Computer Patient-Specific 3D Modeling and Custom-Made Guides for Revision ACL Surgery

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Abstract

Revision anterior cruciate ligament reconstruction (ACLR) is a challenging surgery occurring in 3 to 24% of primary reconstructions. A meticulous planning to study the precise size and location of both femoral and tibial bone tunnels is mandatory. The aim of the study was to evaluate the intra- and interoperator differences in the decision-making process between experienced surgeons after they were asked to make preoperative planning for ACL revision reconstruction with the use of both the computed tomography (CT) scan and a three-dimensional (3D)-printed model of the knee. Data collected from 23 consecutive patients undergoing revision of ACLR for graft failure at a single institute between September 2018 and February 2020 were prospectively reviewed. The double-blinded collected data were presented to three board-certificate attending surgeons. Surgeons were asked to decide whether to perform one-stage or two-stage revision ACLR based on the evaluation of the CT scan images and the 3D-printed custom-made models at two different rounds, T0 and T1, respectively, 7 days apart one from the other. Interoperator consensus following technical mistake was 52% at T0 and 56% at T1 using the CT scans, meanwhile concordance was 95% at T0 and 94% at T1 using the 3D models. Concordance between surgeons following new knee injury was 66% at T0 and 70% at T1 using CT scans, while concordance was 96% both at T0 and T1 using 3D models. Intraoperative variability using 3D models was extremely low: concordance at T0 and T1 was 98%. McNemar test showed a statistical significance in the use of 3D model for preoperative planning ($p < 0.005$). 3D-printed model reliability resulted to be higher compared with CT as intraoperator surgery technique selection was not modified throughout time from T0 to T1 ($p < 0.005$). The use of 3D-printed models had the most impact when evaluating femoral and tibial tunnels, resulting to be a useful instrument during preoperative planning of revision ACLR between attending surgeons with medium-high workflow.

Keywords
- ► revision ACL reconstruction
- ► preoperative planning
- ► 3D-printed model
- ► decision-making process

Anterior cruciate ligament reconstruction (ACLR) is one of the most common orthopaedic surgical procedures performed worldwide,[1] but failures still account for 3 to 24% of primary reconstructions, requiring revision surgical procedures.[2] Evidence describes a rate of revision ACLR of 1.7 to 7.7% with less favorable expected clinical outcome compared with primary ACLRs possibly leading to degenerative changes in the knee biomechanics.[3–8] Therefore, it is important to restore

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knee native anatomy and kinematics to prevent the risk of rerevisions which account for up to 9% of revision ACLR surgery.[9,10]

Both clinical and radiological assessment could manifest an ACL graft failure.[11–14] All potential leading causes of ACLR failure must be fully considered while approaching the patient, as the surgical planning will differ accordingly to the etiology of the failure. Consequently, it is a priority to determine whether to proceed with a two-stage or a one-stage revision.

In case of graft infection, two-stage revision is mandatory regardless of the status of the previous bone tunnels.[9,15–18]

In case of an aseptic graft failure, an in-depth study with high-definition radiological examinations is mandatory to determine the size and position of the tunnels, and other fundamental parameters such as lower limb alignment and tibial slope, before a decision can be made whether to proceed with one-stage revision.[19–23]

At the time this review is presented, no international guidelines are recommended for preoperative planning of ACL revision surgery endorsing a preferred approach when the bone tunnel is < 16 mm.[24]

In this scenario, high-resolution imaging and computer-assisted manufacturing custom-made models may constitute precious tools and may be enrolled in the decision-making process in this complex surgery.[25]

The aim of the study was to evaluate the intra- and interoperator differences in the decision-making process between experienced surgeons after they were asked to make preoperative planning for ACL revision reconstruction with the use of both the computed tomography (CT) scan and a three-dimensional (3D) printed model of the knee.

