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In vitro Biomechanical Testing of Polyurethane External Skeletal Fixator as a Novel Polymer in Fracture Treatment

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ABSTRACT

Background: To determine the temperature, time and biomechanical properties of free-form polyurethane external skeletal fixation (PUESF) and compare them with acrylic external skeletal fixation (ACESF).

Methods: Three different configurations (uniplanar, multiplanar and circular) (n=4 for each configuration) were subjected to compression and bending (n=24 PUESF, n=24 ACESF) and only the uniplanar configuration was subjected to pullout testing (n=4 PUESF, n=4 ACESF). The temperatures of the connecting bar and K-wire were recorded when creating the multiplanar and circular configurations. All the configurations were subjected to axial and bending tests and the uniplanar configuration was subjected to pullout tests.

Result: Regarding the connecting bar temperature and the temperature delivered to the K-wires, the PUESF group reached maximum temperatures of 75.7°C and 38.1°C at 3 minutes and the ACESF group reached maximum temperatures of 87.6°C and 60°C at 9 minutes, respectively ($p<0.001$). Under compression force, the PUESF group showed similar strength to the ACESF group in the uniplanar and circular configurations ($p>0.05$), while it showed less strength than the ACESF group in the multiplanar configuration ($p<0.05$). The PUESF group showed similar strength to the ACESF group in all three configurations under the bending force ($p>0.05$). The ACESF group showed approximately 2 times as much pullout strength as that of the PUESF group ($p<0.05$). Polyurethane showed acceptable mechanical performance compared to acrylic in several test configurations. Polyurethane can be used in clinical trials for free-form external skeletal fixations (ESFs).

Key words: Acrylic, Biomechanical testing, External skeletal fixation, Polyurethane.

INTRODUCTION

External skeletal fixation (ESF) systems, which are used for fracture stabilization in veterinary orthopedics practice, remain popular because of their versatile applicability, minimization of soft tissue damage and cost-effectiveness (Palmer *et al.,* 2012; Kouassi *et al.,* 2020; Sellei *et al.,* 2015). Determining the appropriate structural form of ESF systems is a biomechanical decision and the stability and rigidity of the system are critical for clinical success (Fernando *et al.,* 2021; Orhan *et al.,* 2025). Advances in materials science have enabled the identification of optimal materials, configurations and implantation techniques that satisfy stability objectives (Palmer *et al.,* 2012; Kouassi *et al.,* 2020; Sellei *et al.,* 2015).

Standard fixator components typically use steel, aluminum, carbon composites and titanium. Stainless steel is inexpensive but heavy; alternatives, such as aluminum and titanium, are lighter but more expensive. Furthermore, pin placement in standard fixators is limited by the size and position of clamps. To overcome these limitations and address the difficulty of accessing ready-made systems in veterinary orthopedics, free-form fixators are preferred. In these systems, pin orientation and diameter are not affected by the connecting rods or clamp size, allowing for adaptation to all types of fracture configurations (Kouassi *et al.,* 2020; Amsellem *et al.,* 2010; Fernando *et al.,* 2021; Singh *et al.,* 2023; Tyagi *et al.,* 2023).

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Acrylic and epoxy resins, which are commonly used in free-form fixators, offer sufficient strength. However, acrylic, the most frequently preferred material, is known to pose the risk of thermal necrosis in bone segments by emitting high heat during curing. This situation has necessitated the investigation of alternative thermoset polymers, such as polyurethane, which has a wide range of applications in

the biomedical field. Polyurethane derivatives have been successfully used in veterinary orthopedics as biodegradable implants, joint tissue applications and bone substitutes owing to their biocompatibility, high strength and osseointegration properties. Furthermore, polyurethane is preferred in simulation and orthopedic research because its biomechanical properties are similar to those of living bones (Roe 1997; Montasell *et al.,* 2019; Banoriya *et al.,* 2017; Fernando *et al.,* 2021).

