Clinical research plan approval

Title: A study on 3D printing-assisted platelet-rich plasma combined with autologous periosteum-bone grafting in the treatment of knee cartilage injury

Study type: Prospective randomized controlled study

Funding source: The Second Affiliated Hospital of Nanchang University

Study Duration: January 2026 - December 2029

Date of the documen: September 28, 2025

Project leader: Fu Xiaoling Telephone: 18679102713

Research unit: The Second Affiliated Hospital of Nanchang University

Team leader unit: The Second Affiliated Hospital of Nanchang University

Participating unit: The Second Affiliated Medical College of Nanchang University

Team members						
numbering	name	job title	specialized	Division	GCP certificate number	signature
1	Fu Xiaoling	Deputy Chief Physician	Orthopedics	Tissue test to confirm SAE;	EFY-2021-763	
2	Zhou Bin	Deputy Chief Physician	Orthopedics	Professional group quality controller	EFY-2023GCP-026	
3	Tao Jun	Chief physician	Orthopedics	screening patients, talking about informed consent, and managing patients;	EFY-GCP-2024-234	
4	Hao Liang	Chief physician	Orthopedics	screening patients, talking about informed consent, and managing patients;	GCP2111Y06-280	
5	Sun Kuo	Chief physician	Orthopedics	screening patients, talking about informed consent, and managing patients;		
6	Peng Kun	Deputy Chief Physician	Orthopedics	screening patients, talking about informed consent, and managing patients;	EFY-2021-784	
7	Deng Jianjian	Attending	Orthopedics	screening patients, talking about informed consent, and managing patients;	FY-2021IT- 098	
8	Chen Qisharp	Resident	Orthopedics	screening patients, talking about informed consent, and managing patients; Fill out the CRF form	Not at the moment	
9	Cai Shenghao	Resident	Orthopedics	screening patients, talking about informed consent, and managing patients; Follow	Not at the moment	
10	Xia Yong	Resident	Orthopedi	screening patients, talking about informed consent, and	Not at the	

			cs	managing patients; Data management	moment	
11	Zheng Zuorui	Resident	Orthopedics	Fill out the CRF form; Follow-up	Not at the moment	
12	WALEED KHALID	Resident	Orthopedics	Fill out the CRF form; Data management	Not at the moment	

Summary of the study protocol

It should include the research topic, research purpose, design type, research object, sample size, selection criteria, observation indicators, statistical analysis methods, etc

Research Title:
A study on 3D printing-assisted platelet-rich plasma combined with autologous periosteum-bone grafting in the treatment of knee cartilage injury

Objectives:

(1) To evaluate the accuracy of cartilage damage repair by measuring the chimerism and surface curvature matching degree of 3D printing reconstruction.

(2) The functional and imaging scores of 3D printing-assisted platelerichplasma (PRP) combined with autologous periosteum-bone grafting in the treatment of knee cartilage injury were performed to evaluate the clinical effect and cartilage

repair effect.

Design Type:

Prospective randomized controlled trial Research Objects:

The area of cartilage injury in the unilateral knee joint was >2CM2, and the patients were classified as grade 3-4 by the International Cartilagerepair Society (ICRS).

Sample size: 60 cases (30 patients with 3D printing-assisted autoperiosteal-bone grafting, 30 patients with 3D printing-assisted PRP combined with autologous periosteum-bone grafting)

Selection Criteria:

(1) Age 18~65 years old;

(2) bodymass index (BMI) of 18~30kg/m2;

(3) Knee cartilage injury confirmed by imaging examination, knee cartilage injury 2>cm2, ICRS grade 3-4;

(4) There is no obvious abnormality in the lower limb force line;

(5) No other drug injection or surgical treatment has been performed locally in the knee joint in the past 1 year.

Observation indicators:

(1) Clinical function: Lysholm score, Tegner exercise ability score, and pain numeric score

of the knee joint were obtained by outpatient follow-up before surgery and 1, 3, 6, and 12 months after surgery, written questionnaires, or by trained medical professionals over the phone to evaluate the patient's symptoms and functional improvement.

