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Construct stability in anterior open wedge osteotomy: Assessing 3D-printed polylactic acid wedges against cortical bone

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ABSTRACT

Background: This in-vitro biomechanical study aimed to assess whether using a wedge as a gap filler in anterior open wedge osteotomy of the proximal tibia reduces load on the screw-plate construct and to evaluate if a 3D-printed polylactic acid wedge offers similar biomechanical stability like a bone wedge.
Methods: Twenty-four cadaveric proximal tibiae were randomly assigned to one of three groups: TomoFix plate alone as control group, TomoFix plate with a bone wedge, and TomoFix plate with a 3D-printed polylactic acid wedge. The specimens were subjected to axial loads of 400 N, 800 N, and 1200 N for 1000 cycles. Compression depth and axial stiffness were measured to assess stability.
Findings: There were no significant differences in overall compression depth or axial stiffness between the groups ($p > 0.05$). At 1200 N, hinge fractures occurred in 6 of 8 specimens in the control group, compared to 0 of 8 in the wedge groups. Both bone and polylactic acid wedges improved construct stability, with the polylactic acid wedge performing comparably to the bone wedge.
Interpretation: Gap fillers, whether bone or polylactic acid wedges, may contribute construct stability in anterior open wedge osteotomy of the proximal tibia. The 3D-printed polylactic acid wedge may be biomechanically comparable to the bone wedge, suggesting its potential as an alternative in clinical applications.

1. Introduction

Anterior open wedge osteotomy of the proximal tibia is a surgical treatment option for idopathic or post-traumatic genu recurvatum and posterior instability with insufficiency of the posterior cruciate ligament (PCL) or repeated failure of an PCL graft (Agneskirchner et al., 2004; Ramos Marques et al., 2022; Van Raaij and De Waal, 2006). This involves changing the angle of the tibial plateau in the sagittal plane by means of an osteotomy in the tibial plateau and stabilizing it with a locking plate osteosynthesis. However, there are many aspects to consider with this technique, in particular the positioning and type of plate as well as the decision as to whether or not gap fillers (wedges) should be used (Ramos Marques et al., 2022; Takeuchi et al., 2017). Filling the osteotomy gap could contribute to improved construct stability and possibly reduce the occurrence of complications such as pseudarthrosis formation and loss of correction of the desired angle (Takeuchi et al., 2017). The additional stabilization of the construct with an allogenic bone wedge or a wedge made of bone substitute material could reduce the force on the construct consisting of screws and plate and thus improve the clinical result.

However, the use of foreign materials as filling material means that the associated disadvantages, above all the infection associated with foreign materials, must be considered (Spahn, 2004). A multivariable analysis showed that postoperative infections were positively associated with the use of artificial bone grafts (Kawata et al., 2021). Newer bone substitute materials offer various advantageous properties that could solve the aforementioned problems. They can be designed to have osteoinductive and antimicrobial properties. Furthermore, they can be loaded with antibiotic agents (Serra-Aguado et al., 2022). In the case of opening wedge osteotomies, individual bone cavities are produced for each patient in order to achieve the desired treatment result. Using the method of fused deposition modelling (FDM, 3-D printing), it is possible to produce individualized moulds and, after appropriate preoperative planning, to manufacture precisely fitting wedges made of bone

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replacement material for each patient. With this technique, the dead space after an osteotomy could be nullified.

The aim of this biomechanical in-vitro study is to test whether the addition of a wedge as a gap filler reduces the force on the screw-plate construct in anterior open wedge osteotomy of the proximal tibia. In addition, the hypothesis is put forward that a 3D-printed wedge made of PLA is not inferior to a bony wedge from a biomechanical point of view and contributes to increased construct stability to the same extent as the bony wedge.

2. Methods

2.1. Ethical considerations

This in-vitro study was approved by the local institutional review board. (Ethical Committee of the Medical Faculty of the University of XXBLINDEDXX—VT (No: 23–1391)). This study followed the guidelines for experimental investigation with human subjects required by our institution.

