

Investigating the primary stability of the transversal support tibial plateau concept to retain both cruciate ligaments during total knee arthroplasty

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ABSTRACT

Purpose: The important roles of the anterior cruciate ligament regarding knee stability, physiologic kinematics, and proprioception are unquestioned. Thus, various efforts have been made to retain the ACL during total knee arthroplasty (TKA). Neither of the existing solutions to this problem, i.e. bicruciate retaining prostheses and implantation of two unicondylar prostheses, has been successful because of concept-specific problems as well as general difficulties with implant fixation. The new transversal support tibial plateau concept is a prosthesis of two individual joint surfaces reinforced beneath the articular line by joint surface supports and buttressed by a single transversal support. This configuration, which enables retention of both cruciate ligaments, should provide good bone fixation and ensure long-term alignment of the individual joint surfaces.

Methods: In the current study, four prototypes based on this novel concept were developed and the resulting primary stability was analyzed using adapted load testing.

The test set-up, with the model-loading of specially prepared Sawbones[®] and a sinusoidal oscillating load transmission with 25 000 cycles over 10 increasing load levels, achieved subsidence, which enabled comparison of the four different model variants regarding primary stability in view of bone anchoring.

Results: The model variant (TS_{mobile}) that allowed transverse glide of the joint surface supports along the transversal support revealed the largest subsidence.

Conclusions: A rigid attachment of the joint surface supports of the transversal support tibial plateau thus appears to offer increased primary stability regarding bone anchoring.

Key words: Cruciate retaining, Primary stability, Total knee arthroplasty, Transversal support tibial plateau

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INTRODUCTION

Artificial knee replacement with endoprosthesis has been established now for several decades. In the coming decades, the number of implantations will increase rapidly (1,2).

Depending on the severity and extent of the arthritic changes, as well as the ligament stability of the knee to be treated, different prosthetic types are selected, i.e., unicondylar or bicondylar knee arthroplasty, which can be further broken down into non-constrained, (semi)constrained and fully constrained (hinge) designs.

For the commonly performed total knee arthroplasty (TKA), bicondylar prostheses are generally used as primary treatment. There are multiple designs from which to choose, which are further classified according to preser-

vation of the cruciate ligaments, i.e. bicruciate retaining (BCR), posterior cruciate retaining (PCR), and posterior cruciate sacrificing (PCS).

Although the important role of the anterior cruciate ligament (ACL) regarding knee stability, physiologic kinematics, and proprioception is well recognized, to date no bicruciate-retaining prosthesis has achieved general acceptance (3).

Numerous studies (4-9) have shown that after artificial knee replacement with the popular posterior cruciate retaining (PCR) prosthesis, non-physiologic knee kinematics prevail. Using computer-assisted fluoroscopy to perform in vivo measurements, Dennis et al. (10) found that knees with PCR prostheses perform similarly to non-replaced knees with (ACL) insufficiency.

A further consideration in the selection of knee

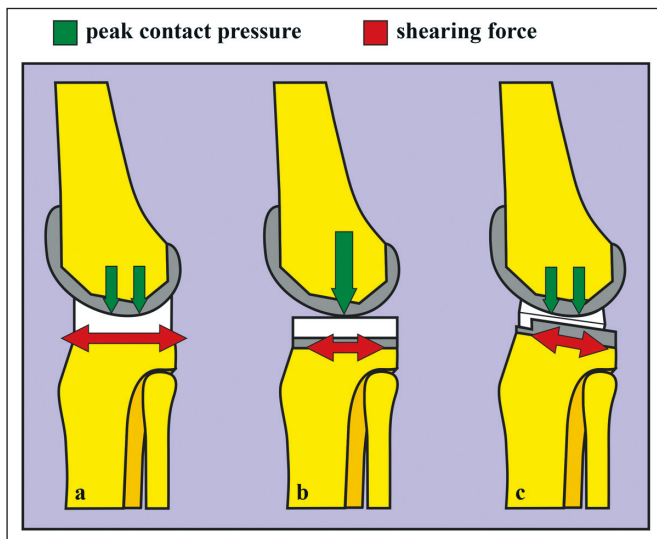


Fig. 1 - The stages of development in the 1970s, according to Buechel and Pappas (30), modified (3):
 a) Congruency without mobility leads to increased risk of loosening,
 b) Mobility without congruency causes increased abrasion,
 c) Mobility with congruency can unite both favorable properties: decreased shearing forces by reduced contact stress.

prostheses is component fixation. Although the femoral component of bicondylar knee prostheses has remained problem-free from the beginning regarding long-term fixation, the tibial plateau fixation concept has required multiple adaptations. This is because of the shearing forces in highly congruent designs, which lead to premature aseptic loosening of the tibial component (Fig. 1a). At this point, two paradigms are well established: less congruent designs with fixed inlays (Fig. 1b), and highly congruent mobile bearing inlays (Fig. 1c).