(2) Imaging evaluation: Bilateral knee MRI examination was performed on the second day after surgery, and the anatomical reconstruction was evaluated by mirror technology, including the chimerism of the bone bone interface between the graft and the host bone, and the match of the surface curvature of the graft and the recipient area. An orthopedic surgeon and an experienced imaging center doctor used the magnetic resonance observation of cartilage repair tissue (MOCART) scoring method to evaluate cartilage repair before surgery and 1 year after surgery.

Statistical analysis methods:

SPSS software was used for data analysis. The continuous data were expressed by (i±s), and the normality test was performed, and the SNK test was used for comparison between groups. Repeated measures analysis of variance was used for comparison of time data before and after intervention within the group, and paired sample f test was used for comparison at two time points. If the data does not meet the normal distribution, the logarithmic transformation is analyzed again. The X2 test was used for the counting data. $P<0.05$ was a statistically significant difference.

Background information on the study

The background and significance of the research are described in detail, the current status of domestic and foreign research is described, the progress and shortcomings of the research field are systematically reviewed, and the basis for the research project is expounded. The references cited should be marked in the background information.

Knee cartilage injury is a common refractory joint disease in athletes and the general population. An epidemiological investigation showed that cartilage damage accounted for 63% of knee arthroscopic surgeries1. Articular cartilage is a non-vascular, nerve-free and lymphatic tissue, which is difficult to repair after cartilage damage, and also affects the subchondral bone2, and the lesion of the subchondral bone will further aggravate cartilage damage, lead to cartilage detachment, accelerate the progression of osteoarthritis, seriously affect joint function, and have a high disability rate and teratogenicity. The treatment of cartilage injury is still a key issue and a major challenge in the field of orthopedics and sports medicine.

Since cartilage injury is often combined with subchondral bone injury2, the ideal intervention should treat both cartilage and subchondral bone. Bone marrow stimulation technology is currently the most commonly used treatment method3, which has the

advantages of low technical requirements, low cost, minimally invasive and mild postoperative pain, and many clinical studies have shown that it can achieve satisfactory short- and medium-term clinical efficacy, but the repaired tissue formed after surgery is fibrocartilage, and it is difficult to repair the lesions of the subchondral bone, and the medium- and long-term efficacy is not good4。 Autologous chondrocyte transplantation and autologous matrix- induced chondrogenesis can achieve good efficacy, but they require multiple surgeries, expensive surgery, high technical requirements, and cannot repair subchondral bone at the same time, and there is still insufficient evidence that such techniques can significantly improve the prognosis5. Although autologous or allogeneic osteochondral transplantation technology can repair cartilage and subchondral bone at the same time, autologous osteochondral transplantation can cause cartilage damage in the donor area, causing potential donor complications such as pain and arthritis6.

Periosteo-bone grafting is grafted into the defect by embedding the periosteum and the derma/cancellous bone underlying it as a whole. Using the cartilage regeneration ability of periosteum to repair cartilage, healthy skin/cancellous bone can replace the subchondral plate and subchondral bone of the lesion, which can not only rebuild the biomechanical structure, but also provide natural attachment and nutritional support for the periosteum, improve the survival rate of the periosteum, and achieve integrated cartilage-subchondral bone repair.

Periosteum-bone grafting can obtain the same clinical and imaging follow-up results as autologous osteochondral transplantation, and has the advantages of not needing to fix the periosteum, avoiding damage to healthy cartilage, low technical difficulty, low complication rate in the donor area, and wide range of sources, and has gradually replaced osteochondral transplantation in clinical practice8.

However, at present, there are still the following problems in the repair of knee cartilage damage by periosteum-bone grafting: 1. Due to the morphological characteristics of the knee joint surface, the curvature of cartilage damage in different parts is inconsistent, and it is difficult for traditional periosteum-bone grafting technology to reconstruct the curvature of the knee joint surface and restore the flatness of the articular surface. Studies have shown that mismatch between the graft and the recipient area can lead to increased contact pressure, degeneration of surrounding healthy cartilage, and easy development of osteoarthritis9. 2. Because the form of injury varies from person to person, traditional periosteum-bone grafting techniques are difficult to dissect and reconstruct defects, and are prone to graft fracture. Studies have shown that reducing the gap between the graft and the bone-bone interface of the recipient area and maintaining the integrity of the graft are the keys to obtaining satisfactory long-term clinical efficacy10. 3. After cartilage injury, a large amount of inflammatory factors will be released in the joint fluid, and the

infiltration and irritation of inflammatory factors are the main causes of pain, and the changes in the microenvironment in the joint will affect the healing ability of the subchondral bone and the regeneration ability of the periosteum11.

