3D Printing in Medicine

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ACL tunnel placement using 3D printed surgical guides – a porcine feasibility study

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Abstract

Background Anterior cruciate ligament reconstruction (ACLR) failures are associated with misplacement of the bone tunnels in up to 88%. The aim of this study is to evaluate the feasibility and accuracy of ACL tunnel placement performed with 3D printed guides.

Methods 3D models of the femur and tibia from ten porcine specimens were reconstructed using CT scans. ACL tunnel aiming guides were created and fitted to the proximal tibial and distal femoral metaphyseal cortices. Each guide comprised two sleeves to secure the guide to the bone using Kirschner wires and one sleeve for inserting the ACL tunnel guide wire. Guides were printed using a biomedically certified resin on the in-house 3D printer. They were fixed to the antero-medial tibia/distal-lateral femur with Kirschner wires and the ACL guide wire was inserted, then the guides were removed and the ACL guide wire was drilled over. Post-operative CT scans were obtained in order to compare the actual positions of the tunnel to the planned positions. Results are presented as medians and ranges since normal distribution could not be confirmed.

Result Median deviations between preoperative plan and actual postoperative positon were 1.15 mm (0.7–3 mm) and 0.75 mm (0.3–2.8 mm) for femoral and tibial tunnels, respectively.

Conclusion Good accuracy of ACL tunnel placement can be achieved using 3D printed guides. Applied to a clinical setting, this technique has the potential to significantly reduce complications due to misplacement of bone tunnels.

Keywords Anterior cruciate ligament reconstruction, ACL tunnel, 3D print, 3D guides, Patient specific surgery, ACL failure

Introduction

Anterior cruciate ligament (ACL) reconstruction (ACLR) is the treatment of choice in young and active patients with ACL tears [3]. Yet, treatment failure, such as persistent instability or re-tear, occurs in 9–15% of patients [19, 20]. Up to 88% of these ACLR failures are associated with tunnel malposition [4, 10, 17]. In the multi-centre ACL Revision Study (MARS) cohort, femoral tunnel malposition was reported as the most common technical failure, followed by tibial tunnel malposition [4]. Furthermore, surgeon experience had little effect on graft failure rates due to tunnel malposition [17, 21]. More reliable reconstruction techniques are therefore needed to reduce ACLR failure [5, 17]. Various methods have been proposed to increase the accuracy of tunnel positioning, but no technique has been widely adopted. 3D printed patient-specific instrument (PSI) has been shown to reduce operative time and improve accuracy in a variety of surgical procedures [1, 8, 9, 12, 13, 15, 18]. The accuracy of radiographic guided freehand techniques for

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ACL tunnel placement has been as low as 3.6 ± 3.20 mm (deviation between planned and actual tunnel position) [5]. Meanwhile studies evaluating the accuracy of PSI for forearm osteotomies and fracture reductions have found much higher accuracies of 0.8 mm (osteotomy), 1 mm ± 0.9 mm (femur fracture reduction), 2.5 mm ± 1.6 (tibia fracture reduction) [6, 22]. PSI may therefore improve the accuracy and reliability of ACL tunnel placement and subsequently reduce the rate of ACL failure due to tunnel malposition.

The aim of this study was to evaluate the feasibility and accuracy of ACLR bone tunnel placement using 3D printed surgical guides in porcine knees. A median deviation of 1.5 mm between planned and actual tunnel position for femur and tibia was hypothesised based on literature values [5, 6, 17], [22].

Methods

3D planning and guide design

Ten complete matured (> 2 years of age) porcine legs were utilized. The cadaveric bones underwent computed tomography (CT) (SOMATOM X.cite, Siemens Healthcare GmbH, Eschborn, Germany), in a high quality of 0.5 mm slices. Femur and tibia were segmented based on CT images and individual 3D models built using the medically certified software "Mimics" and "3-matic" (Materialise GmbH, Munich, Germany). Subsequently, cylindrical bone tunnels for a fictitious ACL reconstruction were created and virtual surgical guides were designed corresponding to the individual bone surface by Boolean operations. The guides were positioned at the lateral distal femur and anteromedial proximal tibia. The guides included drill sleeves for a 2.8 mm guide wire in the desired drill direction. Surgical planning is displayed in Figs. 1 and 2.

