A Biomechanical Comparison of a Tendon Repair Device and 4 Stranded, Cruciate Repair Sutures for Flexor Tendon Ruptured

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Objective: *To compare the biomechanical properties of the single strand monofilament Nylon 2-0 Khon Kaen tendon repair device for flexor tendon repair and standard 4-stranded cruciate repair sutures.*
Material and Method: *80 flexor digitorum longus tendons from fresh cadavers, were cut and sutured by Khon Kaen tendon repair device (core nylon) or 4-stranded, cruciate repair (3-0 monofilament nylon) and both groups were divided into two groups; the first group combined with 5-0 monofilament nylon circumferential epitendinous suture and the second group without epitendinous suture. The sutured tendons were tested by using biomechanical testing machine (LLOYD instruments, LR30K), in rate 5 mm/s. Force, stiffness and energy absorbed at peak force (calculated from the force-displacement curves) and mode of failure were compared.*
Results: *The Khon Kaen tendon repair device (core nylon) without epitendinous sutured group has 2 mm gap force, peak force and stiffness significantly lower than standard 4-stranded, cruciate repair, but with no statistical difference in the epitendinous sutured group; 90% of Khon Kaen tendon repair device failed by suture breakage and 10% failed by ankle pullout.*
Conclusion: *Although the strength of Khon Kaen tendon repair device (core nylon) alone is lower than the strength of 4-stranded, cruciate repair, and 90% mode of failure was core suture breakage, the authors recommended to change core suture from nylon to a stiffer material and re-inforced with epitendinous suture.*

Keywords: *Flexor tendon repair device, Tendon biomechanics, Suture techniques*

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Primary repair of flexor tendon in the fibro-osseous sheath was controversial before Verdan's[1] contributions, and with the recent knowledge that good tendon repair can be achieved by intratendinous knot with minimal tendon sheath irritation, and also able to withstand early mobilization[1-4].

Strickland[3] in 1995 suggested the requirements for good tendon repair were: 1) Sufficient strength throughout healing to permit early motion stress, 2) Minimal interference with vascularity, 3) Minimal gapping, 4) Smooth junction at tendon ends with minimal bulk, 5) Secure knots, and 6) Sutures easily placed in the tendon.

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In zone II flexor tendon repair[4-6], early postoperative mobilization is important to prevent adhesion and decrease tenolysis. In addition, the cyclic motion of the tendon is stimulated the healing process through intrinsic pathway[6].

The well accepted flexor tendon repair technique is multi-strand, core suture and the addition of circumferential suture that proved to have enough strength for early motion stress[5,7,8]. The strength of the sutured techniques are: total number of core suture[9], suture technique[10-13] and suture material[13]. However, re-rupture was found in the early mobilization[1] group that may have been caused by adhesion and gap from repeated flexion force.

Although each core suture repair technique has high tensile strength, every technique requires skill, multiple tendon manipulation that can caused further injury to the tendon. Apart from multi-strand, core suture tendon repair, there is a new innovation, the tendon repair device (Teno Fix Device) which consists of intratendinous stainless steel coil anchor and single multifilament 2-0 stainless steel suture that had higher strength than 4-stranded cruciate 4-0 braided polyester suture repair. Taking mechanism of failure into consideration, it was found that 95% of coil-core combinations (Teno Fix Device) failed by suture/anchor pullout. Although anchor-tendon is a weak point of coil-core combination model, it was shown that the force at 2 mm was also more than 4-strand 3-0, 4-0 suture repair.

From the idea of TenoFix Device, the authors developed the Khon Kaen suture device from stainless steel wire and regular 2-0 nylon suture, and the biomechanical testing was done to compare the presented device with standard 4-stranded 3-0 nylon repaired system.

Research Question: Is Khon Kaen-tendon repair device comparable to 3-0 nylon 4-stranded, cruciate repairs?

Objective

Main objective: to study the biomechanic of Khon Kaen tendon repair device (2-0 nylon) compared with 4-stranded, cruciate repair (3-0 nylon) in flexor tendon repair.

