Orthopaedic Surgery Research
QEII Health Science Centre
Orthopedic Clinic, NHI Site, Room 4810
1796 Summer Street
Halifax, Nova Scotia
B3H 3A7

CONSENT TO TAKE PART IN A CLINICAL TRIAL
Patient Information

STUDY TITLE: Management of Traumatic Bone Defects in Tibial Plateau Fractures with Antibiotic-Impregnated Biodegradable Calcium Sulfate Beads: A Prospective Clinical Trial

CLINICAL STUDY REGISTRATION NUMBER: NCT02456194

PRINCIPAL INVESTIGATOR/ SPONSOR:
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STUDY FUNDER: Biocomposites, Ltd.

1. INTRODUCTION

You have been invited to take part in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study.

The research team will tell you if there are any study timelines for making your decision.

Please ask the research team or the principal investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

The researchers will:

- Discuss the study with you
- Answer your questions
- Be available during the study to deal with problems and answer questions

You are being asked to consider participating in this study because you have broken your *tibial plateau*, the bottom surface of your knee joint.

If you decide not to take part or if you leave the study early, your usual health care will not be affected.

2. WHY IS THIS STUDY BEING CONDUCTED?

The tibial plateau is the flattened surface of the top of the tibia bone (lower leg), which makes it part of the knee joint. If a broken tibial plateau involves a defect or void in the bone, standard practice is to fill this void with bone graft or a bone graft substitute.

The device in this study is a bone graft substitute that contains an antibiotic. This study is being done to learn more about how the study device works in a tibial plateau defect that is not infected. Specifically we are looking at how long it takes the device to be replaced by bone. We will also look at how long it takes for your bone to heal and how well you are functioning.

3. WHAT IS BEING TESTED?

STIMULAN® Rapid Cure is calcium sulfate powder that is combined with a mixing solution and/or antibiotics to make a paste which can be formed into beads. The resulting material is used to fill the void (empty space) in your bone and over time is broken down by your body and replaced with bone during the healing process. For this study, the STIMULAN® Rapid Cure will be made with antibiotics into bead form. The choice of antibiotic is left to the surgeon.

Health Canada has approved the sale or use of STIMULAN® Rapid Cure to treat bone voids or defects created by traumatic injury (for example, tibial plateau fractures like yours).

4. HOW LONG WILL I BE IN THE STUDY?

The length of this study for participants is one year. There are four study visits after your surgery which will coincide with your regular clinical follow-up with your surgeon. The entire study is expected to take about three years to complete and the results should be known in four years.

5. HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that 30 people will participate in this study throughout Canada. We expect that four hospitals will take part in this study and contribute participants until a maximum of 30 is reached.

6. HOW IS THE STUDY BEING DONE?

Should you be eligible (meet the criteria) and wish to take part in this study, you will have surgery to repair your broken bone with the study device (STIMULAN® Rapid Cure with antibiotics) and plate and screws.

You will be asked to return to the hospital for four visits over the next 12 months. These visits are standard of care for your injury.

7. WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

If you want to be in this study and sign this consent form, we will review your medical history and x-rays to see if you can take part. It is possible this may show that you can't be in the study. If you decide to take part in this study, at the time of your surgery your broken bone will be fixed with a plate and screws and the bone void (defect) will be filled with beads of STIMULAN® Rapid Cure prepared with antibiotics. Your surgeon will decide what antibiotic to use.

All devices used in this study are approved for use by Health Canada.

If you take part in the study, you will see your surgeon in the orthopaedic clinic at 6 weeks, 3 months, 6 months, and 12 months after the surgery as shown in the table below.

- At each visit, your study doctor will examine your knee and take routine X-rays.
- The doctor or research coordinator will measure your knee range of motion.
- You will be asked if you have returned to work and your usual activities.

- You will complete a questionnaire about how your knee is functioning (15 minutes), the Knee injury and Osteoarthritis Outcome Score (KOOS). This can be completed while you are waiting to see the doctor.
- At 6 months you will have a CT scan of your knee to see if any of the study device remains and look at how the bone is healing. This CT scan is for research purposes only.

