Case Study

FROM LOAD BEARING TO LOAD SHARING

HOW AMORPHOUS ALLOYS ARE TRANSFORMING PLATE OSTEOSYNTHESIS AND THE IMPACT THIS WILL HAVE ON NEXT-GENERATION BIOMEDICAL APPLICATIONS

DISTAL RADIUS FRACTURE THERAPY

In Germany, approximately 200,000 distal radius fractures are treated per year. The development of treatment approaches to support this fracture healing has undergone many steps of change. From different treatment techniques to new implant systems. However, it has always been limited by the mechanical and biological properties of the materials used. In sum, treatment by plate osteosynthesis suffers from the limitations of miniaturization and customization. Amorphous metals that can be near-net shape manufactured into specific plates with built-in features using 3D printing and injection molding can enable plate osteosynthesis and other approaches in medical technology to improve less invasive and at the same time more stable and reliable recovery processes.

INTRODUCTION: HEALING PROCESS OF DISTAL RADIUS

Distal radius fractures are fractures of the radius close to the wrist and are the most common fracture of the human skeleton. The distal radius fracture usually results from a fall onto the intercepting hand. On the one hand, young, athletically active and risk-taking people who suffer radius fractures as a result of trauma involving considerable force are affected. But much more affected are older patients, mostly patients with osteoporosis, for whom a fracture of the distal radius occurs due to so-called "low energy falls".

Depending on the type of fracture, different procedures are used to stabilize the fracture (known as osteosynthesis procedures). Screws, wires (so-called drill wire supports according to Kapandji), external fixators (an external holding device for comminuted fractures) or metal plates can be used. Most commonly, a distal radius fracture is stabilized by a metal plate (using angular stable plate osteosynthesis). Here, the development of so-called locking compression plates (LCP’s) has revolutionized the classic dynamic compression plates (DCP’s) approach as it is more anatomically specific.

In fractures of the distal radius, secondary fracture healing is most important. Fracture healing is the general healing process of a bone defect. The so-called primary fracture healing, only possible when the fracture ends are in contact, proceeds without visible callus formation, as capillary connective tissue grows into the narrow fracture gap. This stimulates the formation of osteons, which in turn restructure into bone. However, in secondary fracture healing, the healing process takes place with the formation of a callus, depending on four stages after the fracture and represents the regular fracture healing in plate osteosynthesis:

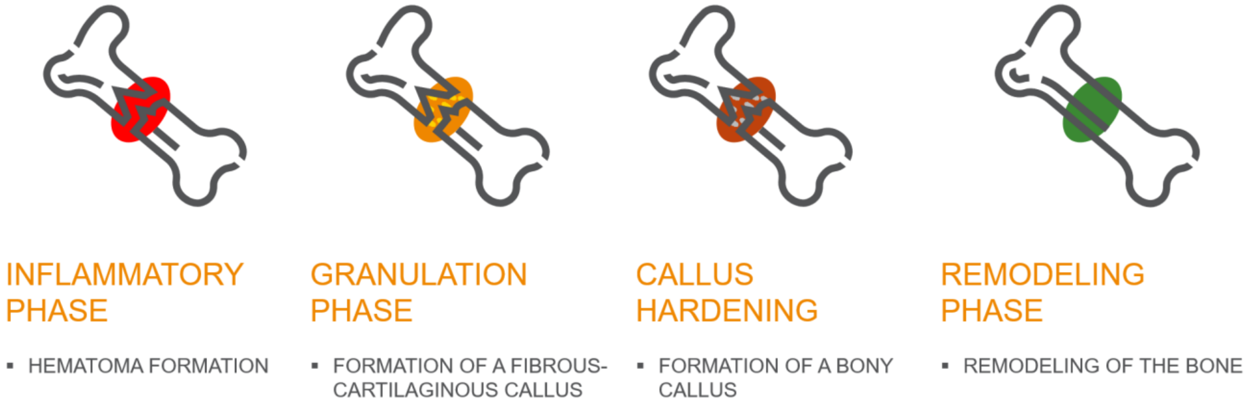

Figure 1: Stages of bone fracture healing

The role of plates in plate osteosynthesis therapy changes from initial load bearing of the fixed bone segments to callus-supporting load distribution in the course of the mentioned stages. The difficulty is that surgeons must emphasize both stability and flexibility in supporting these stages.