Material and Methods

Demographic Data and Preoperative Evaluation

Data collected from 23 consecutive patients undergoing ACLR revision for graft failure at a single institution between September 2018 and February 2020 were prospectively reviewed. All subjects provided signed informed consent before participating in the trial.

Inclusion criteria were: age > 18 years old, ACL surgery reconstruction failure for traumatic or atraumatic causes, and objective knee instability. Exclusion criteria were: septic graft mobilization, inferior limb axial deformity surgical interventions, and nonrepairable lesion associated with primary ACL tear.

Each patient was clinically evaluated by age, sex, body mass index, side of the affected knee, grade of physical activity before injury measured by low < 5 hour/week, moderate 5 to 10 hour/week, high ≥ 10 hour/week, or agonist ≥ 10 hour/week, surgical technique employed for primary ACLR intervention, etiology of ACL graft failure, and time between primary reconstruction and graft failure.

Each recruited patient was radiologically assessed by the use of a high-resolution CT scan and image acquisition was performed on Philips Brilliance ICT 128 (Koninklijke Philips N.V., the Netherlands) with 64 detectors. Image CT acquisition protocol set pitch 0.300, rotation time 0.5, scanning time 10 seconds, and voxel 0.5 mm and both bone and soft tissue windows to be obtained.

CT Image Segmentation Algorithm, 3D Reconstruction, and Printing

The 3D-printed models' data were obtained from CT Digital Imaging and Communications in Medicine (DICOM) files (►**Fig. 1**). The files were loaded and processed using 3D Slicer (Slicer Community, Brigham and Women's Hospital, Harvard University, National Institution of Health), an open-source software distributed under a BSD (Berkeley Source Distribution)-style license (►**Fig. 2**).[26]

Image segmentation was performed with automated thresholding and automated smoothening function. The files were then exported in stereolithography interface (STL) format and transferred to Z-Suite software provided with 3D-printer loan of use (Zortrax, Zortrax S.A, Poland) (►**Fig. 3**). Finally, Z-CODEX files were printed in polyethylene terephthalate glycol (PETG) real-scale model of the femoral and tibial metaphysis (►**Fig. 4**). Mean printing time was 18 hours for each 3D model with mean consumption of 142 g of PETG per model.

Preoperative Planning Decision Process

The double-blinded collected data were presented to three board-certificate attending knee sport surgeons who performed at least 15 ACLR revision surgeries yearly during the previous 5 years. Surgeons were asked to decide whether to perform one-stage or two-stage ACLR revision intervention after CT images and 3D custom-made models were presented to them in two different rounds, T0 and T1, respectively, 7 days apart one from the other (►**Fig. 5**).

Statistical Analysis

Statistical analysis was performed using SPSS statistics software (IBM, Armonk, New York). Each CT images and 3D models case evaluation was paired at T0 and T1. The McNemar test was used to compare the results between the CT images alone versus the 3D models chaperone employment in correctly predicting the surgical technique in revision ACLR tacking an α-value < 0.05 to be statistically significant.

Results

Fourteen men and 9 women were enrolled with age ranging between 22 and 36 years. Baseline characteristics are presented in ►**Table 1**.

Eighteen patients underwent primary ACLR with transtibial technique, 2 patients with anteromedial transportal approach, 2 outside-in technique, and 1 of which had underwent a prior revision surgery with outside-in technique.

Previous technical mistake in transosseous tunnel positioning was the most common cause of revision, occurring in 19 cases out of 23 (►**Fig. 6**). Femoral tunnel was mispositioned in 13 cases, tibial tunnel was mispositioned in 4 cases, and in the remaining 2 cases both tibial and femoral tunnel

