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The effect of glassy carbon and cancellous bone admixture on performance and thermal properties of acrylic bone cements

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ABSTRACT

Purpose: of the research is to physically modify the composition of bone cements with glassy carbon and cancellous bone to improve its performance, reduce polymerization temperature and reduce the ability of cements the effect of admixture on the phenomenon of relaxation.

Design/methodology/approach: SpinePlex bone cement was modified with glassy carbon powder with 20-50 μm granulation with Maxgraft®. Maxgraft cancellous bone has been ground to 20-50 μm grains. Samples of unmodified cements (reference) and modified with glassy carbon and cancellous bone were prepared for the tests. The glassy carbon powder and ground cancellous bone were premixed with the cement copolymer powder, and then the premix prepared this way was spread in a liquid monomer. To delay the polymerization process, all components were cooled before mixing to 15°C. The addition of glassy carbon was 0.4 g and the addition of cancellous bone was 0.2 g per 20 g of cement powder, i.e. about 1.96% by mass. Polymerization temperature, relaxation and differential scanning calorimetry tests were performed on the samples made.

Findings: Additives used allow: to reduce the polymerization temperature, as well as rheological properties. During the studies it was found that the additive which can meet the requirements is glassy carbon in form of powder and cancellous bone.

Research limitations/implications: The results presented in the publication require further advanced research, which will be the subject of further modification attempts by the research team.

Practical implications: The conducted tests showed a significant effect of glassy carbon as a modifier on the mechanical properties of cement after its solidification, but also on the course of the polymerization process. Temperature registration tests during crosslinking, tests of mechanical properties (behaviour of cement samples under load) and DSC differential scanning calorimetry analysis confirmed that the addition of glassy carbon had an effect on each of these aspects.

Originality/value: The original in these studies is the possibility to improve fundamental properties of the selected bone cements by using different than commonly used additives.

Keywords: Bone cement, PMMA, Acrylic bone cement, Vertebroplasty, Kyphoplasty, Glassy carbon, Cancellous bone

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BIOMEDICAL AND DENTAL MATERIALS AND ENGINEERING

1. Introduction

Compression fractures in the spine are relatively common fractures resulting from metabolic diseases of bones, primary and secondary diseases that lower bone quality – osteoporosis, tumours or cancer metastases, haemangiomas, hyperparathyroidism, and can occur as a result of a mechanical injury. However, most often these fractures are not traumatic, while most of them arise as a result of lower bone density due to osteoporosis. Osteoporotic compression fractures are the greatest threat to the elderly, in particular women over 50 [1-8]. Studies have estimated that for every 1,000 people, 1.45 women and 0.73 men suffer from osteoporotic fractures of the spine, annually [9]. Studies have shown that 1 in 1000 women over the age of 50 suffers such a fracture, while at the age of 75 the number increases to up to 3 in 100. Approximately 35% of women after the age of 65 suffer from bone demineralization leading to a decrease in bone quality [10]. Less common secondary osteoporosis, which can be caused by various factors such as inadequate diet, vitamin D deficiency, excessive alcohol consumption or diseases such as diabetes or hyperthyroidism, also leads to more frequent compression fractures [11]. A relationship has also been demonstrated between a compression fracture and higher mortality compared to healthy people [12,13]. All spinal fractures resulting from osteoporosis are compression fractures. A compression fracture in the spine that was not the result of an injury can be defined as a fracture that includes a reduction in the vertebral body height by about 20% relative to the adjacent vertebra or by at least 4 mm as a result of forces smaller than the forces that would cause a fracture of bones with normal bone structure [2,13,14]. Osteoporotic fractures of the spine are divided based on various criteria, e.g. based on the location of the fracture or the type of fracture. Considering the locations of compression fractures, they most often occur in the lower parts of the thoracic segment (Th10-Th12) and the upper parts of the lumbar region (L1-L1).

