# Development of bone tissue-analogous implant of functional capacity and of integration range, microscopic incorporation examination of animal experiment implantation series

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**Introduction**

A widely known fact is that the number of joint damage caused by osteoporosis – outstandingly that of the fracture of the femoral neck – is constantly growing.

In addition to several factors among the causes there are the unfavorable side effects of medicines, which are indispensable in case of certain diseases, but as a side effect they weaken bones. Taking this fact into account the social-health importance of the growing lifetime of the implanted joint implants and its economic-financial significance is very great.

**Justification of development**

The lifetime of different metal-based implants used in medical practice is basically determined by the extent of adherence to bone tissues (excluding their fracture, of course). Today one of the most important tasks of implant developers is to reach the possible strongest and most durable contact between bone tissues and implants. It is well-known that the micromotions developing between the implants and bone tissues under load lead to the degradation of bone tissues, which necessarily will result in the replacement of the implant.

Nowadays there are several procedures, which promote the possible greatest embedment of the bone tissue, in this way the adherence of the implant to the bone tissue can be increased. All of these procedures try to ensure the most favorable conditions for the bone tissue by developing the surface structure of the implant. Favorable surface structures can be developed by using alloys of favorable grain structure in material, with special surface machining and by applying additional layer on the surface of the implant[1,2].

The above-mentioned procedures – although certainly will measurably increase lifetime – have not led to breakthrough (significantly longer increase of lifetime) in the past 25 years[3,4].

We have started our research – which may be regarded credible on the basis of the demonstrated in vivo animal experiments – in a different direction. In mechanical practice, theoretically connection types are divided into two groups: force and shape closing connections. Our goal was to create a connection between the implant and the bone tissue with suitable geometric characteristics, which, compared to the previous methods, in shape closing way increases its stability by an order of magnitude (through bone tissue growing fully into the implant.

We have developed an implant of internationally new integration range, where in course of changing loads of different ways of life, as a result of very complex, heterogeneous load

conditions developing in the vicinity of the implant, bio-analogous, transformed state can develop in the integration range. On the surface of the created implant of integration range there are notches of different forms and directions, on that surface there is a micro-lattice structure (Patent: registration number P0401232, catalogue number 225906).

Following implantation, different load oriented bone tissue parts develop in this integration range, based on our examinations they indicate 100% filling (growing in).

**Method**

Our research-development was carried out in four work phases. The first: planning and preparing the implant of integration structure (basic body + structure), then their in-vitro stability examinations under bone analogous conditions. The second one: producing and preparing pre-in-vivo implants, and surgery plans. The third one: building test implants into sheep (32 implants, 16 sheep), into femur, upper arm and thigh bone places. The fourth: taking out the built in 32 implants, detailed examinations of their state of implantation, evaluation of results.

The implants were made of Ti6A14V-ASTMF 136/ISO 5832-3 bio-compatible basic body and titanium structure of ASTM F 67 material[5]. The integration structure was made with stamping die. Regarding the basic body and the structure, we have tested assemblies with several geometric parameters. The control of the elasticity features, assembly stability, behavior under load of the basic body and the integration structure made in this way (including the control of implant bodies which are analogous to bone growth, cast with epoxy resin) was carried out with tensile – compression tests (experiments) in the Accredited Laboratory of BME Biomechanical Cooperation Research Centre (Identity No.: NAT-1-1614).

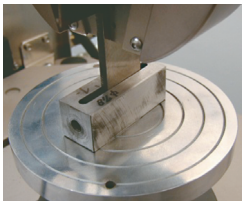
**Discussion**

*Figure 1.* shows an example of the elastic behavior of the integrated structure using Instron 8872 universal servo-hydraulic test machine.