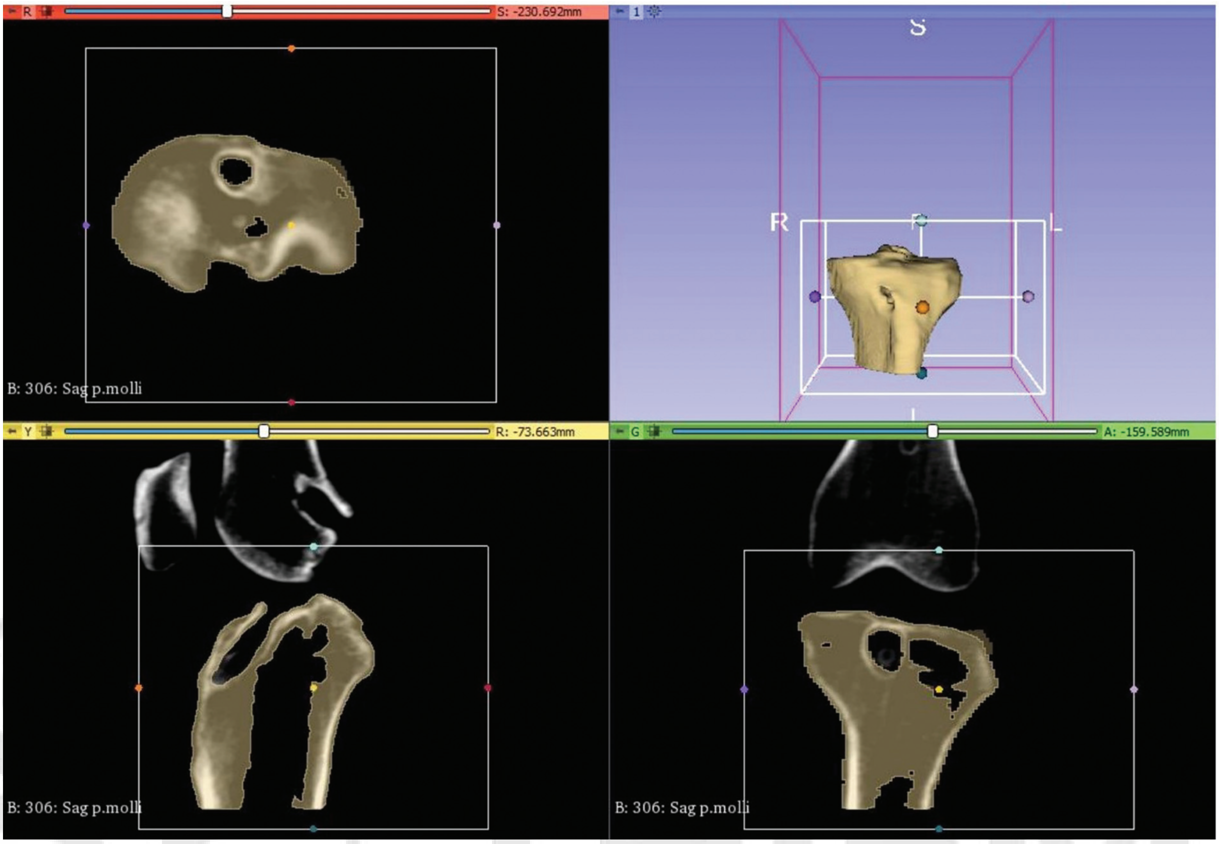

Fig. 1 Example of segmentation with three-dimensional (3D) Slicer software. Image segmentation is a method of dividing a digital image into subgroups called image segments, reducing the complexity of the image and enabling further processing or analysis of each image segment.

were mispositioned. During the follow-up 4 patients incurred in a trauma of the operated knee, resulting in the failure of the reconstructed ACL revision graft. Mean time from primary ACLR to revision surgery was 13.8 months (range 4–48). Interestingly, mean time from primary ACLR to failure was 34 months (range 24–48) following injury, 9.8 months (range 4–13) following technical surgical mistake, and 7 months (range 7–7) due to a combination of the previous. One-stage revision was chosen in 14 cases, two-stage revision in 7 cases.