Due to the type of fracture, we can distinguish: wedge-shaped, two-concave and crush. compression fractures resulting from osteoporosis are stable fractures, because they do not affect the posterior column of the spine and the ligament apparatus, thanks to which these fractures, unlike traumatic fractures, do not give neurological deficiency signs of the core or nerve roots, and do not damage the spinal cord [1-8]. The main consequences of osteoporotic fractures of the spine are severe chronic pain that occurs immediately at the time of injury, a decrease in height, and deepened thoracic kyphosis. Deepened thoracic kyphosis leads to deformation of the figure, and consequently to a reduction in the efficiency of the respiratory system and lung capacity, and it can negatively affect the circulatory and respiratory systems and the digestive system [5,15].

Due to the fact that compression fractures are stable fractures, until recently one method of treating compression fractures of the spine was conservative treatment, which includes bed regimen, rest, pharmacotherapy and an orthopedic corset. However, the use of conservative treatment did not always give satisfactory results, in about 30% of patients the chronic feeling of severe pain leads to a significant decrease in comfort of life.

Since the 1980s, in addition to conservative treatment, transdermal minimally invasive surgical techniques, such as vertebroplasty and kyphoplasty, have been used to treat compression spine fractures. The idea of low-invasive transdermal surgical techniques is to fill the broken vertebral body with bone cement based on poly(methyl methacrylate). Both surgical methods differ in the technique of performing the procedure. Vertebroplasty involves injection and direct filling of a broken vertebral body with low-viscosity, self-curing cement with a cannula [16-19]. Kyphoplasty is used when there is angular deformity of the spine and deepened thoracic kyphosis. Kyphoplasty, unlike vertebroplasty, allows height to be partially restored by inflating a high-pressure balloon inside a broken shaft. Inflation of a high-pressure balloon in the vertebra allows the border plates to be moved away in the shaft and a cavity to be formed, into which bone cement with a higher viscosity and pressure than with vertebroplasty is inserted with a cannula, which reduces the risk of cement leakage outside the treated shaft [20]. Both surgical techniques are performed under fluoroscopy and under local anaesthesia, which is especially important for the elderly suffering from coronary artery disease. Whereas maintaining constant contact with the patient allows for a quick detection of neurological complications and an almost immediate response.

Vertebroplasty and kyphoplasty are highly effective. In both cases, partial or complete subsidence of pain occurred in 95% of patients treated within 72 hours after surgery. Despite the high effectiveness of both treatments, as every treatment, it causes side effects and complications. The main reason for the complications of these procedures is the imperfection of the filling material [16-19, 21].

For 50 years, PMMA bone cement has been the most commonly used material for filling bone defects, stabilizing complex fractures, welding and fixing endoprostheses. Currently used bone cements meet basic mechanical properties, are characterized by good biocompatibility and appropriate handling properties [22-28].

On the other hand, this specific biomaterial is characterized by inadequate biocompatibility, tendency to degrade in the aggressive environment of the body, as well as the high temperature of cement hardening, as a result of which the effectiveness of treatments decreases. The cement hardening process takes place during the polymerization reaction, which is highly exothermic and can reach up to 96 degrees, which significantly exceeds the coagulation of protein and can lead to necrosis surrounding the treated vertebral tissue and nerve endings. Another adverse feature of the polymerization reaction is the shrinkage characteristic of polymer materials and the presence of air, which is associated with porosity and the possibility of reducing mechanical properties. Poor adhesion to natural bone structures associated with poor bioactivity and low osteointegration of current commercial bone cements is another important issue. Postoperative vertebrae also differ in mechanical strength, which leads to a change in the biomechanics of the spine [22-28]. Taking into account the modulus of elasticity in compression of a healthy vertebral body in a human being of 50-800 MPa [26,29,30], and comparing it to the modulus of elasticity in compression of a cemented vertebra, which is in the range of 2000-3700 MPa, it was found that the reason for fractures of the vertebrae adjacent to the postoperative vertebrae is the increased pressure on the adjacent vertebrae as a result of increased rigidity of cemented vertebrae [31-35]. Another important post-operative problem is cement leakage outside the operated vertebral body. Cement can get out through a damaged wall of the stem or through venous plexuses to the intervertebral disc, soft paravertebral tissues, epidural veins or intervertebral holes. A cement leakage may also cause pressure on the meninges or nerve roots. Root or meningeal symptoms are transient and usually disappear after medication and standard conservative treatment. The most serious, though rare, complication associated with cement leakage is leakage into the spinal canal, which can cause spinal damage, pulmonary embolism [37-44] and cardiac embolism [45]. Most often, cement leakage is asymptomatic [46]. One case of permanent root pain observed in a patient [47] is presented in the literature, while spinal cord injury was noted in two cases that required rapid decompression, unfortunately one of them ended with permanent spinal injury [40,48].

