1	The consistency and reliability of six-strand and four-strand flexor tendon repairs: a
2	comparative porcine cadaveric study
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ABSTRACT

The aim of this study was to compare the consistency and reliability of the six-strand Gan modification of the Lim-Tsai flexor tendon repair with the four-strand Adelaide repair, both with 3-0 sutures and with eight to ten runs of simple 5-0 running peripheral suture as well as the influence of the surgeons' level of experience on the strength of the repair in a cadaveric animal setup. Thirty-nine surgeons repaired 78 porcine flexor digitorum profundus tendons with either the Adelaide technique (39 tendons) or the modified Lim-Tsai technique (39 tendons). Each repaired tendon was tested in a material testing machine under a single cycle load-to-failure test. The forces were recorded when the gap between the two tendon stumps reached 1 and 2 mm and when irreversible elongation or total rupture occurred. We found no significant differences in gap formation force and yielding strength of the tendons between the two methods. The surgeon's previous experience in tendon repairs did not improve the consistency, reliability, or tensile strength of repairs. We conclude that if a strong peripheral suture is added, the modified Lim-Tsai repair has the same technical reliability and consistency as the Adelaide repair in term of ultimate loading strength in this test setup.

INTRODUCTION

Multiple flexor tendon core suture configurations have been developed in the pursuit of stronger repair techniques that could withstand forces present in early active rehabilitation. The strength of the repair is often increased by increasing the complexity of the repair. However, technical complexity may increase the rate of technical errors and thus add variability in the tensile properties. This inconsistency, i.e., larger variation, can increase the proportion of repairs that are too weak to withstand the forces present during rehabilitation. Beginner-level surgeons can perform consistent repairs only with relatively simple configurations. Furthermore, regardless of the level of experience, surgeons should not use a complex repair if it does not offer any benefits compared with a simpler technique. While a study found that organized training schedules improved the

53 biomechanical properties of flexor tendon repair, it did not assess whether experience level of the 54 operators affected reliability or consistency (Bari et al., 2012). 55 56 The aim of our study was to compare the consistency (variation of tensile strength) and reliability 57 (how strong 98% of the repairs are) of Adelaide and Gan modified Lim-Tsai repairs, both augmented with a strong peripheral running suture and performed by surgeons with different levels 58 59 of expertise (Gan et al., 2012; Sandow and McMahon, 2011). Assuming that the 6-strand modified 60 Lim-Tsai is a more complex repair than a 4-strand Adelaide repair, we hypothesized that the complexity of repair increases the mean tensile strength but also variability, causing inconsistency 61 62 and lower reliability. We also hypothesized that the experience of the surgeon is associated with 63 consistency, reliability, and mean yield load of the repairs. 64 65 **METHODS** 66 **Participants** 67 We organized a flexor tendon repair workshop for surgical residents and hand surgical fellows and 68 collected demographic data from the participants (Supplementary Table S1). We divided 69 participants into three experience groups: no previous experience repairing flexor tendons in a 70 patient (no experience), one to five previous repairs (some experience), and more than five previous 71 repairs (relatively more experienced). 72 73 Repairs 74 Tutorial videos of both repairs were provided to each participant 1 week before the course, and two 75 experienced hand surgeons gave oral instructions. The total sample (78 tendons) was determined by 76 the number of participants and the size of the workspace. 77 Freshly frozen porcine hind trotters were thawed to room temperature. The flexor digitorum

profundus tendons in the second and third toes were cut with a scalpel. Each of the 39 participants