The first type shows increased inlay abrasion because of the high point pressures in surface contact. However, the use of mobile inlays decreases stability (3). Thus, various guides or stops are generally used to limit mobility, which in turn also increase shearing forces (11).

In conventional designs, fixation of the prosthetic components into the proximal tibia is frequently supported by a central axial stem, either cone-shaped or another geometric form (Fig. 2). However, this design does not allow retention of both cruciate ligaments. With ACL retention, the joint cannot be opened wide enough intra-operatively to allow insertion of a stem of customary length. In addition, the attachment of the ACL in the anterior intercondylar area cannot be maintained with this technique.

In the past, two different approaches have primarily been implemented to retain the ACL during TKA:

One solution was the use of a modified PCR prosthesis, in which the recess for the PCL was extended anteriorly (Fig. 3a). Because of the enlarged recess, the implant bridge anteriorly across the tibial plateau is relatively narrow. Implant failure can result from the torsion loading in



Fig. 2 - Example for a tibial plateau with central stem to support the fixation. Reprinted by courtesy of balanSys™, ©Mathys AG Bettlach.

this region (3). In addition, the short anchoring elements cannot prevent increased implant loosening. Fixation is not as good as that in traditional PCR prostheses, because of the lack of a central stem (12).

Another solution used for ACL retention was the implantation of two unicompartmental knee prostheses. This procedure was reported already in 1984 by Goodfellow and O'Connor (13). Previous studies have reported worse outcomes for the lateral unicompartmental implant versus the medial implant (14). For example, bearing dislocation in particular was greater in the lateral than in the medial compartment using the Oxford Unicompartmental Knee (15).

Unicompartmental components are also difficult to fixate and orientate. In the long-term, varying subsidence by the separate compartments can also be a problem. Even when optimal alignment of both plateaus is attained intra-operatively, implant subsidence can lead to asymmetry of the joint surface levels and misalignment of the components (Fig. 3b). Such unfavorable loading can lead to increased wear and excessive erosion (Fig. 3c).

In recent years, the implantation of two unicompartmental knee prostheses has again been increasingly performed (16-18).

These considerations prompted us to develop the transversal support tibial plateau (TSTP) concept (3, 11). Essentially, the TSTP consists of two individual joint surfaces (JS) reinforced beneath the joint line by joint surface supports (JSS) and buttressed by a single transversal support (TS) (Fig. 4).

This configuration should provide good bone fixation especially for the TS, and ensure long-term alignment of the individual joint surfaces.

Because this is a new treatment concept in the field of tibial plateau fixation, there is no evidence currently