	In Hospital	6 weeks	3 months	6 months	12 months
Clinic Visit		**X**	**X**	**X**	**X**
Range of Motion		**X**	**X**	**X**	**X**
KOOS questionnaire	**X**	**X**	**X**	**X**	**X**
X-rays	**X**	**X**	**X**	**X**	**X**
CT scan				**X**	

Of course you may ask not to have further tests done or to participate in any additional trial procedures at any time.

It is important that you tell the research team about any treatment therapies, drugs or medicines you are taking or wish to take. You must also tell the research team about anything unusual that is happening with your health. This includes any medical problems that seem to be getting worse. If you have to see another doctor or have to go to a hospital, you should let the doctors know that you are in a research study. You should also tell your own doctor as quickly as possible, for your safety.

8. WHAT ABOUT BIRTH CONTROL AND PREGNANCY?

The effects of the study device on unborn babies are unknown. You should not take part in this study if you are pregnant or planning to become pregnant.

Birth Control: If you are of childbearing potential (physically able to have children) and you are sexually active, it is important that you practice an acceptable method of birth control during this study. Avoiding sex (abstinence) is OK for this trial. Other acceptable methods of birth control include tubal ligation (tying the tubes), vasectomy, intrauterine devices (IUD), birth control pills, hormonal implants, injectable contraceptives, and using barrier methods such as condoms, vaginal diaphragm with spermicide, or sponge. If you are not sure about birth control discuss this with your family doctor.

Pregnancy: *Please notify your research team* if you get pregnant during the study. You may need to stop participating in the study if you become pregnant. If necessary, we will ask your permission to refer you to a doctor to look after your pregnancy. If you have a baby, we may also ask if we can study your health records and the baby's to make sure the study treatment has not had any bad effects.

9. ARE THERE RISKS TO THE STUDY?

There are risks with this, or any study. To give you the most complete information available, we have listed many *possible* risks, which may appear alarming. We do not want to alarm you but we do want to make sure that if you decide to try the study, you have had a chance to think about the risks carefully. Please also be aware that there may be risks in participating in this study that we do not know about yet.

STUDY DEVICE
The study device has the same risks as other devices used to treat your injury (i.e. plates, screws, and bone grafts or substitutes). These are discussed with you when you consent to treatment for your injury. These risks include but are not limited to: wound complications, wound drainage, infection, implant breakage or displacement, and sensitivity or allergic reaction to any of the implant materials (including the antibiotic).

QUESTIONNAIRES
You may find the interviews and questionnaires you receive during the course of the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find too distressing.

RADIATION (X-RAYS)
During this study you will have the same number of standard x-rays that are used to diagnosis or treat your existing medical condition. You will receive 1 extra CT scan (X-ray) after you are enrolled in the study. This procedure will expose you to radiation. This radiation exposure is not necessary for your medical care and is for research purposes only. This procedure will be done using established procedures of this institution and be performed by authorized persons. The amount of radiation exposure you will receive is about the same amount that you will receive over a period of 16 days from natural background radiation.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the research team.

10. ARE THERE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not benefit directly from participating in this study. Your participation may or may not help other people with a broken tibial plateau in the future.

11. ARE THERE OTHER CHOICES?

The standard treatment for your injury is surgery to repair the break with a plate and screws and fill the defect with a bone graft or bone graft substitute. Your surgeon will follow you until your bone is healed, regardless of your study participation.

If you do not wish to take part in this study, there are other options to fill the defect in your bone. Your surgeon should have discussed all the options with you. They include:

- Autograft – using your own bone (usually taken from your hip)
- Allograft – using bone from a tissue bank
- Other commercially available bone graft substitutes
- You may also receive the device used in this study (with or without antibiotics) without participating in this study.