Based on the above clinical problems, this project intends to carry out research from the following aspects: 1. Establish a segmentation model of cartilage and subchondral bone, accurately simulate the defect morphology, apply 3D printing technology to print bone guide plates, guide personalized material selection, and improve the matching degree of surface curvature and morphology between the graft and the recipient area; 2. The combined application of PRP and autologous periosteum-bone grafting is rich in a variety of growth factors and anti- inflammatory factors, and has the advantages of repairing cartilage damage and regulating inflammatory reactions12.

References:

(1) Curl WW, Krome J, Gordon ES, et al. Cartilage injuries: a review of 31, 516knee arthroscopies. Arthroscopy, 1997, 13 (4) : 456-460

(2) Bruns J, Werner M, Habermann C. Osteochondritis Dissecans: Etiology,Pathology, and Imaging with a Special Focus on the Knee Joint[J].

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(3) Corr D, Raikin J, O'Neil J, et al. Long-term Outcomes of Microfracture for Treatment of Osteochondral Lesions of the Talus[J]. Foot Ankle Int, 2021: 1071100721995427

(4) Lee KB, Bai LB, Yoon TR, et al. Second-look arthroscopic findings and clinical outcomes after microfracture for osteochondral lesions of the talus[J]. Am J Sports Med, 2009, 37 Suppl 1: 63s-70s

(5) GaoL,Orth P, Cucchiarini M, et al. Autologous Matrix-Induced Chondrogenesis: A Systematic Review of the Clinical Evidence[J]. Am J Sports Med, 2019, 47(1): 222-231

(6) Migliorini F, Maffulli N, Baroncini A, et al. Allograft Versus Autograft Osteochondral Transplant for Chondral Defects of the Talus: Systematic Review and Meta-analysis[J]. Am J Sports Med, 2021: 3635465211037349

(7) Pereira GF, Steele JR, Fletcher AN, et al. Fresh Osteochondral Allograft Transplantation for Osteochondral Lesions of the Talus: A Systematic Review[J]. J Foot Ankle Surg, 2021, 60(3): 585-591

(8) Shi W, Yang S, Xiong S, et al. Comparison of Autologous Osteoperiosteal and Osteochondral Transplantation for the Treatment of Large, Medial Cystic Osteochondral

Lesions of the Talus[J]. Am J Sports Med, 2022: 3635465211068529

（9） Kock LM, Ravetto A, van Donkelaar CC, et al. Tuning the differentiation of periosteumderived cartilage using biochemical and mechanical stimulations[J].

Osteoarthritis Cartilage, 2010, 18(11): 1528-1535

（10） Shimozono Y, Yasui Y, Hurley ET, et al. Concentrated Bone Marrow Aspirate May Decrease Postoperative Cyst Occurrence Rate in Autologous Osteochondral Transplantation for Osteochondral Lesions of the Talus[J]. Arthroscopy, 2019, 35(1): 99-105

（11） Gowd AK，Weimer AE，Rider DE，artilage restoration of bipolar lesions within the patellofemoral joint delays need for arthroplasty：A systematic review of rates of failure[J]．Arthrosc Sports Med Rehabil，2021，3(4)：e11 89 e1197

（12）Belk JW，Kraeutler MJ，Houck DA．Platelet rich plasma versus hyaluronic acid for knee osteoar thritis：A systematic review and meta analysis of randomized controlled trials[J]．Am J Sports Med， 2021，49(1)：249 260

Objectives of the study

The purpose of the study was elaborated, including the study population, exposures, outcomes and methods. It can be expressed as specific hypotheses may be presented in the form of questions.

Overall study design

(1) A single-center prospective randomized controlled study of patients with knee cartilage injury using 3D printing-assisted PRP combined with autologous

periosteum-bone grafting

(2) Design type: prospective randomized controlled trial

(3) Research subjects: Patients with unilateral knee cartilage injury area

>2CM2 and grade 3-4 by the international cartilagerepair society (ICRS).

