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Original article

Pull-out strength of four tibial fixation devices used in anterior cruciate ligament reconstruction

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ABSTRACT

Introduction

In reconstructions of the anterior cruciate ligament (ACL), tibial fixation can be the weak point in the assembly during the early postoperative period. The present study sought to compare pull-out strength between 4 tibial fixation systems used in ACL reconstruction.

Hypothesis

The study hypothesis was that all 4 devices show $\geq 450\text{N}$ pull-out strength with comparable biomechanical breakage characteristics.

Material and methods

An experimental study used a mechanical model to perform axial traction on a synthetic ligament (polypropylene cord folded in 4) implanted in an artificial tibia (Sawbones Proximal Tibia # 1116-2: model: normal anatomy; solid foam; size: medium) using 4 tibial fixation systems: Ligafix® interference screw (SBM™); Bio-Intrafix® (Mitek™); Translig® (SBM™); RIGIDfix® (SBM™). For each system, 4 models were tested using an Instron 5566® traction machine, allowing 100 mm/min stretching up to breakage. Study parameters comprised: pull-out strength, maximal whole assembly slippage, stiffness at breaking point, and type of break.

Results

Mean pull-out strength was $450 \pm 24\text{N}$ (range, 421–488N) for Ligafix®, $415 \pm 60\text{N}$ (327–454N) for Bio-Intrafix®, $539 \pm 66\text{N}$ (449–636N) for RigidFix and $1067 \pm 211\text{N}$ (736–1301N) for Translig®, and was significantly greater for Translig® than for the other devices ($p=0.02$), which did not significantly differ from one another. The expected maximal load of 450N was reached in 100% of cases with Translig® and RIGIDfix® and in 50% of cases with Bio-Intrafix® and Ligafix®. There were no significant differences regarding stiffness. Ligafix® showed significantly less slippage than the others ($p=0.006$), with breakage caused by the ligament sliding between bone and implant.

Discussion

In this in-vitro study, the Translig® fixation device showed better pull-out strength than the other 3 devices tested.

Type of study and level of evidence: Comparative experimental study. Level II

Keywords: Biomechanics, fixation, tibia, anterior cruciate ligament reconstruction, pull-out strength

INTRODUCTION

In surgical reconstruction of the anterior cruciate ligament (ACL), stable mechanical graft fixation is essential to biological integration and to avoid early distension [1 - 3].

In the early postoperative period, tibial fixation is the weak point of the assembly, mainly due to the low bone density of the tibial metaphysis [4 - 6]. According to animal studies, good integration takes 12 weeks [7]. Excessive stress can thus lead to reconstruction failure. Mechanical studies of assembly resistance showed that, at implantation, all types of graft have better pull-out strength than the native ACL [8 - 13].

Transplants are thus able to resist transmitted stress, notably during daily life activity. In the literature, stress related to functional rehabilitation is around 450-500 N [14][15]. There have been several studies of the mechanical properties of various fixation devices [16 - 18]. However, the wide variety of experimental conditions and specimens (anatomic, or animal models) hinders comparison of results. Sawbones™ artificial bones are a synthetic model used in some biomechanical studies [19 - 21], which have the advantage of giving highly reproducible results, unlike, for example, human specimens.

The aim of the present study was to compare biomechanical properties between 4 tibial fixation systems on an in-vitro mechanical model. The study hypothesis was that all 4 have similar biomechanical breakage characteristics, with pull-out strength $\geq 450\text{N}$.

MATERIAL AND METHODS

Four tibial fixation devices were tested by traction to the point of assembly breakage. A mechanical model was used for traction testing, with force vector along the graft axis. A 4-strand synthetic ligament, consisting of a 3.5 mm diameter polypropylene cord (Standers™, Lezennes, France) was fixed to artificial tibias (Sawbones™ Proximal Tibia # 1116-2: model: normal anatomy; solid foam; size: medium. Sawbones™, Malmö, Sweden) (fig.1). The synthetic graft was fixed using the 4 systems.

FIXATION DEVICES

The 4 fixation devices were of 2 types:

1/ Absorbable osteoconductive interference screws:

Ligafix® (SBM™, Lourdes, France) and Bio-Intrafix® (Mitek™, Chesterfield, MO). Both were of 8 mm diameter and 30 mm length. In vivo, Ligafix® consists in press-fit intracancellous fixation, and Bio-Intrafix® in intratendinous press-fit cancellous fixation. The principle consists in crushing the 4 strands of the transplant against the tunnel wall, with 360° graft contact on the bone to optimize osseointegration.