PROBLEM: STABLE FIXATION WITH MICRO MOVEMENT

Generally, these plates all have a low profile and a highly polished surface to avoid negative adhesions and to ensure an uncomplicated explantation. The thinner these plates are after implantation, the better the ligaments and tendons can work, which usually run along the plate above the fracture after the operation. Here, even avoidable increases in plate thickness in the µm range can cause pain or initiate post-traumatic malpositioning. However, if the thickness of the plates is reduced too much, this leads to a decrease in strength. This is due to the limited mechanical properties of the common 316l steels as well as the Ti-based alloys that currently dominate plate designs.

How these mechanical properties, above all the young’s modulus and the strength, which are decisive for the stabilizing and at the same time flexible behavior of the materials, influence small relative movements of the fracture fragments is decisive for the formation of the so-called callus. The callus supports the healing process according to the previously described secondary fracture healing stages. In total, the fragments should not move too loosely, because this increases the risk of angular healing, which, like the avoidance of pain due to malpositioning of the tendon posture, can lead to a restriction of mobility. An upper limit for the targeted stiffness of the fracture is currently not specifically known, so that this micro-movement must be limited differently.

Here it becomes even more elementary to emphasize that although fracture elongation is determinant, the case of failure already occurs when a minimal (usually cyclically progressive) permanent or plastic deformation of the fracture angle occurs. This has a crucial influence on the formation of a callus and leads to permanent deviations from the anatomically correct position of the fragments after healing. Therefore, the main focus when using radial implants should be to minimize permanent deformations during the healing stages of four to six weeks after implantation. In order to determine the relevant properties of an implant, the first approach is usually via examination of the supported bone itself. The aforementioned cyclic fatigue behavior has at least as much influence here. Some studies have focused on the mechanical properties of the bone-implant or implant interface in cortical bone but have not considered fatigue behavior and permanent deformation. Criteria here are not only the different fatigue behaviors per se, but also their temporal occurrence, failure localizations and fracture loads, which are significantly influenced by the mechanical material parameters of elasticity or stiffness, the tilt angle and the resulting reduction of the fracture gap by plastic deformation.

SOLUTION: NEW MATERIAL CLASS WITH CUSTOM-FIT PROPERTY PORTFOLIO

Amorphous alloys have a fundamentally different structure compared to the aforementioned currently used crystalline materials of 316l stainless steels or Ti-based alloys. Shock cooling of the melts results in high cooling rates, which prevents the basic atomic order from equalizing energetically and assuming a basic crystalline structure. The state of the liquid melt is thus solidified so quickly that no phase transformation from liquid to solid takes place and the amorphous structure has neither phase nor grain boundaries. The solidification also results in a very small shrinkage in the near-net shape production.

These general conditions enable properties of the amorphous alloys that were previously impossible in crystalline materials or could only be produced at great expense. With simultaneously high strength and high elasticity, the material offers very strong corrosion and abrasion resistance and can be post treated to high surface quality. The resistance to impurities has even been proven to be biocompatible.

In vitro as well as in vivo studies have already confirmed this, highlighting Zr-based metallic glass, as the amorphous alloys are also called, as a candidate for next-generation biomedical applications.

Thus, amorphous alloys have a great potential to benefit in the field of plate osteosynthesis by near-net shape manufacturing processes. Starting with the high linear elastic behavior, through the total load capacity and the resulting miniaturization with constant stability, to the long-term stability in the fatigue test.

Material	**Bending strength [MPa]**	**Young's modulus [GPa]**	**Elasticity [%]**	**Biocompatiblity**	**Costs**	**Manufacturing methods of LCP's**
316l SS	200	190	0.1	Coating necessary	Low	Machining (drilling, milling, bending, …)
CP Ti Gr. 2	350	105	0.3	Thin passive oxide layer	Medium-Low	Machining (drilling, milling, bending, …)
Ti-6Al-7Nb	1000	110	0.9	High biocompatibility	Medium-High	Machining (drilling, milling, bending, …)
AMLOY ZR02	**2000**	**89**	**2.2**	**High biocompatibility**	**Medium-High**	**3D Printing Injection Molding**

Table 1: Comparison of 316l stainless steel, commercially pure titanium Grade 2, TiNb alloy and AMLOY ZR02

To validate these hypotheses, reference was made to a previous study that found a force curve with an amplitude of 800 N and 2000 cycles at a frequency of 1 Hz to be a conservative scenario for axial loading of the radial bone in the six weeks after implantation.