2.2. Specimen preparation

For this biomechanical study, eight fresh frozen cadaveric proximal tibae were available per group (total of 24 specimen). The mean age at the time of death was 82 years (min. 65 years, max. 87 years). The specimens were stored at −20 °C and thawed at room temperature 16–18 h before dissection and biomechanical testing. Fluoroscopic and clinical examinations were performed to exclude specimens with osteoarthritis or signs of previous surgery and trauma. Specimen were dismantled from all soft tissue including skin, subcutaneous tissue, muscles and ligaments. The proximal tibiae were embedded in aluminium cylinders using a two-component resin (Technovit 4004, Kulzer GmbH, Hanau, Germany). After that an anterior slope correction–flexion osteotomy was carried out as described by Marques et al. (Ramos Marques et al., 2022) The specimens were then randomly assigned to either group 1 (standard TomoFix plate, Synthes, West Chester, Pennsylvania, USA; osteotomy gap empty), group 2 (standard TomoFix plate with a bony wedge as additive augmentation) or group 3 (standard TomoFix plate with a 3D printed PLA wedge as additive augmentation), as shown in Fig. 1.

2.3. Wedge assembling

The 3D-PLA wedge was fabricated using a 3D printer. The dimensions of the 3D wedge were chosen to ensure an optimal fit within the osteotomy gap. To achieve this, in an initial trial run of the experiment, the width and the depth of the osteotomy gap was measured. A slightly oversized width was selected to ensure that the wedge would rest securely on the cortical bone of the osteotomy gap in all specimens, thereby preventing the wedge from sinking into the spongiosa of the tibia under axial load. The depth was determined to be 3.5 cm based on these measurements, and the frontal height was set at 2 cm. The bone wedge was crafted from the distal tibial diaphysis of the specimens using a bone saw, and its height and angle were adjusted to match the 3D-PLA wedge, as shown in Fig. 2. The used filament has a Young's modulus of 3570 MPa.

2.4. Biomechanical testing set-up

After preparation of the tibia it was mounted vertically in a servo-hydraulic testing machine (Zo10, Zwick/Roell, Ulm, Germany). A distal femoral replacement prothesis that was fixed to the mobile traverse of the testing machine was placed on the articular surface of the tibial head. Thus, downward movement of the mobile traverse lead to compression forces onto the proximal tibia, as shown in Fig. 3. Both the proximal femoral and the distal tibial attachment to the testing machine were rigidly fixed, allowing no free movement within the testing set up. The alignment of the platform of the hydraulic test machine as well as the alignment of the tibia was carried out under the control of a spirit level in order to ensure that the tibial articular surface was loaded as evenly as possible. Three different testing scenarios were established. A preload of 5 Newton (N) was applied in all protocols followed by axial pressure until 400 N, 800 N and 1200 N were reached, depending on the testing scenario. The measurement was repeated across 1000 cycles for each scenario. Initially a maximal compression threshold of 2 mm was established as criterion for failure, at which point the testing would be stopped. This is in line with previous biomechanical studies with a similar testing set up (Agneskirchner et al., 2006; Pape et al., 2010). However, during an initial trial run of the biomechanical experiment, this limit was occasionally exceeded at an axial force of 400 N and regularly at an axial force of 800 N in all groups. In order to still analyze the study's hypothesis, the maximum compression limit was increased to 10 mm. Both, the applied force in N, as well as the depth of compression in mm, were documented. The stiffness values were

Fig. 1. Biomechanical testing setup; locking plate alone (left); locking plate with additive bony wedge (middle); locking plate with additive 3D-printed PLA wedge, adjusted with a spirit level (right).