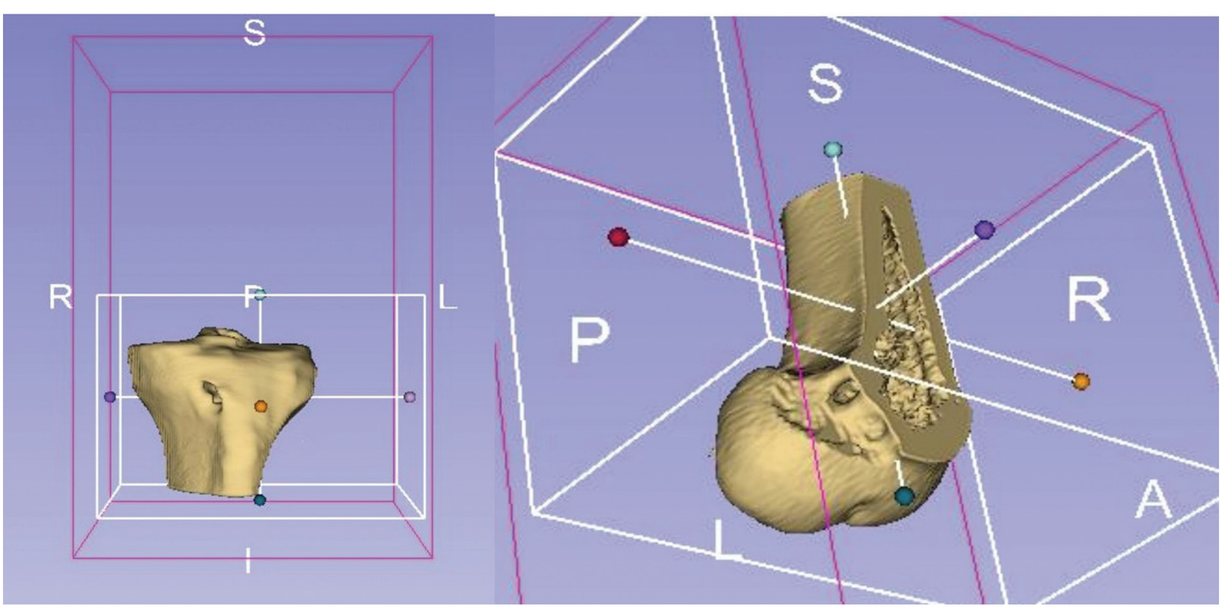

Fig. 2 Patient-specific tibial component three-dimensional (3D) model of the knee obtained from STL images after image segmentation.