repaired two tendons: one with Adelaide and the other with modified Lim-Tsai repair (Figure 1). The order in which repairs were performed was randomized and participants could freely choose in which tendon they performed the first repair. A braided and coated 3-0 polyester (PremiCron®, B. Braun Surgical GmbH, Melsungen, Germany) was used for the Adelaide repair, and a looped 3-0 polyester (Crownjun, Kono Seishakusho Co., Chiba, Japan) was used for the modified Lim-Tsai repair. The repairs were completed with a simple running peripheral suture using 5-0 polypropylene-polyethylene monofilament (Optilene®, B. Braun Surgical GmbH, Melsungen, Germany) with eight to ten runs. After the repair, the tendons were preserved in sealed containers with saline-soaked gauze swabs, and stored them in a –20°C freezer until testing (Hirpara et al., 2008). Before biomechanical testing, we thawed the specimens, measured the cross-sectional area of the tendons with a digital caliper (Alpha Tools®, Bahag AG, Mannheim, Germany), and defined the elliptical cross-sectional areas.

Biomechanical testing

We performed biomechanical testing with a material testing machine embodying a 500 N load cell (LC 500N, Lloyd Instruments, Fareham, United Kingdom) and used NEXYGEN software (Lloyd Materials Testing, AMETEK, Berwyn, PA, USA) to collect data. We used a distraction rate of 20 mm/min and a preload of 0.5 N. The clamps of the testing machine were set 30 mm apart at the beginning of each test. Exceptions to the distance were made in two samples to prevent slipping of the specimens in tendons that were too short to achieve secure mounting to the clamps. In those cases, distance of the clamps was minimally reduced. We recorded yield load in the comparison of tensile strengths of repairs, as it represents the force under which the repair starts to exhibit irreversible elongation, meaning that the repair will not return to its intact size after unloading. We determined yield load with the method introduced by Lotz et al. (1998). The yield load was the intersection of the 0.1 mm offset line and the load-deflection curve. In cases where load-deflection

curve did not express an interpretable yield load, we used the highest measured load during the test (the ultimate load) as the yield load.

We recorded the testing with two perpendicularly placed cameras (Canon EOS 550 D and Canon EOS M, Canon, Tokyo, Japan) for assessment of gap formation. We defined the 1 mm partial and total as well as the 2 mm partial and total gap forces using the video images and the load-deformation curve. Two authors independently assessed the videos for gap formation. The mean of their evaluations was considered as the point where the gap value was determined. The authors also determined failure modes of the repairs based on physical examination of the tendons and the videos. Discrepancies in failure mode were resolved by consensus.

Statistics

We used the standard deviation of the yield load as a measure of consistency of the repairs. We defined reliability as the lower boundary of 95% CI of the yield load (i.e., 2.5% of the repairs have started irreversible deformation before this load). The reliability value is dependent both on the tensile strength and on variance. Low reliability can be due to weak repair or large variability or both. We used Welch's t-test to assess the statistical significance of differences in biomechanical properties of repairs. We considered p < 0.05 to be statistically significant. Since the sample size was based on the number of participants attending the course, we did not perform a prior power analysis. Post hoc analysis showed that the sample size was sufficient to detect 15.5N difference in the yield load (β =0.2; α =0.05; SD 24) and 11N in the ultimate load (β =0.2; α =0.05; SD 19 and 16). We also used 95 confidence intervals (95% CI) to assess how large differences were compatible with the observed data. (Hoenig and Heisey, 2001)

In addition to standard deviations and confidence intervals, we assessed the interaction effect of experience and core suture on mean yield and ultimate load with a two-way repeated measures

analysis of variance. Experience and core suture type were taken as independent variables, whereas yield load and ultimate load were taken as the dependent variables. We used one-way analysis of variance to analyze the differences in cross-sectional areas of the tendons between experience groups. We assessed the difference between evaluators' estimates of gap formation. The formula we used for interobserver variation was $\sqrt{\sum_{i=1}^n \left[100 \times \left(\frac{a_n-b_n}{a_n+b_n}\right)\right]^2/n}$, where a and b are observations of evaluators and b is the number of observed repairs. The lower the percentage, the lower level of dispersion around the mean.

RESULTS

140 Descriptives

A total of 39 doctors repaired 78 tendons. Twenty-four were surgical residents, and twelve were specialized hand surgeons or hand surgery fellows. One surgeon was a specialist paediatric surgeon, and two surgeons did not return the survey (Supplementary Table S1).

