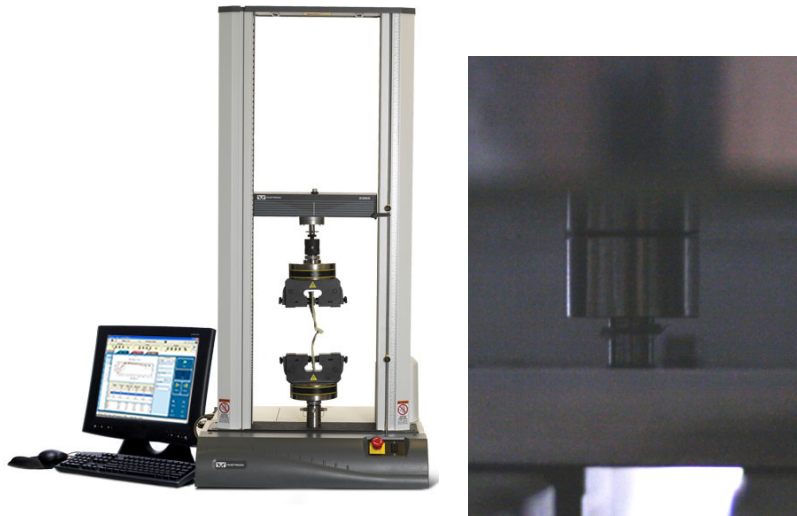


**Figure 2.3.15.** Approximated cortical bone stresses (a) and trabecular bone stresses (b), for a 25Ncm fixing screw torque and an 180 N pretensioning of the abutment

The elastic material which complies with the previously described requirements is the biocompatible silicone used to manufacture intervertebral discs. Because of its high fatigue and abrasion resistance, this material is ideal for the current application. The dimensioning of the pretensioning element has been made theoretically (FEA – Figure 2.3.16) and practical (physical testing – Figure 2.3.17).

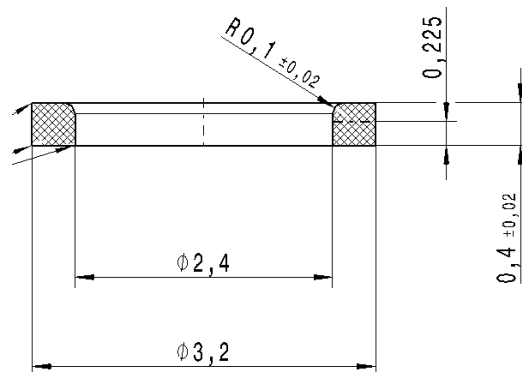


**Figure 2.3.16.** The load-displacement graph and deformation of a 4mm high silicone ring



**Figure 2.3.17.** the physical testing of the silicone rings on an Instron 3366EH equipment

The ring's dimensions resulted from the testing results are presented in Figure 2.3.18.



**Figure 2.3.18.** The silicone ring used to pretension the abutment\*

#### **4. The determining of the implant system parts' materials**

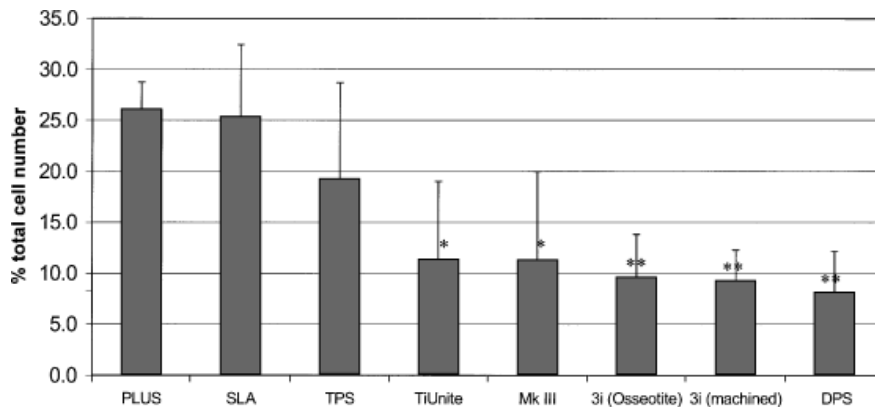
The following research step consists in determining the system components' materials. The most utilized materials in the construction of dental implants are Ti Grade4, Ti Grade5 and Ti Grade23 ELI, these materials being already tested in-vitro and in-vivo, their biocompatibility being certified at an international level (biocompatible materials which present a good osseointegrations as a result of the oxidation –  $\text{TiO}_2$ ).