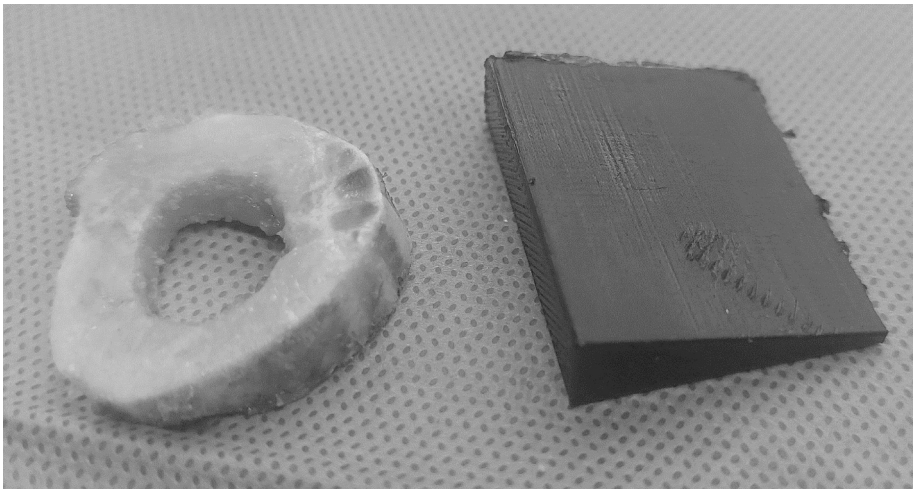

Fig. 2. Customized crafted bone wedge (left) and 3D-printed PLA wedge (right).

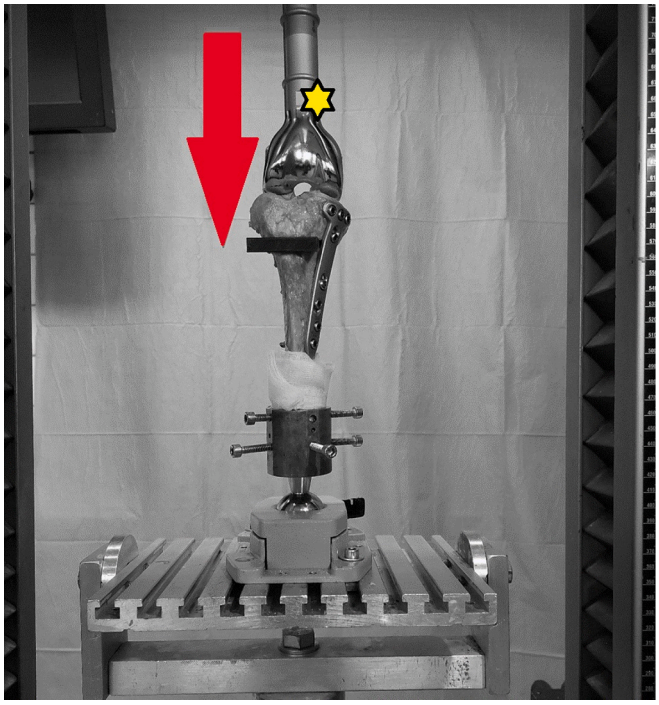

Fig. 3. Biomechanical testing set up; downward movement of the mobile traverse lead to compression forces onto the proximal tibia (red arrow) transmitted by the distal femur prothesis (yellow star). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

determined from the highest load region of the linear load–displacement curve during the protocols in N/mm. When the axial force leads to a fracture of the dorsal cortex of the osteotomy (hinge fracture) the measurement was canceled and was classified as failure.

2.5. Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics Version 29.0 for Mac (IBM Corp, Armonk, NY).

Results are presented as median (min – max) and/or mean ± standard deviation depending on the distribution. ANOVA with Bonferroni post-hoc testing was performed for normally distributed data and the Kruskal-Wallis test with Dunn-Bonferroni test for non-normally distributed data was calculated. We evaluated the differences of failures based on contingency tables with Fisher's exact test or Chi-square test. A p-value of $p < 0.05$ was considered statistically significant. Data sets of measurements classified as failures were excluded from the statistical analysis. Non-inferiority testing was performed to assess whether the PLA-wedges resulted in a reduction in average stiffness that was not greater than a predefined non-inferiority margin. The margin for non-inferiority was set at a reduction of 125 N/mm. This analysis was conducted by calculating the confidence interval (CI) for the difference in average stiffness between the PLA wedge and bone wedge. Non-inferiority was concluded if the lower bound of the CI was greater than −125 N/mm. A one-sided test, comparing the lower bound of the confidence interval (CI) to the predefined non-inferiority margin was performed to confirm the results.