In this study, the aim was to determine the temperature values and curing durations of different configurations of ESF constructions prepared using polyurethane. Their resistance forces against compression, bending and pullout were examined and compared with ESF configurations prepared using acrylic. We hypothesized that polyurethane ESF (PUESF) constructions would cure at a lower temperature (°C) and have the same strength as acrylic ESF (ACESF) constructions.

MATERIALS AND METHODS

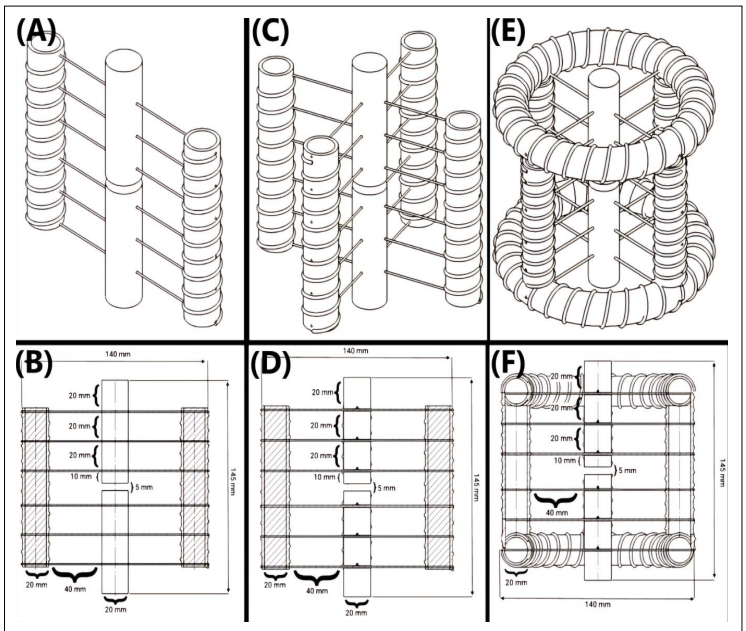
Two groups were established

PUESF and ACESF. A total of 28 specimens were prepared for each group. Four specimens were prepared for each of the uniplanar, multiplanar and circular configurations for both the compression and bending tests and four additional specimens were prepared for the pullout test with the uniplanar configuration for each material. The tests were conducted at the Mechanical Laboratory of the Faculty of Engineering, Harran University, from May 2023 to June 2023. The temperatures of the connecting bar, temperatures transmitted to the K-wire during curing, odor formation and curing time of the polymers were examined for both groups. The comparative nature of this study is based on the comparability of polyurethane, a new polymer for free-form ESFs, to acrylic polymers with different structural properties.

Preparation of ESF constructs

In all tests, ultra-high molecular weight (UHMW) polyethylene rods (PE 1000 Varna Polimer, Istanbul, Turkey) with a diameter of 20 mm and length of 70 mm were used instead of bone. Kirschner (K) wires (1.6 mm made of 316-L stainless steel (Fix Medical, Sanlýurfa, Türkiye) were passed through the UHMW rods at fixed distances. A frame mold was created using moldable polyvinyl chloride (PVC) tubes with a diameter of 20 mm and a wall thickness of 1.0 mm (Çetsan spiral pipe, Istanbul, Türkiye) and the K-wires were passed through them. A pin cutter was used to cut the excess portion of K-wires protruding from the outer surface of the PVC tubes. In the uniplanar and multiplanar configurations, the bases of the PVC tubes were sealed with adhesive tape.

In the uniplanar configuration, K-wires were passed along the same line using a single UHMW polyethylene rod and aligned parallel to each other (Fig 1A, B). Multiplanar (Fig 1C, D) and circular (Fig 1E, F) configurations were prepared using two UHMW



(A) Top-side view of uniplanar configuration. (B) Lateral sectional view of uniplanar configuration. (C) Top-side view of multiplanar configuration. (D) Lateral sectional view of multiplanar configuration. (E) Top-side view of circular configuration. (F) Lateral sectional view of circular configuration. ESF: External skeletal fixation.