2/ Absorbable transverse transfixing fixation systems:

RigidFix® (Mitek™, Chesterfield, MO) absorbable 3.3 mm cross-pins, and Translig® (SBM™, Lourdes, France) 6 mm cross-pins, transfixing the graft in the tunnel, with converging trajectories. In vivo, these systems consist in corticocancellous fixation.

SAMPLE PREPARATION

Sixteen assemblies were performed by a junior surgeon assisted by a senior surgeon: 4 samples per device.

The polypropylene cords were folded in 4 to form an 8mm transplant made up of 4 strands. The 2 ends were tacked with 5 high-resistance sutures (size 2 polyglactin-910 Vicryl®; Ethicon™, Somerville, NJ.) over a length of 20 mm (fig.1).

In each sample, the synthetic ligament was fixed following the manufacturer's instructions and using the device's dedicated instrumentation. It was positioned out-in through an 8 mm tibial bone tunnel, drilled in advance, at the ACL insertion site. Tunnels were drilled in the same way for all samples. We used a 55° tibial guide, to create tunnels long enough to exit at the tibial plateau: i.e., 40 mm. The synthetic ligament was inserted in the tunnel with the sutured parts left outside.

1/ The Ligafix® screws were inserted up against the anteromedial cortex.

The Bio-Intrafix® screws were inserted after separating and individualizing the 4 strands.

2/The RIGIDfix® pins were positioned after drilling 2 parallel transverse holes in the medial side of the tibia, using the dedicated guide. The Translig® pins were positioned after drilling 2 transverse holes in the medial side of the tibia, using the dedicated guide. The pins were then inserted with convergent axis, transfixing the transplant.

BIOMECHANICAL TESTS

A polyurethane resin base was molded onto the proximal tibia at 45° in the sagittal plane (fig. 2) so that graft and tunnel were aligned with the traction axis. The molded resin was then mounted on the experimental device. The orientation used here represented the "worst case" scenario for traction force.

The distal bone extremity of each specimen was fixed to the base of the test machine (Instron 5566, Instron Ltd, High Wycombe, UK). The free end of the synthetic ligament was fixed in self-tightening grips on the dynamic part of the machine. Specimen length (12 cm), knot, tunnel position and exit angle were the same in all cases, so that the study variable would be the particular fixation device itself. A previously

implemented [22] standardized traction protocol was used. Traction force was exerted in the tunnel until breakage of each specimen, with a displacement speed of 100 mm/min (fig. 3). Sixteen trials were performed.

PARAMETERS OF INTEREST

For each device at each test, an experimental profile of slippage curve was recorded as a graph using the system's software (BlueHill, Instron SA France, Elancourt, France).

Data comprised: pull-out strength (force at breaking point), stiffness at breaking point (calculated on the slope of the most linear part of the force/slippage curve), assembly slippage at breaking point (difference in distance between the grips at start and at end of test), and type and location of break (bone, ligament or fixation) assessed on the HD video connected to the Instron® traction device (fig. 4).

STATISTICS

Calculations used Excel 2016 software (Microsoft, Redmond, WA) and statistical analyses SPSS software (SPSS Inc., Chicago, IL)

Numerical data were reported as mean (range) with standard deviation. The significance threshold was set at $p < 0.05$. Descriptive analysis gave means, medians and standard variations. Comparisons used paired Student t test.

Requisite sample size was based on a clinically significant difference between devices of $>100\text{N}$ with expected 50N standard deviation on testing [22]. Four samples per group provided 80% power with 0.05 alpha risk.

RESULTS

Traction test results are shown in Table 1.

1/ Mean pull-out strength for Translig® was $1,067 \pm 211\text{N}$, significantly greater ($p = 0.02$) than for Ligafix® ($450 \pm 24\text{N}$), Bio-Intrafix® ($415 \pm 60\text{N}$) or RIGIDfix® ($539 \pm 66\text{N}$). The expected pull-out strength of 450N was reached in all tests for Translig® and RIGIDfix® and in 50% (2 out of 4 specimens) for Bio-Intrafix® and Ligafix®.

There were no significant differences between the other 3 devices (excluding Translig®) ($p > 0.05$) (fig. 5).

2/ There were no significant differences in stiffness at breakage between the 4 devices ($p > 0.05$) (fig.6).

