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Department of Orthopaedics & Traumatology
The Chinese University of Hong Kong
香港中文大學 矯形外科及創傷學系

Patient Specific Instrumentation (PSI) Referencing High Tibial Osteotomy Technological Transfer and Education: Protocol for a Double-blind, Randomized Controlled Trial (PROTECTED HTO Trial)

Informed consent - Information Sheet

The Department of Orthopedics and Traumatology, Alice Ho Miu Ling Nethersole Hospital and The Department of Orthopedics and Traumatology, The Chinese University of Hong Kong are organizing a randomized control trial (RCT) to explore the surgical outcomes of medial open wedge high tibial osteotomy (MOWHTO) for the treatment of medial compartment knee osteoarthritis with or without the use of 3D printed patient specific metal jig (PSI jig).

Medial open wedge high tibial osteotomy is a surgery performed to treat knee osteoarthritis in young patients. Currently we perform high tibial osteotomy under the guidance of computer navigation to achieve the required alignment and the bone cut (osteotomy) is done by free hand cutting. During the bone cut, there are risks of cutting into the posterior proximal tibia compartment and transecting the neurovascular bundles which is a surgical disaster and may then lead to loss of limb. An inaccuracy bone cut would also increase the chance of lateral hinge fracture. This accuracy of free hand cutting is limited by experience of surgeons. Although in our high tibial osteotomy operation transection of neurovascular bundles has never happened given our meticulous surgical technique, further protection and guidance are seeked to improve surgical accuracy and safety to benefit our patients. Recently with the advancement of technology in our department, we performed computed tomography for the patient's lower limb and 3D reconstruct the image. Based on the 3D reconstructed image, we planned our planned bone cut on computer software Materialize 3-matic and we then 3D printed a metal jig that has a slot to produce the osteotomy and also protected the neurovascular bundles. Therefore these metal jigs are specific to each patients (PSI). We have performed a few cases of HTO under this extra metal jig protection and guidance and noted it has improved accuracy and safety clinically. However, whether it has scientific significance difference in accuracy is not known.

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We would like to invite your participation in this study. It is purely voluntary. It is a randomized control (RCT) study. Total 36 patients will be recruited in this study.

If you are candidate for high tibial osteotomy surgery, you would be invited to participate into this study.

All the pre-operative and post-operative clinical assessment and radiological assessment would be the same as our current practice for high tibial osteotomy.

The only difference for the study participants in this study is then they would be randomly allocated to the control and intervention group. The control group would have the high tibial osteotomy done by free hand bone cutting during osteotomy as our current practice and the intervention group wound have the 3D metal jig (Patient specific) guided bone cutting during osteotomy.

So the difference in the intervention group is that they have an additional metal jig to guide bone cutting and protect neurovascular bundles.

If you agree to join the study, baseline assessments and post-operation follow-ups will be arranged, data related to you functional and physical performance will be collected.

Details of assessments and follow-up are listed and summarized in the following table:

Timeline of Assessment and follow-up

	Before surgery	Immediate before discharge	3 months post-op	6 months post-op	1 year post-op	2 year post-op
Knee Society knee score	✓			✓	✓	✓
Knee Society function score	✓			✓	✓	✓
Oxford Knee Score	✓			✓	✓	✓
Lysholm Knee Scoring Scale	✓			✓	✓	✓
Range of motion	✓	✓	✓	✓	✓	✓
Pain Visual Analog Scale (VAS) score	✓	✓	✓	✓	✓	✓
Computed tomography	✓	✓	✓			

scanogram	✓		✓			
Knee X-Rays	✓	✓	✓	✓	✓	✓

Potential complications and/or risks of interventions

- The 3D printed patient specific metal jig (PSI jig)

  The 3D printed patient specific metal jig (PSI jig) is based on the patient's individual CT image and theoretically and in our experience is more accurate than free hand bone cut. However, whether it is truly more accurate or inaccurate is unknown in scientific literature.

  Patient may have allergy to the metal used in the metal jig. But as the jig is just for temporary use and not retaining in the body and metal allergy itself is rare, the chance of allergic reaction is considered rare.