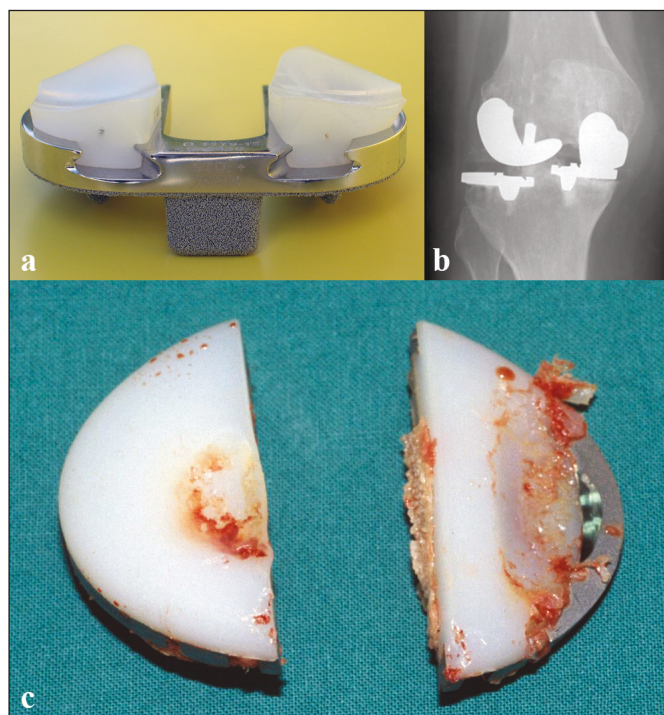


Fig. 3 - Current approaches to retain both cruciate ligaments in total knee arthroplasty:
 a) LCS® Bicurciate Retaining Prosthesis as an example of a PCR prosthesis derivative: fixation is not as good as in traditional PCR prostheses because of the lack of a central stem. Only short anchoring wings can be used.
 b) Radiograph of a knee treated with two unicondylar knee prostheses: even when optimal alignment of both plateaus is attained intra-operatively, implant subsidence can lead to asymmetry of the joint surface levels and misalignment of the components. Such unfavorable loading and wear can lead to increased PE abrasion.
 c) Explant from Fig. 3b: the medial PE inlay was completely eroded after only six years and revision arthroplasty was required (3).
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available regarding primary stability. In addition, because this remains a mere treatment concept, a definitive design has not yet been established. The current study then examines the primary stability of four different prototypes designed using the principle of two individual joint surfaces supported as one beneath the articular plane.

MATERIALS AND METHODS

Initially, four different prototypes of the TSTP concept were developed, and corresponding models produced for implantation.

Model 1 (TS_{fixed}, Fig. 5a): This version most closely resembles the original illustrative model (Fig. 4). Both individual joint surfaces (JS) are screwed to the joint surface supports (JSS) so that they are form-fitting and rotationally



Fig. 4 - The transversal support tibial plateau consists of two joint surfaces (JS), reinforced beneath the joint line by two joint surface supports (JSS) and buttressed by a single transversal support (TS) (3).
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stable. The JSS are set at an angle of 60°, simplifying the intra-operative drilling technique. Fixation to the transversal support (TS) is performed by a single secured screw coupling.

Model 2 (TS_{mobile}, Fig. 5b): As in model 1, the two JS are connected to the JSS with screw couplings. In contrast, however, the TS fits into the JSS with a keyed design assembly not fixed in the transverse axis, thus allowing relative movement of the individual JSS.

Model 3 (VS_{plus}, Fig. 5c): The attachments of both JS to the JSS are screw couplings, as for model 1. However, through the distally extended JSS they form a V-shaped (VS) framework with an angle of 50°. The two JSS are intertwined and secured with the TS, which has been reduced to a small screw. As for model 2, there is no additional cortical support for this region.

Model 4 (VS_{standard}, Fig. 5d): This model is principally an analog of model 3; however, in this version the TS is completely discarded, and the original support concept is reduced to the direct connection of the two JSS, a V-shaped (VS) framework.

The four prototypes were initially drafted using computer-aided design (CAD, CATIA V5, Dassault Systèmes, Vélizy-Villacoublay, France). Next, the models were pro-

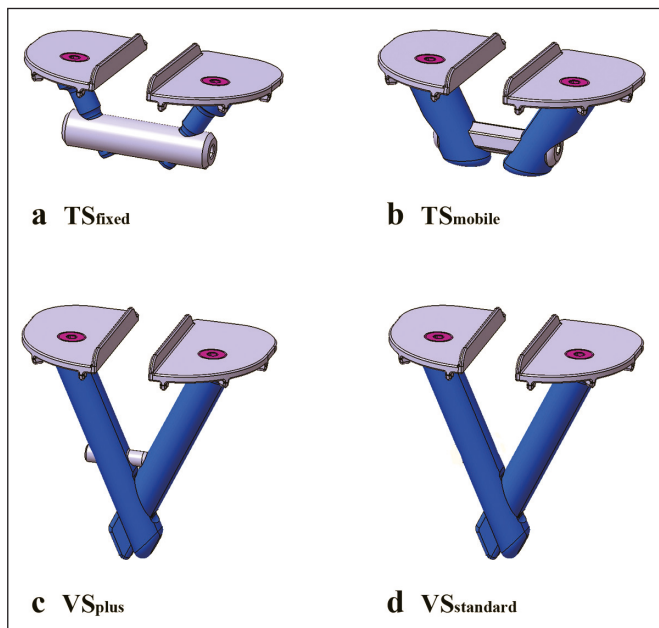


Fig. 5 - Different prototypes of the TSTP concept:
 a) Model 1 (TS_{fixed}): Both individual joint surfaces (JS) are screwed to the joint surface supports (JSS) so that they are form-fitting and rotationally stable. Fixation to the transversal support (TS) is performed by a single secured screw coupling.
 b) Model 2 (TS_{mobile}): In this model, the TS fits into the JSS with a keyed design assembly that is not fixed in the transverse axis, thus allowing relative movement of the individual JSS.
 c) Model 3 (VS_{plus}): Here the distally extended JSS forms a V-shaped framework stabilized over a reduced TS.
 d) Model 4 ($VS_{standard}$): This is an analog of the VS_{plus} design; however, the TS is completely excluded.

duced using a CNC milling machine (Deckel DMU50, DECKEL MAHO Pfronten GmbH, Pfronten, Germany) and a CNC turning machine (Benzinger TNC, Carl Benzinger GmbH, Pforzheim, Germany). A typical implant alloy of CoCr29Mo was selected as material.