3/ Mean assembly slippage at breakage was $15.24 \pm 4.6\text{ mm}$ for Ligafix®, which was significantly less than for the other 3 devices ($p = 0.0006$): $30 \pm 4.2\text{ mm}$ for Bio-Intrafix®, $31.7 \pm 3.75\text{ mm}$ for RIGIDfix®, and $33.45 \pm 1.5\text{ mm}$ for Translig® (fig. 7), with no significant difference between the 3 ($p > 0.05$). Type of break varied between devices (Table 2): with Translig®, the pins broke without bending, and the bone fractured in 1 case (fig. 8).

Discussion

The main result in the present study was that the Translig® transverse system showed maximal load exceeding 1,000N, significantly greater than in the other 3 systems. Another important finding was Ligafix® showed significantly less slippage before failure. The study hypothesis that all 4 systems show similar biomechanical failure characteristics, with ≥ 450 N pull-out strength, was only partially confirmed.

The present mechanical study assessed tibial fixation device quality in ACL reconstruction, simulating immediate postoperative stress. The 4 devices were compared on a normalized protocol of traction along the bone tunnel axis, with simple preparation, so that observed differences would be largely due to differences in fixation. The 4 devices could be divided into 2 types according to means of fixation: interference screws, and transverse devices. In the present test set-up, loading is applied directly on the fixation, without friction due to graft angulation at the tunnel exit; this is the “worst case” mechanical scenario, never encountered in practice but much studied in the literature [23][24].

In the present study, the Translig® device showed significantly greater pull-out strength than the other 3 devices ($p=0.02$): i.e., it is able to resist much higher loadings in case of unforeseen stress.

The length of the Ligafix® system was 30 mm and the diameter equaled that of the tunnel (8 mm). Slippage ranged between 10.83 and 19.46 mm and pull-out strength between 421 and 488N, in line with the literature.

Table 3 shows results from biomechanical studies comparing similar devices. Giurea et al. [25] reported results similar to the present, notably for Translig®.

Scannell et al. [18] used a different protocol, with cyclic loading preceding stretching to breaking point: Intrafix® showed the best resistance; this device was not included in the present study. Kousa et al. [26] reported results similar to Scannell's: mean maximal loads were highest for Intrafix® and Washerloc®; the present resistance results were in agreement.

The present 4 systems showed no differences in stiffness. Ligafix® had the greatest mean stiffness (38.9 N/mm), followed by Translig® (33.22 N/mm). Although differences were not significant, it was noteworthy that Ligafix® showed significantly less slippage ($p=0.006$), but with lower pull-out strength than Translig®. These findings are concordant, and are explained by the different means of breakage.

For Ligafix®, the main means of failure was the ligament sliding between the bone and the screw. During the trials, the graft showed little slippage, but then suddenly slid. We think that this means of breakage largely accounts for the stiffness results. The Bio-Intrafix® interference screw also failed by ligament sliding, but this time the whole system was carried away. In the transverse Translig® and RIGIDfix® systems, failure came from fracture of the fixation system. A case of bone fracture was observed with Translig®, probably due to high maximal pull-out

strength and the cortical fixation. These findings show that stress was higher within the transverse devices but was situated at the bone-implant interface in interference devices.

ACL trauma often concerns a change in direction during a shock-absorbing or deceleration movement [27]. In sports such as soccer or basketball, maximal shock-absorbing load on the ACL is 1,294 N [28], greater than the mean maximal loads in the present study, except for Translig® (up to 1,301N).

The present study had certain limitations. Firstly, it was conducted in vitro, mimicking a complex in-vivo situation. The model was chosen to be as simple as possible: Sawbones™ proximal tibia with synthetic ligament to limit measurement bias, at the price of faithfulness to clinical conditions. Various studies [29][30], however, have used such models for mechanical testing, making results highly reproducible. Observed differences were therefore entirely attributable to the different devices. Secondly, stress was static rather than cyclic; thus graft lengthening was not assessed, but only slippage of the assembly as a whole. Cyclic measurement, however, would not have been appropriate on a synthetic model. Thirdly, no comparison was made with other fixations systems, such as adaptable endobuttons; we do not use these implants in our practice.

Finally, it is important to bear in mind that this in-vitro study focused exclusively on the mechanical properties of graft fixation, and took no account of biological factors such as healing and transplant osseointegration in the tunnel.