Material and Method

Eighty flexor tendons from 11 donated fresh cadavers with not less than 3 millimeters in diameter and 10 centimeters in length were used. The tendons were measured by Vernier caliper before divided and after sutured, then were divided into 4 groups:

a. 20 tendons were repaired with 4-stranded cruciate repairs with circumferential epitendinous suture

b. 20 tendons were repaired with 4-stranded cruciate repairs without circumferential epitendinous suture

c. 20 tendons were repaired with Khon Kaen tendon repair device with circumferential epitendinous suture

d. 20 tendons were repaired with Khon Kaen tendon repair device without circumferential epitendinous suture.

In Khon Kaen-tendon repair device groups, the flexor tendons were divided (Fig. 1) and repaired by piercing No. 20 needle (a guided needle) from the cut surface and came up through the stabbed wound to about 1 cm from the cut surface (Fig. 2); the coil components were placed at the tip of the needle then passed to the core suture (tied with a stopper) through the coil and the guided needle, onto the other side; the guided needle was passed through proximal stabbed wound about 1 cm from the cutting edge through the cutting edge; then the core suture was threaded into the needle, removed and the core suture tightened until the tendon edge was folded. The core suture was clamped and tied with a stopper, then the clamp was released and the coil was embedded in the tendon fiber to cover the all the device components within the tendon.

In 4-strand 3-0 nylon cruciate repair technique groups, the tendons were repaired by 3-0 nylon cruciate repair technique, as shown in Fig. 8.

For the epitendinous groups, additional circumferential, continuous sutures with 5-0 monofilament nylon were done.

After tendons were repaired and removed from the hands by being excised proximal to A1 pulley and at the insertion, the tendons were tested by using Biomechanical Testing Machine (LLOYD instruments, LR30K, [Fig. 9]) within 48 hours (under 4°C preservation).

Both tendon ends were fixed with a special clamp and the tendon was pulled until failure (gap = 2 millimeters). The result was reported by the computer in force-displacement curve. The 2 mm gap force was recorded in Newton (2-mm gapping force (N)), peak force (N), force to failure (N), and energy absorbed at peak force (N-mm). The modes of failure (knot breakage, suture breakage, suture/anchor pullout, crimp slippage) were recorded.

Statistical analysis

The data were analyzed with one-way analysis of variance with statistical software package (SPSS) version15.0. The Bonferroni comparison analyzed the indifferent variation groups and the Tamhane comparison analyzed the different variation groups. The statistical significance is p-value < 0.05

Results

The present had 4 groups; each group with 20 tendons was studied. The diameter of suture site of 4-stranded cruciate repair was 4.145 ± 0.64 mm and the Khon Kaen-tendon repair device (2-0 nylon) is 4.094 ± 0.62 mm, no statistical significance.

2 mm gapping force, The Khon Kaen tendon repair group (2-0 nylon) (2.1 ± 0.64 N) was less than the