3D printing and processing

Printing was performed using a professional stereolithography (SLA) 3D printer and resin, certified for biocompatibility (Form 3B/Biomed Amber, Formlabs, Berlin, Germany). Post-printing processing included washing (Form Wash) with Isopropanol 99.9% for 20 min, drying (3 h at room temperature) and curing for 35 min at 60° Celsius with a wave length of 405 nm (Form Cure, Formlabs, Berlin, Germany). Supporting structures necessary for 3D printing were removed with a side cutter. Sterilization was performed following our in-house autoclave protocol for 18 min at 134 °C (Euro Selectomat, MMMGroups GmbH, Munich, Germany).

Surgical preparation

An attending orthopedic surgeon and an orthopedic resident performed the surgical preparations. In the direct contact zone of the surgical guides, meticulous removal of the periosteum was performed to allow optimal fit. The guides were applied to the distal femur and proximal tibia and fixated by Kirschner wires (diameter 2.8 mm, Stryker, Kalamazoo, Michigan, USA) through the guide (Fig. 3). Through an additional drill sleeve in the planned direction of the ACL tunnel, the drill guide wire (diameter 2.8 mm, Stryker, Kalamazoo, Michigan, USA) was inserted into the bone. The surgical guide was removed after guide wire placement and the wire was over-drilled with a cannulated drill bit (diameter 6 mm, DePuy Synthes MedTech, Zuchwil, Switzerland). The bone tunnels were rinsed with water to remove debris in favor of accurate segmentation of the tunnels.

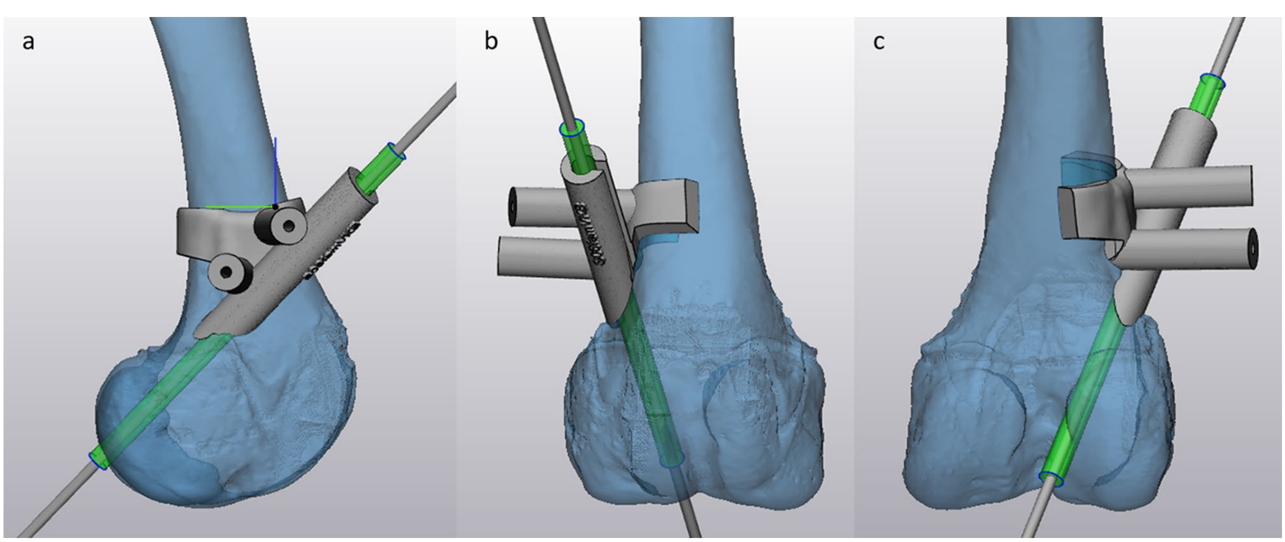

Fig. 1 Planning of the femoral ACL tunnel guide with Materialise 3-matic software. Planning of the femoral ACL tunnel guide with Materialise 3-matic software in lateral (**a**), frontal (**b**) and back (**c**) view. The green cylinder indicates the planned bone tunnel

