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Comparable Tibial Tunnel Widening despite Compound Differences of Bioabsorbable Interference Screws in Anterior Cruciate Ligament Reconstruction: a Retrospective Study

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SUMMARY

Purpose. To evaluate the effect of β-tricalcium phosphate (BCP) concentration in bioabsorbable interference screws on tibial tunnel widening after hamstring anterior cruciate ligament reconstruction.

Methods. A total of 37 patients with a mean follow-up of 4.6 years were included for analysis. Bioabsorbable interference screws containing 60% BCP and 40% poly-L,D-lactic acid (PLDLA) (60BCP group) or bioabsorbable interference screws containing 30% BCP and 70% PLDLA (30BCP group) were used for tibial graft fixation. A 16-slice multislice computertomography scanner with post-process multislab reconstructions was used for tibial tunnel evaluation. The tibial tunnel diameter was measured at the midpoint of the tunnel. Tunnel widening was defined as an increase of more than 2 mm compared to the intraoperative drill diameter.

Results. Patient demographics were not statistically different between both groups. The number of patients that showed tibial tunnel widening was high but did not differ statistically significant between the 60BCP and 30BCP group: 76% (n = 17) *versus* 75% (n = 20) for 60BCP and 30BCP group, respectively. The average increase in tibial tunnel diameter did not differ statistically significant between the groups; the tibial tunnel diameter increased with an average of 3.36 mm (SD 1.86) and 2.94 mm (SD 1.63) for the 60BCP and 30BCP group, respectively.

Conclusions. A high incidence of tibial tunnel widening was observed when bioabsorbable interference screws containing different concentrations of β-tricalcium phosphate were used to fixate the hamstring graft in anterior cruciate ligament reconstruction. Increasing the concentration β-tricalcium phosphate did not result in less tunnel widening.

KEY WORDS

ACL; anterior cruciate ligament reconstruction; bioabsorbable screw; tunnel widening; tunnel enlargement.

INTRODUCTION

Tunnel widening (TW) is a well-known phenomenon after anterior cruciate ligament (ACL) reconstruction (1-3) TW can be of importance in revision surgery as it complicates proper graft placement and fixation, making two-stage ACL revision surgery necessary (4). As there is an increasing incidence in ACL reconstruction and revision surgery, postoperative TW may affect many patients (5).

The etiology of TW is multifactorial, including mechanical, biological and surgical factors such as type of graft fixation (6, 7). Metallic interference screws (MIS) were traditionally used for graft fixation. These screws were associated with an increased risk of graft damage and difficulty of implant removal (8). In order to address these concerns, bioabsorbable interference screws (BIS) have been introduced with good clinical results (1, 2), but comparing to MIS the BIS are unfortunately leading to more TW (8). Initially, BIS were predominately made of poly-L-lactic acid (PLLA) and subsequently poly-L,D-lactic acid (PLDLA) (9). β-tricalcium phosphate (BCP) was added to increase absorption rate while facilitating bony ingrowth by stimulating osteogenesis (10). The purpose of this study was to compare the incidence and degree of tibial TW between two BIS with different BCP concentrations after hamstring ACL reconstruction. We hypothesized BIS with higher concentrations of BCP showing less tibial TW than BIS with lower concentration of BCP.

MATERIALS AND METHODS

This study was approved by the local ethical institutional review board (IRB; METC-Z, Heerlen, the Netherlands - Date of approval: July 12, 2016) and all patients provided oral and written informed consent before enrollment (IRB no 16-T-41). Patients who underwent an ACL reconstruction between January 2012 and May 2014 were recalled for radiological evaluation. Inclusion criteria were: ACL reconstruction using hamstring graft and use of bioabsorbable screws for tibial graft fixation. Exclusion criteria were: revision ACL surgery, rerupture and screw removal. A total of 37 patients with a mean follow-up of 4.6 years were included in the analysis (**figure 1**). For tibial graft fixation two different bioabsorbable screws were used: 1) ComposiTCPTM interference screw (Biomet, Warsaw, Indiana, United States) containing 60% BCP and 40% PLDLA (60BCP group) or 2) Biocomposite interference screwTM (Arthrex, Naples, Florida, United States) containing 30% BCP and 70% PLDLA (30BCP group). The screws are comparable in design.