(4) Interventions: 3D printing, PRP

(5) Allocation ratio: 30 patients with 3D printing-assisted autologous periosteum-bone grafting, and 30 patients with 3D printing-assisted PRP combined with autologous periosteum-bone grafting research objectives to verify the safety and efficacy of 3D printing-assisted platelet-rich plasma combined with autologous osteoperiosteal transplantation in the treatment of knee cartilage injury.

Research objectives

Overall Objectives:

The application of 3D printing to assist platelet-rich plasma combined with autologous osteoperiosteal transplantation in the treatment of knee cartilage injury can accurately restore surface curvature, anatomically reconstruct the defect morphology, improve the cartilage repair effect, and improve clinical efficacy and knee joint function.

(1) Based on the deep learning method of knee cartilage and subchondral bone segmentation, a segmentation model of cartilage and subchondral bone is established, and the three-dimensional reconstruction of cartilage and subchondral bone is carried out through the method of body drawing and surface drawing, so as to visually display the cartilage defect at the knee junction from multiple angles, and 3D print the bone extraction template to improve the graft matching degree.
(2) The application of PRP combined with autologous periosteum-bone grafting technology to repair cartilage defects can improve the cartilage repair effect and improve clinical efficacy.

Achieveable results and intellectual property information:

(1) Establish a segmentation model of cartilage and subchondral bone, formulate a 3D printing bone retrieval module and personalized bone extraction process, and combine PRP and autologous periosteum-bone grafting technology to form an integrated anatomical-biological-functional repair technology for cartilage defects.
(2) Publish 1-3 high-level SCI research papers, apply for 1-2 patents, and train 1-3 graduate students

Study design

1. Research site and research population Research site

Institution: Department of Orthopedics, The Second Affiliated Hospital of Nanchang University

Time Frame: January 1, 2025 to December 31, 2027 (case inclusion and intervention period)

Selection of research objects Implementation of norms Source: Orthopedic outpatient/inpatient department, patients with unilateral knee cartilage injury confirmed by MRI

Inclusion criteria: (1) Age 18-65 years; ②BMI 18-30 kg/m²; (3) Cartilage damage area >2cm² and ICRS grade 3-4; (4) The lower limb force line is normal:

Exclusion Criteria: (1) Osteoporosis; (2) Immature bones; (3) combined meniscus/ligament injury; (4) Knee joint effusion; (5) History of immunosuppressant use

Sampling method: Continuous enrollment (non-probability sampling) until sample size is reached

Grouping method: block randomization (block size 4), stratified by ICRS grading (3/4 grade).Follow-up strategy: Outpatient follow-up at 1/3/6/12 months after surgery, and telephone follow-up visits (≤ 2 times) for those who lost follow-up

2. Sample size calculation

Sampling method: Continuous enrollment (non-probability sampling) until sample size is reached

Grouping method: block randomization (block size 4), stratified by ICRS grading (3/4 grade).

Follow-up strategy: Outpatient follow-up at 1/3/6/12 months after surgery, and telephone follow-up visits (≤ 2 times) for those who lost follow-up

2. Sample size calculation

Primary endpoint: MOCART score (continuous variable) at 12 months postoperatively

Parameter setting (based on previous literature and pre-experiments):

Expected mean value of PRP group: 85 points The expected mean of the control group: 70 points

Pooled standard deviation (SD): 12 points α=0.05 (bilateral), β=0.20 (80% grasp)

Between-group difference: 15 points (clinically significant difference) Formula and calculation

$$n = \frac{2(SD)^2(Z_{1-\alpha/2}+Z_{1-\beta})^2}{\Delta^2} = \frac{2\times12^2\times(1.96+0.84)^2}{15^2} \approx 21\text{ 例/组}$$

Adjust with final sample size

Consider a 20% dropout rate: $n_{adjusted} = 21 / (1-0.2) = 26.25 \rightarrow 27 example/group $

, g statistical mation)

Actual in clusion: 30 cases/group (60 cases in total), meetin requirements and reserving redundancy.

Calcu lation tool: PASS 2021 software (verification confir mation).