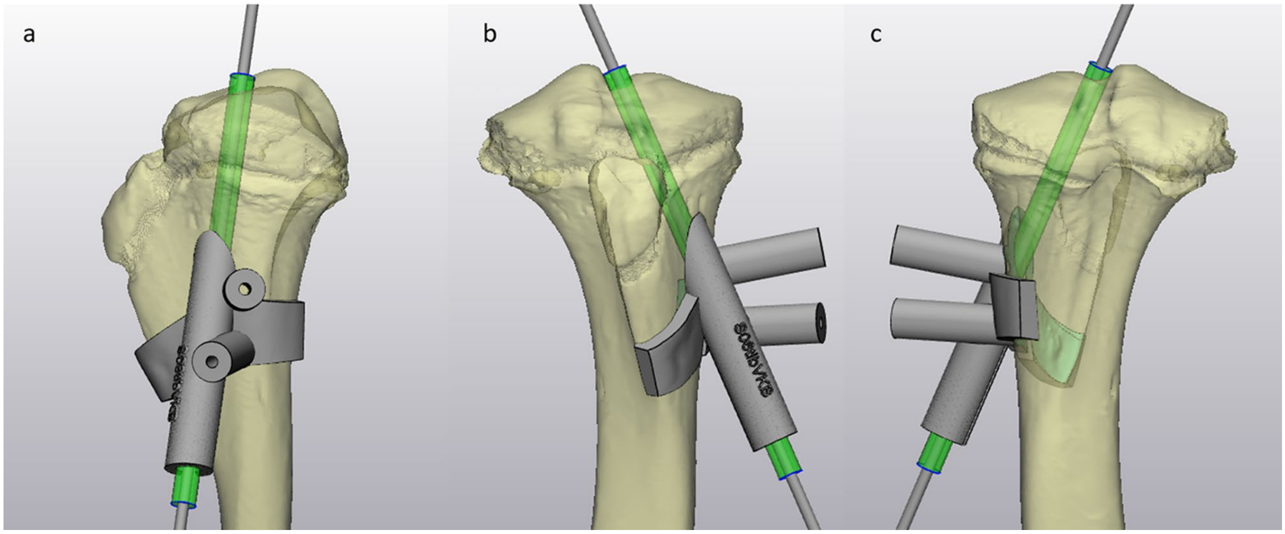

Fig. 2 Planning of the tibial ACL tunnel guide with Materialise 3-matic software. Planning of the tibial ACL tunnel guide with Materialise 3-matic software in medial. (**a**), frontal (**b**) and back (**c**) view. The green cylinder indicates the planned bone tunnel