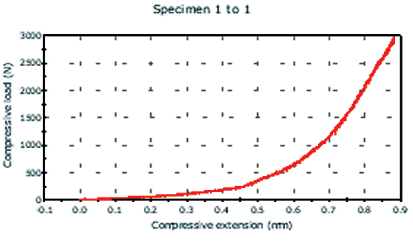
Pre-in vivo experiments were carried out for implantation. *Figure 2* shows an example of that in cadaver environment.

When preparing the integration structure, an important task regarding the final surface features is to avoid the exaggerated immune load and blood circulation load. Therefore we have

*a)*
Instruments to determine radial elastic behavior



*b)*
Instruments on the pressure plate of the loading machine




*c)*
A typical diagram of radial elastic behavior

*Figure 1.* Determination of the elastic behavior of the implant structure

*Figure 2.* Pre-in vivo implantation experiments in cadaver environment

to solve the removal of non-desirable microscopic surface particles coming from manufacturing technology. To this end electrochemical post-machining was deemed to be suitable.

*Figure 3* shows the microscopic image of a surface machined with electrochemical treatment.

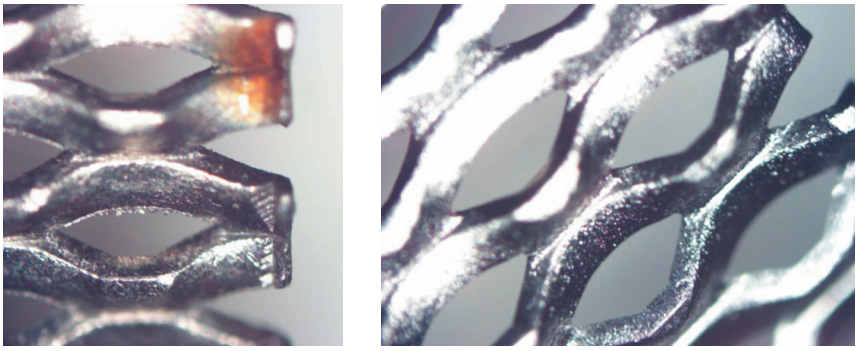
Merino sheep have been used for the in-vivo experiments of implants, which have been implanted into the locations of upper arm and femur. The operations were performed in PRIMAVET animal hospital on the basis of previously prepared surgery plans. (We have attached a detailed research plan to our experiment and animal husbandry application to the Animal Hygiene and Control Station in the capital (Budapest) indicating the outstanding human justification of the experiment series, highlighting the lifetime problems of big joint implants. (The permission was given for sheep as operation subjects.)

In case of each animal, before implantation hematological and bio-chemical data sheets were made about each animal and their heart action was recorded on ECG.

*Figure 4. a* shows a picture about a phase of the operations, while *Figure 4. b* shows the X-ray following implantation. The implantations were carried out between March and August, 2007 in seven phases.

Following building in (operations) of joint implants, promoting bone recovery with gradual, moderate, physical motion is the routine.

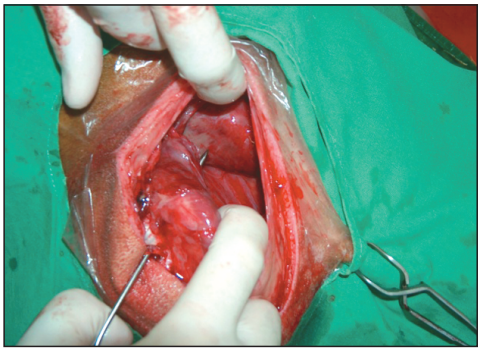
The promotion of bone recovery, however, by so-called oriented foods is unknown in human medical, veterinary and animal feeding fields.