Conventional test setups could not fully unload the system due to the measurement technique as this would cause problems with specimen alignment, therefore this setup is ideally suited for fatigue behavior measurement. Throughout the measurement, force was determined by weights and displacement by a digital gauge. Sample materials included CP Ti Grade 2 and AMLOY ZR02.

Figure 2: Fixation of the radius plate in the test setup

Figure 3: Experimental setup for the comparative measurement of TiGr2 and AMLOY ZR02 LCP's

After the fatigue test, a load-to-failure test was also performed to check the stability of the system. Recorded values of deflection and force were used to measure characteristic values of the implant such as stiffness, elastic deformation, plastic deformation and tilt angle. All plates were attached at one end with 7 steel screws for a stable base condition. The load was generated on the proximal side for a bending moment at the critical point causing the deformation comparable across materials. The results are based on the measured loads, displacements and cycles.

RESULT: BALANCE OF TOTAL LOAD CAPACITY AND HIGH LINEAR ELASTIC BEHAVIOR

Looking at the results of the elastic range tests, the influence of the amorphous microstructure on the plate performance quickly becomes clear. For the elastic test (see figure 4 and 5), loading was started at low values, each load was repeated 3 times, displacement under load and after unloading (plastic displacement) was measured. Amorphous metal plate (BMG H #6) shows pronounced elastic behavior up to 14mm displacement at 40N load. Ti plate is elastic below 5-10N, above 10N displacement is mainly due to plastic deformation. Overall, good repeatability for BMG (3 specimens, 3x repetition of one specimen) is observed at 0.6%.

In the subsequent fatigue test (see figure 6), For Ti Gr2 the minimum elastic weight was 500g, based on preliminary tests. After the first run, the weight was increased to 750g and 1000g. All loads showed plastic deformation, but 1000g was significantly higher than the other specimens. For the amorphous metal plate (BMG H #1, BMG H #6), a load of 2000g was tested on two plates (90 and 140 µm thickness). The plastic deformation was always below the 100 µm limit.

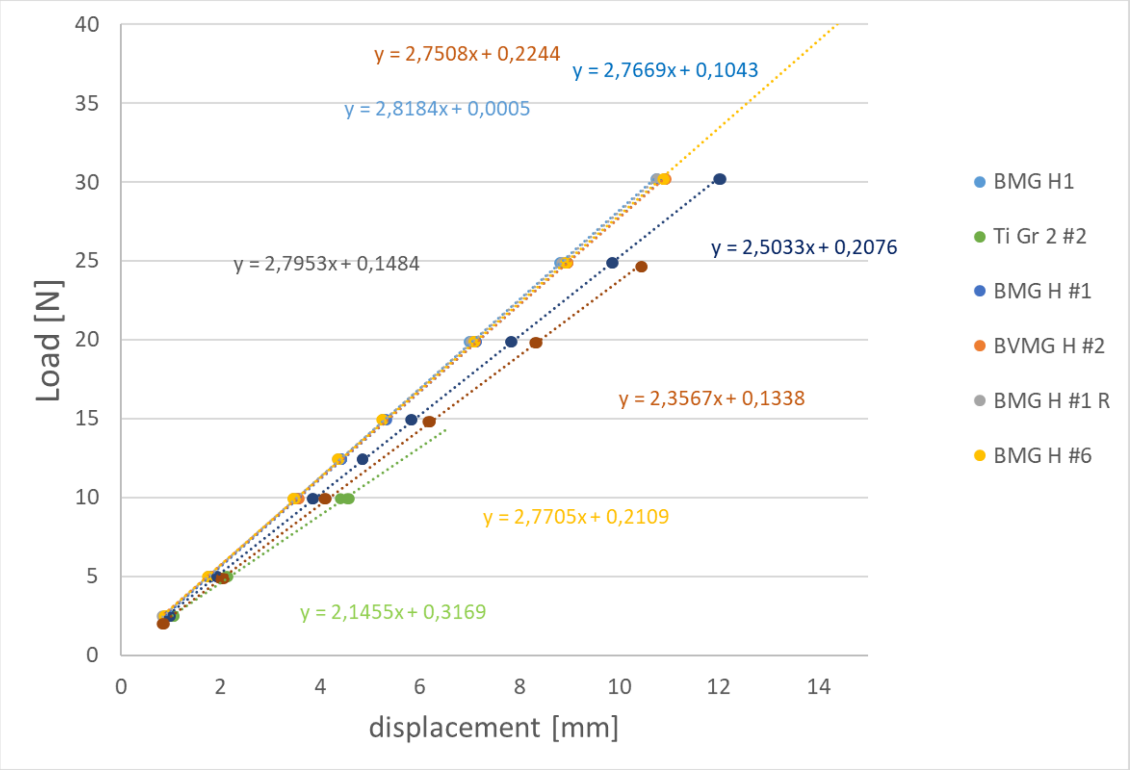

Figure 4: Elastic range test (Load [N] vs. displacement [mm])