The mean cross-sectional area of all tendons was 24 mm 2 (95% CI, 23 to 25 mm 2). The cross-sectional area did not differ between repair methods (Table 1) or experience groups (p = 0.75). Interobserver variability for 1 mm partial, 1 mm total, 2 mm partial, and 2 mm total gap values was 8%, 9%, 5%, and 5%, respectively. We excluded three samples from the analysis due to technical errors. Two Adelaide repair samples slipped from clamps during the biomechanical testing. Additionally, there was a software failure of the testing machine during testing of a modified Lim-Tsai repair sample leading to a failure of recording the test.

Failure mechanism

For core sutures, 44 repairs failed by suture pullout, 19 repairs by suture breakage, and 12 repairs by knot unravelling. For peripheral sutures, 59 repairs failed by suture pullout, 14 repairs by suture breakage, and two by knot unravelling (Table 2).

Consistency, reliability and effect of surgeon's experience

SD of yield as well as gap loads were comparable in both Adelaide and modified Lim-Tsai (Table 1). Consistency of these techniques was uniform. We did not find a difference in reliability between the repairs. the lower boundary of the 95% CI of the yield loads, ultimate loads, and gap loads was comparable for both repair methods. Mean difference (between Adelaide and Gan modified Lim-Tsai) in the yield load was 3N (95% CI -8N to 14N; p=0.59) (Table 1). Results of the two-way repeated measures analysis of variance revealed that the interaction effect was not statistically significant (p = 0.98), which indicated that the experience of the participants did not modify the yield load in either Adelaide or modified Lim-Tsai repairs. We also found no interaction effect regarding ultimate load and experience (p = 0.59).

DISCUSSION

We found that in a porcine flexor digitorum profundus tendon model, a four-strand Adelaide core suture and six-strand Gan modified Lim-Tsai core suture, both with a strong peripheral running suture, were similar with respect to their tensile strength, repair consistency, and reliability. The complexity of the repair neither improved the yield strength nor decreased the strength of the weakest repairs. Surgeon's previous experience in tendon repairs did not improve the consistency, reliability, or tensile strength of repairs.

We chose yield load instead of ultimate load because in mean ultimate load, most repairs have already started to irreversibly fail far below this load (Lotz et al., 1998). A repair with large variance may, in fact, result in higher incidence of irreversible changes eventually to rupture under cyclic loading even if it had a higher mean load. The total variance of yield load consists of two independent factors: variance of the core and peripheral repairs (Linnanmäki et al., 2018). Peripheral suture significantly affects yield load, which usually occurs when the peripheral repair fails (Lotz et al., 1998). Although more strands in the core repair usually improve the ultimate

force, the yield depends more on the peripheral suture and the distribution of tension between the core and the peripheral repairs. This may have led to similar consistency between the two configurations in our study despite the differences in core sutures.

The Adelaide repair is known for its simplicity (Sandow and McMahon, 2011). The Tsugelocks of the modified Lim-Tsai repair are more complicated to perform than the cross-locks of the Adelaide repair, and locking loops in the modified Lim-Tsai repairs could also hamper equal load sharing between the strands We hypothesized that since the modified Lim-Tsai repair is more complex, it would have lower consistency and reliability than the Adelaide repair, but also that previous experience would compensate for this. However, our results rejected our hypotheses. The modified Lim-Tsai repair uses six strands that consist of three double strands, while the Adelaide repair consists of four single strands, but there is an equal number of locking points where suture grasps the tendon (four locking loops in both repairs) despite the difference in the number of suture strands. This may partially explain the similar strength in both repairs, at least as far as failure by suture pullout is concerned. Haimovici et al. (2012) showed that increasing the number of strands with looped suture does not improve biomechanical properties of the repair. Calfee et al. (2015) corroborated this finding by reporting that looped 3–0 repairs were inferior to single stranded 3–0 repairs in terms of gap and ultimate load. During early active mobilization, it is estimated that up to 35 N loads are subjected to the FDP tendon (Schuind et al., 1992) and more than 97 % of Adelaide and modified Lim-Tsai repairs in our study would theoretically have withstood these forces in terms of lower boundary of 95% confidence interval of yield load (Table 1).