Fig 1: ESF designs used in the study.

polyethylene rods. To simulate unstable fracture conditions, a 5-mm gap was left between the rods. The K-wires were crossed at an angle of 90° while ensuring that they did not interfere with each other. In the circular configuration, after the connecting rods were constructed as in the multiplanar configuration, they were connected by circularly fixing moldable PVC tubes at the proximal and distal ends. (Tyagi *et al.,* 2014a; Tyagi *et al.,* 2014b; Tyagi *et al.,* 2015).

Liquid polyurethane (Tpol Tech, Istanbul, Turkey) was used in the PUESF group. Components A (1 kg of polyol) and B (1 kg of isocyanate) of the polyurethane were mixed together in a 1:1 ratio. Self-curing dental acrylic (Imicryl Cold Acrylic, Konya, Türkiye) was used in the ACESF group. The acrylic was mixed with methyl methacrylate powder (1 kg) and a liquid hardener (500 ml) at a 2.4:1 ratio. The ratios were obtained from the manufacturer's recommendations. Before starting the mixtures, the weights of polyurethane and acrylic were measured using a digital precision balance (Shimadzu BL-3200H, Shimadzu Corporation, Japan).

In the PUESF group, the A and B components of polyurethane were mixed for equal durations (60 s) using a wooden spatula in a plastic container. Then, the liquefied polyurethane was drawn into a 50 ml irrigation syringe. For the uniplanar and multiplanar configurations, semi-liquid polyurethane was poured into the proximal ring through the top openings of the connecting bars, while for the circular configuration, it was poured through the four open points that had been left exposed. The mixture was thoroughly combined into connecting bars and rings, without forming any cavities. The same procedures were applied to acrylic in the ACESF group. The polymers were prepared in a temperature-controlled environment (24.0-25.1°C) with no airflow. During curing, the temperature (°C) of the connecting bars and pins was monitored for 60 min.

The temperatures were monitored using a standard-focused laser-marked infrared thermometer (Testo Quicktemp 860-T2, Testo AG, Germany), for which regular calibration checks were conducted by the Faculty of Engineering at Harran University. A fixed setup was prepared; the constructs were clamped in a vice and their temperatures were measured at a distance of 30 cm. The surface temperatures of the polyurethane and acrylic during curing were determined at the level of the third K-wire from the top of the connecting bar. The temperature transmitted to the K-wire was measured at the center of the 3rd K-wire from the top (2 cm from the connecting bar).

The curing time was measured as the time between filling the connecting bar with the polymers and the moment at which the maximum temperature of the connecting bar occurred. Because more polymers and K-wires were used in the multiplanar and circular constructs, these configurations were chosen for measurements to determine the curing time and maximum temperatures in the constructs and K-wires. All the measurements were conducted by the same person. Any notable differences (odor) were noted during the preparation of the constructs with both polyurethane and acrylic.

One day after curing, all constructs were weighed using a digital precision balance (±0.001 g accuracy). Three measurements were performed for each configuration and the average values were recorded.

Mechanical testing

Uniplanar, multiplanar and circular configurations were used for the compression and bending tests (n=4 for uniplanar, multiplanar and circular configurations). The pullout test was performed in a uniplanar configuration (n=4 for PUESF and n=4 for ACESF) (Tyagi *et al.,* 2014a; Tyagi *et al.,* 2014b; Tyagi *et al.,* 2015). A bending test was conducted as a three-point bending test. A testing machine with a load capacity of 100 kN (Shimadzu AG-Xplus Universal; Shimadzu Corporation, Japan) was used for the tests.

The structural integrity of the entire structure was evaluated in this study. In the mechanical tests, loads were applied in a way that would affect the entire structure and the maximum force that the whole structure could withstand was determined. In the compression and bending tests, the loads were applied directly to the UHMW rod and it was assumed that the load was distributed along the length of the construct. The constructs were subjected to static loading at a constant crosshead speed of 15 mm/s, until catastrophic structural deformation occurred. Load-displacement curves were created by collecting data on force (load in N) and displacement (in mm) every 0.1 seconds. The ultimate strength was defined as the maximum force in the constructs measured in the load–displacement curve at the moment of catastrophic structural deformation. The point referred to as 'catastrophic structural deformation' was defined as the moment in the load-displacement graph when the force started to decrease and the displacement started to increase rapidly. The tests were visually monitored and stopped thereafter.