3. Bias control measures Design phase.

Types of bias	Control measures
Selection bias	- Strictly follow inclusion/exclusion criteria - Hierarchical randomization (balancing ICRS grading impact)
Information bias	-Double-blind imaging evaluation: orthopedic and radiologist independent reading (not knowing grouping) -Standardized scale training (Lysholm/Tegner)
Confounding bias	- Multivariate analysis adjusts for covariates such as age, BMI, and damage area

Implementation phase

Surgical standardization: All surgeries are performed by the same senior doctor (annual operation volume >600 units).

PRP preparation quality control: fixed centrifugation parameters (1500g × 10min), operated by special personnel.

Data collection: Electronic CRF real-time verification (e.g., postoperative score should not be better than preoperative).

Analysis phase:

Sensitivity analysis:

1. They were analyzed separately by PPS vs FAS
2. Nonparametric test for MOCART score (Wilcoxon rank sum)

Subgroup analysis: The interaction effect between the group and the injury area (≤4cm ^{2} vs >4cm^2) was tested technology-related bias control

Verification of 3D printing accuracy: The matching error between preoperative simulation and postoperative MRI was controlled at <0.5mm

Deep learning model: ablation experiment verifies the stability of segmentation algorithm (DSC>0.85).

Safety evaluation (including definition and evaluation of adverse events and serious adverse events, etc.)

Within 12 months after surgery, the MOCART score was performed by MRI imaging to

observe the safety of this product. Evaluate the stability of the implant and whether the implant is loose, dislocated, deformed, or fractured.

Adverse events should be closely observed and evaluated in the trial, and clinical adverse reactions should be followed up until symptoms disappear, and strictly recorded in the original case table and case report form.

3D printing technology can simulate the morphology and curvature of the lesion area, which has been widely used in the field of orthopedics, and the role of PRP and periosteum-grafting in the repair of talar cartilage damage has been clinically and imaging, respectively, and is a safe treatment. Therefore, the risk assessment is the minimum risk.

Side effects and adverse events

1. Infection: including skin infection and deep wound infection, antibacterial drugs should be used before and after surgery.

2. Venous thrombosis and pulmonary embolism: When it comes to lower limb surgery, lower limb thrombosis is more common, and most of them can be cured;

Elevate the affected limb, use hemostatic drugs with caution and control the time of medication.

3. Neurovascular injury: In cases with unclear anatomical structure or serious neurovascular involvement, try to pay attention to the operation during the

operation.

4. Heart, lung and brain complications are rare, but in severe cases they can be life-threatening.

5. Fractures: Intraoperative fractures are more common in elderly patients with severe osteoporosis, and postoperative fractures are mostly caused by patients

not fully following the doctor's instructions for functional rehabilitation.

6. Loosening or infection around the graft continues to occur after surgery

7. Poor activity.

Reasons for serious adverse events:

1. Causing death; 2. Threatening life; 3. Causing hospitalization or prolongation of hospitalization; 4. Causing continuous or significant loss of function of the human

body. The probability of complications is related to the patient's physical condition, the

difficulty of surgery and other factors, but most of these complications can be cured. Before surgery, the doctor should evaluate the patient's physical condition, estimate the risk of surgery and the probability of complications, and make corresponding treatment and prevention.

Data collection and management

1.Survey content (CRF form) Measurement and collection of indicators including exposure and outcomes. Clearly define variables such as outcomes, exposure, predictors, potential confounders, and effect modifiers.		
Variable type	Specific indicators	Measurement Methods/Tools
Outcome indicators		
Primary endpoint	MOCART score at 12 months postoperatively	MRI imaging evaluation (double-blind reading)
Secondary endpoints	Lysholm score, Tegner motor score, pain NRS score (preoperatively, 1/3/6/12 months postoperatively)	Standardized scale (outpatient/tele phone follow- up)
Exposure variables		
Intervention grouping	PRP+periosteum-bone graft group vs periosteum-bone graft group	Randomly assign records
PRP preparation parameters	Centrifugal force (1500g), centrifugation time (10min), blood collection volume (18ml)	Laboratory operation records
3D printing matching	Graft chimerism, surface curvature matching (MRI mirror assessment on postoperative day 2)	Quantitative analysis of 3D reconstruction software
Confounding factors		
Demographic characteristics	Age, gender, BMI, trauma history	Baseline questionnaire
Disease characteristics	Cartilage injury area (cm^2), ICRS grade (grade 3/4), injury site	Preoperative MRI evaluation
Concomitant lesions	History of meniscus injury, ligament injury (exclusion	Preoperative arthroscopic recordings

