TPM Vol. 32, No. S1, 2025
ISSN: 1972-6325
https://www.tpmap.org/

Open Access

EVALUATING THE COMPRESSIVE STRENGTH OF CALCIUM SULFATE-CALCIUM PHOSPHATE BONE GRAFT COMPOSITE WITH POLYGLYCOLIC ACID FIBERS: A BIODEGRADABLE SPACER ALTERNATIVE

MOHAMMED ALI KHASHAB
ORTHOPEDIC SURGERY 'DEPARTMENT OF ORTHOPEDIC SURGERY, MINISTRY OF NATIONAL GUARD-HEALTH AFFAIRS, JEDDAH, SAUDI ARABIA; 'KING ABDULLAH INTERNATIONAL MEDICAL RESEARCH CENTER, JEDDAH, SAUDI ARABIA, 'COLLEGE OF MEDICINE, KING SAUD BIN ABDULAZIZ UNIVERSITY FOR HEALTH SCIENCES, JEDDAH, SAUDI ARABIA, EMAIL: dr_khashab@yahoo.com

Abstract:
Background: Injectable tricalcium phosphate/calcium sulfate (TCP-CS) granules are used as a synthetic bone graft replacement. They are designed to be inserted into a bony space during surgery, where they cure to form a strong ceramic in vivo. TCP-CS bone grafts have been reported to achieve an immediate intra-operative strength of 40 megapascals within the first 2 hours.
Purpose: This study evaluates the compressive strength of TCP-CS when used as a spacer. The research then assesses the impact of adding polyglycolic acid fibers has on the strength of the composite, followed by a comparison of both mixtures.
Materials and Methods: The study compared two groups: an experimental group with TCP-CS bone graft mixed with 100 absorbable polyglycolic acid fibers, and a control group with TCP-CS only. Using ASTM protocols, the materials were mixed and injected into cylindrical molds (12.7 mm diameter, 8 mm height), and incubated in saline baths at 32°C (stage one) and 37°C (stage two) for up to 24 hours. Compressive strength was then tested at 60 minutes, 135 minutes, and 24 hours.
Results and Discussion: The compressive strength of TCP-CS with fibers was greater than TCP-CS alone after 24 hours. The TCP-CS alone samples softened and cracked after 24 hours at 37°C, while fiber-reinforced samples remained stronger. Differences in initial compressive strength compared to previous studies may be due to variations in sample size and preparation. The addition of fibers enhanced strength, but ideal physical properties for maintaining disc height and promoting fusion remain uncertain.
Conclusion: In conclusion, injectable, eco-friendly cement with better physical properties is still missing. A reproducible, sensible string structure might strengthen the cement composite to provide the needed physical strength and stiffness and create macro channel structures suitable for bone ingrowth in vivo. Further development is needed to achieve the desired physical properties and support bone ingrowth effectively.

INTRODUCTION:

Injectable tricalcium phosphate/calcium sulfate (TCP-CS) granules are synthetic bone graft substitutes designed to be mixed then injected into bony defects during surgery, where they form a strong ceramic in vivo. These granules are used to surgically treat created defects or trauma-induced bone injuries. Spinal surgeons use implantable fusion devices to replace original bone grafts and keep intervertebral spaces open for bone growth [1]. TCP-CS is advantageous because it is effective and minimizes complications associated with graft harvesting. [2,3]. TCP-CS is resorbable and supports bone regeneration during healing. Compared to autografts, TCP-CS has demonstrated superior bone density and compressive strength, with a reported 645% increase in strength over traditional autografts after 13 weeks [4].The purpose of using either bone grafts or original bone is to restore biological and functional compatibility, providing decompression of the bone, removal of dead tissue, structural bearing, and a base for repair and remodeling of subchondral bone [5].
TCP-CS offers a less invasive alternative to rigid non-absorbable cages, maintaining disc height and resorbing as it is replaced by natural bone. This material also shows promise in treating various bone voids, including femoral head transplants and bone cysts, with minimal issues at the donor site[.The triphasic composition of TCP-CS, combining calcium sulfate and calcium phosphate, demonstrates tiered dissolution kinetics in vitro. Faster-dissolving calcium sulfate is released first, leaving behind a highly porous, slower-resorbing calcium phosphate structure that retains the original geometry of the set cement. This triphasic structure exhibits multifunctional and improved properties over

individual components. [6].This study aims to evaluate the compressive strength of TCP-CS in the axial direction for use as a bone spacer and compare it to TCP-CS mixed with absorbable polyglycolic fibers to enhance physical strength. Two TCP-CS groups will be tested against each other for efficacy in clinical environments using the American Society for Testing and Materials (ASTM) , international test protocols to determine if the addition of fibers improves the material's performance.