Compression

The fixator constructs were placed on metal cylinders and mounted on the testing machine. A compressive force (N) was applied to all configurations along the longitudinal axis at 15 mm/min from the top of the proximal UHMW rod until failure (Fig 2A, B, C). The failure mode was considered to be the moment of catastrophic structural deformation of the connecting bars by converging or tilting.

Bending

The fixator constructs were mounted on the bending test setup of the testing machine. To prevent slippage, the constructs were supported and held in place using metal wedges. In all the configurations, a bending force (N) was applied at a rate of 15 mm/min perpendicular to the long axis of the UHMW rods with a uniform distribution (Fig 2D, E and F). The mode of failure was considered to occur when catastrophic structural deformation occurred with the

bending of the connecting bars and UHMW rods moving away from each other.

Pullout

The pullout test was performed on a single UHMW rod with a uniplanar configuration (three K-wires). To prevent the construct from slipping, axial tensile forces (N) were applied to the connecting bars, which were fixed between the crossheads of the testing device (Fig 2G and H). The failure mode was considered to occur when catastrophic structural deformation occurred with stripping of the K-wires from the connecting bar interface points.

Statistical analysis

Statistical analyses were performed using Jamovi (version 2.3) and Minitab 17 software. Equality of variance and normal distribution tests were performed to confirm the assumptions of parametric methods ($p>0.05$). An independent sample t-test for pairwise comparisons and a two-way ANOVA for repeated measures were performed. Tukey's multiple comparison test was performed for means that differed according to the ANOVA results. Results are presented as mean ± standard deviation (SD). For all tests, the significance level was set at $p<0.05$.

Results and Discussion

Compression

The ACESF group had a higher compressive strength than the PUESF group in all configurations. The PUESF group's compressive strength was close to that of the ACESF group in the uniplanar and circular configurations against compressive force ($p>0.05$), whereas the PUESF group showed lower compressive strength than the ACESF group in the multiplanar configuration ($p<0.05$). In both groups, the multiplanar and circular configurations were similar and stronger than the uniplanar configuration ($p<0.05$; Table 1).

Bending

The PUESF group showed a similar bending strength to the ACESF group in all three configurations against bending forces ($p>0.05$). However, the ACESF group exhibited a higher bending strength in all the configurations. In both groups, the uniplanar configuration was the weakest, the multiplanar configuration was the strongest and the circular configuration was the strongest ($p<0.05$; Table 1).

Pullout

The constructs in the ACESF group showed approximately 2 times the pullout strength of those in the PUESF group ($p<0.05$; Table 1).

Connecting bar temperatures

The curing time of The PUESF group was 3 min, after which the temperature started to decrease gradually. The ACESF group's curing time was 9 min, after which the temperature gradually decreased ($p<0.001$). The maximum side bar temperature was 75.73±2.16°C in the PUESF group and 87.64±9.82°C in the ACESF group ($p<0.001$, Fig 3). The ACESF group was cured at elevated temperatures for a longer time than the PUESF group ($p<0.001$). There was no odor during the creation of the PUESFs, whereas an irritating odor occurred during the creation of the ACESFs.

K-wire temperatures

In the PUESF group, the temperature transmitted to the K-wire reached its highest level at 3 min and then started to



(A) Compression test on uniplanar configuration. (B) Compression test on multiplanar configuration. (C) Compression test on circular configuration. (D) Bending test on uniplanar configuration. (E) Bending test on multiplanar configuration. (F) Bending test on circular configuration. (G) Lateral view of pullout test on uniplanar configuration. (H) Dorsal view of pullout test on uniplanar configuration.