For stability testing, the uncemented models were implanted into synthetic bone (Sawbones®) using specially manufactured targeting and insertion devices (Fig. 6). We deliberately chose a synthetic material to eliminate compounding variables, e.g. varying bone quality in cadaver specimens or animal models. The synthetic bone specimens chosen were large left fourth generation composite tibiae. Particular rigidity and pore density parameters of the synthetic cancellous bone can be selected. For example, density properties of the cancellous elements range from 6.25 - 62.5 pounds per cubic foot (pcf) or 100 – 1000 kg/m³. Since bone quality in patients is often already diminished by the time TKA is indicated, synthetic cancellous bone with correspondingly reduced density of 12.5 pcf with large pores was selected to simulate realistic conditions.

During preliminary testing, the hard synthetic bone surrounding the tibial resection plane did not allow

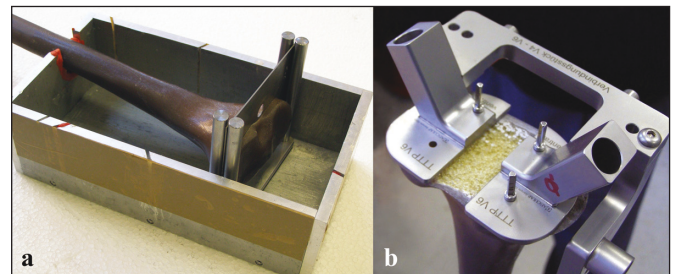


Fig. 6 - Insertion and targeting devices for consistent implantation of the prototypes into synthetic bone:
 a) Cutting guide for selective preparation of the proximal tibia,
 b) Targeting device for correctly aligned implantation of the JSS and the TS.

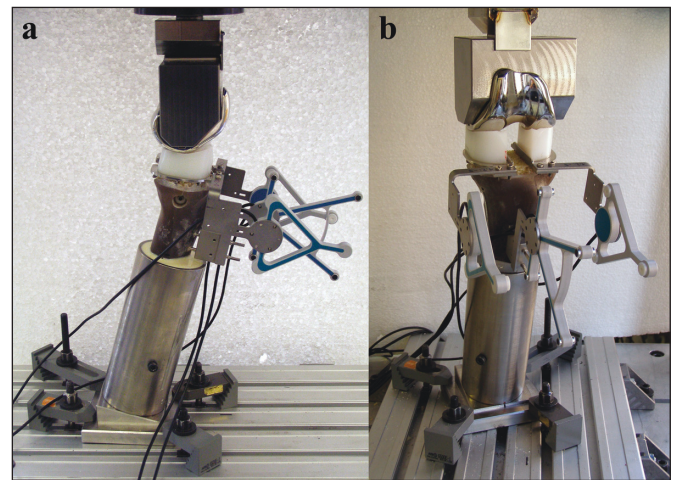


Fig. 7 - Test Set-Up: sinusoidal load application with a four-column dynamic test machine (Dyna-Mess, Stolberg, Germany). A special control device was used to distribute axial force over a conventional femoral component (e.motion® size F7, Aesculap AG, Tuttlingen, Germany) and the fitted inlays. To measure the relative motion between the JS and the bone, an ultrasound-based 3D motion analysis system (CMS20BI, Zebris, Isny, Germany) was used.

relevant positional motion. Therefore, the Sawbones® were specially prepared by grinding the cortex in the tibial plateau resection plane area. The test set-up (Fig. 7) for cyclical load application of the components was assembled using the standard ASTM F1800-07 (19) and ISO 14879-1 (20) with a corresponding load ratio F_{min}/F_{max} of 1:10 (Tab. I). The sinusoidal load, with a cycle duration of one second, was applied using a four column dynamic test machine (Dyna-Mess, Stolberg, Germany). A special control device was used to distribute the axial force over a conventional bicondylar femoral component (e.motion® size F7, Aesculap AG, Tuttlingen, Germany) and the corresponding inlays in a proportion of 60%/40% between medial and lateral as suggested by Zhao et al. (21), as well as a deflection of the point transmission of force to a proportion of 70%/30% towards posterior as suggested by Jong et