MATERIALS AND METHODS:

Materials:
The study's main objective is to find out the use of TCP-CS as a spacer and to compare its physical strength with and without the incorporation of fibers.
UHMWPE mold:
It is an ultra-high-molecular-weight polyethylene. The molecular mass varies from 3.5 to 7.5 million amu (atomic mass units). It is used because it has extensively long chains that are intermingled and connected to form a bed, due to which it has strong intermolecular interactions. Polyethylene is the compound that is responsible for the firmness and strength of the mold. The molded material exhibits the highest impact strength.
Cylindrical specimens:
Two groups of specimens are prepared. One is made up of TCP-CS only, while the other is composed of polyglycolic acid fibers and TCP-CS. It is done by placing a specimen on the compression testing machine's surface, and the desired samples are obtained. The TCP-CS s a combination of calcium sulfate, calcium phosphate, and a synthetic biomaterial used widely in injectable bone graft substitute.
Polyglycolic acid fibers:
It is a simple polymer that is biodegradable. It has absorbable synthetic, braided fibers. It can be prepared from glycolic acid by the process of polymerization.
Saline Bath:
It is prepared by adding 3.6 kg of sea salt, 3.2 kg of NaCl, and 227 grams of magnesium sulfate to 114 liters of water.

METHODS:

Compressive testing:
The particular technique is used because it reveals that the material can tolerate how much compression is subjected to high tensile strength and pressure. It determines the material's response under the crushing load, and the strength rate in this case that is used is 25.4 mm/min. The strength of the test specimen is measured by this method. The maximum compression load was recorded through this process.
The study revolves around formulating two experimental groups and two control groups. The materials were tested under the guidelines of ASTM. The paste was prepared using the specimens, and it is injected into the mold. The details of both groups consisted of formulating new methods that can be used in research development. The experimental and control groups were developed, which were then checked based on two stages, and the results were derived based on their compression strengths, aiming to find the best material used as an injectable bone graft substitute to prevent any kind of deep-invasive procedure.
Biodegradable compounds were preferred for the study compared to metals because they are temporary and less stiff. A compression testing machine generates cylindrical specimens, and this process is done after placing the sample in the mold for thirty minutes. The fiber size is kept in consideration in accordance with the rules of ASTM.
The literature has shown several instances where biodegradable polymers were used to manufacture therapeutic devices. It includes prostheses, scaffolds, etc. They are biodegradable, which provide efficient therapy to patients.
Grouping of specimens:
The study consists of preparing two specimens with different compositions and studying their differences. A control group is studied irrespective of the variables measured, whereas the experimental group has one variable at a time. In this case, the variables in the tensile and compressive strengths of the two specimens that are tested are based on two major stages.
Protocol:
Samples are kept in the mold for 30 minutes. The cylindrical test specimens have a size of 12.7 mm. The fiber size is 0.4×10mm. The experimental group had 100 fibers that were mixed into the powder. The samples were placed in the saline bath at a temperature of 32 °C. It was tested at four subsequent intervals.
Experimental group:
Samples are made up of TCP-CS and polyglycolic acid fibers, an absorbable, synthetic, braided fiber.