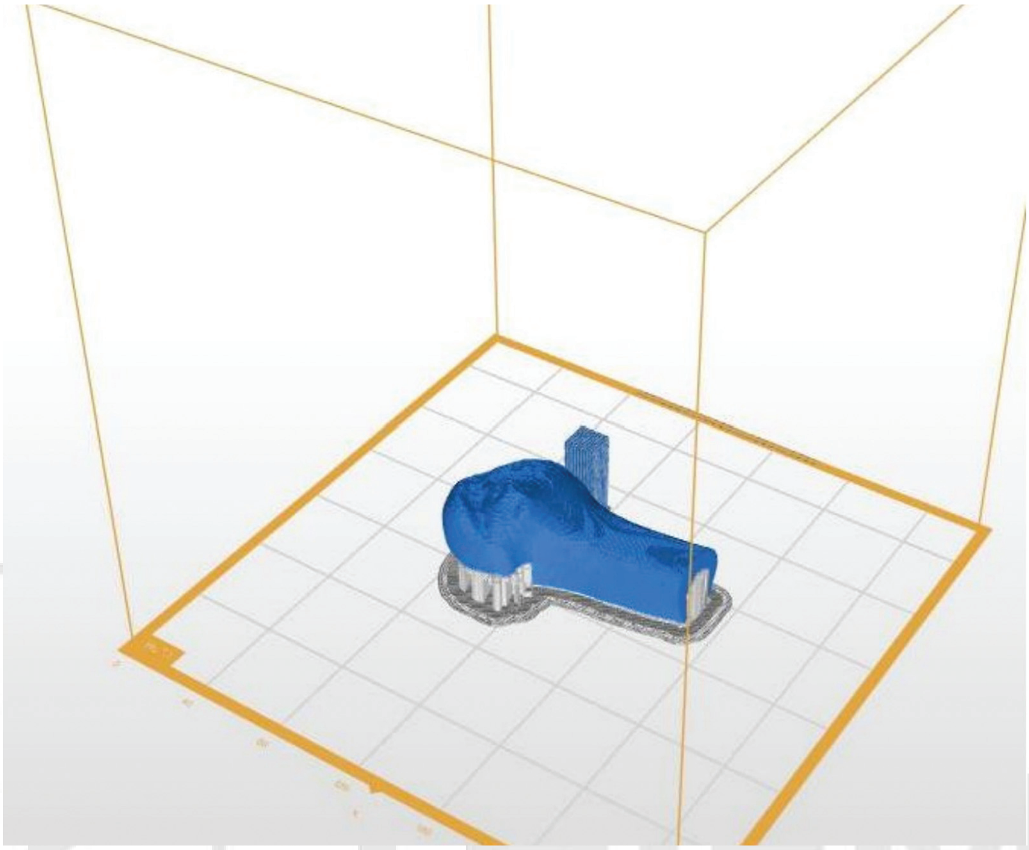

Fig. 3 Z-Suite software working on the virtual three-dimensional (3D)-printed model. For each model the following printing characteristics were set up: Nozzle diameter: 0.4 mm; Layer: 0.20 mm; Quality: High; Infill: 20%; Fan speed: Auto; Seam: Random; Outer contours: 0.00; Holes: 0.00; Contour-infill gap: 0.40; Contour-top gap: 0.00; Surface layers Top: 5; Surface layers Bottom: 3; Support Lite: No; Smart bridges: No; Max. wall thickness: 3.13 mm; First layer gap: 0.20 mm; Raft Enabled: Yes; Raft layers: 4; Platform-raft gap: 0.30 mm; Raft Density: 100%; Raft Print speed: 100%; Raft Flow ratio: 100%; Support Density: 5.00 mm; Gap XY: 0.16.

Interoperator consensus for ACL revision surgery approach consequent to tunnel mispositioning was 52% at T0 and 56% at T1 using CT scans, meanwhile concordance was 95% at T0 and 94% at T1 using 3D models.

Concordance between surgeons concerning ACL revision following new knee injury was 66% at T0 and 70% at T1 using CT scans, meanwhile using 3D models, concordance was 96% both at T0 and T1.

Intraoperative variability using 3D models was extremely low: concordance at T0 and T1 was 98%.

Attending surgeons' accordance toward the revision strategy once the 3D-printed model was considered changed significantly compared with the consensus collected from CT solely consideration ($p < 0.005$). Finally, 3D-printed model reliability resulted to be higher compared with CT as intraoperator surgery technique selection was not modified throughout time period from T0 to T1 ($p < 0.005$).

Discussion

The aim of this study was to investigate whether knee patient-specific 3D model is an accurate and useful tool in the preoperative planning of revision ACLR surgery. The use of custom-made computer-assisted design (CAD) models had the most impact when evaluating femoral and tibial tunnel, resulting to be a useful instrument during preoperative planning increasing overall agreement when planning revision ACLR between attending surgeon with medium-high workflow. This finding resulted to be true with enough statistical power ($p < 0.005$) although it has been proven in a limited cohort.