criteria)		
Effect modifiers	BMI stratification (<24 vs ⩾24) and damage area stratification (2-4cm² vs >4cm²).	Subgroup analysis variables
2.Data management and statistical analysis (data management: including paper/spreadsheet, database creation and entry, whether to double enter, whether to collect electronic data; Database cleaning and locking, data archiving, etc. Statistical analysis: statistical description, inter-group comparison, multivariate analysis and other methods, confounding factor control methods, subgroup analysis and interaction effect analysis, missing value treatment methods, sensitivity analysis, etc.)		
Data management process tache	mplement the norms	
Data acquisition	- Paper CRF → Two-person independent entry into electronic database (EpiData or REDCap) - Image data: DICOM files are encrypted and stored to match subject IDs	
quality control	- Logical verification rules (e.g., postoperative scoring> preoperative scoring trigger verification) - Randomly select 10% of CRFs for source data verification (SDV)	
Database lock	Lock after blind audit Changes must be signed and approved by the PI	
Data archiving	The original CRF is kept for 15 years, and the electronic database is backed up to the hospital's encrypted server	

Statistical analysis plan

1. Statistical description

-Continuous variables: 'Mean± standard deviation' (normal) or 'Median (P25, P75)' (non-normal).

- Categorical variables: frequency (percentage).

- Comparison of baseline equilibrium between the two groups: t- test/Mann-Whitney U test (continuous variable); Chi-square test (categorical variable).

2. Primary outcome analysis

-**Primary endpoint (MOCART score)**: Analysis of covariance (ANCOVA), with baseline score as covariate and group as fixed factor

-**Secondary endpoint (functional score)**: Repeated measures analysis of variance (group × time interaction effects).

-If the spherical test P<0.05, use the Greenhouse-Geisser correction

-Comparison between groups: Bonferroni correction

3. Consuming control and sensitivity analysis

-**Multivariate model**: Establish multiple linear regression for the primary endpoint, adjusting for age, BMI, and damage area

-**Subgroup analysis**: Stratified by BMI/injury area, to test the interaction effect of stratification factors × groups

-**Sensitivity Analysis**:: Protocol set (PPS) vs full analysis set (FAS).

Nonparametric tests (e.g., Wilcoxon rank-sum test for MOCART scores).

4. Missing data processing

-≤5% missing: Delete missing cases directly

->5% missing: multiple imputation (continuous variables: predicted mean matching; Categorical variables: Logistic regression imputation).

5. Additional analysis

-Correlation of graft match with MOCART score (Pearson/Spearman correlation).

-Dose-effect relationship within PRP group (PRP volume vs functional score improvement).

Principles of statistical analysis

The statistical analysis of the main and secondary efficacy indicators and safety indicators of the trial will be performed according to the protocol dataset, that is, all the subject data that meet the requirements of the trial protocol will be statistically analyzed, and the mean ± standard deviation will be used for the mean data. The frequency (or composition ratio) of the counting data is used. Two- sided test t-test and equivalence test were used for continuous data, χ2 test (or exact Fisher test) was used for count data, and Mann-Whitney rank test was used for rank data.

Primary and secondary efficacy indicators (measurement data) were adopted

(1) Statistical description;

(2) Analysis of variance;

Safety indicators (count data), adopted

(1) Statistical description;

(2) Analysis of variance;

Quality management plan (please introduce the relevant measures to ensure the quality and progress of the project)

Feasibility analysis

(1) The applicant has been engaged in clinical and basic research on joint diseases for a long time, and the first completer has won the first prize of Jiangxi Provincial Science and Technology Progress Award and Jiangxi Medical Youth Science and Technology Innovation Award, presided over and completed a national youth fund, a national regional fund, and a key research and development project related to cartilage repair, with solid research experience, and completed more than 600 joint surgeries every year, with rich surgical experience, and team members have rich clinical research experience, which can ensure postoperative investigation and follow-up. It can ensure the smooth progress of this study;

(2) The applicant's unit has a sufficient number of patients with cartilage damage and has various equipment to implement the study;

(3) This group has accumulated a good preliminary work foundation in PRP, cartilage segmentation, 3D printing and autologous periosteal-bone graft surgery (see the basic part of the research). Based on the above reasons, this project has good feasibility.