TABLE I - TEST SETUP

Synthetic bone	Sawbones®, Cellular Rigid Polyurethane Foam 12.5 pcf Density
Impulse generator	Four-columned dynamic test machine (10 kN), Dyna-Mess, Stolberg, Germany
Load transmission	Eccentric load: 60% medial, 40% der lateral, point transmission of force 70/30 posterior
Load application	Sinusoidal oscillation, $F_{min}/F_{max} = 1:10$; cycle duration 1 s
Load level	$F_{min} 90 \text{ N} - 360 \text{ N}$; $F_{max} 900 \text{ N} - 3600 \text{ N}$
Load step-up	$F_{min} 30 \text{ N}$; $F_{max} 300 \text{ N}$
Number of load levels	10
Number of cycles	2500 cycles per load level, total 25 000 cycles
Measuring system	Ultrasound-based 3D motion analysis system CMS20BI, Zebris, Isny, Germany
Recording mode	each 50 th cycle, duration 2 s
Sample rate	25 Hz

al. (22). A total of ten measurements were performed. Initial measurements had a starting load level of $F_{min} = 90 \text{ N}$ and $F_{max} = 900 \text{ N}$. The subsequent nine measurements proceeded with gradual increases, concluding with a maximal load level of $F_{min} 360 \text{ N}$ and $F_{max} 3600 \text{ N}$.

An ultrasound-based 3D motion analysis system (CMS20BI, Zebris, Isny, Germany) was used to determine the relative motion between the JS and the bone. To accomplish this, a specially manufactured mounting device was necessary to attach the probe to the JS (Fig. 8). To assess the relative movements of the JS, two moving points (MP) were defined as measuring points anteriorly and posteriorly on the tibial plateau, and the positional changes compared to reference points in the synthetic bone and analyzed. Recordings were taken each 50th cycle for two seconds with a sample rate of 25 Hz. Three series of tests were performed for each profile.

To estimate and test the effect of the model and the moving point on subsidence, a linear regression model was fit to the data.

Subsidence measures were transformed using the natural logarithm to comply with the model assumptions. All comparisons were a-priory planned and tested at the statistical significance level of $P < 0.05$. Calculations were performed using the statistical software R, R Development Core Team (23), version 2.10, R Foundation for statistical Computing, Vienna, Austria (23).



Fig. 8 - Individual joint surface (JS) with mounting device to attach the ultrasound probe.

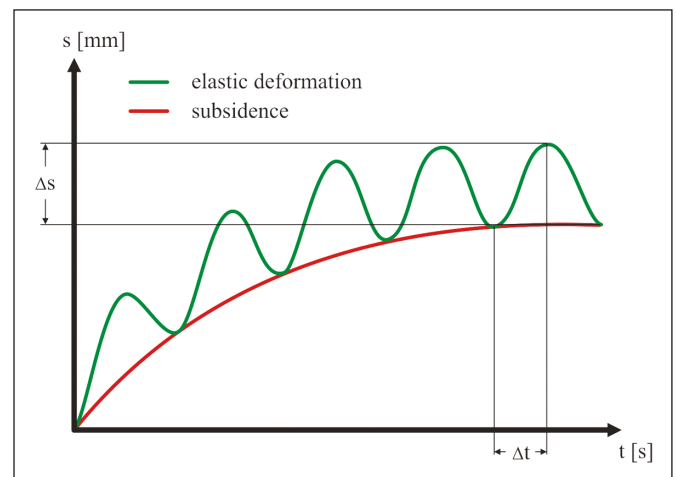


Fig. 9 - Micromotion between implant and bone consists of subsidence and elastic deformation. Subsidence was an irreversible change of implant position and elastic deformation was fully reversible after unloading.

RESULTS

Micromotion between implant and bone consists of two superimposed movement components, i.e., subsidence and elastic deformation (Fig. 9). Subsidence is an irreversible change in implant position, which remains after unloading of the implant. Elastic deformation is evoked through the cyclical loading, and is fully reversible on removal of load. Within one load grade, with increasing time, subsidence nears a constant level, whereas elastic deformation continues with the same amplitude.