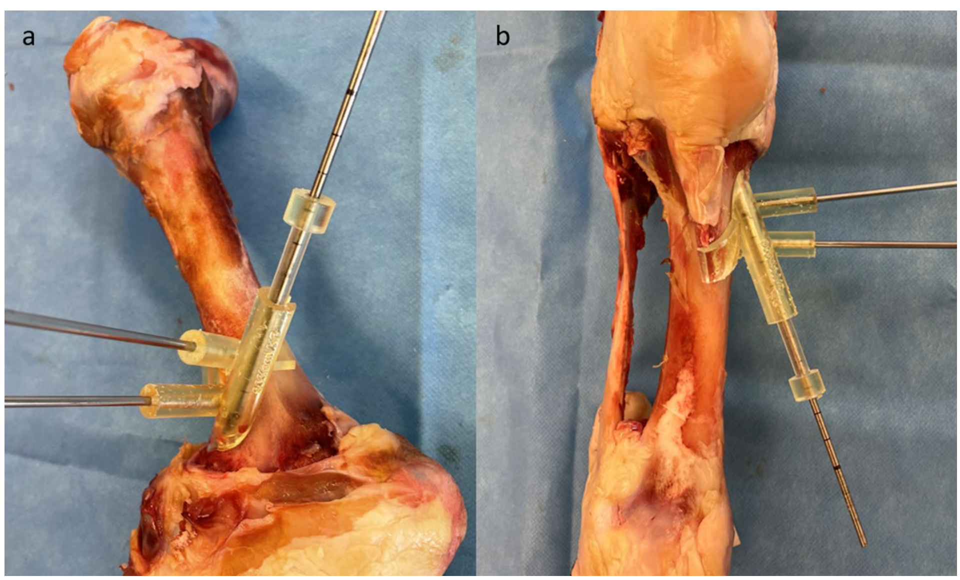

Fig. 3 Surgical preparation of the porcine specimen. (**a**) shows the fit of the 3D printed femoral guide after fixation with 2.8 mm Kirschner wires and 2.8 mm drill pin insertion. (**b**) shows the tibial guide after fixation with 2.8 mm Kirschner wires and 2.8 mm drill pin insertion. In both cases the drill pin was inserted via a 3D printed drill sleeve

Postoperative analysis

The porcine specimens underwent postoperative CT imaging and 3D models of the bones and the drilled tunnels were created as described above.

3D analysis and determination of the deviation from the plan was performed with Materialise 3-matic software. The postoperative 3D models of tibia and femur were compared to the preoperative models (plan). The software enables accurate superimposition by a global registration tool (min. 200 iterations). To determine the accuracy of the ACL tunnel, a 3D model of the actual tunnel was created during segmentation. The bones were masked out, leaving the planned tunnel and the post-interventional tunnels. As shown in Figs. 4 and 5, the distance of the center of the planned tunnel to the center of the post-interventional tunnel was measured at the intra-articular end of the tunnel.

Sample size calculation

A priori power analysis was performed based on the average between the historic value known from literature and the expected tunnel position deviation of 1.5 mm (± 1 mm), estimated on the basis of previous 3D guided projects [5, 6, 22]. Thereby a minimal sample size of eight