3. Results

The average stiffness was overall 446.2(97.63–962.98)N/mm, for the first 500 cycles 468.41(99.33–991.48)N/mm and for the last 500 it was 424.02(95.94–934.48)N/mm. Axial stiffness for all groups is shown in Table 1 and Fig. 5. For all applied forces stiffness is shown in Table 3. There was no significant difference for axial stiffness between the groups. Neither overall ($p = 0.9$), for the first 500 cycles ($p = 0.94$) and the last 500 cycles ($p = 0.92$).

The average compression depth was 2.03(0.48–5.55)mm for all cycles. For the first 500 it was 1.93(0.46–5.06)mm and for the last 500 it was 2.13(0.49–6.04)mm. The average compression depth for the different groups is shown in Table 2 and Fig. 4. There was no significant difference regarding the compression depth between the groups overall ($p = 0.98$), for the first ($p = 0.99$) and last 500 cycles ($p = 0.97$).

In total six hinge fractures occurred at 1200 N when only a plate alone was used. No hinge fracture occurred when a gap filler was used. In two specimens the compression threshold was exceeded at 800 N when only a plate alone was used. When a gap filler was used the threshold was exceeded in two specimens with a bony wedge and in three specimens with the 3D wedge at 1200 N (Table 4). There was no

Table 1
average N/mm averaged over all measurements for each group.

	mean stiffness (N/mm)	Range (minimum–maximum) of stiffness (N/mm)
3D-wedge	440,45	152,45–857.63
bony wedge	454,61	178,74–883.36
plate solo	442,35	97,63–962.98

Table 2
average compression of the osteotomy gap in mm averaged over all measurements for each group.

	mean (mm)	minimum–maximum (mm)
3D-wedge	2,09	0,64–5,55
bony wedge	1,98	0,7–4,41
plate solo	2,02	0,48–4,53

statistically significant difference in failures according to the analysis of the contingency tables.

Non-inferiority of the PLA-wedge compared to the bone wedge could be statistically proven ($p = 0.039$). The valid measurements for each scenario are shown in Table 5.

4. Discussion

The study results suggest that the biomechanical properties of a 3D-PLA wedge may be comparable to those of a bone wedge. Additionally, the findings indicate that the use of a gap filler, whether a bone wedge or a 3D-PLA wedge, could contribute to construct stability compared to using a locking plate alone, although further research is required to substantiate this effect.

The initial analysis of the results suggests that there is no difference in construct stability among the three groups. The average axial force in Newtons required to compress each construct by 1 mm across all measurements ranges from 440 to 455 N for all groups, as shown in Table 1. A statistically significant difference is not present, with $p > 0.05$. Similarly, the mean axial compression distance in millimeters averaged across all measurements reveals very similar results. In all three groups, the construct was compressed by approximately 2 mm (1.98–2.09 mm), as shown in Table 2. Again, there is no statistically significant difference between the groups ($p > 0.05$).