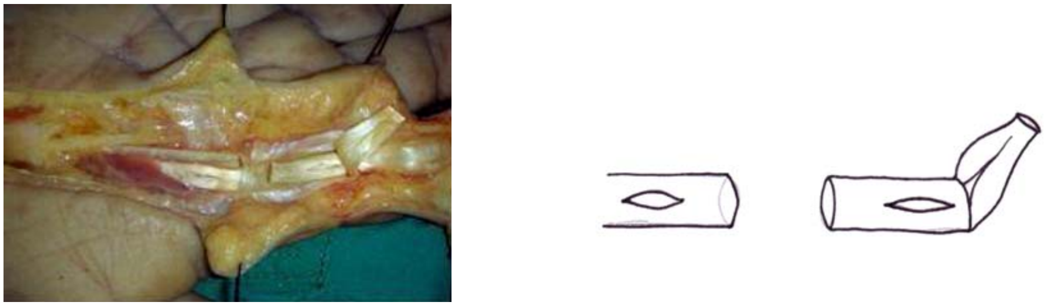

Fig. 1 The flexor tendon was cut the longitudinal stab was done

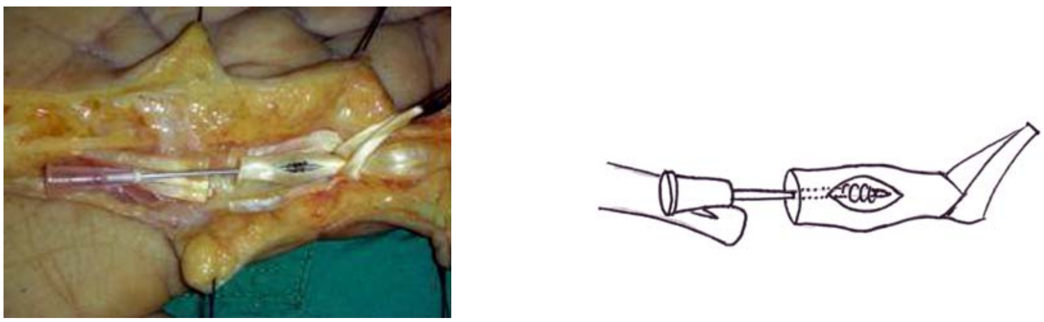

Fig. 2 Pierce No. 20 needle (the guided needle) from the cut surface and came up through the stabbed wound then the coil component was placed over the tip of the needle

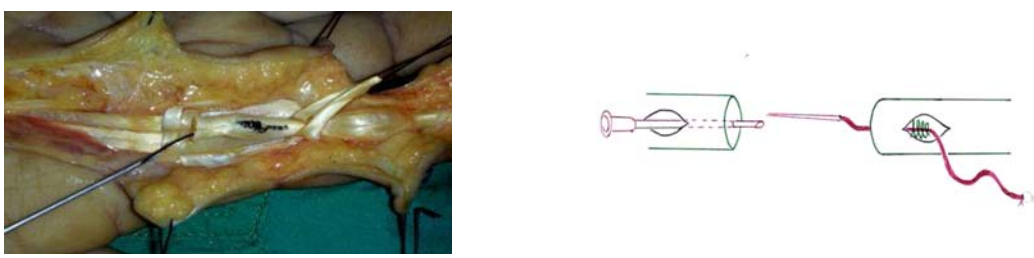

Fig. 3 Core suture tied with stopper that passes the core component through the edge

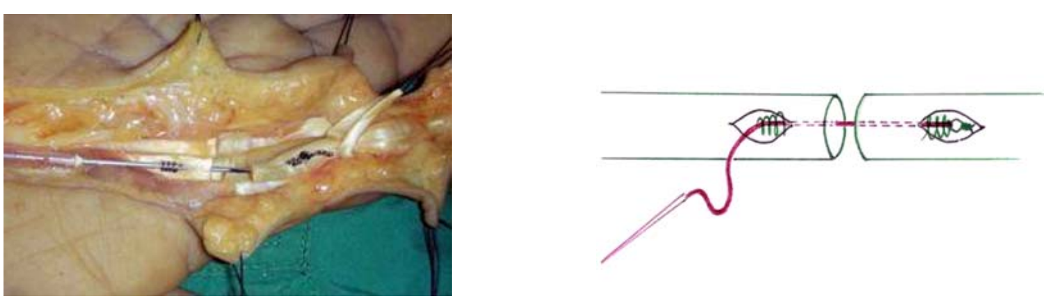

Fig. 4 In the other side, the needle No. 20 was pierce from the wound to the edge and the core suture was thread then remove the needle

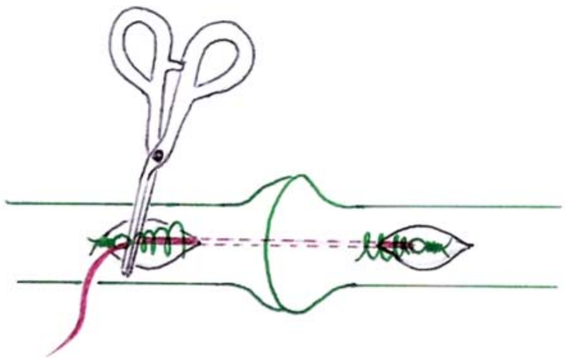

Fig. 5 The 2-0 Nylon core suture was tightening until the tendon edge was folded. The core suture was clamped and tied with stopper. Then the clamp was released and the coil was twisted and wrapped the tendon fiber. The device components were lined within the tendon

Fig. 6 The longitudinal incisions were closed with 5-0 nylon incorporated suture within coil component