Fig 2: Mechanical tests used in the study.

decrease gradually. That in the ACESF group occurred at 9 min and then started to decrease gradually ($p<0.001$). The maximum temperature delivered to the K-wire was 38.14±5.24°C in the PUESF group and 60.03±9.46°C in the ACESF group ($p<0.001$; Fig 4). The ACESF group transmitted heat to the K-wires for a longer time and at a higher temperature than the PUESF group ($p<0.001$).

ESF weights

In the PUESF group, the uniplanar configuration (153.43±1.24 g) was the lightest, the multiplanar configuration (264.28 ±1.12 g) was heavier and the circular configuration (536.25±3.08 g) was the heaviest. In the ACESF group, the uniplanar configuration (157.24±2.06 g) was the lightest, the multiplanar configuration (265.65±1.45 g) was heavier and the circular configuration (538.43±4.93 g) was the heaviest. The difference in weight between the groups was not statistically significant in any of the three configurations ($p>0.05$).

Some polymer composites have begun to replace metals in orthopedics and dentistry because of their superior properties compared to metals (Krishnakumar *et al.,* 2021). Free-form ESFs made using polymeric materials are inexpensive and relatively lightweight compared with standard fixators (Sellei *et al.,* 2015; Leitch *et al.,* 2018; Tyagi *et al.,* 2014; Aithal *et al.,* 2019; Tyagi *et al.,* 2015). In addition, the absence of clamps reduces the weight and cost without changing the strength of the construction (Leitch *et al.,* 2018; Staudte *et al.,* 2004). In this study, the uniplanar configuration was the lightest and the circular configuration was the heaviest; this difference was proportional to the amount of polymer material used in both groups. The PUESF constructs were not heavier than the ACESF constructs.

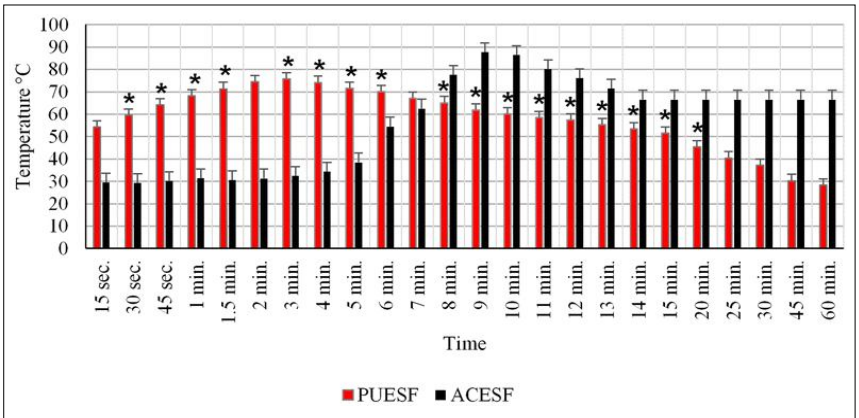
In free-form ESF systems, polyurethane and acrylic account for most of the cost, aside from the pins. Various acrylics are commercially available, including acrylic bone cement and dental acrylic. Dental acrylic was used for the

Table 1: Compression, bending and pullout test results of uniplanar, multiplanar and circular configurations of PUESF and ACESF groups (mean ± standard deviation (SD)). Results are given in Newtons (N).

Test mode	Groups	Uniplanar	Multiplanar	Circular	p
Compression	PUESF	$838.58±17.57^{b}$	$2140.48±21.39^{Ba}$	$2233.69±74.80^{a}$	<0.05
	ACESF	$987.05±88.39^{b}$	$2332.55±38.82^{Aa}$	$2415.69±142.39^{a}$	<0.05
p	0.151	0.005	0.301		
Bending	PUESF	$329.48±21.40^{c}$	$1085.59±77.48^{b}$	$1589.34±53.51^{a}$	<0.05
	ACESF	$359.96±13.82^{c}$	$1309.64±44.87^{b}$	$1762.61±56.18^{a}$	<0.05
p	0.277	0.222	0.067		
Pullout	PUESF	$487.46±37.17^{B}$	-	-	
	ACESF	$951.54±34.26^{A}$	-	-	
p	0.001				

Note: ^{A,B}: The differences between groups in the same column are statistically significant ($p<0.05$). ^{a,b,c}: The difference between configurations in the same row was significant ($p<0.05$).