Because of the reduced dimensions of the screw and of the small wallthickness of the abutment, the two parts will be manufactured from the toughest of the presented materials: Ti Grade5.

Following the analysis of the fizical and mechanical properties of Ti Grade4, Ti Grade5 and Ti Grade23 ELI it is concluded that the material that will be used to manufacture the implant body is Ti Grad23 ELI because of its high mechanical resistance and moderate fragility (compared to Ti Grade5), as the current implant is to be used also in clinical cases where small diameter implants must be inserted in the posterior region of the oral cavity.

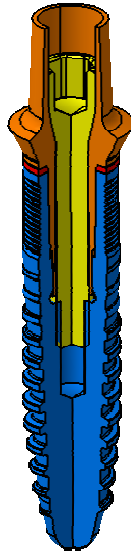
A comparative study, from the osseointegration efficiency of different implant surface texturing techniques is presented in Figure 2.4.1. This study shows the number of osseoblasts grown on the implant surface in the same time frame.

According to [Sammons et.al., 2005], [Elias et.al., 2008], [Huang, et.al., 2010], [Uggeri et.al., 2010] and [Vanzillotta et.al., 2006], the moust effective surface treatment of a titanium alloy implant is the blasting with TiO<sub>2</sub> pellets, followed by acid etching with hydrofluoric acid and its neutralising, with a final surface roughness of R<sub>a</sub>=1, R<sub>z</sub>max.=3 [Hansson&Norton, 1999].



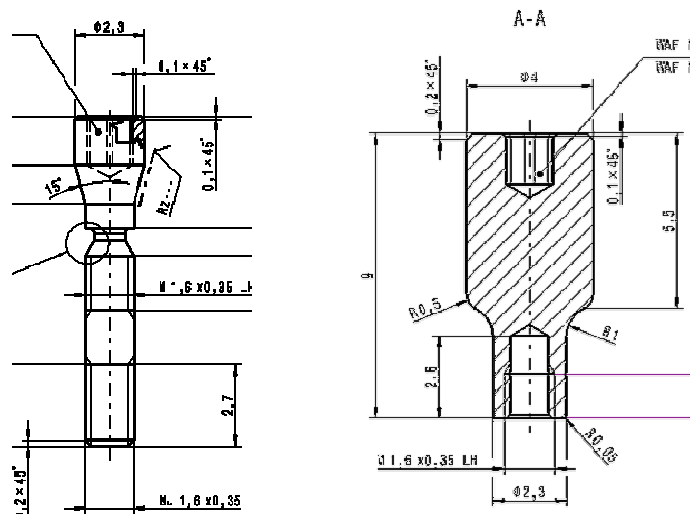
**Figure 2.4.1.** The growing of osseoblasts on differently textured dental implant surfaces; PLUS-blasted, acid etched, neutralized; SLA- blasted, acid etched, neutralized; TPS-Ti plasma sprayed; TiUnite-electrochemically worked; MkIII-mashined (finishing); 3i (Osseotite)-acid etched; 3i- mashined; DPS- mashined

Having defined all nominal dimensions and material data of the system's parts, the final design of the dental implant can be generated (Figure 2.4.2).