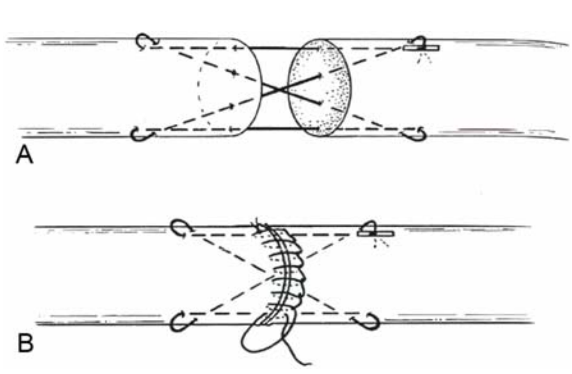

Fig. 7 The 4-stranded cruciate repair (A) and continuous epitendinous suture (B)

Fig. 8 Biomechanical testing machine (LLOYD instruments, LR30K)

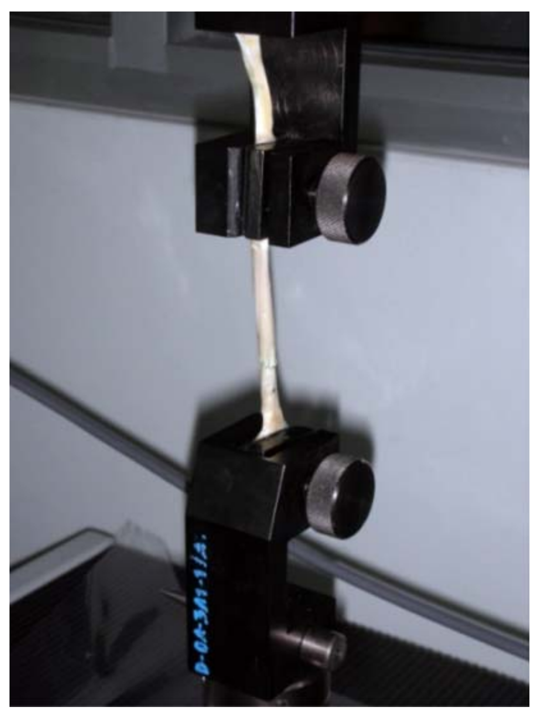

Fig. 9 Special clamps were used to fix the tendon during biomechanical test

4-stranded cruciate repair group (4.5 ± 0.83 N) ($p < 0.001$) statistical significance. In the epitendinous repair group, the 2 mm gap force of Khon Kaen tendon repair device (2-0 nylon) with epitendinous suture (38.3 ± 11.78 N) was not different from 4-stranded, cruciate repair with epitendinous suture (42.4 ± 6.82 N) ($p = 0.897$).

Peak force, the authors did not find a difference between both groups p-value = 0.084 in only core suture and p-value = 0.579 in core suture with epitendinous suture.

Energy absorbed by the repair (area under force-displacement curve) showed no statistical significance between 4-stranded, cruciate repair and the Khon Kaen-tendon repair group (2-0 nylon) ($p = 0.915$).

Gap at peak force: The Khon Kaen-tendon repair group (2-0 nylon) (21.58 ± 2.71 mm) had a gap at peak force, more than 4-stranded cruciate repair (15.02 ± 5.01 mm) with statistical significance ($p < 0.001$), not significant in the epitendinous study.

The stiffness at peak force of Khon Kaen-tendon repair group (2-0 nylon) (0.96 ± 0.18 N/mm) was less than 4-stranded, cruciate repair (1.78 ± 0.32 N/mm) ($p < 0.001$), but not significant in the epitendinous suture study.

The mechanisms of failure (Table 2) were: 4-stranded, cruciate repair groups failed with suture breakage 67.5% (27 in 40), suture pullout 17.5% (7 in 40), and knot breakage 15% (6 in 40). In the Khon Kaen-tendon repair group (2-0 nylon) failed with suture breakage 90% (18 in 20), anchor pullout 10% (2 in 20), did not fail with knot breakage and climp slippage. When studying the Khon Kaen-tendon repair with epitendinous suture failed with suture breakage 45% (9 in 20), anchor pullout 35% (7 in 20) and knot breakage 20% (4 in 20), no failure with climp slippage.

Discussion

The hypothesis of this presented study is the tendon repair with Khon Kaen tendon repair device (2-0 nylon) have the strength higher than (3-0 nylon) 4-stranded cruciate repair.

Sufficient strength

The remarkable properties of stainless steel wire is high strength and high stiffness but can't be used in tendon suture in normal technique because it is too hard to suture. The tendon is shredded. The tied wire caused a large knot that obstructed both edges of the tendon.