New treatments become available for this sort of condition at different times and in different parts of the world. Like many other hospitals, we do not feel it is helpful to test more than one experimental treatment for the same condition at the same time in the same person. This could even be dangerous. So you will not undergo two experimental procedures during the same time period.

You are free to seek other opinions or choices in other hospitals or cities if you wish.

12. WHAT HAPPENS AT THE END OF THE STUDY?

At the end of the study, your surgeon will continue to follow you until your bone has healed. You may ask the research team for a copy of the study results when they become available.

13. WHAT ARE MY RESPONSIBILITIES?

As a study participant you will be expected to:

- Follow the directions of the Principal Investigator
- Attend scheduled follow-up visits
- Report all medications being taken or that you plan on taking
- Report any changes in your health to the Principal Investigator
- Report any problems that you experience that you think might be related to participating in the study

14. CAN MY PARTICIPATION IN THIS STUDY END EARLY?

The Nova Scotia Health Authority Research Ethics Board and the principal investigator (Dr. Ross Leighton) have the right to stop patient recruitment or cancel the study at any time.

The principal investigator may decide to remove you from this study without your consent for any of the following reasons:

- The treatment does not work for you;
- You do not follow the directions of the research team;
- You are experiencing side effects that are harmful to your health or well-being;
- There is new information that shows that being in this study is not in your best interests;
- You become pregnant or plan to come pregnant or plan to discontinue acceptable birth control.

If you are withdrawn from this study, a member of the research team will discuss the reasons with you and plans will be made for your continued care outside of the study.

You can also choose to end your participation at any time. If you choose to withdraw from this study by providing notice to the research team, your decision will have no effect on your current or future medical treatment and healthcare. Your health records may be examined in connection with this study or further analyses related to it. Your health records will only be made available as described above. However the above agencies, including the sponsor, will only look at and use study related records up to the date of your withdrawal from the study, except where it is necessary to ensure that the study is scientifically reliable and to report side effects associated with the study device as required by regulatory authorities.

If you withdraw your consent, the information about you that was collected before you left the study will still be used (for example, your responses to the questionnaire at each visit). No new information about you will be collected without your permission.

15. WHAT ABOUT NEW INFORMATION?

It is possible that new information may become available while you are in the study about side effects or a new treatment for your condition. You will be told about any other new information that might affect your health, welfare, or willingness to stay in the study and will be asked whether you wish to continue taking part in the study or not.

16. WILL IT COST ME ANYTHING?

Compensation: Participation in this study will not involve any additional costs to you. You will not be paid to participate in this study. You will be reimbursed for parking for your CT scan visit.

Research Related Injury: The device being used in connection with this study has already received approval from the regulatory authorities in Canada. In the event that you suffer injury as a direct result of participating in this study, normal legal rules on compensation will apply. By signing this consent form you are in no way waiving your legal rights or releasing the principal investigator and sponsor from their legal and professional responsibilities.

17. WHAT ABOUT MY PRIVACY AND CONFIDENTIALITY

Protecting your privacy is an important part of this study and every effort to protect your privacy will be made. However, complete privacy cannot be guaranteed. For example, the principal investigator may be required by law to allow access to research records. Your family doctor may be told that you are taking part in this study.

If the results of this study are presented to the public, nobody will be able to tell that you were in the study.

If you decide to participate in this study, the research team will collect personal health information from you and your health record. The research team will collect and use only the information they need for this study and to judge the safety and usefulness of the study treatment.

"Personal health information" is health information about you that could identify you because it includes information such as your:

- Name,
- Address,
- Telephone number,
- Month and year of birth (mm/yy),
- Gender,
- Information from the study interviews and questionnaires;
- New and existing medical records, or
- The types, dates and results of various tests and procedures.

Access to Records

Other people may need to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines. These people might include:

- The Nova Scotia Health Authority Research Ethics Board (NSHA REB) and people working for or with the NSHA REB because they oversee the ethical conduct of research studies within the Nova Scotia Health Authority.