TPM Vol. 32, No. S1, 2025
ISSN: 1972-6325
https://www.tpmap.org/

Open Access

Control group:
Samples are made up of the TCP-CS only.
The ASTM international test protocol was used for testing. The specimens are mixed according to the manufacturers' directions. The paste was injected into a polished UHMWPE mold—a cylindrical test specimen measuring 12.7 mm in diameter by 8 mm in height. The samples remained in the mold for 30 minutes. Two groups were created; the first group, {Experimental Group}, was made up of TCP-CS fibers mixed with polyglycolic acid fibers, absorbable, synthetic, braided fibers. The fiber size is 0.4 x 10 mm. The fiber group had 100 fibers mixed into the dry powder. The second group, {control group}, was made up of the TCP-CS only. All specimens were pushed out and placed in a saline bath at 32 °C for stage one and 37 °C for stage two. The materials were then made to test the use of specimens. They were done at four subsequent intervals, which were 60 minutes, 135 minutes, and 24 hours. The rate was set at 24.5 mm/min.
The test has been conducted over two main stages:
Stage one:
Five samples of TCP-CS / fibers group and five samples of TCP-CS only group were tested at 60 minutes. Five samples of TCP-CS /fiber group and five samples of TCP-CS -only group were tested after 135 minutes of incubation in the saline bath at 32 °C.
Stage two:
Five samples of TCP-CS /fibers group and five samples of TCP-CS only group were tested after 24 hours of incubation in the saline bath at 37 °C. All specimens were pushed out and placed in a saline bath.
Ethical Considerations:
This study did not involve human participants, animal subjects, or patient data. All procedures were conducted in accordance with institutional guidelines for the ethical use of materials in laboratory-based research. Ethical approval for this experimental study was obtained from the King Abdullah International Medical Research Center (KAIMRC) Committee at, Jeddah, Saudi Arabia (Approval No: NRJ25/056/4). The materials used were commercially available and handled according to safety protocols recommended by the manufacturer and the American Society for Testing and Materials (ASTM) standards.

RESULTS

The specimens were tested between steel platens in air at a rate of 25.4 mm/min (0.43 mm/s). Force, displacement, and the maximum compression load were monitored and recorded throughout the test. The median mechanical strength of TCP-CS after 60 and 135 minutes of incubation in a saline bath at 32 °C was 19.2 MPa and 20.3 MPa, respectively. TCP-CS with polyglycolic acid fibers showed compressive strengths of 16 MPa and 21.7 MPa after 60 and 135 minutes of incubation in the saline bath (see Table 1). After 24 hours of incubation, the median compressive strength of TCP-CS was 12.9 MPa, while TCP-CS mixed with polyglycolic acid fibers had a compressive strength of 20.7 MPa (see Table 2).
We observed that the compressive strength of TCP-CS with polyglycolic acid fibers after 24 hours in the saline bath was higher than that of plain TCP-CS. This improvement could be due to the addition of polyglycolic acid fibers, which may act as a filler, reinforcing the composite and enhancing its mechanical properties.

Table 1

Group	TCP-CS with Polyglycolic acid Fiber (32C)					Median	Mean	SD	TCP-CS (32C)					Median	Mean	SD
Samples	**1**	**2**	**3**	**4**	**5**				**1**	**2**	**3**	**4**	**5**			
Ultimate Load (N) after 60 mins incubation	**1480**	**1745**	**2438**	**2610**	**2732**	**2438**			**1625**	**1790**	**2024**	**2330**	**2615**	**2024**		
Compressive Strength (MPa) after 60 mins incubation	**11.7**	**13.8**	**19.2**	**20.6**	**21.6**	**19.2**			**12.8**	**14.1**	**16**	**18.4**	**20.6**	**16**		
Ultimate load after 135 mins incubation	**1636**	**2510**	**2638**	**2785**	**2867**	**2638**			**2390**	**2635**	**2754**	**2871**	**3125**	**2754**		

TPM Vol. 32, No. S1, 2025
ISSN: 1972-6325
https://www.tpmap.org/

Open Access

Compressive Strength (MPa) after 135 mins incubation	**12.9**	**19.8**	**20.3**	**22.02**	**22.6**	**20.3**			**18.9**	**20.8**	**21.7**	**22.7**	**24.7**	**21.7**		

Table 2

Group	TCP-CS with Polyglycolic acid Fiber (32C)					**Median**	**Mean**	**SD**	**TCP-CS (32C)**					**Median**	**Mean**	**SD**
Samples	**1**	**2**	**3**	**4**	**5**				**1**	**2**	**3**	**4**	**5**			
Ultimate Load (N) after 24hr Incubation	**2255**	**2450**	**2618**	**3100**	**3230**	**2618**			**1450**	**1525**	**1631**	**1740**	**2250**	**1631**		
Compressive Strength (MPa) after 24hr Incubation	**17.8**	**19.37**	**20.7**	**24.51**	**25.54**	**20.7**			**11.6**	**12.06**	**12.9**	**13.7**	**17.79**	**12.9**		