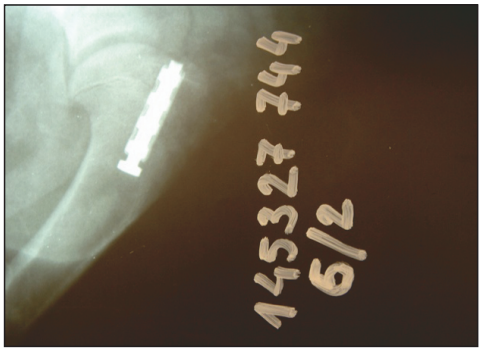
*a)*
Surfaces before electrochemical machining (50×)

*b)*
Surfaces after electrochemical machining (50×)

*Figure 3.* Surface features developed with electrochemical machining



*a)*
Operation phase of building in implant




*b)*
X-ray of built-in implant

*Figure 4.* Building in implant and X-ray

Regarding our project, we deemed it expedient and prospective to carry out primary experiments also in this field for sheep.

Since no scientific experiment is known in this subject, oriented food supply based on the most important mineral and vitamin needs of bone recovery and bone building was provided for sheep (this time we will not go into details in this field).

Following implant operations each sheep stayed in animal hospital for 5 days for medical observation. We can conclude and it justifies the success of operations that all the 16 animals were transported in good post-operative condition to open-air site in the country.

The operated animals did not show any negative behavior during the whole period.

The bones containing implants were taken out continuously after 7–11 months.

The 32 bones containing implants were shaped by cutting as they are needed mainly for mechanical preparation of microscopic examination sections, safe gripping and also for making them suitable to be gripped with grip unit made by us into test machine for pull-out examination.

The sections for microscopic examination were prepared by ISOMET 1000 precision cutting machine. Several sections from bones were made that the building in of the implant basic body and the integration structure could be examined under different environmental venous access and different bone structure conditions. It was necessary since X ray indicating only planar position about the implants was at our disposal.

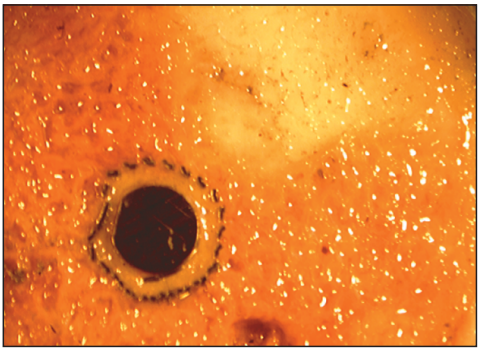
The bone/implant sections were made approximately perpendicular to the axis of the implant that the bone integration could be examined in the whole periphery of the implant.

The implant/bone pictures indicate that integration, the growing of the bone into the inner part of the lattice-like structure constituting part of the implant on the side of the implant is complete in the whole range.

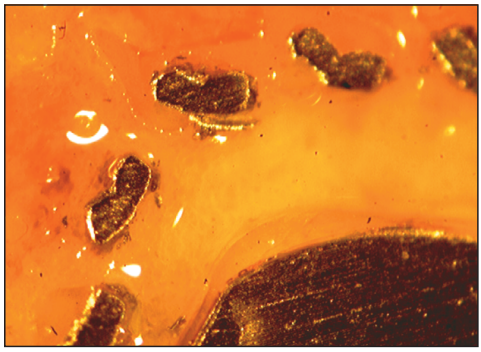
(BMS 143 stereo microscope was used for the pictures with digital camera.)

**Results**

*Figure 5* shows the incorporation sections of implants marked 5 and 9 as examples in 1:1 and 45 times magnifying.