Use of Your Study Information

Any study data about you that is sent outside of the Nova Scotia Health Authority will have a code and will not contain your name or address, or any information that directly identifies you.

De-identified study data may be transferred to:

- Companies working for and with the sponsor.

Your information may be transferred outside of Canada to other employees, contractors, processors and agents working on behalf of the Sponsor and/or to regulatory bodies for the purposes stated above. If your information is transferred outside of Canada, Sponsor will take all reasonable steps to protect your information. Your information will be securely stored and accessed by only authorized personnel from the Sponsor or those working on the Sponsor's behalf and possibly, the relevant government health authorities having access to it.

The sponsor and companies working for and with the sponsor will use the information collected about you during the study, for the purposes of analyzing and reporting the results of this study, and for product performance monitoring and management procedures so that patient outcomes are continually improved; and for ensuring compliance with medical, ethical and medical device laws and regulations. Study data that is sent outside of the Nova Scotia Health Authority will be used for the research purposes explained in this consent form.

The research team and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The research team will keep any personal health information about you in a secure and confidential location for 7 years and then destroy it according to NSHA policy. Your personal health information will not be shared with others without your permission.

After your part in the study ends, we may continue to review your health records for safety and data accuracy until the study is finished or you withdraw your consent.

The REB and people working for or with the REB may also contact you personally for quality assurance purposes.

Your Access to Records

You have the right to access, review, and request changes to your study data.

18. DECLARATION OF FINANCIAL INTEREST

The funder has provided a research grant to the Principal Investigator (PI) and/or the Principal Investigator's institution to conduct this study. The amount of payment is sufficient to cover the costs of conducting the study.

19. WHAT ABOUT QUESTIONS OR PROBLEMS?

For further information about the study you may call the principal investigator who is the person in charge of this study or any other research team member listed below.

If you experience any symptoms or possible side effects or other medical problems, please let the Principal Investigator know immediately.

If you can't reach the Principal Investigator, or it is after regular business hours, speak to the orthopaedic physician or resident on call. The afterhour's number is **(902) 473-2222.**

This doctor may not be the one you usually see while in this study. Please call the Principal Investigator or research coordinator the next business day to tell them about the possible side effects or other medical problems you experienced.

The Principal Investigator is:	**Dr. Ross Leighton**	
Telephone:	**(902) 473-4035**	
Your Research Coordinators are:	**Ms. Kelly Trask**	**Ms. Shelley MacDonald**
Telephone:	**(902) 473-3161**	**(902) 473-4098**

20. WHAT ARE MY RIGHTS?

You have the right to all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction before you make any decision. You also have the right to ask questions and to receive answers throughout this study. You have the right to withdraw your consent at any time.

If you have any questions about your rights as a research participant, contact Patient Relations at (902) 473-2133 or healthcareexperience@nshealth.ca. If you are calling us long distance (NS, NB and PEI), please use our toll free number 1-855-799-0990.

In the next part you will be asked if you agree (consent) to join this study. If the answer is "yes", please sign the form.

21. CONSENT FORM SIGNATURE PAGE

I have reviewed all of the information in this consent form related to the study called:

Management of Traumatic Bone Defects in Tibial Plateau Fractures with Antibiotic-Impregnated Biodegradable Calcium Sulfate Beads: A Prospective Clinical Trial

I have been given the opportunity to discuss this study. All of my questions have been answered to my satisfaction.

I authorize access to my personal health information, and research study data as explained in this form.

This signature on this consent form means that I agree to take part in this study. I understand that I am free to withdraw at any time without affecting my future care.

_____	_____	____ / _____ / ___
Signature of Participant	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Investigator	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Person Conducting Consent Discussion	Name (Printed)	Year Month Day*
_____	_____	____ / _____ / ___
Signature of Substitute Decision Maker	Name (Printed)	Year Month Day*

Note: Please fill in the dates personally

I WILL BE GIVEN A SIGNED COPY OF THIS CONSENT FORM

Thank you for your time and patience!