Abbreviations: PUESF: Polyurethane external skeletal fixation; ACESF: Acrylic external skeletal fixation.



ACESF: Acrylic external skeletal fixation; PUESF: Polyurethane external skeletal fixation; SD: Standard deviation.

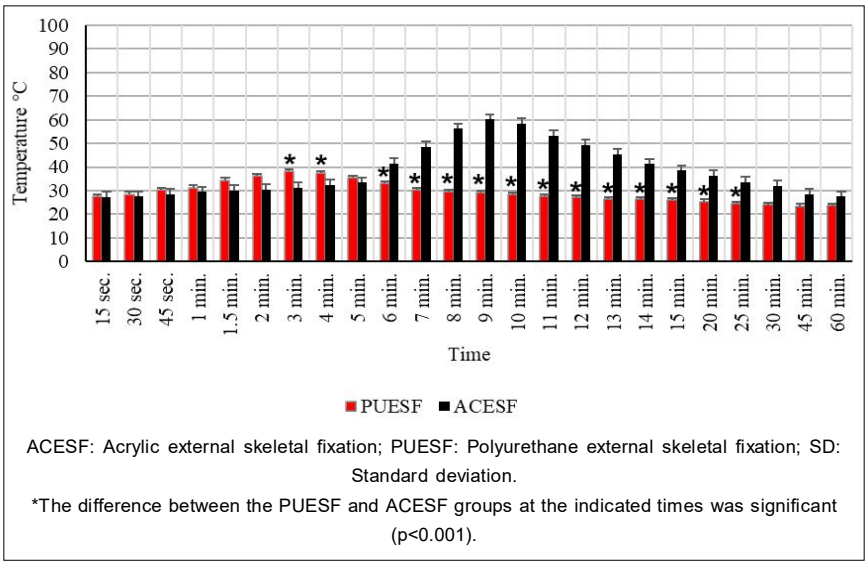
*The difference between the PUESF and ACESF groups at the indicated times was significant ($p<0.001$).

Fig 3: Connecting bar surface temperatures (°C) according to time during curing in PUESF and ACESF groups (mean ± SD).

comparison because it is widely used clinically and can be obtained relatively easily. Polyurethane, which consists of polyol (component A) and isocyanate (component B), is commercially available and readily obtained. In the price analysis between polyurethane and acrylic, 2 kg of polyurethane (1 kg of A and 1 kg of B) cost $16.52 USD and dental acrylic consisting of 1 kg of powder and 500 ml of liquid cost $61.84 USD. Polyurethane was cost-effective and made polyurethane constructions advantageous over acrylic in this regard.

Polymethylmethacrylates can reach temperatures between 50 and 100°C during curing (Amsellem *et al.,* 2010; Roe *et al.,* 1997; Martinez *et al.,* 1997). However, it was determined that necrosis begins in tissues when the temperature of the pins exceeds 70°C (Fukushima *et al.,* 2002). This is particularly true for acrylic, which reaches an average maximum surface temperatures of 90.5°C and remains at temperatures >60°C for 5-9.5 minutes (Leitch *et al.,* 2018). The maximum temperature of the epoxy material is approximately half that of acrylic and never reaches 60°C (Leitch *et al.,* 2018; Martinez *et al.,* 1997; Arias *et al.,* 2015). The curing temperature can be reduced by cooling the acrylic column with saline solution or by increasing the powder/liquid ratio. However, a low temperature may lead to incomplete curing and poor mechanical properties (Amsellem *et al.,* 2010; Arias *et al.,* 2015). In this study, the mean maximum surface temperatures reached 75.7°C at 3 min in the PUESF group and 87.6°C at 9 min in the ACESF group at the connecting bar. The mean maximum temperature transmitted to the K-wires reached 38.1°C at 3 min and 60°C at 9 min. Because more polyurethane was used in the multiplanar and circular configurations, these configurations were preferred to determine the maximum temperatures in the construction and K-wires and to observe possible problems. The short curing time of polyurethane may be advantageous in terms of shortening the operation time; however, it requires quick action during construction. Acrylic acid creates the possibility of thermal injury to bone tissue because it conducts heat to the pins for a longer time and at high temperatures. However, polyurethane transfers heat at body temperature; therefore, it does not pose a risk of necrosis and does not require cooling. Another important advantage over acrylic is that no irritating odor is encountered when polyurethane is used.