For each of the four models, three measurements of

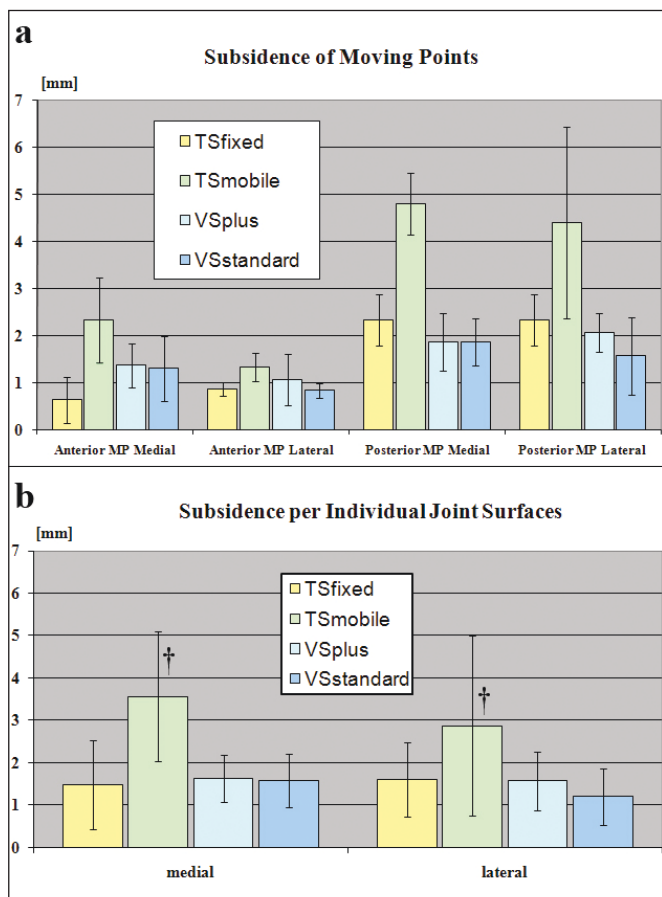


Fig. 10 - Summary of average values per prototype:
 a) All endpoints of subsidence after the highest load level (F_{min} 360 N / F_{max} 3600 N),
 b) Depiction of the summarized averages from anterior and posterior of each JS.
 † JS subsidence was significantly larger for the variant TS_{mobile} than for the other three models ($P < 0.001$).

subsidence were taken at each of the four moving points (MP), resulting in a total of 48 measurements.

Subsidence tended to increase for all four different models with increasing load levels, and the largest sub-

sidence was measured for each model at the highest load level (F_{min} 360 N / F_{max} 3600 N). Closer inspection of this end state of subsidence follows. The largest measured average of each of the three test series was 4.8 mm (SD 0.7 mm) for the posterior medial MP of TS_{mobile} and the smallest was 0.6 mm (SD 0.5 mm) for the anterior medial MP of TS_{fixed} (Fig. 10a). JS subsidence was apparent on the combined anterior and posterior MP measurements (Fig. 10b). With 3.6 mm (SD 1.5 mm) medially and 2.9 mm (SD 2.1 mm) laterally, JS subsidence was statistically significantly larger for the TS_{mobile} design concept than for the other three models ($P < 0.001$; Tab. II).

After calculation of the averages from all four MPs (anterior medial, anterior lateral, posterior medial, and posterior lateral), total implant subsidence could be approximated (Fig. 11a). Similar to the individual analysis, with 3.2 mm (SD 1.8 mm), Variant TS_{mobile} subsided significantly more than the other three models ($P < 0.001$; Tab II).

Finally, the average subsidence was calculated for each MP from all models (Fig. 11b). Here, the margin of difference between the anterior and posterior MPs versus that between the medial and lateral MPs was significantly larger ($P < 0.001$), as was direct contrast between the anterior and posterior MPs ($P < 0.001$); Table II.

Along with the measurements, additional findings from the implantation procedure were:

TS_{fixed} : This design called for the TS alignment to be 35 mm beneath the joint line. Thus, drilling took place in the tibial region that narrows considerably. This resulted in a tendency for the drill to deviate from the desired course.

TS_{mobile} : After loading was finished, some extent of bone fissuring was evident. This appeared to stem from increased marginal cortical contact by the JSS, which in this prototype are constructed with a proportionately large diameter.