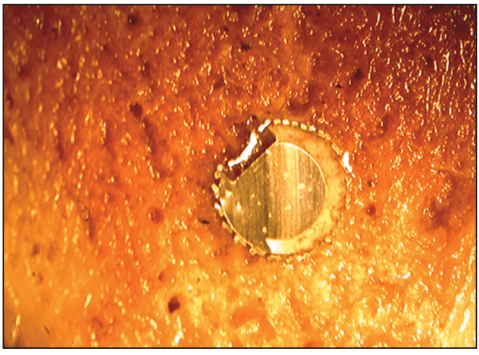


M 1:1 scale

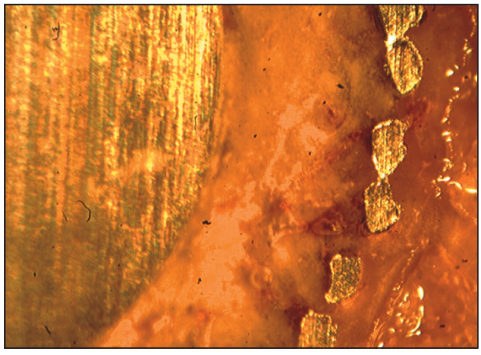


M 45:1 scale

*a)* Section pictures of implant marked 5



M 1:1 scale



M 45:1 scale

*b)* Section pictures of implant marked 9

*Figure 5.* Incorporation of implants following their removal on the basis of pictures taken about the sections

Then, the load bearing capacity of bone integration, the behavior of implant under load and the upper limit of load were examined.

The bones containing implants were shaped by cutting for these examinations that the "outer" end part of the implant would become free.

Gradually growing load was used for this end part. (The other, inner ends of the implants were in the medullary cavity.)

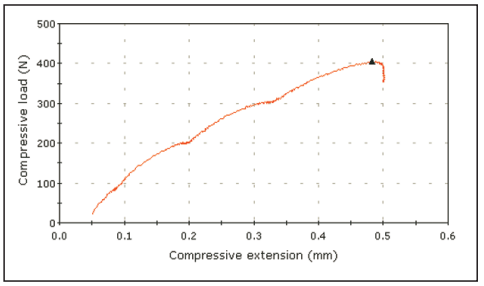
(This load direction is similar to the physiological load direction of human medullary cavity implants.)

Load was increased until connection among bone integration developed with bone incorporation, the implant and the bone was broken.

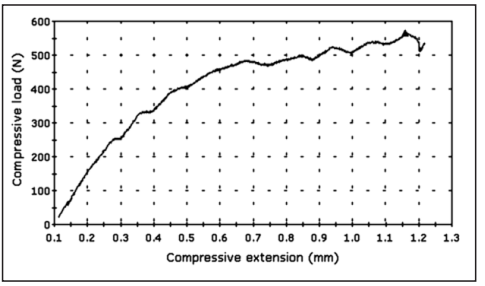
The speed of load was 0.01 mm/sec.

The diagrams show the displacement of implants from their original positions as a function of load until connection-breakage from the bone surrounding the implant.

*Figure 6* shows the load taking capacity of implants marked 1 and 4 as examples.




*a)* Implant marked 1




*b)* Implant marked 4

*Figure 6.* Determination of load taking capacity of implants with compression examination

The diagrams in *Figure 6* indicate that the loading limit of implants was between 360 N and 550 N. This difference comes from the fact that the four implants were in bone tissue parts to different extents. Since the medium diameter of the integration range of the implant is 6 mm and the length of the part integrated by the bone is 15–20 mm, the measured load limit values are very high. These load limit values are qualified very high since incorporation of bones in 90% took place in spongiosus(-like) bone.

These results, extended to human field, can be interpreted in the following way:

The diameter of the implant part of intermedullar position, which has contact with incorporation bone for human purposes is about double, its incorporation length is 5-6-fold of the implants examined previously.

To this extent the loadability of the implant of integration range according to the project means a capacity of load limit between 3600 N and 5500 N (of 351 kg and 541 kg mass).

On the basis of the microscopic examination series according to the previous pattern and load testing diagrams, we can conclude that the developed joint implant structure of spatial integration range ensures smooth blood supply, in this way undisturbed ossification through full biological bone incorporation and it is able to take very great load.

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***The presented results were achieved in the framework of the project GVOP-3.1.1 – 2004 – 05 – 0357/3.0 "Research-development of joint implants of biological integration suitable for long lifetime" in the Cooperation Research Centre for Biomechanics of Budapest University of Technology and Economics (BKKK BME).***

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