Surgical technique

All patients underwent a single-bundle ACL reconstruction using autologous semitendinosus and gracilis graft.

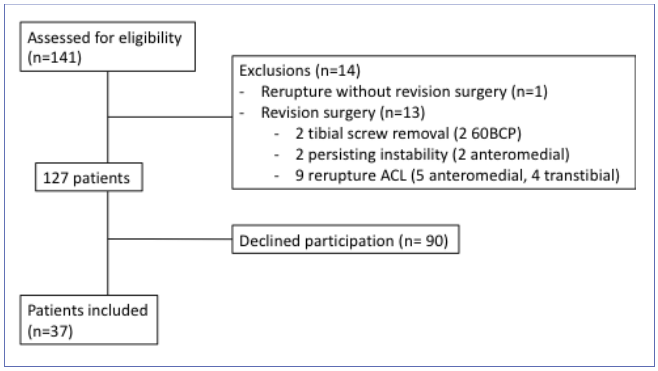

Figure 1. Flowchart of the patients included in the study.

An oblique incision was performed to harvest the semitendinosus and gracilis. A transtibial or anteromedial technique, randomly chosen, was used for femoral tunnel placement. In the transtibial technique, a cannulated reamer was used transtibially to create the femoral tunnel. A Transfix screwTM (Arthrex, Naples, FL, United States) was used for femoral fixation. In the anteromedial technique, an accessory anteromedial portal was made to define the femoral origin of the native ACL. The knee was then flexed to 120-130° and the guidewire was advanced. The tunnel was drilled with a cannulated reamer. A cortical button (Toggle Loc, Biomet, Warsaw, Indiana, United States) was used for femoral fixation of the graft. The tibial tunnel was prepared in the footprint of the ACL at an angle of 45° to the tibial shaft. Tibial fixation was performed in 20° of flexion using a randomly chosen BIS. The diameter of the chosen screw is always 1 mm bigger than the drilled diameter. All operations were conducted by one single experienced surgeon.

Radiological evaluation

A 16-slice multislice computertomotography (MSCT) scanner (MX 8000, Philips Medical Systems, Cleveland, OH, United States) with post-process multislab reconstructions (Horos DICOM medical image viewer, v2.2.0, general public license, United States) on sagittal, coronal and axial planes was used for tibial tunnel evaluation. Slice thickness was 1 mm. The tibial tunnel diameter was measured at the midpoint of the tibial tunnel, perpendicular to the tunnel axis between the two widest sclerotic margins, on the axial plane of the 2D reconstruction (**figure 2**). TW was defined as an increase of more than 2 mm in the tibial tunnel diameter compared to the intraoperative drill diameter (2). Furthermore, the intraclass correlation coefficient (ICC) was calculated to evaluate the reliability of the measurements, the second measurements are conducted by an independent researcher.

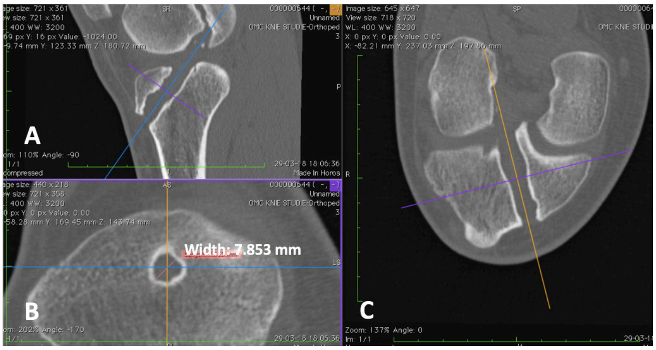

Figure 2. Measurements of the tunnel diameter at the midpoint of the tibial tunnel using computerized tomography. **(A)** sagital view; **(B)** axial view; **(C)** coronal view. The tibial tunnel diameter was measured at the midpoint of the tibial tunnel on the axial plane of the 2D reconstruction, perpendicular to the tunnel axis between the two widest sclerotic margins.