**Figure 2.4.2.** The developed dental implant model

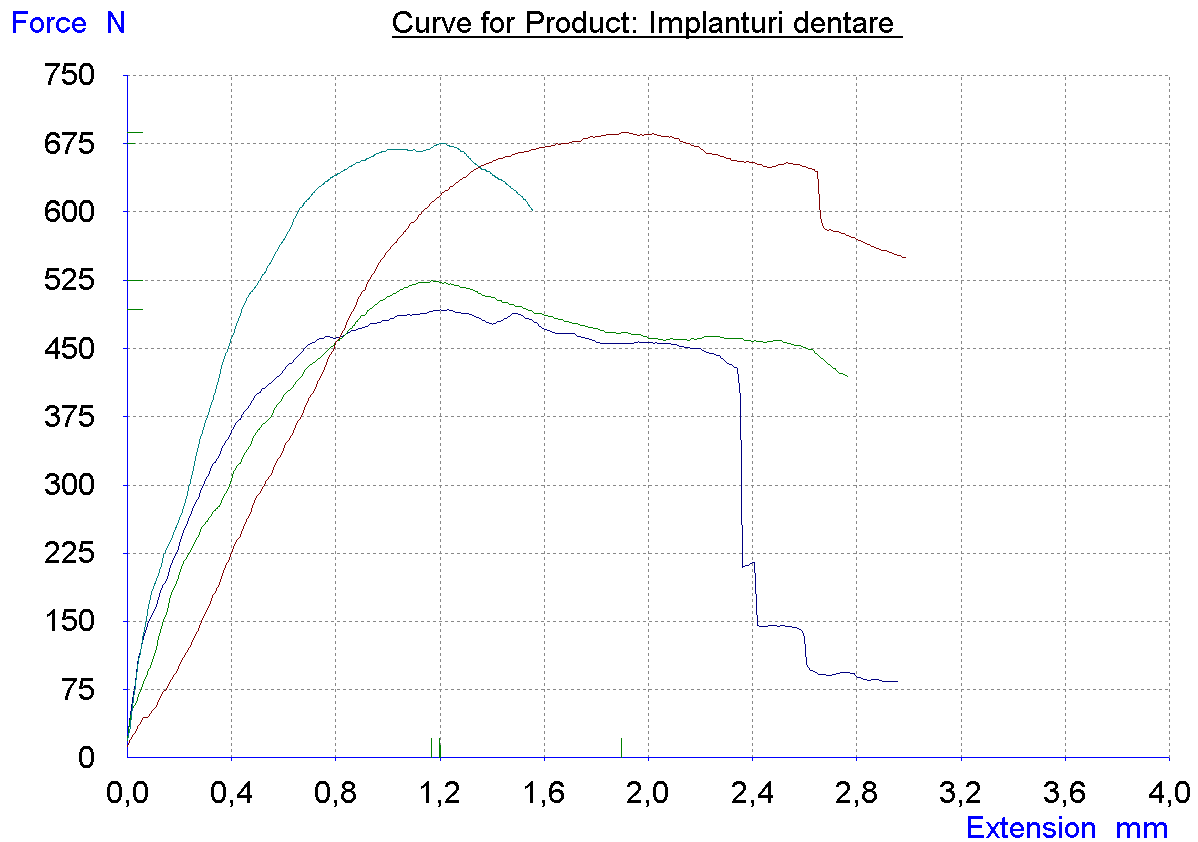
After the defining of the system, a general dental implant vulnerability has been attempted to be removed: the difficult extraction of broken fixing screws. Therefore, the extraction system presentd in Figure 2.4.3 has been designed, its innovation consisting in the left hand threading of the superior area of the fixing screw.



**Figure 2.4.3.** Broken fixing screws extraction system

## 5. The testing of the developed dental implant system's prototypes

As a result of the finite element analyses developed, as well as of the physical testing conducted within the INCDMTM, it has been proven that the current implant system presents a static breaking limit of 687N and a probable fatigue limit of 343N, these values being superior to the ones resulted from the testing of the 3 previous dental implant systems analysed (system A, system B and system C).



Implant system	Fstatic max. [N]	Ffatigue [N]
— System A	493	240
— System B	524	270
— System C	675	337
— BioMime	687	343

**Figure 2.5.1.** The static force-displacement curves of the specimens tested within the current research



**Figure 2.5.1.** The developed dental implant prototype

## 6. Conclusions

Following the developed research, the original elements of the developed dental implant system within this paper are:

- a new thread profile, which distributes more efficiently the stresses in the bone and contributes to the improving of the implant's primary stability;
- a new thread profile variation which ensures a more efficient (atraumatic) stress distribution in the trabecular bone, the atraumatic insertion of the implant in the bone and the improving of the initial stability of the implant;
- the implementation of a shock absorbing system in the implant which will decrease bone resorption;
- the utilization of the MJ thread for the abutment fixing screw, limiting its movement under fatigue loading and implicitly its unscrewing;
- the design of a broken fixing screw extraction system;
- the possibility of using a screw locking paste.

As a result of the developed tests, it is concluded that the current implant presents mechanical properties superior to the ones of the other 3 systems tested within the current research.