While differences emerged in mechanical performance, it is difficult to say whether these have real clinical impact.

Conclusion

In the present experimental conditions, transverse fixation devices, and especially the Translig® device with convergent pins, showed greater pull-out strength.

In vitro, the mechanical stress on the 4 fixation devices on synthetic dry bone was similar to that in daily life activity and early rehabilitation, but less than in intensive rehabilitation.

Conflicts of interest:

J.-N. Argenson is an occasional consultant for Zimmer, Symbios and Adler, and Zimmer/Biomet.
The other authors have no conflicts of interest to disclose.

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	LIGAFIX	BIO-INTRAFIX	RIGIDFIX	TRANSLIG
<i>Mean maximal load (N)</i>	450 p=0.11	415 p=0.18	539 p=0.09	1,067** p=0.02
<i>Range</i>	421-488	327-454	449-636	736-1,301
<i>Standard deviation</i>	24	60	66	211
<i>Mean stiffness (N/mm)</i>	38.9 p=0.08	14.49 p =0.11	26.59 p=0.07	33.22 p=0.09
<i>Range</i>	34.4-47.3	12.05-17.6	23.93-28.26	29.15-40.18
<i>Standard deviation</i>	5.86	2.3	1.96	5.21
<i>Mean slippage (mm)</i>	15.24** p=0.006	30 p=0.09	31.7 p=0.07	33.45 p=0.06
<i>Range</i>	10.83-19.46	25.7-35.33	27-36.3	31.8-35.5
<i>Standard deviation</i>	4.6	4.2	3.75	1.5

Table 1: Traction test results: maximal; load (N), stiffness (N/mm), and transplant slippage (mm)

	Ligament sliding	Ligament sliding carrying implant away	System folds and breaks	Direct system breakage	Bone fracture
LIGAFIX	4				
BIO-INTRAFIX		4			
RIGIDFIX			4		

Table 2: Means of breakage according to device

Report	Interference screw	Transverse device
<i>Giurea et al. [1]</i>	RCI Screw® 445 N	Stirup® 898 N
<i>Scannel et al. [2]</i>	Intrafix® 656 N	Washerloc® 630 N
	Delta Screw® 430 N	
	Retro Screw® 285 N	
<i>Kousa et al. [3]</i>	Intrafix® 1332 N	Washerloc® 975 N
	SmartScrew ACL® 665 N	Tandem spiked washer® 769 N
	BioScrew® 612 N	
	SoftSilk® 471 N	