Table 1. 2-mm gap force, peak force, gap at peak force, stiffness at peak force, energy absorbed to peak force of all repairs

	4-strand cruciate		KK1-core Nylon	
	w-epiten	wo-epiten	w-epiten	wo-epiten
2 mm gap force (N)	42.40 (6.82)	4.50 (0.83)	38.30 (11.79)	2.10 (0.64)
Peak force (N)	49.32 (8.72)	26.19 (8.08)	42.98 (13.39)	20.43 (2.56)
Gap at peak force	15.17 (4.76)	15.02 (5.01)	11.73 (2.89)	21.58 (2.71)
Stiffness at peak force (N/mm)	3.49 (0.94)	1.78 (0.32)	3.75 (1.13)	0.96 (0.18)
Energy absorbed to peak force (N-mm)	547.595 (136.31)	220.41 (133.90)	441.87 (145.08)	174.08 (39.07)

Table 2. Mode of failure

	4-stranded cruciate		KK1-core Nylon	
	w-epiten	wo-epiten	w-epiten	wo-epiten
Knot breakage	4 (20%)	2 (10%)	4 (20%)	0
Suture breakage	12 (60%)	15 (75%)	9 (45%)	18 (90%)
Suture/anchor pullout	4 (20%)	3 (15%)	7 (35%)	2 (10%)
Crimp slippage	0	0	0	0
Total	20	20	20	20

The Biomechanical Analyses of Tendon Fixation Device (Teno Fix device)[16]: The tendon fixation device, which was a coil-core combination model, has more strength and energy absorbed at 2 mm gap and was higher than 4-stranded, core suture repair.

The authors designed the Khon Kaen-tendon repair device for the coil component and combined it with various suture materials by tying it with a loop stopper and then proping the loop stopper to the coil anchor. The helical configuration of coil component will integrate the tendon fibers after releasing the clamp. The authors were convinced that the single 2-0 nylon monofilament sutured with a Khon Kaen-tendon repair device had a higher strength than 3-0 nylon 4-stranded, cruciate repair and the repaired tendons were smooth and had no bulking thus producing better gliding within the pulley.

Although the main objective was to compare the strength of the core suture, the authors added an epitendinous suture group for clinical relevance.

The 4-stranded, cruciate repair and the Khon Kaen-tendon repair group had 2-mm.gap force of 4.5 $\pm$ 0.83 N and 2.1 $\pm$ 0.64 N sequentially. From observation, the nylon stretched much more before suture breakage that caused 2-mm gap force.

Although the peak force of 4-stranded, cruciate repair (without epitendinous suture) in the presented study is higher than the presented[19] (22.2 N), there is no statistical significance with the Khon Kaen-tendon repair group. The peak force can determine the strength of the repair; but the 2-mm gap force is more important in clinical use because the gap > 2 mm decreases the tendon healing and increases the adhesion formation to limit tendon gliding.

When energy absorbed up to peak force, there are no statistical significances because the Khon Kaen-tendon repair group had a gap to peak force more than the 4-stranded, cruciate repair group.

The epitendinous study, the 4-stranded, cruciate repair group had 2 mm gap force of 42.4 N and peak force 49.32 N that is close to a previous study[17]. In another group, the Khon Kaen tendon repair device (2-0 nylon) with epitendinous suture has 2 mm gap force 38.5 N and peak force 42.98 N; both were higher than other techniques such as modified Kessler[10,18,19], modified Savage[10], cruciate[10,18] repair techniques.

The Khon Kaen suture device also had helical configuration that could restrain the tendon fiber and could be combined into the larger and stiffer core suture material. The result is single strand core suture which has strength enough for tendon repair.

The modes of failure of Khon Kaen tendon repair group (2-0 nylon) have suture breakage 90%. The authors concluded that the weak point is the nylon core suture; to modify this, the core suture could be replace by stainless steel wire, which is stiffer and stronger than nylon.

Smooth junction with minimal bulk

The Khon Kaen-tendon repair group (2-0 nylon) have repaired site diameter, by increasing it from 4.02 mm to 4.18 mm and 4-stranded, cruciate increased from 4.18 mm. to 4.39 mm. Although both groups show no statistical significance, the Khon Kaen-tendon repair device has single-strand for core suture, with smooth junction and minimal bulking.