- High tibial osteotomy

  The high tibial osteotomy is performed in control and intervention group as in our current standard practice. The risks described below is intrinsic to high tibial osteotomy but not related to the PSI jig (intervention in this study): bleeding, infection, damage surrounding structure, bone malunion, nonunion, implant failure, pain, fracture, malalignment, progression of osteoarthritis

- X-ray and scanogram and plain computed tomography

  X-ray and scanogram and plain computed tomography are common medical imaging tests which use electromagnetic radiation with a very short wavelength to produce the image. The radiation dosage in diagnostic procedures is considered safe for adults and far below the dosage that will cause damage. These imaging are also required as in current standard practice of high tibial osteotomy for three-dimensional

  planning of bone cut and also for follow-up to look for complications like iatrogenic fractures, malpositioning of implants, etc.

Rights, confidentiality and Insurance

We would like to invite your participation in this study. Your participation into the study is purely voluntary. You have the right to terminate or withdraw from the study at any time, without having to explain your decision and with no consequences to your medical care. Your participation or not will not affect the service being provided to you in this hospital at all. Should new information arise which is deemed to be relevant as to the consent of the patients to the clinical investigation, such information will immediately be reported to you.

Treatment procedures in this study have been recorded in a protocol which has been approved by the Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee (the CUHK-NTEC CREC). All the information collected will be coded and analyzed for this research study. Your personal information will remain strictly confidential. You must be aware that the results of this clinical study may be published without revealing the identity of the individuals involved. Information could only be accessed by related research staff, regulatory authorities and ethics committee.

Clinical trial indemnity and insurance will be purchased for you via the Faculty and Planning office, Faculty of Medicine, the Chinese University of Hong Kong. You are requested to report any unexpected or unusual symptom to the physician who is responsible for the study.

Contacts

This research study is to explore the surgical outcomes of medial open wedge high tibial osteotomy (MOWHTO) for the treatment of medial compartment knee osteoarthritis with or without the 3D printed patient specific metal jig (PSI jig). We sincerely hope that you can support this. Any clarification regarding the clinical study can be directed to the principal investigator of the study, Dr. Lau Chun Man Lawrence at 35052211, or the CUHK-NTEC CREC at 35053935. If there's any trial-related injury, please telephone the principal investigator, Dr. Lau Chun Man Lawrence at 35052211, appropriate follow ups and medical care will be arranged.

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1. Through this declaration, I accept to participate to the trial "PROTECTED HTO trial" study according to the modalities described in the protocol.
2. I was given an information sheet and I received explanations regarding the nature, the duration and possible side effects that could result from the study and I was told what I will be asked to do.
3. I was given the information of alternative treatment for my orthopaedic condition and it is my will to choose this clinical trial as my choice of treatment.
4. I declare that I have understood the explanations that were given to me as well as the aims, risks and limitations of the treatment proposed.

   In particular, I declare that I have understood and accepted the possible risks connected with the implantation of the 3D printed patient specific metal jig (PSI jig) which were explained to me by the physician who is responsible for the study, the most frequent of which are: bleeding, infection, damage surrounding structure, bone malunion, nonunion, implant failure, pain, fracture, malalignment, progression of osteoarthritis, radiation, inaccuracy jig, allergy.
5. I accept to collaborate with the physician responsible for the study and report to him any unexpected or unusual symptom I may have.
6. I have been informed that this study is covered by the university insurance policy.
7. I have been informed that this study has been submitted to the Joint CUHK-NTEC CREC for approval.
8. I have been informed that my refusal to participate to the study will not incur any penalty and I declare to accept to participate in the study voluntarily.
9. I am free to withdraw from the study at any time, without having to motivate my decision and without my decision causing any harm to the continuation of my therapy.
10. I accept that the study results may be disclosed to the competent authorities. My name and address will remain confidential.
11. By signing this document, I accept that my clinical report be examined by anyone duly appointed by them.

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Informed consent – consent form

(Patient's name)	*(Patient's HKID number)*
(Patient's signature)	*(Date)*
(Physician's name - Print name of person obtaining consent)	*(Physician's code)*
*(*Physician's signature - Signature of person obtaining consent*)*	*(Date)*