VS_{plus} : Long fixation, which could be implanted with relatively little bone-sparing. The long JSS barely avoided contact with the cortex of the narrowed tibia. Depending on the geometric configuration of the tibia, there is a risk of perforation. Because of the additional tensioning of

TABLE II - THE COLUMN "ESTIMATE" DENOTES THE ESTIMATED SUBSIDENCE ON THE LOGARITHMIC SCALE. THE COLUMN "95% CI" DENOTES THE 95% CONFIDENCE INTERVALS AND THE LAST COLUMN DENOTES THE P-VALUE. THE INTERCEPT CORRESPONDS TO THE MEAN SUBSIDENCE ON THE LOGARITHMIC SCALE

	Estimate	95% CI	P-value
(Intercept)	0.46	[0.34; 0.58]	<0.001
Model: TS_{mobile} - mean of TS_{fixed} , VS_{plus} , $VS_{standard}$	0.73	[0.46; 1.0]	<0.001
Model: TS_{fixed} - mean of VS_{plus} , $VS_{standard}$	-0.10	[-0.38; 0.19]	0.51
Model: VS_{plus} - $VS_{standard}$	0.16	[-0.17; 0.49]	0.34
MP: (medial-lateral) - (anterior-posterior)	0.92	[0.59; 1.25]	<0.001
MP: anterior - posterior	-0.80	[-1.03; -0.57]	<0.001
MP: posteromedial - posterolateral	-0.07	[-0.39; 0.26]	0.70

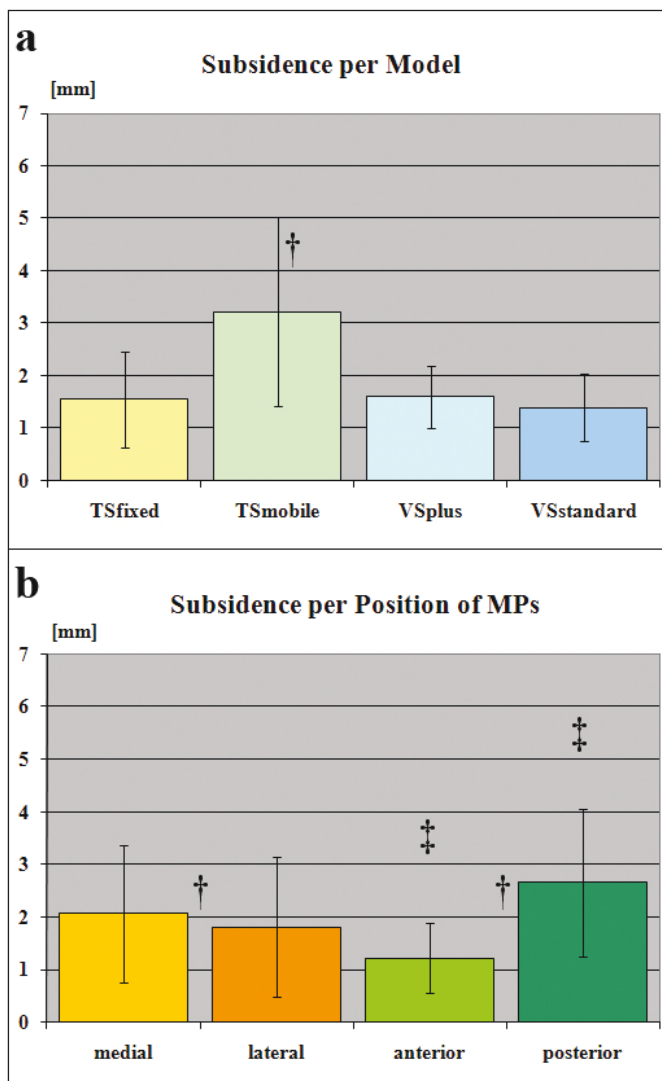


Fig. 11 - a) Total subsidence per implant.
 † Variant TS_{mobile} subsided significantly more than the other three models ($P < .001$).
b) Summary of the average values of the four different models by individual MP.
 † Margin of difference between anterior and posterior MPs compared to that between medial and lateral is significantly larger ($P < 0.001$).
 ‡ Direct contrast between anterior and posterior MPs is statistically significant ($P < 0.001$).

the JSS with the TS screw, there was some construction-related tipping of both JS towards each other.

$VS_{standard}$: Similar to VS_{plus} but without the JS tipping.

DISCUSSION

Most importantly, retention of the ACL in an endoprosthesis-treated knee joint should achieve the following: increased stability, physiologic motion of the joint with improved gait pattern, as well as improved proprio-

ception and balance. According to Buechel and Pappas (24), abrasion is the limiting factor of long-term implant survival, if fixation problems are avoided for the first 10 to 20 years. The gains in inherent stability of the endoprosthesis-treated knee joint because of the retained ACL could preclude the need for restraint from mobile bearing inlays, and allow higher congruence with less fettered movement. In this way, shearing forces and contact point pressures could be avoided. However, with advanced arthritic changes, it may be that the ACL is so impaired as to be insufficient.