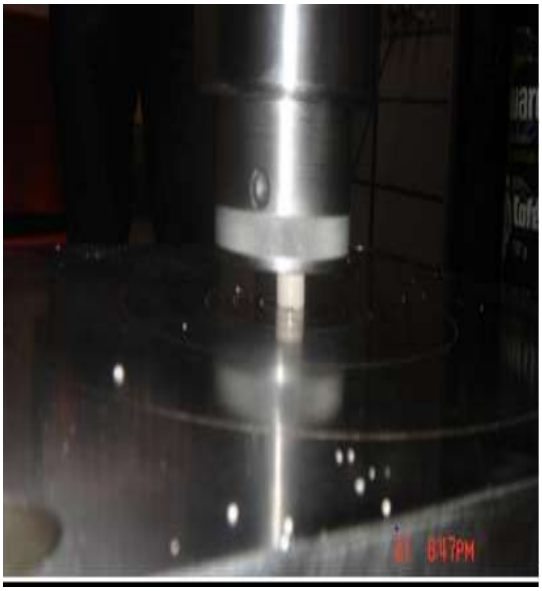
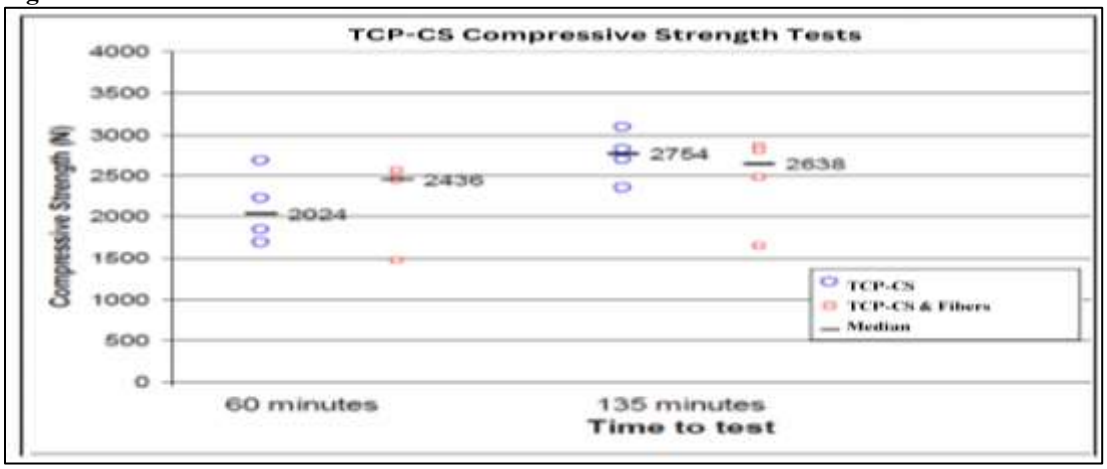