## ***Chapter III – Research regarding the improving of the dental implant manufacturing***

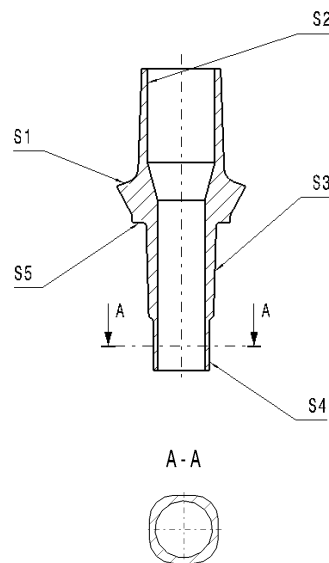
### **1. The design and optimization of the dental implant manufacturing process**

Production optimization is a term with a broad meaning, this being possible only by the collaboration between engineering and managerial competences. Summarized, this concept can be defined as the functioning of a production system at its maximum performance, cost and quality parameters.

#### **1.1. The optimization of the manufacturing process from a technical point of view**

##### **1.1.1. The design of the manufacturing technology of the “abutment” part**

###### *I. Technical study*



**Figure 3.1.1.** The determining of the worked surfaces



## II. Designing the technological process

Operation 1. Exterior lathing+through cutting S1+S5

Operation 2. Finishing milling S4

Operation 3. Heat treatment

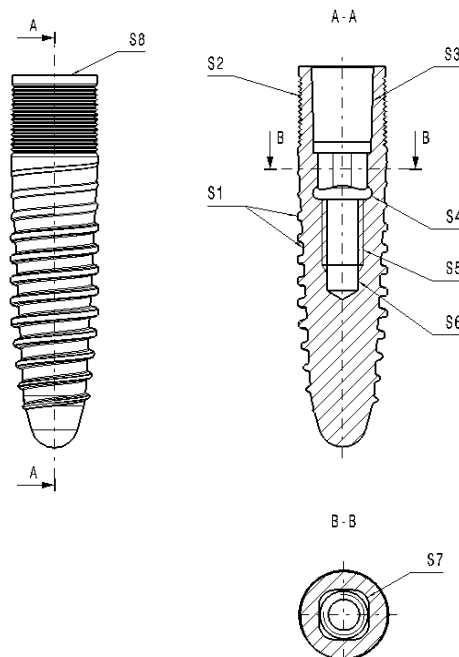
Operation 4. Boring+reaming S2

Operation 5. Rectifying S3

Operation 6. Final quality control

### 1.1.2. The design of the manufacturing technology of the “dental implant” part

#### I. Technical study



**Figura 3.1.2.** The determining of the worked surfaces

## II. Designing the technological process

Operation 1. Exterior lathing+through cutting S1+S2+S8

- Exterior lathing+through cutting (variant 1)

- Cold working (plastic deformation)+through cutting (variant 2)

- Operation 2. Intermediary quality control S1+S2
- Operation 3. Boring S6
- Operation 4. Milling S7
- Operation 5. Milling S6
- Operation 6. Tapping S5
- Operation 7. Blasting+acid etching S1+S2
- Operation 8. Heat treatment
- Operation 9. Interior conical rectifying S3
- Operația 10. Final quality control