Table 3: Pull-out strength of devices in the literature



Figure 1: Synthetic ligaments, prepared



Figure 2: Molded resin on proximal tibia

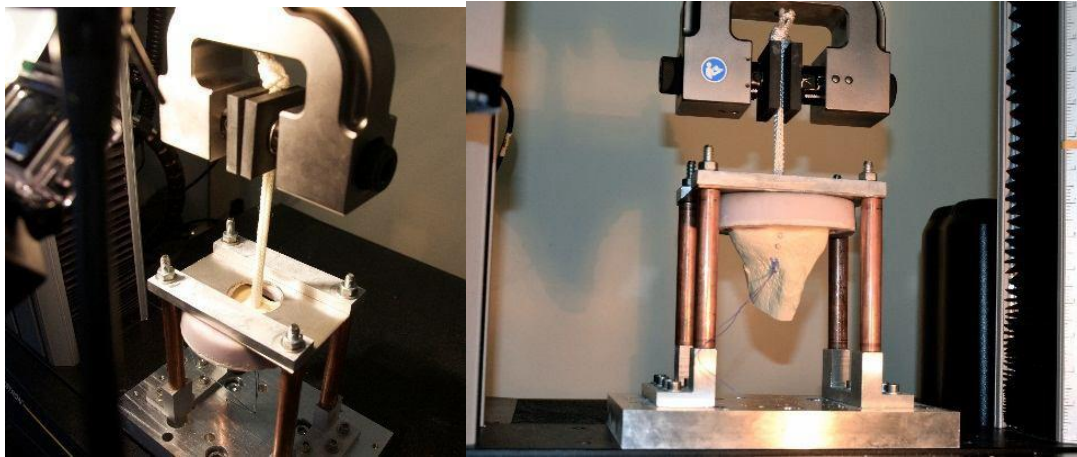


Figure 3: INSTRON 5566

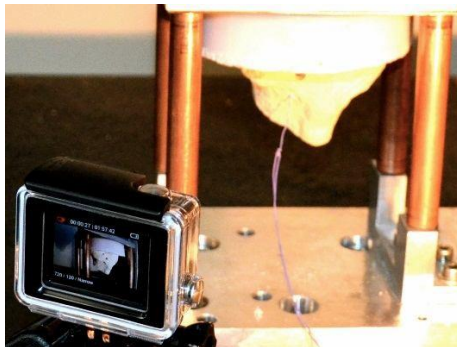
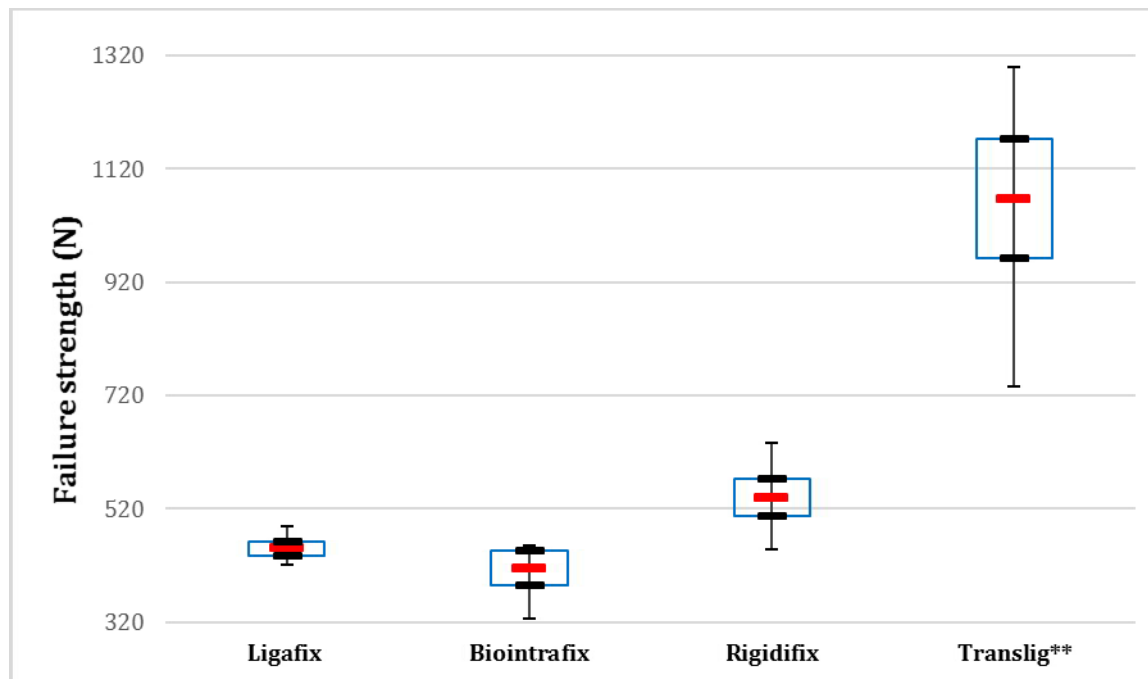


Figure 4 : HD vidéo to determine type of break

Figure 5: Mean failure strength and standard deviation (** $p < 0.05$)



Accept

Figure 6: Mean stiffness and standard deviation for each device.