Kitamura et al proposed a similar review in a retrospective fashion and addressed 3D-printed models to be a useful tool when planning revision ACLR for early career sports physicians and board certificate who may not be familiar with revision surgery.[27] Differences between results of the current study and Kitamura et al work may originate from the different questions surgeons were called to answer. The intention of this study was to assess whether revision surgery was performed with one-stage approach or two-stage approach. Differently, Kitamura et al proposed to evaluate if sport medicine operators would rather reuse the femoral tunnel and/or the tibial tunnel in the revision surgery after ACL graft failure according to 3D models. Moreover, the final results may have been influenced by the lower number of participants enrolled in the review compared with this study. Finally, neither quantitative nor qualitative assessment of the attending surgeon's experience was stated in Kitamura et al's report, but distinction was expressed between experienced and resident physicians. In

Fig. 4 Final patient-specific femoral and tibial component real-scale three-dimensional (3D)-printed model. Red straws show tunnel position and direction.

his study, there was a high overall agreement rate between the fellow physicians with the surgical approach when evaluating both the tibial and femoral tunnels using the 3D-printed models compared with CT alone, but the same results did not occur for attending surgeons. In this regard, differences in findings may result from the fact that in our study attending surgeons might be less experienced than surgeons in the Kitamura et al's team leading to a higher agreement in the current study between operators and in-between operator, accordingly with Kitamura et al's experience.

Preliminary results of this study suggest that CT imaging solely does not always allow a shared consensus when planning revision ACLR staging.

This finding is particularly true in those cases when femoral tunnel mispositioning is the driving force to graft failure. This information may be collateral to the higher number of femoral tunnels mispositioning reported to be causing graft failure in the current study.

When planning and revising an ACL surgery with new femoral tunnel positioning that interacts with the previous tunnel, several challenges and difficulties might arise. As already mentioned, when creating a new femoral tunnel, it might overlap with the previous tunnel weakening the bone structure and compromising the strength of the new tunnel due to the removal of bone during the initial surgery. Moreover, inserting a bone graft or other supportive materials to reinforce the new tunnel might be challenging due to the presence of the previous tunnel and the integration of the graft might be compromised because of the altered bone structure and the presence of scar tissue. The presence of the old tunnel might also compromise the integrity of the bone, making it more susceptible to fracture or other structural issues during the creation of the new tunnel. Finally, the weakened quality and the altered anatomy of the bone can reduce the stability of the new ACLR and the accurate placement of the new tunnel undermining the overall stability and success of the ACL revision surgery.

In the current study, the anatomical assessment of the previous tunnel placement was performed with CAD 3D models of the knee joint to precisely evaluate the bone quality, the remaining tunnel size, the available space and

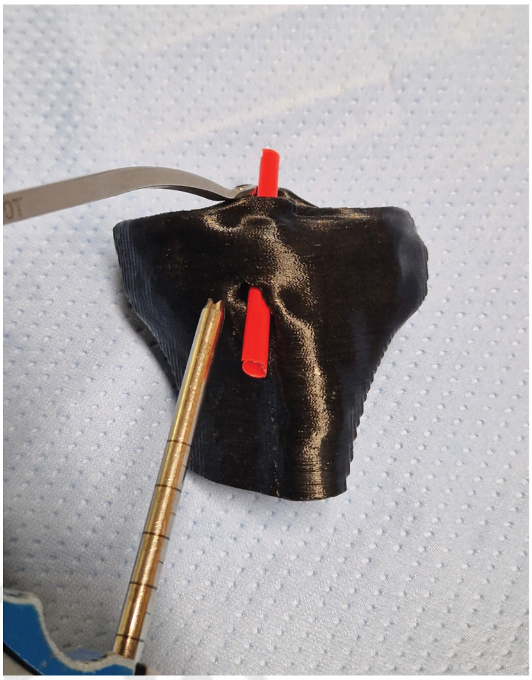

Fig. 5 Patient-specific tibial component three-dimensional (3D) model showing a tape passing through the previous tunnel indicating its direction. The image also shows an outside-in compass visually attempting to confirm one of the possible positions of the new tunnel. In this case, a two-stage revision was performed, because the 3D testing did not yield sufficient evidence to establish the reliability of the one-stage approach.