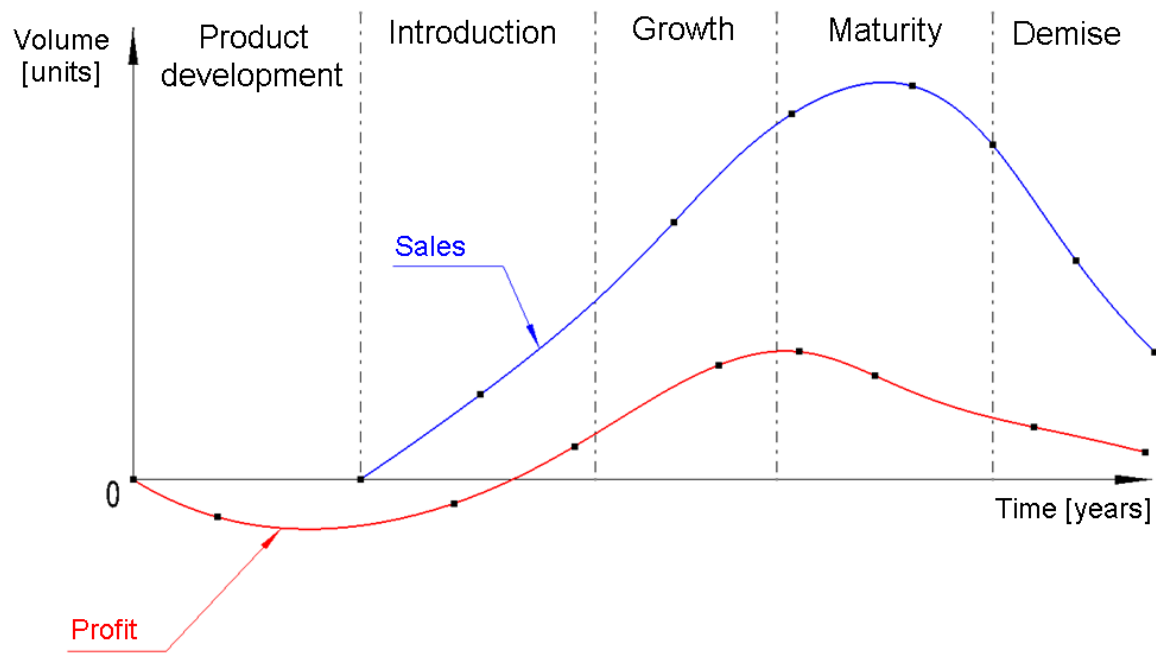
Once the manufacturing technology has been defined, a logistical optimization of the work space can be effected. To this end, some of the soft-wares that might be used are Delmia from Dassault Systems and Plant Simulation from Siemens, the last being also taught within the Lucian Blaga University.

After defining the manufacturing technology and the logistical optimization of the manufacturing processes, the optimization leaves the technical field and focuses on the managerial branch of the organization.

## **1.2. The managerial optimization of the manufacturing process**

The product lifecycle presents all stages through which a product passes from its conception phase to its withdrawing one (Figure 3.1.3).

The current development phase of the project corresponds to the “Product development” stage. However, further on, management and marketing strategies, tuned to the current fabrication setup, will be approached.



**Figure 3.1.3.** Product life cycle

Based on the Aberdeen Group recommendations for production processes within an enterprise, the following short and medium term strategies are proposed:

1. Incipient stage (externalized production / production cell)

- a) The naming of a council responsible with the analysis and approval of investments.
- b) Technological process optimization in order to minimize losses.
- c) Manufacturing process standardization.

2. Medium stage (expansion on more fabrication cells)

- a) Automatic data collection, with the end goal of optimizing the production process.
- b) The deployment of a technological platform able to link/supervise all production processes. This will also lead to the production processes cross-linking.
- c) The implementation of a reporting system which will offer the decisional board of the organization maximum process visibility.

## **2. Conclusions**

The production optimization must be realized from both technical and managerial points of view, in order to obtain an as high as possible performance/costs ratio. In the current product development stage it is recommended the production externalization because of the following test necessary for the product to reach maturity, and the prototypes costs do not justify the necessary investments to build a production line. Such an initiative is recommended after identifying the specific (regional) market target consumer segment.

At the time of creation of a medium series production line, as a result of the analysis developed in this chapter, it is recommended the naming of a council designated with funds approval, and of a multidisciplinary team to effect the production operations, team formed from at least one engineer, one informatician and one technician.

# Chapter IV – The informatization of dental implant development

## 1. The informatization of the dental implant development and production

The development and production of any product begins with the approval of the product concept and the planning of the development stages.

A computer aided product development cycle approved for implementation has the following base structure (Figure 4.1.1).