Research Basis

(1) The project team proposed a parallel expansion U-Net (dila-UNet) to extract deep features, achieve more accurate bits, generate adversarial network (GAN) connection mechanism and contrast learning module, compared with the current state-of-the-art deep learning algorithm, the accuracy of segmentation area is increased by 3.8%, the judgment anomaly rate is reduced by 1.82%, and finer edge recognition is achieved. MFA-Net:Multiple Feature Association Network for medical image segmentation. [J]. Comput Biol Med,2023,:106834。 The conditions of 3D printing have been explored, and the preliminary exploration of assisted personalized bone retrieval has been carried out

(2) Rich experience in developing new technologies, which have been commended by the hospital as "advanced in China" and "advanced in the province". Periosteum-bone graft repair cartilage damage has been declared a new technology in the hospital, and the acquisition tool of periosteum-bone graft has been improved, and a patent is being applied. The application of this technology has carried out corresponding cases and obtained good follow-up results

Pre-assessment and risk control plan of project risk benefits

Please describe the risks and benefits that may be borne by the researcher, subjects, and medical institutions when carrying out this project; If there is a risk, please introduce the measures and feasibility of risk control.

Benefit/risk assessment

Expected benefits

(1) Patient benefits: 3D printing-assisted PRP combined with autologous periosteum-bone grafting repairs knee cartilage damage, relieves pain, improves knee joint mobility, delays the occurrence of osteoarthritis, and improves knee joint function. (2) Social benefits: Through the research of this project, a more accurate and effective method will be provided for the repair of knee cartilage damage, promoting the development of cartilage repair technology, and conducive to the improvement of the treatment level of joint diseases.

Risk assessment

3D printing technology can simulate the morphology and curvature of the lesion area, which has been widely used in the field of orthopedics, and the role of PRP and periosteum-grafting in the repair of talar cartilage damage has been clinically and imaging, respectively, and is a safe treatment. Therefore, the risk assessment is the minimum risk

Morality and ethics

Ethics Committee (should describe how the plan was approved by the Research Ethics Committee/Institutional Review Committee)

(1) Research plan: The purpose, methods, participant recruitment process, risk assessment and control measures of this study have been explained in detail in the application form.

(2) Informed consent form (ICF): There is a clear informed consent form, which clarifies the various rights and rights of participants (voluntary withdrawal,

privacy protection, data use).

(3) Data management plan: It has a complete data collection, storage (such as anonymization), sharing and destruction party

(4) Participant recruitment materials: recruited through the hospital platform.

(5) Researcher qualification certificate: Team members have ethics training certificates.

(6) Conflict of interest statement: There is no potential interest relationship with the

partner.

Patient information and informed consent

(1) Who will obtain informed consent The investigator should usually be responsible for obtaining the subject's informed consent. The patient instructions may also be explained to the subject by a qualified study coordinator, and informed consent will be obtained by the investigator and confirmed that the subject is aware of all information related to the trial15. Application for in- hospital funding projects of the Second Affiliated Hospital of Nanchang University

(2) How to obtain informed consent After the subject is fully informed of the study information by a qualified person, the subject or his/her legal representative shall sign and date the informed consent form, and the researcher who performs the informed consent process shall also sign the name and date on the informed consent form.

(3) Compensation clause for harm caused by participation in the trial The sponsor shall take appropriate measures to ensure that the subject and the investigator can be compensated or compensated: First, the sponsor shall bear the diagnosis and treatment costs of the subject related to the damage or death of the clinical trial, as well as the corresponding compensation. The sponsor and the investigator shall promptly pay the compensation or compensation given to the subject. Second, the methods and methods provided by the sponsor to the subjects shall comply with relevant laws and regulations. Third, the sponsor shall provide the experimental drug to the subjects free of charge and pay for the medical testing costs related to the clinical trial

Relevant information on human genetic resources

Human genetic resources materials refer to organs, tissues, cells and other genetic materials containing human genomes, genes and other genetic materials.

Human genetic resources information refers to data and other information materials generated by human genetic resources materials.

Not involved