In research centres worldwide are conducted studies on polymer modifications of bone cements in order to develop cements with improved utility and durability properties by undertaking attempts to modify it using non-polymerising additives to acryl cements such as: carbon, polyurethane, polyethylene, steel and glass fibres, apatite powder, aramid fibres, ceramic glass, or starch. The development of polymer composites for medical applications in order to acquire better bio-materials as synthetic bone substitutes is a future direction [23,49].

An attempt to modify bone cement with ceramic powder has been undertaken in works [50-53]. Studies have shown that ceramic powder additive has a positive influence on volumetric shrinkage related to the polymerisation process. In studies presented by A. Balin it has been shown that cement blended with ceramics caused a reduction of linear shrinkage by approximately 30%. This phenomenon has been justified with reduction of percentage content of monomer in the mass of acrylic bone cement and filling this mass with particles of oxide ceramics, which stops the shrinkage of cement mass [23,54,55]. A small increase of elasticity modules in conditions of bending, stretching, and compressing a blended surgical implant has also been observed. Changes of durability and utility properties at small additions of oxide ceramics are important from the clinical application point of view [23,50,53-56]. Addition of hard particles to a fragile PMMA polymer warp has a positive impact on reinforcement of composite and growth of elasticity module [23].

Physical cement modifications aimed at improving its bio-activity and bio-functional properties cause additional impediments such as destruction of the modifier by high temperature occurring during the polymerisation reaction, too rapid release of bio-active additive to surrounding tissues, or rinsing of bio-active additives by body fluids. Another complication during modification using bio-active additives of polymer cement is an adverse influence on physical, mechanical, and functional properties. Therefore, it is important to conduct multidisciplinary studies on modified cement [26,57-59].

An alternative for antibiotics used in current polymer cements can be metal nanoparticles e.g. silver and copper and chitosan nanoparticles. Studies have shown that cement modified with Ag and Cu nanometals has shown bactericidal effects while chitosan nanoparticles prevented the survival of live bacteria on the surface of cement modified with chitosan [60,61]. It is presumed that the probability of micro-organisms developing resistance to silver is low because silver nanoparticles are characterised by broad spectrum of antibacterial activity and low bacterial resistance [60,61].

Many research centres have also undertaken attempts to modify polymer bone cement using a mineralised collagen. A positive influence of mineral collagen additive has been shown in literature, where cement modified in such way shows good osteogenic activity when compared to commercial surgical cements and significantly improves its mechanical properties, as well as cytocompatibility. Chinese researchers Cui and Qui [34,35, 62-64] have confirmed the improvement of elasticity module and osseointegration of modified MC bone cement using in vitro tests on animals. It has been found that new tissues have gradually grown in the porous structure of cement after bones have absorbed the collagen. Cements modified with mineral collagen have shown a better proliferation and adhesion of pre-osteoblasts in relation to commercial cements, which in turn increases the ability to integrate bone cement in vertebrae and can effectively protect against cement tearing off from sick vertebrae. Modification of cement with mineral collagen causes the reduction of elasticity module during compression and stiffness of cemented vertebrae, which results in smaller pressure of treated vertebrae on adjacent vertebrae and leads to reduction of risk of repeated break of adjacent vertebrae [34,35, 62-64].