However, a more detailed analysis of the results, where measurements are examined individually according to the applied force (400 N, 800 N, and 1200 N), reveals that the equality of the aforementioned biomechanical properties only holds at lower forces. Significant differences are not observed at applied forces of 400 N and 800 N. At 1200 N, however, almost all measurements in the group with the locking plate without a gap filler had to be terminated. This was due to the occurrence of a hinge fracture in 6 out of 8 specimens at 1200 N. In contrast, in the group with the 3D-PLA wedge, only 3 out of 8, and in the group with the bone wedge, only 2 out of 8 specimens had to be terminated, as shown in Table 3. In these two groups, however, the measurements were not terminated due to a hinge fracture, but rather because the hydraulic testing machine automatically halted the measurements upon reaching a

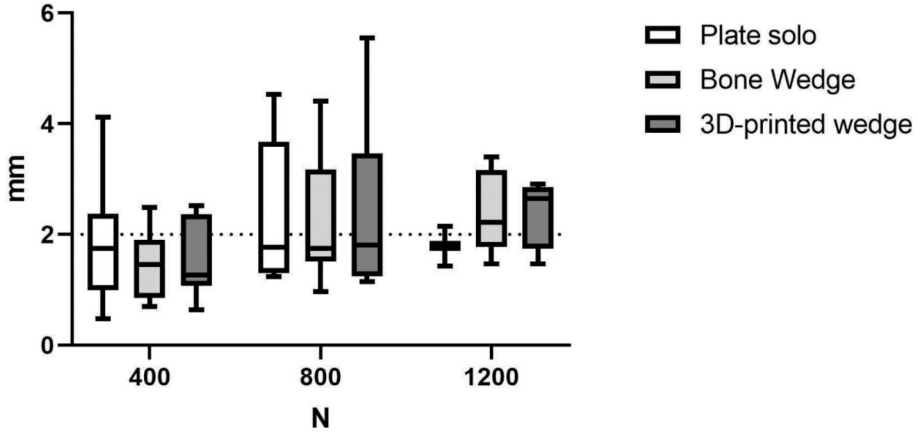

Fig. 4. Box-and-whiskers plots displaying the distribution of the average maximal compression depth for different applied forces. The box represents the interquartile range (IQR, 25th to 75th percentile), with the median (50th percentile) shown as a horizontal line within the box. Whiskers extend from the 2.5th to the 97.5th percentile, capturing 95 % of the data. Any outliers beyond this range would be plotted individually.

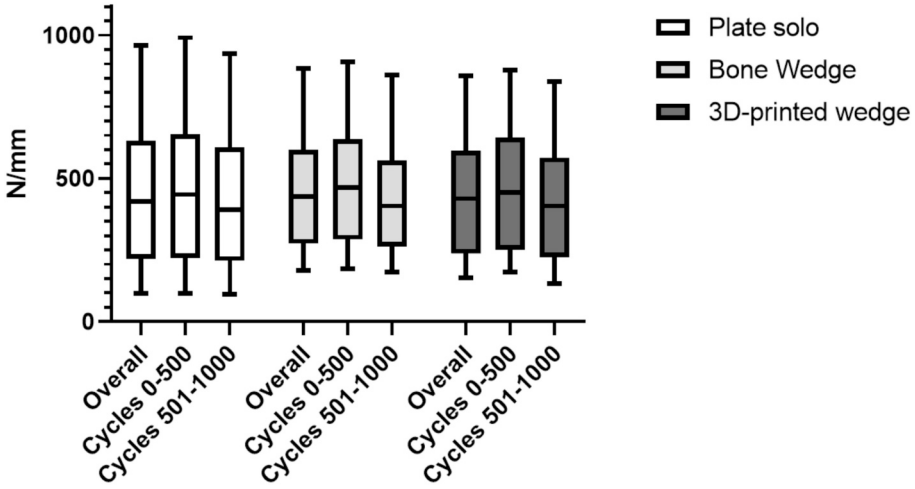

Fig. 5. Box-and-whiskers plots displaying the distribution of stiffness measured in N/mm from the Load-Displacement curve. Across all cycles aswell as first and last 500 cycles. The box represents the interquartile range (IQR, 25th to 75th percentile), with the median (50th percentile) shown as a horizontal line within the box. Whiskers extend from the 2.5th to the 97.5th percentile, capturing 95 % of the data. Any outliers beyond this range would be plotted individually.