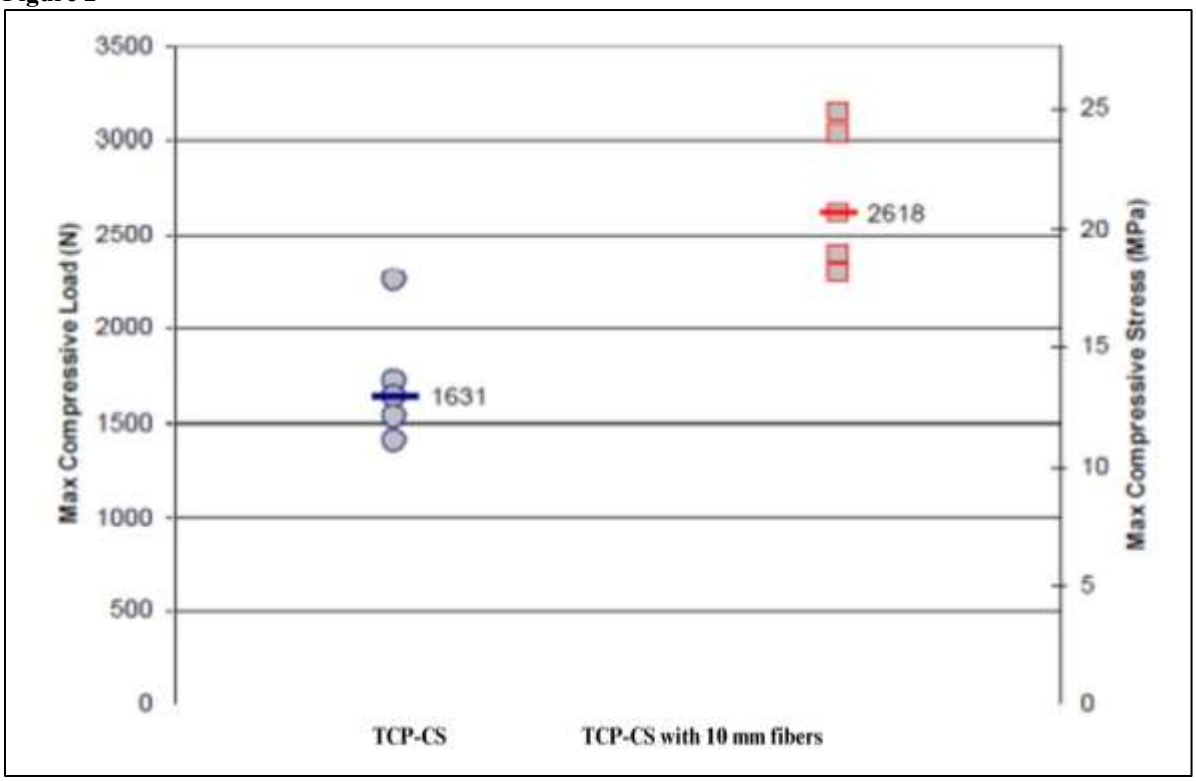
Figure 1



TPM Vol. 32, No. S1, 2025
ISSN: 1972-6325
https://www.tpmap.org/

Open Access

Figure 2



DISCUSSION:

The ultimate compressive stress (MPa) is based on the median compressive strengths. It is the strength that the material can endure before it fractures or breaks. It is calculated as follows:

$$F = P/A$$

Where F = compressive strength (specimen in Mpa)

P = maximum load or compression applied to the specimen. It has been recorded for 60 minutes and 135 minutes after incubation in a saline bath. The test is done to determine the practical method that can be used for the implant and fusion process so that the actual bone can be formed gradually after the injectable procedure. Median compressive strength is determined at the last stage before the material cannot tolerate the pressure.

The study aims to use an injectable biodegradable implant that can be delivered through a small window made in the disc, which will be a desirable option. The material should provide adequate physical strength to maintain the disc height and promote the fusion process until the fusion forms. It will resorb gradually and be replaced by a normal bone. This study was done to determine the real-time applications of TCP-CS if used in a bone-like material. It is a material that provides mechanical support for the inter-body space. It was assumed that the experiment would result in a compressive strength of 40 MPa, but it was not reproduced after a time of two hours (120 minutes).

In the past, propylene-glycol-co-fumaric acid was used in the fusion of inter-body cages, and the results were that they increased in stiffness and load failure [7]. There was no difference between the bone graft and the biocage. Previous studies have shown that the fusion process results in osteopenia, and these studies have been conducted in dogs and humans. The use of biodegradable implants is common in today's modern age, Bio absorbable materials and implants are also used in the rib cages for fusion purposes. TCP-CS is used in this practice, and it is preferred in clinical settings because it allows faster and more predictable bone regeneration. It is a more potent form of regeneration and is considered one of the fastest types of regeneration. In clinical procedures, a mixture of calcium sulfate is injected in vitro into the degenerated bone, and the area first absorbs calcium sulfate [8]. It promotes stem cell proliferation, and regeneration occurs in much less time. In fibrous cysts and certain other conditions, bone grafts are used for quick regeneration of bones. The bone cyst has been operated on using the same method, and it fills the bone's cavity by replacing it with productive material. this research is a basic study and focuses on the testing material physical strength to check whether it is advisable to proceed to pre-clinical study , and the numbers that are obtained from the results are not agreeable enough to make this method a part of the pre-clinical setting. The previous research suggests the use of bone grafts in clinical procedures that have benefited patients. Calcium sulfate and calcium phosphate mixtures

with TCP have helped with the lesion procedures. It is an effective treatment for bone lesion procedures [9]. In some methods, a cancellous allograft bone chip was used, and it is more effective as compared to the mixtures of TCP-CS bone graft substitute [10].

Unfortunately, the perfect compressive physical potency that would preserve the disc height without causing stress shielding in conjunction with the posterior instrumentation is unknown. In our first stage of the study, we could not reproduce the 40 MPa initial compressive strength at 2 hours. This could be due to differences in the sample size cylinder sizes (12.7 x 8 mm vs. 6 x 12 mm), the time samples are left in the mold (30 minutes vs. 1 hour.), and the weak vacuum used at this stage. The lab conditions and the instrument's density also affect the experiment and the study design because the diameters of the cylinders are different from each other. The investigation results were not reproduced as they were estimated because the conditions in the lab are different and they keep fluctuating because of the lab's temperature.