Lee et al. (25) prospectively reviewed 107 consecutive primary total knee arthroplasties performed over a one-year period. In 41 knees (38%), the ACL was deficient at the time of surgery. Only 12% of patients recalled an event consistent with an ACL-type injury or prior history of instability. For the remaining 26%, rupture of the ACL occurred from a combination of attrition and encroachment of the intercondylar notch by osteophytes, resulting in impingement.

On the other hand, for cases where TKA is indicated, some 60% of ACLs are usable, even when they are not completely normal. In these times where we continually strive to perform minimally invasive surgery (MIS), it is difficult to imagine that the sacrifice of the ACL, generally recognized as a structure vital to knee biomechanics, could accompany the designation "MIS-TKA."

In a matched paired study, Confalonieri et al. (17) found that retention of the ACL through implantation of two unicondylar knee prostheses yielded shorter hospitalizations as well as better post-operative functionality compared to TKA. Compared to normal unilateral insertion of unicondylar knee prostheses, implantation of two unicondylar knee prostheses achieves the same good functional outcomes (18).

However, in the long-term the problems of implant fixation and alignment of the individual unicondylar components remain. The fixation arrangement of the TS beneath the joint surface in particular should offer both, good primary stability as well as good osteointegration and secondary stability because of the more constant press-fit. This, along with a reduction of torsional load when compared to an anterior interface (Fig. 3a), should prevent material failure (3). The TSTP could achieve a very good overlap of the three crucial mechanical factors, i.e., stability of the treated knee, secure fixation of the prosthetic components, and high congruence of the mobile bearing inlays.

In the current study, four different models were analyzed in the laboratory regarding primary stability. Clearly, the use of synthetic instead of cadaveric bone is a limitation of the study, as shown in the preliminary tests with the too-hard cortex. On the other hand, regarding reproducibility and comparability of the models, the use of synthetic bone is advantageous, since cadaveric specimens

have inter-individual bone quality differences. This is reflected by the results summarized in Figure 11b, showing the primary applied load proportions with distribution of 60%/40% medial to lateral and 70%/30% posterior to anterior in the resultant subsidence of the MPs. One can conclude that using this test set-up, with the model-loading of specially prepared Sawbones® and a sinusoidal oscillating load transmission of 25 000 cycles over 10 increasing load levels, subsidence does result and, thus, comparisons can be made among the different model types regarding primary stability. In comparison to force and distribution measured in vivo (26-28), the force distribution chosen in this study was extreme, i.e., a worst case scenario. The extreme load distribution was reflected in the significant margin of difference between the anterior and posterior MPs versus that between medial and lateral, as well as with significantly more subsidence posteriorly.

Implant subsidence was significantly greater for the TS_{mobile} versus the other three models, which showed comparable levels. The essential difference of TS_{mobile} versus the other models was the transverse movement allowed along the TS. Thus, a rigid connection holding the JSS appears to provide increased primary stability in terms of bone fixation of the TSTP.

The disadvantages of the V-shaped variants VS_{plus} and VS_{standard} were the relatively non-bone sparing implantation technique as well as perforation risk in the narrowed region of the tibia. On the other hand, implantation of a larger TS requires a small additional approach, which can be performed either medially or laterally depending on the interval of the TS to the jointline (29).

A further study should compare the primary stability of the favored TS_{fixed} model with that of conventional TKA and bilateral unicondylar implants using the test assembly detailed here. An additional study should examine the geometry of the proximal tibia to determine the most favorable interval from the transversal support to the joint surface.

The test assembly with the loading of specially prepared Sawbones® with a sinusoidal oscillating load trans-

mission of 25 000 cycles over 10 increasing load levels was sufficient to achieve subsidence, allowing comparison of the four different TS models especially regarding primary stability and thus bone fixation. Variant TS_{mobile} which permitted motion of the joint surface supports in the transverse axis along the transversal support, revealed the greatest subsidence. Thus, within the transversal support tibial plateau concept, a rigid junction connecting the joint surface supports appears to provide increased primary stability, i.e., better bone fixation.

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Conflict of interest: A patent application has been submitted by the corresponding author for the TSTP concept, and a licensing agreement exists with the company Aesculap AG. However, in spite of the potential conflict of interest, the contribution is impartial and the product neutral, because to date the principle introduced is based on experimental prototypes and has not been transferred to a product.

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