Table 3
mean N/mm per group and respective test scenario in relation to applied axial force.

	applied force (N)	n	mean siffness (N/mm)	Range (minimum–maximum) of stiffness (N/mm)
3D-wedge	400	8	354,77	172,05–728,67
	800	8	460,34	152,45–747,79
	1200	5	572,03	434,55–857,63
bony wedge	400	8	363,13	178,74–646,85
	800	8	474,66	182,68–883,36
	1200	6	568,87	370,73–857,63
plate solo	400	8	353,64	97,63–962,98
	800	6	462,36	177,98–688,86
	1200	2	737,15	592,41–881,89

compression depth of >10 mm, which had been predefined as a stopping criterion.

At 800 N, in the group with only the TomoFix plate without a gap filler, 2 out of 8 specimens had their measurements terminated due to excessive compression of more than 10 mm. In contrast, all 8 specimens in both wedge groups completed the measurements, as shown in Table 3. The differences in the occurrence of hinge fractures and the increased compression observed already at 800 N highlight the enhanced construct stability achieved through the use of a wedge compared to the use of a locking plate alone, as shown in Table 4. While this trend is supported by biomechanical observations, it is important to acknowledge that the statistical analysis does not confirm a significant difference ($p > 0.05$). This limitation is likely due to the small sample size, which may have reduced the power to detect a meaningful difference. Future studies with larger cohorts are needed to further investigate this potential effect.

The present study results contradict previous biomechanical results by Pape et al., who tested cadaveric tibiae following high tibial osteotomy (HTO) using a TomoFix plate under an axial load of 2000 N with 1000 cycles without a gap filler. They observed a very high primary stability of the plate, which prevented significant displacement even in cases of lateral cortex fracture (Pape et al., 2010). Similar biomechanical studies have also demonstrated the exceptionally high primary stability achieved during HTO using a TomoFix plate (Agneskirchner et al., 2006; Stoffel et al., 2004). However, it is important to consider that the studies focused on a medial opening high tibial osteotomy (mo-HTO), while the present study investigates an anterior open wedge osteotomy. Although the plate placement is the same, the cutting planes in the proximal tibia differ significantly. Türkmen et al. elaborated further on cutting planes and compared monoplanar and biplanar techniques in medial opening-wedge osteotomy, demonstrating that biplanar osteotomies allow for larger wedge openings and significantly reduce the risk of lateral cortex fractures (Türkmen et al., 2017). These findings highlight the biomechanical advantages of biplanar osteotomies in procedures that require substantial angular corrections. However, it is important to note that while the benefits of biplanar osteotomies are well-documented in the context of medial opening-wedge osteotomies, their application to anterior opening-wedge osteotomies has not been explored in the literature to date. Given the similar principles of angular correction and the potential for lateral cortex disruption, future studies should investigate whether a biplanar technique could be applicable and provide similar mechanical benefits in anterior opening-wedge osteotomies.

Table 4
Terminated measurement for specific group and force applied.

	Compression Threshold Exceeded	Hinge fracture occured
3D-wedge 400 N	0/8	0/8
800 N	0/8	0/8
1200 N	3/8	0/8
bony wedge 400 N	0/8	0/8
800 N	0/8	0/8
1200 N	2/8	0/8
plate solo 400 N	0/8	0/8
800 N	2/8	0/8
1200 N	0/8	6/8

Table 5
Valid measurements for each scenario and applied force.

	Plate solo	bony wedge	3D-wedge	
400 N	8	8	8	24
800 N	6	8	8	22
1200 N	2	5	4	11
	16	21	20	57