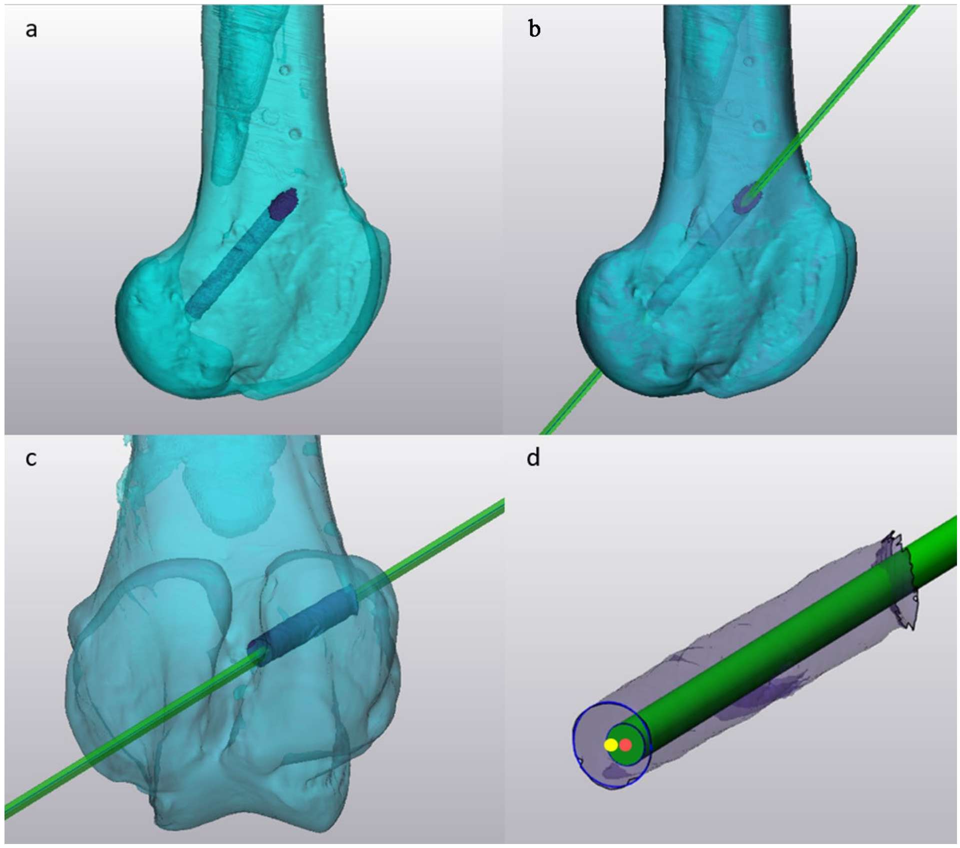

Fig. 4 Example of femoral post-operative comparison of the drilled tunnel to the planned tunnel in Materialise 3-matic. (**a**) shows the postoperative bone model (turquoise) and the segmented drill tunnel (lilac). (**b** and **c**) show superimposed pre- (marine) and post-interventional (turquoise) bone models, segmented drill tunnel (lilac) and planned drill guide (green) in lateral and p.a. view. (**d**) in a more detailed view, the bone tunnel (transparent lilac) and the planned drill guidewire (green) were cut at the level exiting the bone. The yellow point marks the center of the achieved bone tunnel and the red point marks the centre of the planned bone tunnel. The distance between these two centre pointes was measured

cadavers would be necessary to achieve a power level of 0.8 and a significance level of $p = 0.05$ assuming a standard deviation of 1.8 mm. A sample size of 10 cadavers was chosen based on this calculation.

Statistical analysis

SPSS statistics was used for data analysis (IBM SPSS Statistics, Version 25 for Windows). Data was not normally distributed according to Kolmogorov-Smirnov-Test and thus median and ranges are presented.

Results

Femoral ACL tunnels showed a median deviation (Range) of 1.15 mm (0.70–3.00 mm) between preoperative planned position and postoperative actual position. Tibial ACL tunnels showed a median deviation (Range) of 0.75 mm (0.30–2.80 mm) between preoperative planned position and postoperative actual position. The accuracy of the femoral and tibial bone tunnels is illustrated with boxplots in Fig. 6.

Discussion

The most important finding was that a high accuracy of ACLR tunnel positioning could be achieved using this technique. Our hypothesis is confirmed by our results, as a median deviation of 1.15 mm and 0.75 mm was found for the femoral and tibial ACL bone tunnel, respectively.

Several studies reported that anatomical ACL reconstruction, where a graft is placed within the anatomical ACL footprint, would result in better clinical results and lower failure rates than isometric placement [7, 11]. However, using contemporary anatomical techniques, the position of reconstructed grafts to the native femoral ACL footprint has been reported to differ significantly with 3.6 mm ± 2.6 mm, even if performed by experienced surgeons. Comparison of tibial tunnel placement to the center of the native ACL at the tibial attachment site revealed a mean difference of 6.24 mm ± 3.20 mm [5, 14, 17]. One third (femoral)/one quarter (tibial) of the tunnels did not even overlap the anatomical femoral footprint, although an anatomical position was desired [5, 14, 17]. In our study, the highest difference between drilled