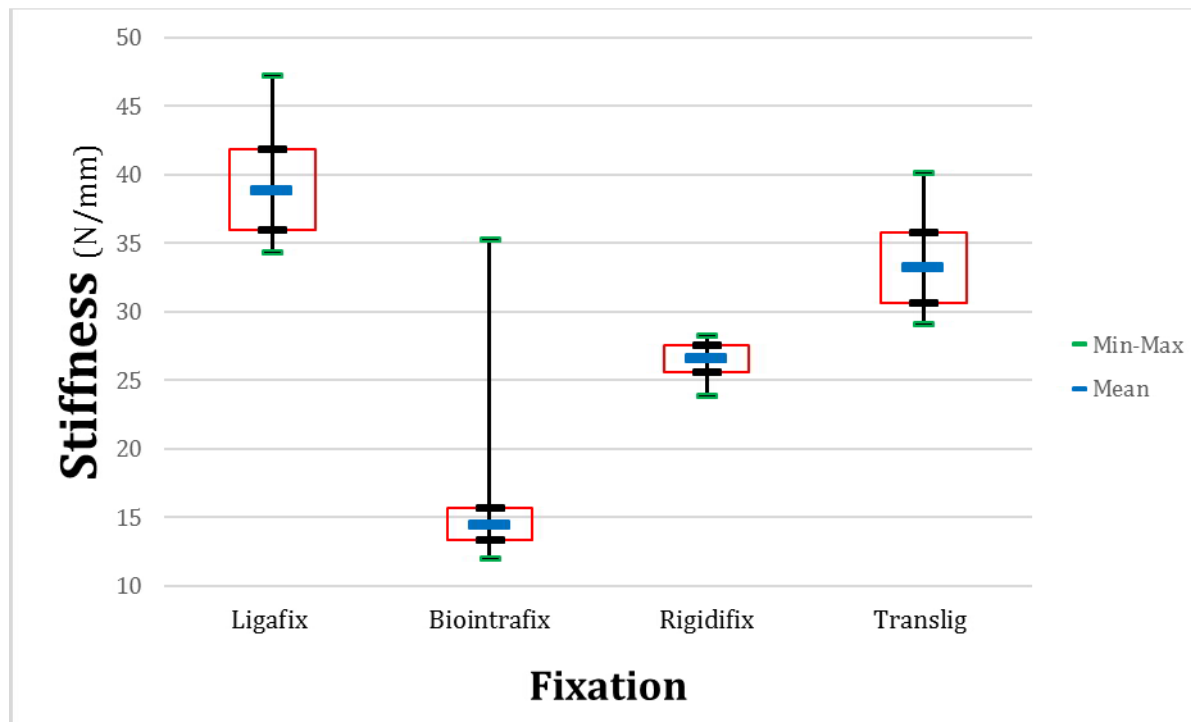


Figure 7: Mean slippage and standard deviation (**p<0.005)

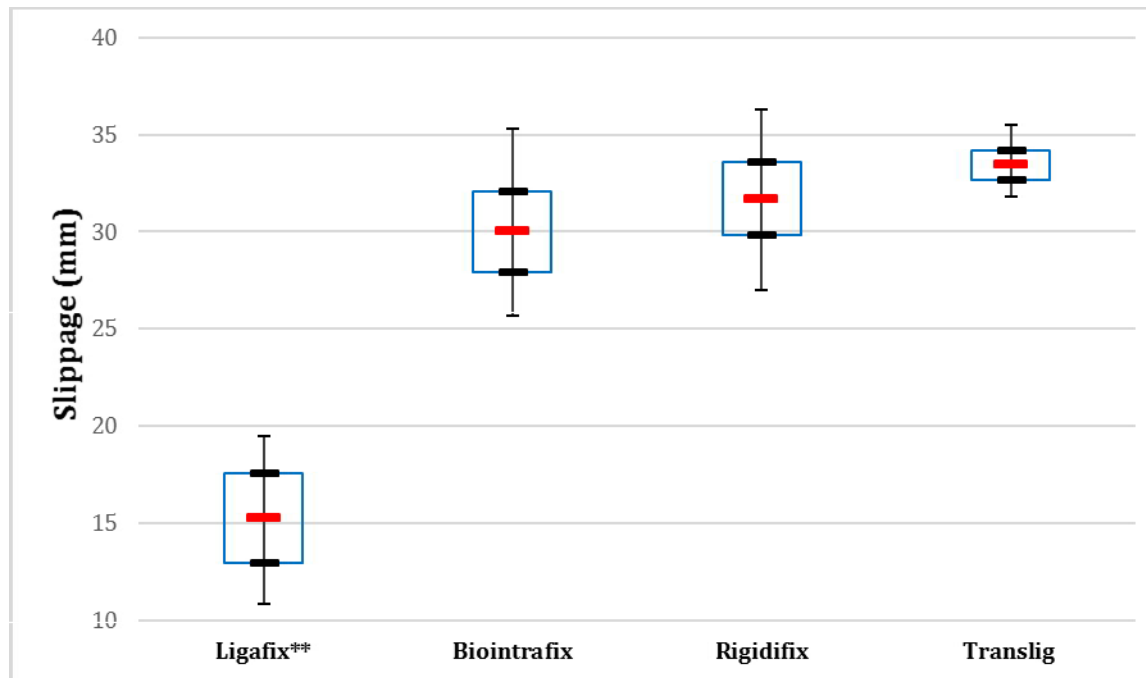


Figure 8: Fracture with Translig® device