We conclude that the primary stability after an anterior open wedge osteotomy is considerably lower than after an mo-HTO. Load parameters of 2000 N are present in physiological in vivo forces during a gaitcycle of test person with normal weight and height (Taylor et al., 2004). The present study results suggest that postoperative offloading is recommended following an anterior open wedge osteotomy, as a load of only 1200 N already led to significant displacement and even fractures when no gap filler was used. The use of gap fillers may therefore help prevent secondary displacement and possibly the occurrence of mal union, which is in line with the conclusions by Takeuchi et al., who found that bone substitutes distributed the stress concentration around the osteotomy gap and prevented dislocation regardless of the plate position in HTO (Takeuchi et al., 2017). A systematic review investigating the effects of bone substitute materials in high tibial osteotomies (HTOs) recommends the use of bone substitutes when the osteotomy gap exceeds 10 mm and therefore supporting the positive effects of gap fillers found in the present study. However, the treatment of the osteotomy gap remains controversial due to the highly heterogeneous data available (Bei et al., 2022). The risk of infection associated with foreign material is particularly concerning. Spahn et al. observed severe deep infections only in the group using synthetic bone grafts in their study (Spahn, 2004). The multivariate study by Kawata et al., which included a large patient population of over 12,000 patients, also demonstrates the association between infection and the use of artificial bone grafts, further highlighting the risk of infection (Kawata et al., 2021). The aforementioned systematic review on the other hand found no statistically significant difference in the incidence of infections when gap fillers were used compared to when they were not used (Bei et al., 2022). Nevertheless, to ensure the safe application of proximal tibial osteotomy, the risk of potential infection following an open wedge osteotomy must be minimized as much as possible. Recently, it has been possible to produce polylactic acid (PLA) scaffolds infused with sodium alginate, which is cross-linked with both divalent calcium and zinc cations, in order to give the PLA properties that make it interesting for use as a bioactive bone replacement material. The PLA scaffolds have been shown to have excellent antibacterial activities (Serra-Aguado et al., 2022). It demonstrates antibacterial activity against gram-positive methicillin-resistant *Staphylococcus epidermidis* and gram-negative *Pseudomonas aeruginosa* and could be loaded with targeted antibiotic medications.

Another concerning complication following open wedge osteotomy is nonunion or pseudarthrosis. The data on this issue remain contradictory. While Hernigou et al. describe a slight advantage of beta-tricalcium phosphate allografts over autografts (Hernigou et al., 2017), the study by Jung et al. indicates that both auto- and allografts facilitate faster healing of the osteotomy gap (Jung et al., 2020). Conversely, Nha et al. demonstrate that the use of bone grafts provided no benefits (Nha et al., 2018). The systematic review also fails to provide clarity due to the highly heterogeneous data available (Bei et al., 2022). The chemically modified PLA substance has already demonstrated promising in vivo bone regeneration capacity, as evidenced by tomography and histological analysis in a rabbit model (Serra-Aguado et al.,

2022). In the future, the issue of nonunion could potentially be addressed through the further development of such modified PLA wedges.

Currently, autologous and allogeneic wedges appear to be somewhat equivalent. As an autologous bone graft, a tricortical bone graft from the iliac crest is typically used (Aryee et al., 2008). However, it is important to mention the donor site morbidity associated with harvesting a tricortical bone graft that include possible postoperative pain, blood loss, haematoma, infection, fracture, neurovascular injury and longer operative time (Campana et al., 2014). With allogenic bone grafts this downside can be avoided, which makes the use of gap fillers crafted from synthetic bone substitute materials, such as PLA, even more beneficial.

Overall, it must be considered that all the aforementioned studies focused on medial opening HTOs, whereas the present study analyzed the biomechanical effects following anterior open wedge osteotomy. Data on anterior open wedge osteotomy is very limited, and comparable studies investigating the aspects discussed above simply do not exist yet. This scarcity of data is likely due to the much lower frequency of the anterior open wedge osteotomy procedure. However, given the similarities between the two procedures, referencing HTO literature for discussion purposes seems legitimate. When comparing the above-mentioned biomechanical measurements from HTO studies with the present data, it becomes evident that anterior open-wedge osteotomy creates a significantly more biomechanical unstable situation compared to HTO. This finding further supports the necessity of postoperative partial weight-bearing and the use of gap fillers.