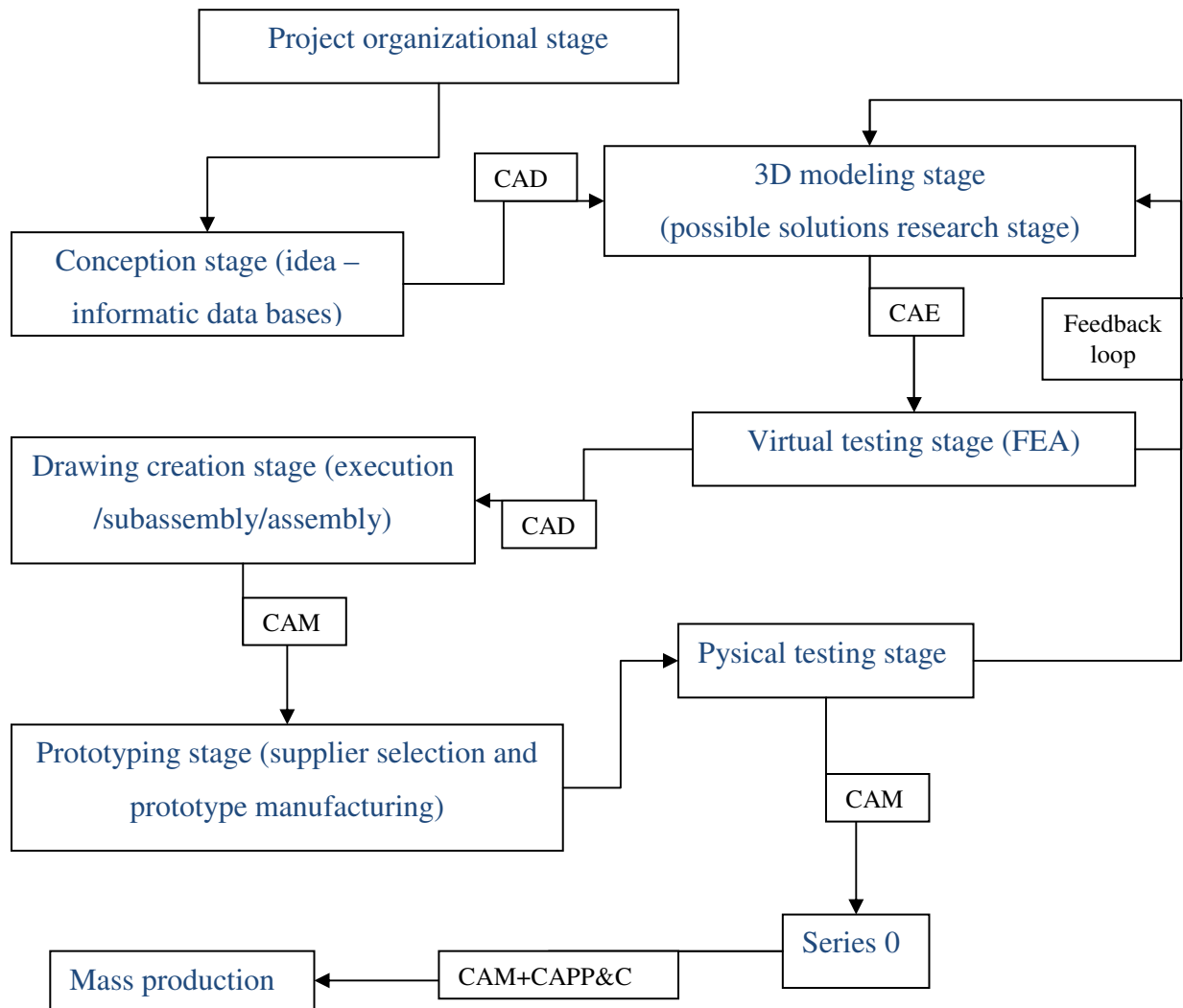


Figure 4.1.1. Main computer aided product development stages

Within the current project, the highest used tool of product development was “virtual engineering”. This tool allows time and costs savings within the product development process, mainly by replacing the physical prototype and tests with virtual ones, numerically simulated by a computer.

Within the developed study, after the establishing of the research theme, the project stages planning was effected, using MS Project (Figure 4.1.2).