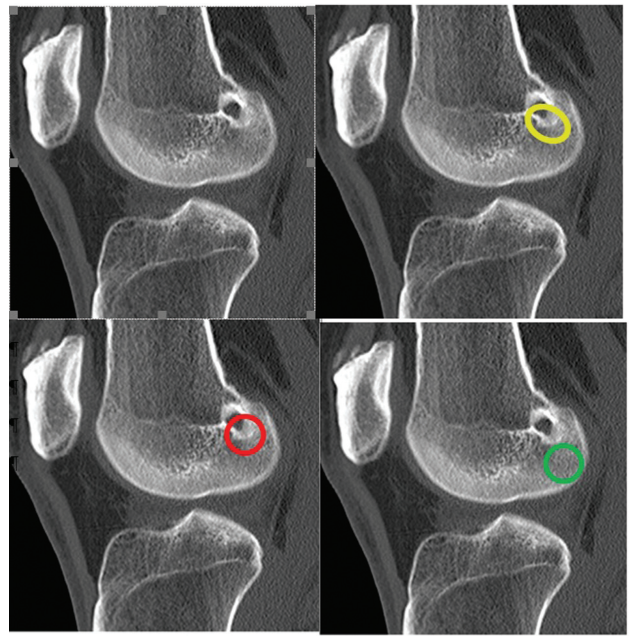

Fig. 6 Femoral tunnel mispositioning of a 28-year-old right male knee. Overlapping tunnels can weaken the bone between them, potentially leading to a higher risk of fracture or compromise in the structural integrity of the bone. The previous tunnel might also cause widening or damage to the bone, making it less structurally sound. Redrilling a tunnel in this compromised bone can lead to further weakening or difficulty in obtaining secure fixation for the new graft. *Top left*: Previous anterior cruciate ligament (ACL) femoral tunnel. *Top right*: Native ACL femoral footprint. *Bottom left*: 1-degree stage revision ACL not recommended due to possible tunnels interaction (native ACL femoral footprint round tunnel diameter: 10 mm, area: 78 mm^2). *Bottom right*: 1-degree stage revision ACL possible showing no tunnel interaction (red circle tunnel: dimension: 5×10 mm, area: 50 mm^2).

location, and to choose the appropriate graft that fits within the limitations of the altered bone structure. Each patient may have unique anatomical considerations that cannot be taken lightly. A comprehensive preoperative assessment and discussion with patient-specific 3D models can help tailor the surgical plan to individual needs.

Finally, the choice of technique often depends on the surgeon's expertise, the specific characteristics of the patient's knee anatomy, the condition of the previous tunnels, and the desired anatomical reconstruction. Patient-specific 3D models may help the surgeons to endorse that the preferred technique can be suitable for the ACL graft, mimicking the native ACL function as closely as possible.

At date, current guidelines do not recommend clear indication between one-stage or two-stage ACLR unless the bone tunnel have been expanded over 16 mm.[23] Another major issue presents itself when tunnels are in partial anatomical position possibly resulting in a coalescence of the new ones determining another failure.

This study is preliminary research in this branch, which need for improvement in study design and larger recruited cohort.

A limitation of this study is the number of recruited population. A potential future improvement of this study relying on larger cohorts could determine defined guidelines establishing indications for a two-stage revision according to bone tunnel width and verticalization, both features easily and quickly assessable with patient-specific knee real-scale 3D model.

At date, the financial cost of 3D custom-made model represents another intrinsic limitation in this study. The cost of 3D custom-made models has been estimated at €250 each. Authors think that the continuous spreading of 3D printer and CAD software are leading to price lowering of materials, production line, and machines. A proof of that is the present study has been realized with open-source software Slicer (Slicer Community, Brigham and Women's Hospital, Harvard University, National Institution of Health) for segmentation of DICOM and consecutive production of the plastic model.