Conclusion

The present study is the flexor tendon repair zone II of fresh cadavers similar to practice and the repaired tendons were measured for tensile strength by the Biomechanical Testing Machine (LLOYD instruments, LR30K) which rendered the results very reliable.

The 2-mm gap force and energy absorbed at peak force of Khon Kaen tendon repair group (2-0 nylon) was lower than 4-stranded, cruciate repair group, with some statistical significance and it would address and revise as necessary the core to stainless steel wire in a further study.

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การศึกษาวิเคราะห์ชีวกลศาสตร์ของ tendon repair device เทียบกับ 4-stranded cruciater Repair suture ในการเย็บซ่อม flexor tendon

สุรเชษฐ ตันทัดประเสริฐ, พลศักดิ์ จีระวิพูลวรรณ, วีระชัย โควสุวรรณ, โกวิท ไชยศิวามงคล

ข้อปัญหาและเหตุผล: *การเย็บซ่อม flexor tendon ด้วย flexor tendon repair device (Khon Kaen tendon repair device) สามารถนำ suture ขนาดเส้นผ่าศูนย์กลางใหญ่กว่ามาประสาน กับ tendon repair device (coil-core combination)*

วัตถุประสงค์: *เพื่อศึกษาคุณสมบัติทางชีวกลศาสตร์ของการเย็บซ่อม flexor tendon ด้วย Khon Kaen tendon repair device (single strand 2-0 nylon) เปรียบเทียบกับ standard 4-stranded cruciate repair sutures*

เกณฑ์การคัดเลือก: *Flexor digitorum profundus จากศพอาจารย์ใหญ่ (fresh cadaver) จำนวน 80 เส้น ที่มีขนาดเส้นผ่าศูนย์กลางมากกว่า 3 มิลลิเมตร และ ยาวมากกว่า 10 เซนติเมตร*

วัสดุและวิธีการ: *ตัด flexor tendon ทั้งหมด 80 เส้น แบ่งเป็น 2 กลุ่ม กลุ่มแรกเย็บซ่อมด้วย Khon Kaen tendon repair device กลุ่มที่ 2 เย็บซ่อมด้วย 4-stranded cruciate repair (3-0 monofilament nylon) โดยทั้ง 2 กลุ่ม ศึกษาทั้งที่เย็บ และไม่เย็บ circumferential epitendinous suture (5-0 monofilament nylon) นำเอ็นทุกเส้นทดสอบ โดยใช้ biomechanical testing machine (LLOYD instruments, LR30K) กำหนดให้ออกแรงดึงด้วย อัตราเร็วคงที่ 5 mm/sec เครื่องจะรายงานผลเป็น force, stiffness และ energy absorbed at peak force โดยคำนวณจาก force-displacement curve*

ผลการศึกษา: *พบว่าในกลุ่ม Khon Kaen tendon repair device (core nylon) ที่ไม่เย็บด้วย epitendinous มี 2-mm gap force (2.1 $\pm$ 0.64 N), peak force (20.43ฑ2.56 N) และ stiffness (0.96 $\pm$ 0.18 N/mm) ต่ำกว่ากลุ่ม standard 4-stranded cruciate repair อย่างมีนัยสำคัญทางสถิติ ส่วนในการศึกษาที่เย็บ epitendinous ทั้ง 2 กลุ่ม พบว่าไม่ต่างกันทางสถิติ จากการศึกษา Khon Kaen Suture Device (core nylon) ส่วนใหญ่จะขาดจาก suture breakage (90%) และ 10% ขาดจาก anchor pullout*

สรุป: *แม้กลุ่ม Khon Kaen Suture Device (core nylon) repair จะมีความแข็งแรงที่ต่ำกว่า standard 4-stranded cruciate repair แต่เมื่อพิจารณาดู mode of failure พบว่าเอ็นส่วนใหญ่ขาดจาก tendon breakage หากเปลี่ยน core suture ให้มีความแข็งแรงมากขึ้น เพื่อแก้ไขตรงจุดอ่อนของ Khon Kaen tendon repair device (core nylon) และน่าจะเพิ่มความแข็งแรงของอุปกรณ์เย็บเอ็นจนสามารถนำมาใช้ในการเย็บซ่อมเอ็นได้จริง*