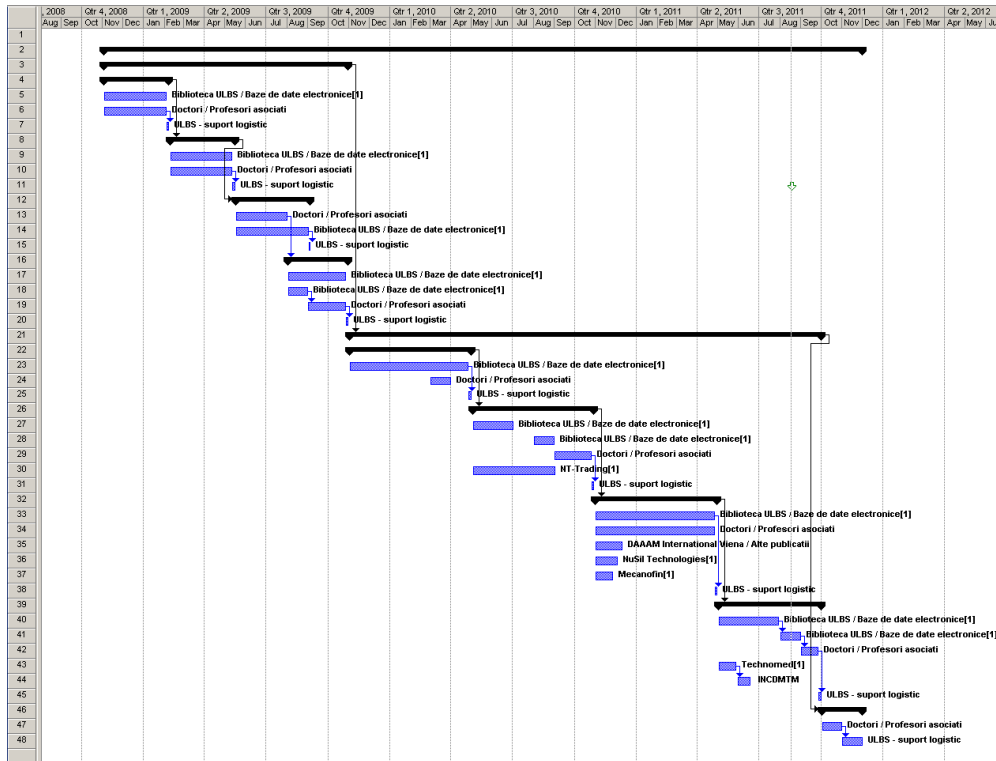


Figure 4.1.2. Gantt graphic generated based on the project’s stages and resources

Other informational sources used during in the current project are the scientific data bases within ULBS. Informatic data acquisition systems have also been used during the static and fatigue testing of the analysed implants. The internet is also considered an informatic resource. It has been used with double role: information gathering and communication with the project partners, suppliers, ULBS members, etc.. Parts of the infromatical resource are also the softwares utilized in the data editing (ex.: MS Office).

## **Final conclusions and main paper contributions**

The developed study aimed at developing an improved dental implant system. According to the analyses results, this goal has been reached.

The original elements of the paper consist as much of the end result as of the methodology and tools employed in the research.

More to the point, the original contributions of the current thesis are:

- The dental implants concept presentation from a techno-medical point of view, employing an interdisciplinary approach of the theme. As a result, both dental implant morfo-functional aspects, belonging to the technical field, have been detailed, as well as implantation protocols and annex procedures and indications, belonging to the medical field, after previously making an introduction to general implantology and the bio-materials science. This approach provides a better understanding of the “dental implant” concept, it being more than just a Ti screw or an incision followed by the implant insertion.
- The development of an own dental implants analysis criteria set. Compared to the other already existing classifications on this subject, the current study represents a more detailed approach of the subject from both criteria number and relevance, as well as of the interdisciplinary approach employed in its development.
- The analysis of over 200 dental implant systems according to the previously mentioned criteria. This classification permits a structured overview of the dental implant market from a morfo-functional point of view, it being possible to be used by both medics and well informed patients in determining the implant systems most suited for each clinical situation. From the researchers’ point of view, it offers an overview of the current dental implant market and on its technical advancements and limitations of the current systems, as well as on their development direction.
- The development of an own scientific research program, both generalized and particularized on the current theme, as a result of bibliographical study and through the adopting of the individual informational fund concept described Prof. Vitalie Belous.

- The employing, in the product development, of classic engineering, virtual engineering and creative research concepts and tools, combining the time and cost saving of the virtual engineering, with the originality of creative research and with the scientific approach of traditional engineering.
- The employing of project management, manufacturing management and marketing concepts and resources into the development of an improved dental implant system, as well as into its short and medium term production planning and short term marketing strategy (product promoting on the local market);
- Employing the creative methods named brain storming, the Delphi method, consonant association and comparison, the morfo-functional structures of a natural tooth have been identified with the ones of a pneumatic suspension's, leading to the development of a dental implant system based on the functional principles of the two, pneumatic suspensions offering the technical solutions necessary for the integration of the natural tooth's functionality in the developed dental implant's design.