Another aspect is that the use of a bony or PLA wedge does not create an entirely rigid construct, allowing for continued micromovements, as shown in Table 2 and Fig. 4. Micromovement at the fracture site generates fluid flow and shear stress on the cell membrane, which can induce mechano-coupling and activate pathways that enhance osteoblast formation and activity, suggesting that iatrogenically applied forces can improve fracture healing (Stewart et al., 2020).

Finally, a major advantage of a 3D-printed PLA wedge is that the planned osteotomy and the resulting cavity can be pre-calculated using CT imaging. This allows for the design of a PLA wedge in the planning software that will perfectly fill the created cavity. As a result, the cavity is minimized, and the planned correction angle can be achieved and maintained with greater accuracy. This could theoretically lead to improved radiological outcomes and potentially better clinical treatment results.

The fact that from a biomechanical point of view the 3D-printed PLA wedge is not inferior to a bone wedge opens up potentially very advantageous application possibilities in anterior open wedge osteotomy of the proximal tibia. The bioactive properties, such as antimicrobial and osteoinductive effects, have yet to be fully translated into clinical practice, but they potentially offer excellent capabilities for addressing the described challenges in the future. The promising biomechanical properties demonstrated by the 3D-printed PLA wedge in this study provide a solid foundation for further pursuing this therapeutic approach. Furthermore, it is quite conceivable that these advantages could also be utilized in other opening osteotomies, such as the medial open wedge osteotomy of the proximal tibia as well as the lateral open-wedge osteotomy of the distal femur.

4.1. Limitations

The present study has several limitations. Firstly, the small sample size may harbour the risk of a type two error. This is a well-known and common drawback of biomechanical research, resulting from the difficulty in obtaining suitable cadaveric samples. In addition the small sample size may have contributed to non-statistically significant results that can only be proven in larger sample sizes. Secondly, this study as well as most biomechanical studies face the problem of a big age difference of the older cadaver samples compared to the usually much younger patient population of interest. The two remaining specimens in the group with the locking plate without any gap fillers at 1200 N demonstrated higher construct stability than the other two groups where a gap filler was used. This contradictory finding could be attributed to factors such as higher pre-test stability, superior bone quality, or an imprecisely cut osteotomy resulting in a thicker posterior cortex of the proximal tibia. However, the very small number of specimens in this group makes a statistical comparison with the other two groups impossible, and they should be excluded from analysis for these reasons. Due to resource constraints, it was not possible to produce an individual fitting wedge for every single specimen tested with the 3D wedge, which does not accurately represent the clinical scenario and therefore, the use of a single oversized wedge should be acknowledged as a study limitation. Lastly, biomechanical study conditions do not accurately reflect the physiological reality that is to be investigated in the studies.

5. Conclusion

This study provides preliminary evidence suggesting that gap fillers, such as PLA or bone wedges, may contribute to the stability of anterior open wedge osteotomy constructs compared to the use of a locking plate alone. Furthermore, the biomechanical performance of the 3D-printed PLA wedge appeared comparable to that of a cortical bone wedge. While these findings support the potential of PLA wedges, they remain experimental, and further development is needed. However, the results should encourage continued research into this field, with the hope that, through further investigation and refinement, 3D-printed PLA wedges could eventually present a viable alternative in clinical practice.

Declaration of generative AI

The authors declare that there was no use of generative AI, not in scientific writing nor composing any other parts of the manuscript.

CRediT authorship contribution statement

Kai Hoffeld: Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Jan P. Hockmann:** Visualization, Software, Methodology, Formal analysis, Data curation. **Christopher Wahlers:** Writing – review & editing, Software, Investigation, Conceptualization. **Peer Eysel:** Validation, Supervision. **Michael Hackl:** Writing – review & editing, Resources, Conceptualization. **Johannes Oppermann:** Writing – review & editing, Validation, Supervision, Project administration.

Informed consent

Due to cadaveric character of this study, no informed consent was needed.

Ethical approval

Ethical approval for this study was given by the Institutional Review Board of the University Cologne (VT (No: 21-1454))

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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None.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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