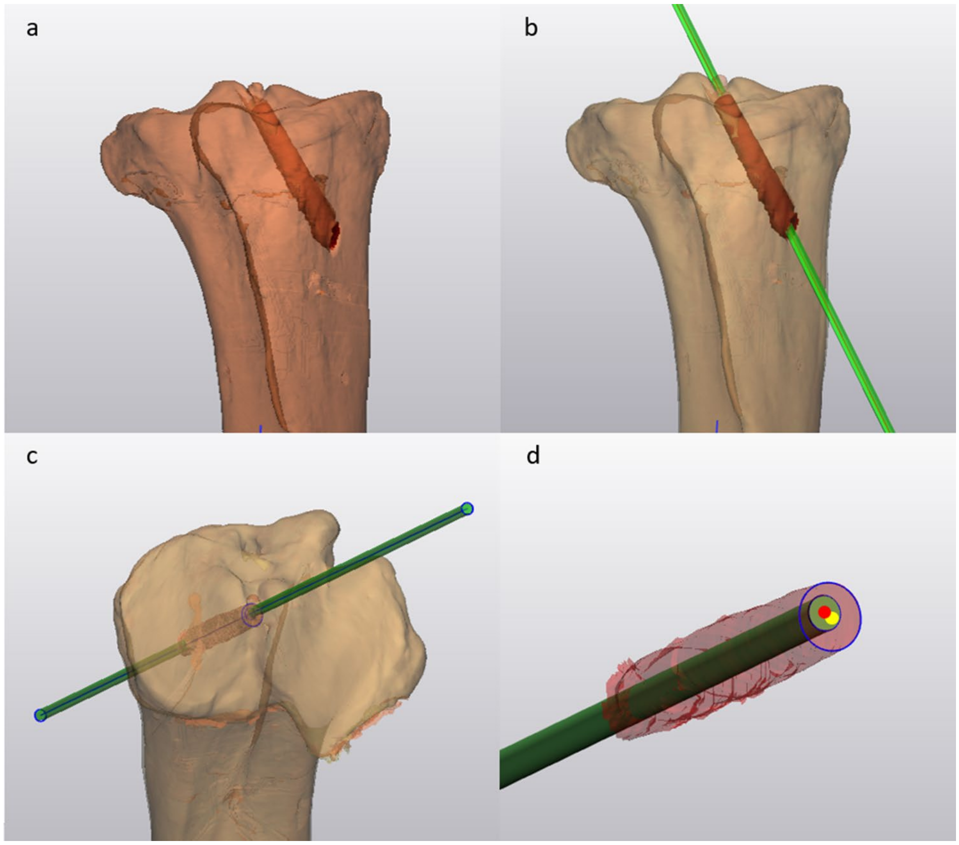

Fig. 5 Example of tibial post-interventional comparison of the drilled tunnel to the planned tunnel in Materialise 3-matic. (**a**) shows the postoperative bone model (orange) and the segmented drill tunnel (red). (**b** and **c**) show superimposed pre- (yellow) and post-interventional (orange) bone models, segmented drill tunnel (red) and planned drill guide (green) in lateral and p.a. view. (**d**) In a more detailed view, the bone tunnel (transparent red) and the planned drill guidewire (green) were cut at the level exiting the bone. The yellow point marks the centre of the achieved bone tunnel and the red point marks the centre of the planned tunnel. The distance between these two centre pointes was measured.