The accurate in vivo reproducibility of the printed models could be settled using navigation system, robot-assisted technology, or augmented reality, granting high level of precision of what was planned during preoperative evaluation. Thus, the in vivo reproducibility of this model has to be proven in a randomized controlled trial.

Finally, 3D custom-made models could be a useful tool recommending a reproducible interoperator and intraoperator surgical indication due to an unrestricted overall sight of the anatomical region, allowing the surgeon to look at the bone tunnel trajectory in a cleverer approach then conventional imaging, offering a clear picture of the existing bone tunnel, and consecutively performing a safer surgery.

Table 1 Patients' demographic data and baseline characteristics are shown

Patient demographic and baseline								
Patient ID	Sex	Laterality	Age	Etiology of failure	BMI	ACLR technique	Revision ACLR approach	Time from ACLR (mo)
1	Female	Left	31	FTE	22	TT	Single stage	6
2	Male	Right	25	FTE	20	TT	Two stage	12
3	Male	Right	22	FTE	29.4	DB	Two stage	8
4	Female	Left	25	FTE	24	TT	Single stage	9
5	Male	Right	29	FTE	25	TT	Single stage	12
6	Male	Left	27	FTE	20.2	OI	Single stage	10
7	Female	Left	23	FTE	21	TT	Single stage	12
8	Male	Right	24	FTE	22.5	TT	Two stage	9
9	Male	Left	27	FTE	24.2	AM	Single stage	10
10	Female	Left	25	FTE	19.5	TT	Single stage	13
11	Male	Right	22	FTE	21	TT	Single stage	11
12	Female	Left	23	FTE	23	TT	Two stage	9
13	Male	Right	28	FTE	21.5	AM	Single stage	7
14	Female	Left	25	FTE + TTE	26.8	TT	Single stage	7
15	Female	Right	24	FTE + TTE	18.8	TT	Single stage	9
16	Male	Right	22	TTE	25	TT	Two stage	11
17	Female	Right	36	TTE	24.2	TT	Single stage	13
18	Male	Left	29	TTE	19.8	TT	Single stage	9
19	Female	Left	23	TTE	23.7	TT	Two stage	14
20	Male	Left	27	New injury	23.3	OI	Single stage	30
21	Male	Right	30	New injury	25.1	TT	Single stage	48
22	Male	Left	28	New injury	22.5	TT	Single stage	36
23	Male	Left	26	New injury	25.8	TT	Single stage	24

Abbreviations: ACLR, anterior cruciate ligament reconstruction; AM, anteromedial; BMI, body mass index; DB, double-bundle; FTE, femoral tunnel technical error; IQR, interquartile range; OI, outside-in; TT, transtibial; TTE, tibial tunnel technical error.
Note: 23 patients were enrolled and included in the current study (M:F 14:9) with mean age of 25 years old (range 35–50) and mean body mass index (BMI) of 22.5 (range 20.6–24.2). Primary ACLR were performed with transtibial approach in 18 cases (78%), with anteromedial approach in 2 cases (8%), with outside-in approach in 2 cases (8%), and with double-bundle technique in 1 case (4%). Mean time from ACLR to failure was 10 months (IQR 9–12.75), particularly mean time from ACLR to failure due to a new injury was 22 months (IQR 28.5–39) and due to surgical technical error was 9 months (IQR 8.5–11.5). The etiology of the graft failure resulted from a new injury in 4 cases (16%), from surgical technical error of the femoral tunnel in 13 cases (13%), from a surgical technical error of the tibial tunnel in 4 cases (24%), and from a combination of a new trauma and a surgical error in 2 cases (8%). One-stage approach was performed in 16 cases (69%), conversely a two-stage approach was performed in 7 cases (31%).

Ethical Statement

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of Interest

None declared.

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