To improve the performance of acrylic bone cements, attempts to physically and chemically modify the currently used cements are being made. Admixture of cements with various additives significantly affects their mechanical, rheological, biological compatibility and functional properties. Modification and improvement of bone cements is an important aspect to improve patients' quality of life, and reduce the risk of operational complications associated with the imperfection of currently used acrylic bone cements, and to learn about their relationships to use these biomaterials more safely and consciously. The modification of bone cement with glassy carbon was aimed at reducing the polymerization temperature and reducing the stiffness of hardened cement.

2. Materials used and sample preparation

The research used bone cement based on SpinePlex poly(methyl methacrylate) from Stryker (USA) commonly used to fill bone defects in the spine and glassy carbon from Alfa Aesar powder (USA) type 1 with a grain size between 20 and 50 µm and cancellous bone Maxgraft® from Botiss Biomaterials (Germany) and Ringer's solution. According to the product technical data sheet, the composition of the individual components of SpinePlex cement is given in Table 1 and the composition of Ringer's solution used in the studies is presented in Table 2.

Table 1.
Chemical composition of PMMA (manufacturer's data)

Chemical composition of SpinePlex cement components			
20 g powder		10 ml ampoule	
Polymethyl methacrylate	11.5%	Methyl methacrylate	9.75 ml
Methyl methacrylate/styrene copolymer + benzoyl peroxide	58.5%	N, N-dimethyl-para-toluidine	0.25ml
Barium sulfate	6.0%	Hydroquinone	0.75mg

Table 2.
Chemical composition of Ringer's solution*

Substance	Concentration, $g \cdot l^{-1}$
Sodium chloride	8,60
Potassium chloride	0,30
Hexahydrate calcium chloride	0,48

*The solution contained ions with the following concentrations, $mmol \cdot l^{-1}$, Na^{+}= 147,16, K^{+}=4,02, Ca^{2+}= 4,38, Cl^{-}=155,56.

SpinePlex bone cement was modified with glassy carbon powder with 20-50 µm granulation with Maxgraft®. Maxgraft cancellous bone has been ground to 20-50 µm grains. Samples of unmodified cements (reference) and modified with glassy carbon and cancellous bone were prepared for the tests. The glassy carbon powder and ground cancellous bone were premixed with the cement copolymer powder, and then the premix prepared this way was spread in a liquid monomer. After adding additives to cement during mixing has been observed an increase in viscosity of the modified cement. To delay the polymerization process, all components were cooled before mixing to 15°C. The addition of glassy carbon was 0.4 g and the addition of cancellous bone was 0.2 g per 20 g of cement powder, i.e. about 1.96% by mass. To assess the temperature change of the polymerizing cement in conditions close to natural, an experiment was prepared consisting in the application of cements into cavities made in the pig bones of the spine. Temperature changes were recorded in two areas using thermocouples placed directly from the mass of cement applied and at a distance of about 2 mm from the bone application site. The K-type thermocouple was placed in a drilled hole with a diameter of 2.5mm to a depth of about 10 mm. Before placing the thermocouple, thermal grease was applied to the hole. The second thermocouple was placed directly in the cement mass, filling the hole in the tested place. The thermocouples were connected to the Pico Technology temperature recording device. The collected results were processed in the PicoLog 6 program.

The next study was an analysis of the change in compressive force affecting the tested samples (test samples were prepared from hardened cube-shaped cement) recorded during 4500 s. During the measurement, its decrease (relaxation of introduced stress into the sample) over time was recorded. For this purpose, a station equipped with an AXIS 500FB digital sensor with a maximum load of 500 N was used. Due to the fact that cement is placed in the body and is exposed to an aggressive environment inside the human body, relaxation studies of modified and commercial cements after ageing for 8 weeks were also performed in Ringer's solution imitating the body's environment at 37°C. To compare the effect of Ringer's solution on the relaxation process under load, tests were also made for non-liquid cements.