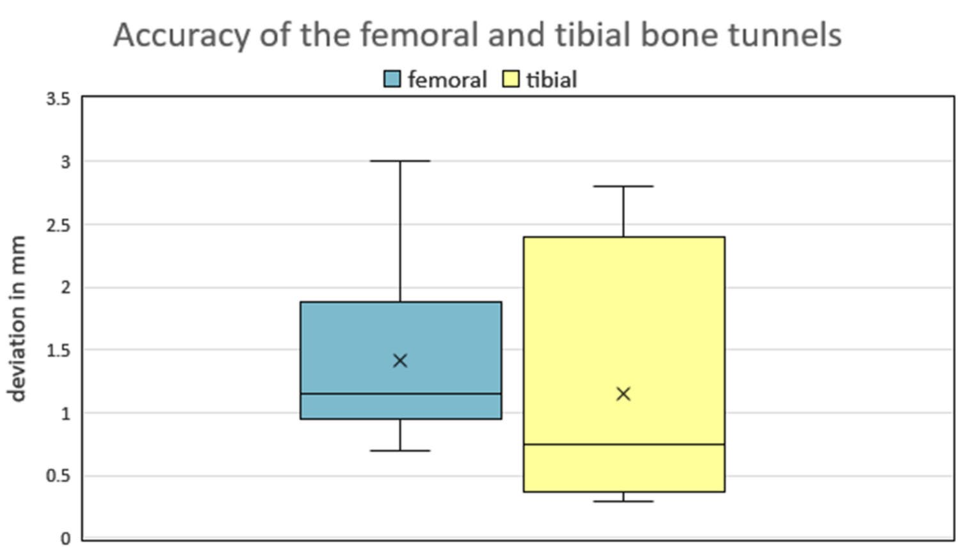

Fig. 6 Boxplot of deviation between preoperative and postoperative tunnel position. The distribution of tunnel deviations in millimeters (mm) for both the tibial (yellow) and femoral (blue) tunnels. The central box in each category represents the interquartile range (IQR) of the tunnel deviation values, with the median indicated by the horizontal line inside the box. The "x" inside the box represents the mean value.

and planned tunnel was 3.0 mm, suggesting that outliers can be reduced with the help of the 3D printed guides.

The 3D planning of femoral ACL tunnel positioning and their execution with 3D printed PSI has only been explored by one other study using a different approach [16]. Rankin et al. presented a 3D printed ACL femoral tunnel guide, based on MRI scan of the contralateral uninjured knee. The guides were used arthroscopically and were shaped according to the inner part of the lateral femoral condyle. They allowed the surgeon to visualize the optimal starting point of the femoral tunnel via an opening within the guide. The authors found no statistical difference in size and positioning of the center of the ACL femoral footprint when compared to the original CAD model and MRI scans in two dimensions ($p = 0.375$). Compared to the presented technique, an inside-out technique was performed and only the femoral tunnel was drilled with the help of a 3D aiming guide. Moreover, there was no 3D analysis of the tunnels, which might have influenced their results. Nevertheless, their results are auspicious and support the arthroscopic usage of the patient-specific 3D printing technology.

This study has several limitations. First, soft tissue conditions were not considered. To use the guides in their current configuration in a human knee, detachment of the pes anserinus and part of the medial collateral ligament (MCL) would be necessary. Further studies based on human cadavers using adapted guides that respect soft tissues are needed before our results gain clinical relevance. Second, the 3D models were based on CT scans, although MRI is the common tool to diagnose ACL lesions. Furthermore, the anatomical footprints of our specimens could only be estimated based on anatomic studies. However, this should not have influence our results since the accuracy assessment was based on the comparsion between pre-and postoperative and not between native footprint and postoperative footprint. Third, in conventional ACLR small incisions are used, while bigger approaches are needed for the presented technique. Moreover, the periosteum needs to be elevated to guarantee accurate fit of the guides to the bone in the contact zone. Nevertheless, even applied in tibial osteotomies, this technique has shown to lead to sufficient bone healing [2, 22]. These potential disadvantages might be compensated by a higher accuracy and therefore, reduction of consecutive failures.

Conclusion

A high accuracy of ACL tunnel placement using 3D guides can be achieved. Applied to a clinical setting, this technique has the potential to significantly reduce complications due to misplacement of bone tunnels.

Author contributions

S.E. performed the 3D planning and analysis and drafted the manuscript. S.H. designed the figures and contributed to the writing of the manuscript. A.H. designed the study and contributed to the writing of the manuscript. A.H. and S.E. performed the surgeries. F.K. supervised the project, the main conceptual ideas and outline. All authors discussed the results, corrected and approved the final version of the manuscript.

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Data availability

All data analysed during this study are included in this article.

Declarations

Ethics approval and consent to participate

No ethical approval was needed.

Consent for publication

All authors approved the version to be published.

Competing interests

The authors have no competing interests to declare.

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