During our second stage (the 24 hours), the critical time for testing the construct's physical strength is when the patient gets out of bed (most of the patient would be on bed rest for 24 hours after posterior lumbar instrumented fusion). The samples appeared quite hard when removed from the mold at 30 minutes, but after 24 hours of incubation at 37 °C in a saline bath, the non-fiber specimens seemed to be soft (not well set), and there was a visible crack on the sides and ends of all the samples.

It was unclear whether the 37-°C saline bath affected the setting, and more so in the non-fiber specimens. The addition of fibers to TCP-CS has improved it's physical strength compared to TCP-CS only group at 24 hours.

In this experiment, polyglycolic acid fibers are used with a mixture of TCP-CS that is not showing agreeable results from the investigation. Propylene glycol, co-fumaric acid, and scaffold were compared with metallic cages of different sizes. Studies have been performed comparing the size of metallic cages to determine their clinical role [7]. Biodegradable cages have gotten much attention in recent years because of their use in spinal procedures. Pre-clinical studies have been done to determine the usefulness of bio grafts and compare them with different metallic cages. Compression tests are done in these procedures to determine the yielding strength of the materials. The optimization technique has benefited the researchers in a variety of ways. Spinal fusion is used as a treatment option for vertebral lesions or stabilization [11].

CONCLUSION:

The experiment was performed using TCP-CS as a spacer due to its ability to fill bone spaces, with a comparative strength of 40 MPa.While the study aimed to evaluate the compressive strength of TCP-CS for spinal fusion applications, the results did not meet the 40 MPa target.Further research is needed to optimize the material properties and test conditions to ensure its viability for clinical use in spinal procedures.Further research is needed to address the discrepancies found and to optimize the material for clinical use. In conclusion, injectable, eco-friendly cement with better physical properties is still missing. A reproducible, sensible string structure might strengthen the cement composite to provide the needed physical strength and stiffness and create macro channel structures suitable for bone ingrowth in vivo.

REFERNCES

1.Brodke DS, Khandkar AC, Rao MS, Lakshminarayanan R. Radiolucent spinal fusion cage: Google Patents. 2004.
2. Kotnis NA, Parasu N, Finlay K, Jurriaans E, Ghert M. Chronology of the radiographic appearances of the calcium sulfate–calcium phosphate synthetic bone graft composite following resection of bone tumors—a preliminary study of the normal post-operative appearances. Skeletal Radiol. 2011;40(5):563-70.
3. Brandoff JF, Silber JS, Vaccaro AR. Contemporary alternatives to synthetic bone grafts for spine surgery. Am J Orthop (Belle Mead NJ). 2008;37(8):410-4.
4. Fillingham YA, Lenart BA, Gitelis S. Function after injection of benign bone lesions with a bioceramic. Clin Orthop Relat Res. 2012;470(7):2014-20. doi: 10.1007/s11999-012-2251-5.
5. Civinini R, De Biase P, Carulli C, Matassi F, Nistri L, Capanna R, et al. The use of an injectable calcium sulfate/calcium phosphate bioceramic in the treatment of osteonecrosis of the femoral head. Int Orthop. 2012;36(8):1583-8. doi: 10.1007/s00264-012-1525-6.
6. Fillingham YA, Cvetanovich GL, Haughom BD, Erickson BJ, Gitelis S. Bioceramic bone graft substitute for treatment of unicameral bone cysts. J Orthop Surg (Hong Kong). 2016;24(2):222-7. doi: 10.1177/1602400220.
7. Kandziora F, Pflugmacher R, Kleemann R, Duda G, Wise DL, Trantolo DJ, et al. Biomechanical analysis of biodegradable interbody fusion cages augmented with poly (propylene glycol-co-fumaric acid). Spine (Phila Pa 1976). 2002;27(15):1644-51.

8. Pflugmacher R, Eindorf T, Scholz M, Gumnior S, Krall C, Schleicher P, et al. Biodegradierbarer cage. Chirurg. 2004;75(10):1003-12.
9. Urban RM, Turner TM, Hall DJ, Inoue N, Gitelis S. Increased bone formation using calcium sulfate-calcium phosphate composite graft. Clin Orthop Relat Res. 2007;459:110-7.
10. Wright PRO-DENSE™ Bone Graft Substitute. 2020.
11. Kang H, Hollister SJ, La Marca F, Park P, Lin CY. Porous biodegradable lumbar interbody fusion cage design and fabrication using integrated global-local topology optimization with laser sintering. J Biomech Eng. 2013;135(10).