<u>Presentation of research results</u>

Polymerization reaction study and polymerization temperature measurement of modified and commercial bone cements. Earlier results of experimental studies on modification of glassy carbon cements used for hip arthroplasty reported in the literature [23] allow concluding that thanks to the modification of the composition of glassy cements, it is possible to reduce the maximum polymerization temperature during cement hardening. Figure 1 presents graphs of temperature change over time recorded with the use of commercial (non-doped) bone cement, and results of cement modified (before its application) with glassy carbon.

The registered graphs of the dependence of cement polymerization temperature in time, it was observed that glassy carbon doped cement has a much lower polymerization temperature than unmodified commercial cement. Comparing the PMMA thermal conductivity coefficients with glassy carbon, the addition of glassy carbon to the mass of cement based on the PMMA matrix increases the thermal conductivity coefficient of cement modified in this way, by receiving heat by glassy carbon particles during MMA polymerization [23] Analysing the graphs, a shift of polymerization curves for modified cement in the direction of smaller time values in relation to commercial cement was also observed, which means an increase in cement curing speed and thus a shorter time of cement application (Tab. 3) to the compression of the

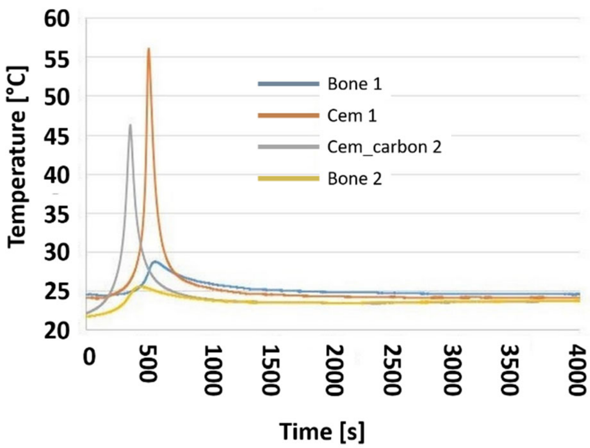

Fig. 1. Polymerization temperature changes over time for commercial cement and bone modified cement. Bone 1 for unmodified cement, Bone 2 for modified cement

vertebral body (faster kinetics of the polymerization reaction). Based on the results obtained during the conducted polymerization tests, the curing time of doped and un-doped cements was determined in accordance with ISO 5833:2002 and according to the formula:

$$T\,set = \frac{(T_{max} - T_{ot})}{2}, \qquad (1)$$

where T_{max} – maximum temperature, T_{ot} – ambient temperature, T_{set} – curing temperature.

Table 3.
Comparison of maximum temperature, ambient temperature, curing temperature, curing time for commercial and modified cement

Parameters	Commercial cement	Modified cement
Maximum temperature T_{max}, °C	56.0	46.5
Ambient temperature T_{ot}, °C	28	26
Curing temperature T_{set}, °C	42.0	36.5
Curing time t_{set}, s	532	316

3. Understanding cement and composite relaxation processes and commercial cement

The tested materials in the application environment are subjected to a different state of stress, while in applications strengthening the vertebral bodies of the spine, they mainly transmit compressive stresses. In a loaded environment, the material must be able to withstand cyclic and static, complex load patterns. During human movement, the phenomenon of cement destruction occurs because it is subjected to cyclical change of high-value loads. For good biofunctionality of cement in a loaded environment, the tendency of polymer bone cements to cyclical relaxation during cement loading, and its return to the initial state, is of great importance. The mentioned cement characteristics cause that patients after the stage of physical activity experienced cement relaxation, while during the rest period the material returned to its initial state. Relaxation is based on slow changes in stress values, accompanying permanent deformations over a long period of time [23,65].