Statistical analysis

Statistical analysis was performed using SPSS version 24.0 (SPSS, Inc, Chicago, IL, U.S.A.). Descriptive statistics were used to summarize data. Statistically significant differences between the groups were analyzed with Mann-Whitney U test. We conducted a post-hoc power analysis to reveal the statistical power of the study. Results are presented as either frequencies (%) or mean (standard deviation, SD). The level of statistical significance was set at $p \leq 0.05$.

RESULTS

In this study 37 patients were included: 20 patients in the 30BCP group, and 17 patients in the 60BCP group. **Table I** shows the patient demographics. Both groups were not significantly different with one exception. A transtibial technique for femoral tunnel placement was used significantly more in the 30BCP than in the 60BCP group ($p = 0.007$); 65% (n = 13) in the 30BCP group *versus* 18% (n = 3) in the 60BCP group. The number of patients that showed tibial TW, was high but did not differ significantly between the 30BCP and 60BCP group: 75% (n = 15) *versus* 76% (n = 14). In these cases, in which TW was shown, tunnel diameter increased with an average of 2.94 mm (SD, 1.63) and 3.36 mm (SD, 1.86) as compared to the intraoperative drill diameter for the 30BCP and 60BCP group, respectively (**table II**). The calculated ICC was between 0.84 and 0.99 indicating a good to excellent reliability (11).

DISCUSSION

The most important finding of the present study was that bioabsorbable interference screws with a high concentration of β-tricalcium phosphate did not show less tibial tunnel widening as compared to screws with lower β-tricalcium phosphate concentrations.

Theoretically, a calcium phosphate such as BCP, Hydroxyapatite (HA) or calciumcarbonaat is added to the bioabsorbable screw to increase the absorption rates, enhance osteogenesis and reduce oxidation (12). Screws with an added calciumcarbonaat lead to less TW (12), but there is no consensus about the variation of the composition. A higher concentration of BCP in BIS reduces TW by promoting bony ingrowth in several processes: 1) BCP degrades into phosphate and calcium ions promoting bony ingrowth, and 2) BCP releases basic salts (high pH) normalizing the acidic environment created by degradation of L-lactic acid (PLLA) (10). The resulting higher pH might reduce local reaction during the degradation process. However, this study did not show lower incidence of TW when using BIS with higher BCP concentrations. Interestingly, we observed a high incidence of TW using BIS with both high and low concentrations of BCP. Our findings are comparable with the literature. Wang *et al.* (9) studied BIS that consisted of 30% BCP and 70% PLLA. They showed TW at the tip of the screw suggesting screw-bone contact is necessary for bony ingrowth. In a recent case series report (13) bioabsorbable screw related complications in children and adolescent were reported. In their study

Table I. Patient characteristics.

	60BCP group n = 17	30BCP group n = 20	P-value
Age, years (SD)	31.2 (6.4)	31.9 (7.7)	0.892
Male, n (%)	11 (65)	10 (50)	0.509

Table II. Measurements of the increased diameter of the midpoint of the tibial tunnel.

	30BCP group n = 20	60BCP group n = 17	P-value
Increased diameter	2.94 (1.63)	3.36 (1.86)	0.424

Results are in mm and (SD.)

925 screws were used with a complication rate of 9.6%. The most common surgical indication was pain at the tibial site (93%) and intra-articular screw issues (7%) like sterile cyst formation. After screw removal 93% of the patients had complete resolution of screw site symptoms. There were serious concerns about bony ingrowth.

Barber and Dockery (14-16) have performed multiple studies on several bioabsorbable screws to evaluate postimplantation bony ingrowth, each study used about 20 screws. They showed that screws containing 25% BCP and 75% PLLA have 75% osteoconductivity and in only 10% the tibial tunnel was totally ossificated (14). In another study they showed that 19% of the tunnel was fully ossificated when screws consisted of 30% BCP and 70% PLLA (15). On the other hand, 25% of the tunnels showed total ossification when screws made of 23% BCP were used (16). They concluded that there is no "best concentration" of BCP and none of the BIS used has showed total ossification.

Combining this with our results we've serious concerns about the bony ingrowth and ossification capacity of bioabsorbable screws. Besides all these bioabsorbable screws there are also novel studies with polyether-ethyl ketone (PEEK) screws, but these are showing the same amount of tunnelwidening (17) as the PLLA-BCP screws.