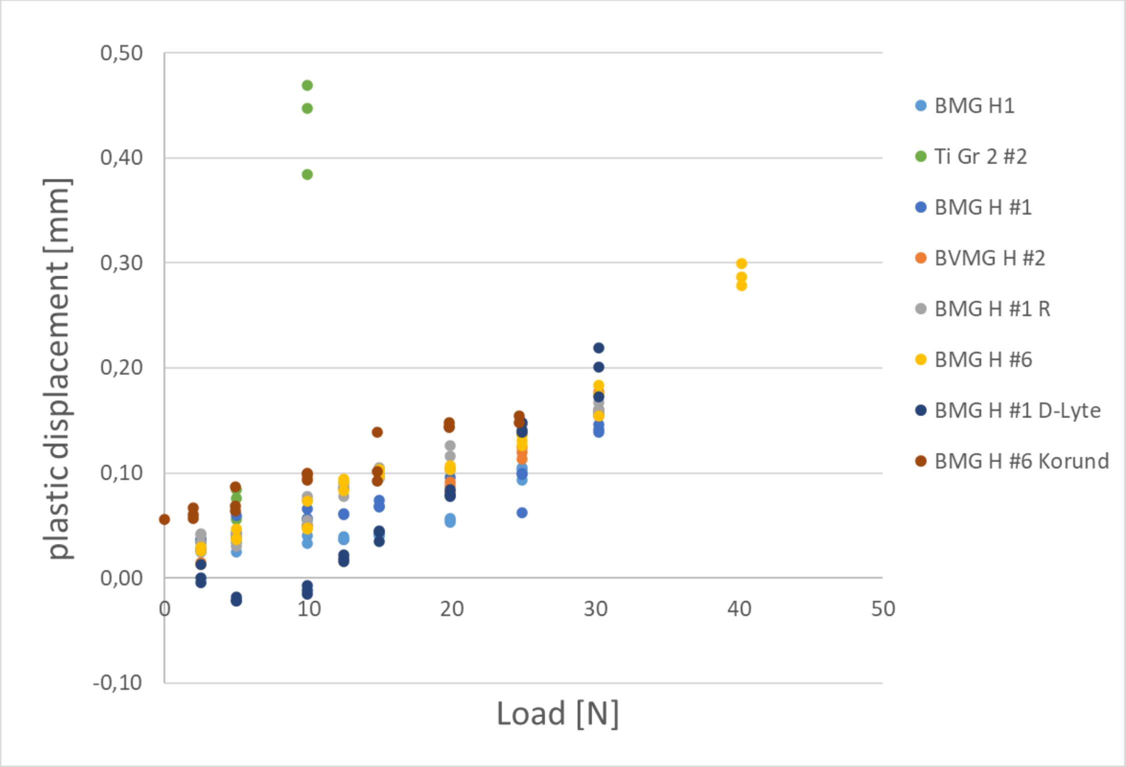

Figure 5: Elastic range test (Load [N] vs. plastic displacement [mm])