Surgical cement is a material with viscoelastic properties. Creep phenomena are also observed, resulting from the constant influence of body weight on compressed vertebrae. The simplest mechanical model to characterize viscoelastic materials is the Maxwell model. In this model, the phenomenon of relaxation can be represented as shortening of an extended spring and extending the damper, with an unchanged total length. When the spring is shortened, the force required to keep it stretched decreases, which is equivalent to the disappearance of stress in real bodies [66].

Rheological phenomena (Fig. 2), including the phenomenon of relaxation occurring in polymers, can be associated with their characteristic viscoelastic properties, which are not a simple result of Hooke's elastic and Newton's viscous properties [66].

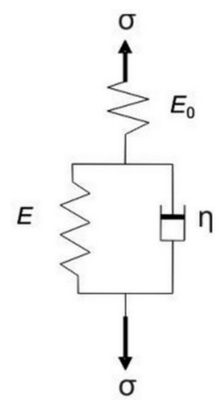

Fig. 2. Rheological phenomena [66]

This phenomenon has a third result, which is the phenomenon of inflexibility characterized by the fact that reversible deformations are characterized by two components: one – "immediate" and the other “delayed ", which requires a longer time to return to the initial state – from a few minutes to a few hours. The rate of determining deformation in polymeric materials depends on their structure as well as the dynamics of molecular movement. The effect of the deforming force in polymeric materials depends to a large extent on the temperature and varies from elastic for short times to viscous for long times [23,65,66].

Analysing the results (Figs. 3 and 4) of the course of load decrease as a function of the duration of force in the relaxation test, it has been observed that doped and un-doped cements, aged in an environment that mimics the body's environment, show greater plasticity compared to un-doped cements, and in the literature [34] this phenomenon was justified by the release of an increased amount of monomer which can lead to material plasticizing. Glassy carbon-doped cements aged in Ringer's solution are less capable of plastic deformation than commercial cement, due to the lower monomer percentage of the cement-carbon composite obtained [23].