Bari et al. (2012) suggested that both senior and junior residents benefit from flexor tendon repair training. In their study, the post-tutorial load-to-failure results (2 mm gap load and ultimate load) were 25 N and 27 N higher than before the tutorial, respectively. The difference in the tensile strength of the repair between the experience groups decreased after curriculum-based education. In our study, we provided both videos and hands-on assistance during the workshop, which may explain the lack of difference between experience groups.

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In general, a 6-strand core suture is much stronger than a 4-strand core suture repair, as shown in many previous studies (Gan et al., 2012; Wu and Tang, 2014a). The possible weaker ultimate strength of the Lim-Tsai suture than other 6-strand repairs was found 20 years ago in a study of Xie et al. (2002). It is unclear whether the modification of Lim-Tsai suture is the same from the original repair method in term of the strength. However, our data indicate its ultimate strength is actually similar to a 4-strand repair. In a recent study, another 6-strand repair (Yoshizu #1 repair) has been shown to be weaker in gap resistance (Wu and Tang, 2021). Therefore, different configurations of 6-strand repair do have different strengths in term of gap resistance or ultimate strength.

Our study has limitations that include experimental circumstances and the use of porcine tendons, which are larger than human flexor digitorum profundus tendons, and that the results from this study may be different from tendon injury repairs in patients. Our tendon repairs included a peripheral suture, which is popular clinically (Gibson et al., 2016) although some studies suggest that it may be not necessary or can be simplified if a very strong core repair is used (Giesen et al., 2018; Tang, 2018). In addition, the workshop was primarily targeted for residents, and the numbers of samples and experienced surgeons involved were relatively small. This may be a cause for a lack of correlation between experience and repair properties. The sample size was based on practical circumstances and not on power calculations, but the confidence intervals of the estimates in yield and ultimate load suggest that 14N differences between the groups were unlikely (Table 1). Surgeons made only two repairs, so the consistency and reliability of repairs made by single surgeon could not be assessed. In addition, we used yield load, and, in some specimens, the yield load was the same as the ultimate strength in our measurements. The standard deviation of test data of ultimate strength was small, but that of the gap forces was all quite large. This may reflect experience levels of these participants who might have made repairs that produced variations in gap resistance but not in ultimate strength. However, the gap formation force is more important in determining the impact of a repair (Wu et al., 2021, Wu and Tang, 2014b; 2021). No cyclic loading

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was used for the assessment, which is another weakness of this study (Wu et al., 2021, Wu and Tang, 2014b; 2021).

The most important weakness of this study is that a peripheral suture with eight to ten runs of a 5-0 suture was added to the core sutures. Eight to ten runs of peripheral sutures produces a very strong suture in itself, which usually achieves a strength close to a 4-strand repair. Therefore, the results can be markedly affected by addition of the strong peripheral suture, blurring any differences in core suture strength. Clinically, 5-0 sutures are not commonly used for peripheral suture, and if used, consist of fewer than 10 to 12 runs. This weakness renders the entire experimental setting different from a clinical setting. The findings of this study should be interpreted carefully. The ultimate strengths of the tendons of average 77 or 78 N are much higher than those usually seen in the pig tendons, which likely indicate an effect of the strong peripheral suture. However, based on the available data, we conclude that if a strong peripheral suture is added, the modified Lim-Tsai repair has the same technical reliability and consistency as the Adelaide repair in terms of ultimate loading strength, though the former was a more familiar technique for the more experienced participants. Only one surgeon had performed the Adelaide repair before the study.