Explicitly, the novelty elements of the dental implant system developed are:

#### 1. The implant body thread profile and its variation type

This feature has a quadruple role:

- a) stress reduction in the superior trabecular region through the utilization of a round thread;
- b) the assuming of the quasi-butters thread of most of the chewing load, especially in immediate loading clinical cases;
- c) the providing of a small friction angle between the bone and the thread, by using the quasi-butters thread, which leads to a good initial stability, preventing the implant unscrewing, especially in immediate loading clinical cases;
- d) because of the variation type of the thread, a good bone condensation is generated, which ensures a good initial stability of the implant in the maxilla bone.

#### 2. The abutment pretensioning by using a biocompatible silicone ring

The utilization of such a ring ensures both a better stress distribution in the maxilla bone, as well as a bacteriostatic environment in the application area – bacteria are the main cause of periimplantitis (the bone erosion up to the loss of the implant structure).



3. The covering of the abutment area which comes in contact with the gingiva with a layer of Ti3Ag (material which assures the growth inhibition of all bacteria in the oral cavity), or, when not available, Ag (material which decisively inhibits the streptococcus growth).

In order to acquire the distribution permit of this implant model for restorative purposes, the in-vitro testing according to ISO 14801:2008 must be finalized and in-vivo testing on animals and humans must be conducted.

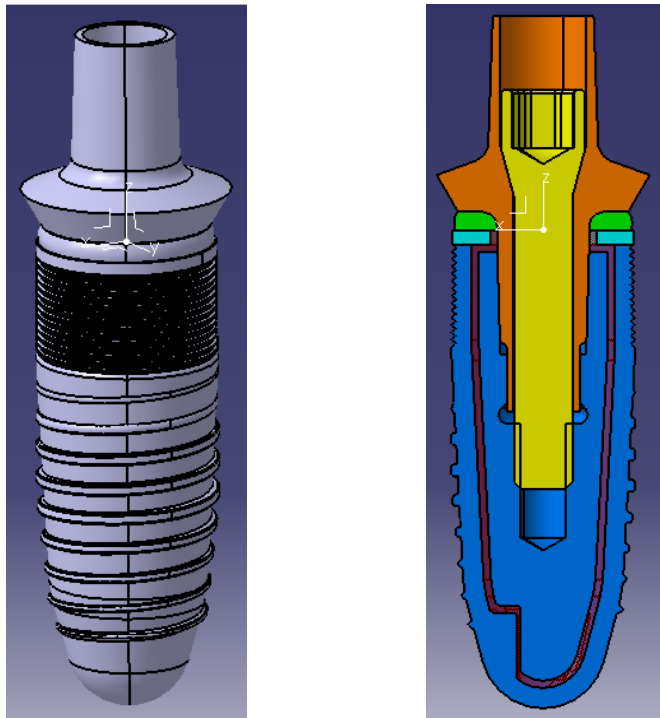
## **Future research directions**

The dental implant developed in the current project, due to its geometrical and material properties, is able to integrate in the maxilla bone, proving a good initial stability, an efficient stress distribution and a local bacteriostatic property.

What has not been fully achieved in this paper is the biomimetics of a natural tooth, because of the limited available space of the implant developed and analysed according to ISO 14801:2008. As result, a concept model has been created, based on the same principles as the previous one, but which presents a relative motion relative to the implanted bone area. The diameter of this implant is 5mm, according to the author's considerations, this being the minimum necessary space for the implementation of the current functional concept. It is a relatively simple one, and is inspired by the functionality of pneumatic springs – the utilization of silicone as a periodontal ligament substitute.

The dental implant model is based on the research of Arturo N Natali [Natali, 2003 (2)], according to which a 0,239mm thick periodontal ligament can be maximum compressed with 63% at a force of 1000KPa and an acceleration of 0,0052 %/s, resulting a deformation of 0,15mm of the ligament. The model is provided with an anti-rotational mechanism situated between the inner and outer implant body parts and a travel limiter. The minimum silicone layer thickness between the body's inner and outer part is 0,2mm, the prosthetic structure travel depending on the bio-silicone's compression rate (Figure1).

More detailed investigations are strongly recommended in order to fully dimension/develop the proposed dental implant system model's parts.



**Figure 1.** The 3D model of the dental implant model proposed for future studies

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