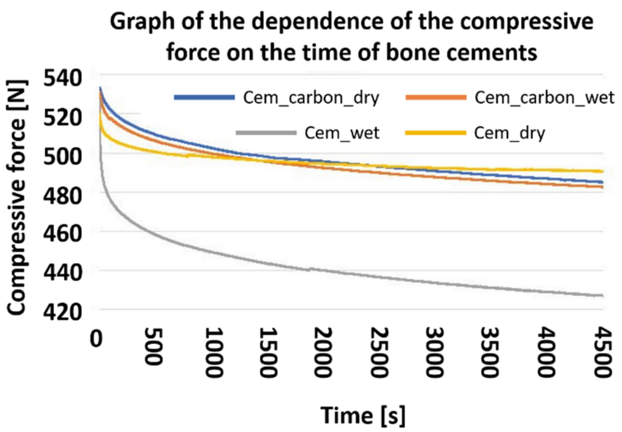

Fig. 3. Changes in compressive force values for modified and unmodified cements

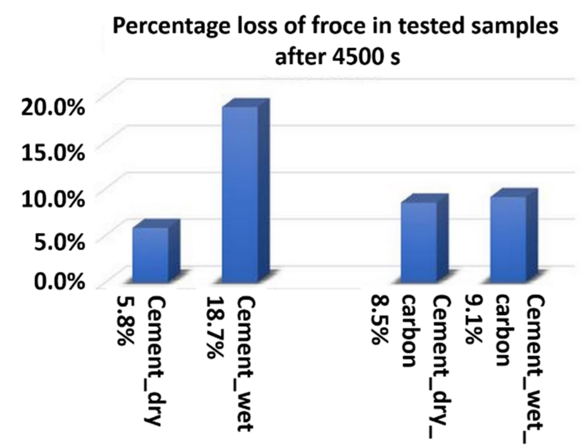

Fig. 4. Percentage loss of compressive force in tested samples after 4500 s

4. The thermal analysis of modified and unmodified cement

The analysis of the thermal properties of modified and unmodified bone cements was made by means of differential scanning calorimetry (DSC test) on the DSC 214 Polyma NETZSCH measuring stand. The prepared samples of cements weighing about 12 mg were heated from a temperature of 298.15 K (25°C) to dynamically 310.15 K (37°C). After heating, the sample was stabilized at 310.15 K (37°C) for 30 minutes, followed by heating the sample at a rate of 5 K/min to 393.15 K (120°C) keeping this temperature for 2 minutes, after which they were cooled at a rate of 2 K/min to 323.15 K (50°C).

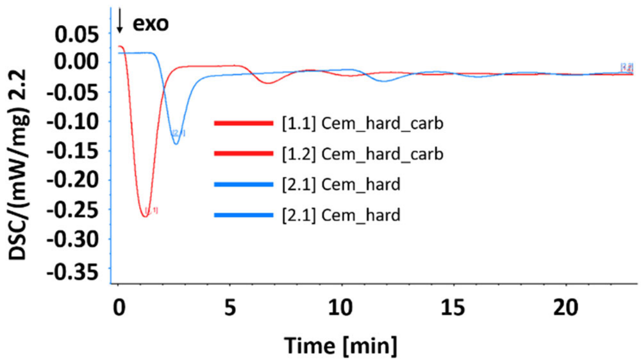

Fig. 5. DSC thermograms. [1.1] – cement modified with glassy carbon and [2.1] – commercial cement

The thermograms obtained in the tests (Fig. 5) for commercial and doped cement show significant differences in the course of the DSC curve. Higher dynamics of the polymerization process for doped cement compared to commercial cement can be observed in thermograms. A small difference can also be observed when quenching the polymerization process where the doped cement has the ability to stabilize the polymerization reaction faster compared to unmodified cement.

5. Conclusions

Physical modification of bone cements is one of the simplest methods of changing their properties. Due to the high viscosity of cements and their short polymerization time, the process of mixing cement with additives must be limited to the minimum necessary to obtain a homogeneous mass before applying it.

The conducted tests showed a significant effect of glassy carbon as a modifier on the mechanical properties of cement after its solidification, but also on the course of the polymerization process. Temperature registration tests during crosslinking, tests of mechanical properties (behaviour of cement samples under load) and DSC differential scanning calorimetry analysis confirmed that the addition of glassy carbon had an effect on each of these aspects.

The test on the polymerization reaction of modified and unmodified cement in bone showed that the doped cement has a much lower polymerization temperature (46.5°C) than commercial cements (56.0°C), which from the point of view of medical use and application inside the human body is very beneficial due to less thermal damage to surrounding tissues. On the other hand, the addition of glassy carbon had an effect on cement curing time and cement handling, which has a significant effect on the application time during the procedure by the doctor. Modified cement had an effect on cement viscosity, which is also important in choosing cement for the appropriate surgical technique. Modification of cement with glassy carbon and cancellous bone resulted in a significant reduction in fluidity (viscosity), which on the one hand may hinder application and cause the need to apply higher pressures during application.

On the other hand, this unfavourable feature in further clinical trials may turn out to be more beneficial because, on the one hand, higher values of applied pressure will cause the glued parts to spread, resulting in a thicker layer of cement, and on the other hand, its higher viscosity will not allow it to flow beyond the application spot.

Differential scanning calorimetry studies have shown greater dynamics of the polymerization process and faster quenching of the reaction observed by quenching of the exothermic thermal effects accompanying the polymerization reaction. This is beneficial because stabilization and reduction of heat release in the area of applied cement and reduction of temperature in the treatment area occur faster.

The addition of glassy carbon and Maxgraft also caused a significant reduction to almost zero differences when trying to compress dry and soaked samples in Ringer's liquid, which results in more predictable behaviour of the cement applied in real conditions.

The results presented in the publication require further advanced research, which will be the subject of further modification attempts by the research team.

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