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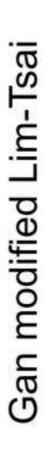
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- 302 FIGURE LEGENDS
- Figure 1. The two core suture configurations used in this study: Adelaide and Gan modified Lim-
- 304 Tsai with peripheral sutures.
- 305 SUPPLEMENTARY MATERIAL
- **306 Table S1**

Adelaide



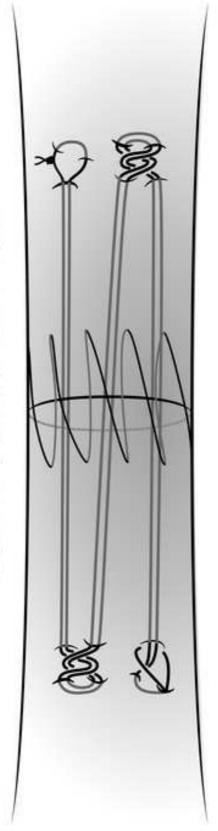


Table 1. Biomechanical measurements comparing two methods of flexor tendon repair

Measurement	Method of repair								
	Adelaide			Gan modified Lim-Tsai			Mean		
	Mean	SD	95% CI	Mean	SD	95% CI	difference	95% CI	<i>p</i> -value
Yield load *									
All	52	24	44–60	49	24	41–57	3.0	-8.1–14	0.59
0 repairs (n = 20)	56	26	44–68	53	24	41–65			0.70
1-5 repairs (n = 8)	49	17	33–64	46	21	29–64			0.83
> 5 repairs (n = 8)	47	26	25–69	46	29	20-73			0.98
Ultimate load	78	16	73–84	77	19	71–84	0.8	-7.5–9.1	0.84
1 mm partial load	50	23	42–57	48	21	41–56	1.5	-8.9–12	0.78
1 mm total load	63	21	56-70	59	19	52-65	4.6	-4.9–14	0.33
2 mm partial load	58	23	50-65	54	19	47–61	3.9	-6.0–14	0.43
2 mm total load	67	21	60–74	61	19	54–67	6.4	-3.1–16	0.19
Cross-sectional area	24	4.5	23–26	24	4.4	23–25			0.86
(mm ²)									

Data are given in Newton unless otherwise mentioned

^{*:} according to the surgeon's experience. N= number of surgeons. 0 repairs: no previous experience; 1-5 repairs= one to five previously performed repairs; > 5 repairs: more than five previously performed repairs. The level of experience was unknown for two surgeons.

Table 2. Failure mechanisms of two methods of flexor tendon repair according to the surgeons' experience

			Method of repair									
	Adelaide		Gan modified Lim-Tsai									
Suture Suture Knot			Suture	Suture	Knot							
pullout	breakage	unraveling	pullout	breakage	unraveling							
27	8	2	32	6	0							
16	3	1	20	1	0							
4	2	1	6	2	0							
6	2	0	5	2	0							
18	10	9	26	9	3							
11	3	6	15	5	1							
3	3	1	4	3	1							
3	3	2	5	1	1							
	pullout 27 16 4 6 18 11 3	pullout breakage 27 8 16 3 4 2 6 2 18 10 11 3 3 3	pullout breakage unraveling 27 8 2 16 3 1 4 2 1 6 2 0 18 10 9 11 3 6 3 3 1	pullout breakage unraveling pullout 27 8 2 32 16 3 1 20 4 2 1 6 6 2 0 5 18 10 9 26 11 3 6 15 3 3 1 4	pullout breakage unraveling pullout breakage 27 8 2 32 6 16 3 1 20 1 4 2 1 6 2 6 2 0 5 2 18 10 9 26 9 11 3 6 15 5 3 3 1 4 3							

Data are number of cases

*: according to the surgeon's experience. 0 repairs: no previous experience; 1-5 repairs= one to five previously performed repairs; > 5 repairs: more than five previously performed repairs. The level of experience was unknown for two surgeons.