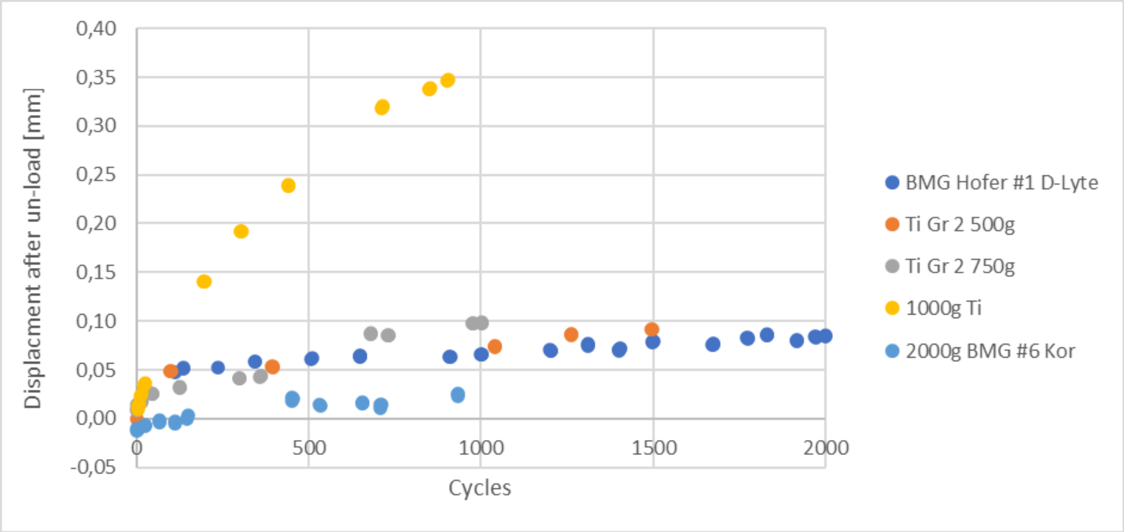

Figure 6: Cycling and fatigue behavior test

The figures show that all plates withstand the tests. However, the big but decisive difference, is that the titanium plates show plastic deformation even at small loads. As described in the literature, 2000 cycles should occur without plastic deformation. The amorphous metal plate remained below 100µm plastic deformation even in this interval. With adapted designs, even completely linear elastic deflections would be possible.

> **This higher elasticity and dimensional stability can withstand even higher loads and, due to the high strength, does not even break at loads where the compared crystalline materials are already plastically deformed and buckled away.**

What do we learn from this for the application in radial plate osteosynthesis? – The high elastic behavior coupled with the high strength provides ideal basic conditions in terms of the therapy characteristics of absolute stability and micromobility and fulfills the role of the plates from the approach of load bearing to load sharing and the actual support of bone remodeling. Bones are prevented from being rigidly fixed and locking plate systems can ideally adapt in performance and functionality. Post-traumatic failures and callus malformations and thus pain after explantation are prevented.

But that's not all. With amorphous metals, the plates can be made thinner due to their strength, and the AO principles of fracture treatment from anatomic reduction to gentle and less invasive treatment can be achieved more easily.

OUTLOOK

In addition to this functional expansion through the material and manufacturing process used, it is also possible to combine the potential in the area of individualization and miniaturization. Local adaptations can be easily made by additive manufacturing processes for the purpose of necessary stiffness, reinforcement and also at weak points where you would generally like to thicken or thin out. If this procedure is taken to its logical conclusion, the complete fitting process of the patient after injury is possible by means of the manufacture of personalized prostheses. While the hematomas are swelling down, the implant is 3D-printed and can be used functionally with almost no reworking. The complexity of the entire manufacturing process and much manual rework (from CNC programming to manual high polishing) is cost-effectively converted. In the process, sockets, threads and all kinds of features can already be enabled by direct printing without milling operations.

Limitations in the transformation task of the distal radius plate are certainly in weight-bearing bones such as the tibia or fibia. But thinking of plate osteosyntheses with amorphous implants in non-weight-bearing plates such as the clavicle, the elbow, the radius head prosthesis, the CMF area or even in rods of pedicle screws, there are nearly no limits to the beneficial use of amorphous metals in medical technology.

Join us as we set new standards and establish a new class of materials for next-generation biomedical applications.

Heraeus

AMLOY

START YOUR AMORPHOUS JOURNEY NOW

About Heraeus

Heraeus, the technology group headquartered in Hanau, Germany, is a leading international family-owned portfolio company. The company’s roots go back to a family pharmacy started in 1660. Today, the Heraeus group includes businesses in the environmental, electronics, health and industrial applications sectors. Customers benefit from innovative technologies and solutions based on broad materials expertise and technological leadership.

In the 2020 financial year, the FORTUNE Global 500 listed group generated revenues of €31.5 billion with approximately 14,800 employees in 40 countries. Heraeus is one of the top 10 family-owned companies in Germany and holds a leading position in its global markets.

About Heraeus AMLOY

Heraeus AMLOY specializes in the development of amorphous alloys and the production of amorphous components. These enable completely new high-tech applications due to their unique material properties such as high strength combined with high elasticity as well as corrosion resistance and biocompatibility.