In this study, a multisliced CT scanner was used to evaluate TW. In literature, imaging methods such as radiographs, CT and MRI have been used to assess TW after ACL reconstruction (1). Radiographs are sufficient in defining positioning of the tunnel (18). Moreover, radiographs have the benefit of widespread availability and low cost. However, previous studies demonstrated that measurement of TW on radiographs may result in an underestimation of TW (19). MRI allows an accurate evaluation of TW and soft tissue (20). However, MRI is susceptible for artefacts caused by metallic implants such as buttons, screws or pins. These artefacts can limit evaluation of TW. Besides, sclerotic margins of bone tunnels are poorly visualized compared to CT (21). CT provides an accurate assessment of the size and shape of the tunnel walls with high reliability and has been considered the gold standard in assessing TW after ACL reconstruction (1, 22). Measurements should be performed in 3D CT, if available, as TW does not seem to be an organized symmetric expansion of the tunnel (22).

The tibial tunnel diameter was measured at the midpoint of the tibial tunnel, perpendicular to the tunnel axis (23). We found ICC scores between 0.84 and 0.99, which indicates this measurement conditions provide optimal accuracy for measuring tibial tunnel diameter. Measuring tunnel diameter exactly perpendicular to the tibial tunnel is a requirement to avoid overestimation of this measurement (1). Therefore, different methods have been reported in the literature to evaluate TW on CT, varying from measuring at one level in the tibial tunnel until five different levels. Beus *et al*. created an overview of these different methods for assessing tunnel widening on CT without consensus of the most suitable level to perform these measurements. None of these options were considered as golden standard. As TW can be induced by absorption processes around the bioabsorbable screw, it was thought that measuring should be done in the middle of the tibial tunnel, nearby this point is mostly also the tip of the screw located (9, 24).

In the present study the ACL reconstruction was performed using a single-bundle hamstrings graft with screw fixation and a transtibial or anteromedial technique for femoral fixation with screw or button. There are endless possibilities for conducting an ACL reconstruction. We've used a direct fixation method with BIS, but you could also choose cortico-cancellous transfixation with a cross pin or a cortical suspensory fixation using adjustable loops with buttons (25). Mayr *et al*. showed less tibial TW using adjustable loops with buttons compared to the direct fixation with BIS (2), but Giorgio *et al*. is showing less tibial TW using BIS as a fixation compared to a tightrope system with buttons (26). So, there is still no consensus about the best fixation technique.

This study has several limitations. Firstly, the retrospective design of this study has inherent limitations due to the risk of bias and confounding. However, patient characteristics were not significantly different between the groups. Secondly, the study population was relatively small. We conducted a power analysis which revealed that based on the results of the present study approximately 105 patients in each group would be needed to obtain recommended statistical power. Randomized controlled trials with increased number of patients are needed to confirm our results. Thirdly, transtibial tunnel placement was less frequently performed in the 60BCP group compared to the 30BCP group, which makes it important analyzing the influence of the technique on TW. Previous studies demonstrated higher incidence of tibial TW after transtibial ACL reconstruction as compared to the anteromedial technique (27). The transtibial technique increases anterior joint laxity which leads to TW. However, a previous study demonstrated that screw properties have more influence on TW than the chosen surgical technique (28).

CONCLUSIONS

Bioabsorbable interference screws containing different concentrations of β-tricalcium phosphate showed high incidence of tibial tunnel widening after anterior cruciate ligament reconstruction. An increased concentration of β-tricalcium phosphate in the bioabsorbable interference screws did not result in less tibial tunnel widening as compared to the screws with a lower concentration.

FUNDINGS
None.

DATA AVAILABILITY
All of the relevant data of this study is available at the Orthopaedics research Department at Zuyderland Medical centre, Dr. H. vd Hoffplein, Sittard-Geleen, The Netherlands.

CONTRIBUTIONS
All authors agreed to be accountable for all aspects of the work. GK, RB: data collection. GK, MS: methodology and statistics. GK: first draft, editing. BK, MS, EJ: writing and editing. MS, EJ: conceptualization and study design, supervision.

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CONFLICT OF INTERESTS
The authors declare that they have no conflict of interests.

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