In biomechanical tests, the main factors contributing to the fixation stability of ESF structures under compressive load are the number of pins, pin diameter, planes through which the pins pass and number of connecting bars. Fixator stiffness increases with increasing complexity of the fixator configuration (Sellei *et al.,* 2015; Tyagi *et al.,* 2014; Tyagi *et al.,* 2015; Lewis *et al.,* 2016; Deiss *et al.,* 2013). A study using acrylic emphasized that the uniplanar configuration was the weakest and the circular configuration was the strongest under compression, bending and torsion loading. The multiplanar and circular configurations exhibited similar values in the compression tests and there was a significant difference between the uniplanar, multiplanar and circular configurations in the bending tests (Tyagi *et al.,* 2015). Similar findings were reported in another study using epoxy (Tyagi *et al.,* 2014). In the present study, the strengths of the multiplanar and circular configurations were close to each other and stronger than the uniplanar configuration in the compression test. The uniplanar configuration was the weakest, the multiplanar configuration was stronger and the circular configuration was the strongest in the bending test because of the increasing pin number and complexity in terms of the maximum force. The acrylic constructions exhibited higher strengths under compression and bending forces.



ACESF: Acrylic external skeletal fixation; PUESF: Polyurethane external skeletal fixation; SD: Standard deviation.

*The difference between the PUESF and ACESF groups at the indicated times was significant ($p<0.001$).

Fig 4: K-wire temperatures (°C) according to time during curing in PUESF and ACESF groups (mean ± SD).

Although there was a significant difference between the PUESF and ACESF groups in the multiplanar configuration in the compression test, the circular configuration had similar values in the bending test. Although the biomechanical properties of PUESF were weaker than those of acrylic in this study, PUESF configurations require prospective clinical studies on the versatility of configurations and adequate durability.

There were also other significant limitations to this study. The fundamental concepts in evaluating biomechanical tests include strain, stress, strength, stiffness, shear and modulus of elasticity (Alexandre *et al.,* 2023). The strength parameter was evaluated because the aim of this study was to determine the ultimate strength of the constructs at the time of catastrophic damage. Another limitation is the inability to evaluate parameters such as strain, stress, stiffness and shear (Alexandre *et al.,* 2023), along with the lack of torsional loading and fatigue testing.

The main aim of this *in vitro* study was to determine the maximum forces that PUESF constructs of different configurations can withstand and compare them with ACESF constructs. Loading levels provide some insight into the promotion of fracture healing with adequate immobilization but cannot be used to fully assess the impact of the complex forces acting on the fracture site during the healing process. However, we cannot rule out that exceptionally high loading levels may jeopardize fixation in PUESF systems, because the stiffness of the construction is not determined.

CONCLUSION

The results show that polyurethane can be an alternative to acrylic for ESF construction because the conduction temperature of pins does not exceed body temperature, fast curing and low cost. ESF systems created with polyurethane can be used for free-form ESFs in the treatment of bone fractures in animals because of their light weight, size and acceptable mechanical properties. However, prospective clinical studies are needed to determine their ability to promote bone healing in cases of fractures.

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Disclaimers

The views and conclusions expressed in this article are solely those of the authors and do not necessarily represent the views of their affiliated institutions. The authors are responsible for the accuracy and completeness of the information provided but do not accept any liability for any direct or indirect losses resulting from the use of this content.

Conflict of interest

Ünal Yavuz has a pending patent related to this study. The other authors have no conflicts of interest to declare.

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