

+ Evidence in focus

Collection of evidence

INSTABILITY EXCELLENCE Shoulder Repair Portfolio

- Q-FIX[®] All-Suture Anchor
- MICRORAPTOR[®] KNOTLESS Suture Anchor
- DOUBLE ENDOBUTTON[®] Fixation Device
- GLENOID BONE LOSS SYSTEMS
Advanced Instability Solutions

February 2024

Smith+Nephew



Overview

This collection summarises the clinical evidence on the **INSTABILITY EXCELLENCE** Shoulder Repair portfolio

Redefining peak performance for shoulder instability repairs

Click the products below to view the product summary

Navigation tips

Interactivity has been included throughout the collection to aid navigation

Table of contents

will take you to a table of evidence, organised by product.



arrows at the bottom of each page will take you to the previous or subsequent page, as indicated

Full summary

will take you to the **Evidence in focus** full summary of the relevant study

Published paper

will take you to the journal website where the study is published

Table of contents

→ **Click on the arrow** by the study reference to view the study overview.



Author	Key finding
Key evidence	
Douglass, et al. 2018¹	Q-FIX 1.8mm Anchor could be associated with differentiated performance in various bone densities due to the unique active deployment mechanism
Ruder, et al. 2019²	Q-FIX 1.8mm Anchors showed less displacement with cyclic loading than Iconix™ (Stryker, USA) 1mm and JuggerKnot™ (Zimmer Biomet, USA) 1.5mm anchors
Byrd, et al. 2019³	Q-FIX 1.8mm Anchor demonstrated very low incidence (1.6%) of pullout in acetabular labral repair
Ergün, et al. 2020⁴	The Q-FIX Anchor exhibited the lowest suture displacement under cyclic loading
Erikson, et al. 2017⁵	Second-generation all-suture Anchors (SUTUREFIX® ULTRA 1.7mm Anchor) demonstrated superior biomechanical performance, comparing the load to 2mm displacement, over first-generation all-suture Anchors
Liu, et al. 2019⁶	Compared with the conventional straight guide, a curved-guide system (OSTEORAPTOR® Curved Suture Anchor) provides better placement of the most inferior suture anchor during arthroscopic Bankart repair
White, et al. 2021⁷	Q-FIX Anchors demonstrated a very low rate of failure (0.2%), improvements in clinical outcomes at six-month follow-up, and no surgical failures reported at 1-year follow-up post-labral reconstruction

Indications for use

The Q-FIX All-Suture Anchor System is intended to be used for soft tissue to bone fixation for:

Shoulder: Bankart lesion repair; SLAP lesion repair; acromio-clavicular repair; capsular shift/capsulolabral reconstruction; deltoid repair; rotator cuff tear repair; biceps tenodesis

Foot & Ankle: Medial/Lateral repair and reconstruction; midfoot and forefoot repair; Hallux valgus reconstruction; Metatarsal ligament/tendon repair or reconstruction; Achilles tendon repair

Elbow: Ulnar or radial collateral ligament reconstruction; lateral epicondylitis repair; biceps tendon reattachment

Knee: Extra-capsular repair: medial collateral ligament (MCL), lateral collateral ligament (LCL) and posterior oblique ligament; Iliotibial band tenodesis (IBT); patellar tendon repair; vastus medialis obliquus advancement (VMO); joint capsule closure

Hip: Acetabular labral repair

→ **Key study**

→ **Supporting study**

Table of contents

→ Click on the **arrow** by the study reference to view the study overview.



MICRORAPTOR[®]
KNOTLESS
Suture Anchor

Author	Key finding
Key evidence	
Hanypsiak, et al. 2014⁸	Considerable variations in knot strength exist between arthroscopic knots tied by surgeons. A large standard deviation exists from one arthroscopic knot to another with the same surgeon
Kim, et al. 2013⁹	Intentional placements of knot stacks away from the articulating cartilage were demonstrated to shift towards the cartilage after motion of the shoulder
Matache, et al. 2021¹⁰	Operative time can be reduced when using knotless anchors. Clinical results also showed no sacrifice in performance when comparing a knotted versus a knotless repair

Indications for use

MICRORAPTOR KNOTLESS Suture Anchors is intended for use only for the reattachment of soft tissue to bone for the following indications:

Hip: Acetabular labrum repair/reconstruction

Shoulder: Capsular stabilisation; Bankart repair; Anterior shoulder instability; SLAP lesion repairs; Capsular shift or capsulolabral reconstructions. Biceps tenodesis

→ Supporting study

Table of contents

→ **Click on the arrow** by the study reference to view the study overview.



DOUBLE ENDOBUTTON[®]
Fixation Device

Author	Key finding
Key evidence	
Banffy, et al. 2023¹¹	In patients with glenoid bone loss associated with anterior instability, the DOUBLE ENDOBUTTON Fixation Device demonstrated favourable clinical and patient-reported outcomes
Boileau, et al. 2019¹²	The DOUBLE ENDOBUTTON Fixation Device demonstrated accurate graft positioning, low revision rates, no hardware complications, and high levels of patient satisfaction
Boileau, et al. 2022¹³	Compared with hand tensioning, mechanical tensioning of the DOUBLE ENDOBUTTON Fixation Device with Glenoid Bone Loss Suture Tensioner achieves significantly higher bone healing rates in arthroscopic Latarjet procedures (94 vs 75%)
Kazum, et al. 2019¹⁴	No difference was observed between the biomechanical properties of cannulated screws versus the DOUBLE ENDOBUTTON Fixation Device in Bristow Latarjet procedures
Taverna, et al. 2020¹⁵	Arthroscopically-assisted Latarjet with the DOUBLE ENDOBUTTON Fixation Device resulted in a low recurrence rate, high patient satisfaction, PROMs and return to sport at pre-injury level, as well as accurate graft placement

Indications for use

The Double ENDOBUTTON Fixation Device is intended for the treatment of anterior glenoid bone loss using the Latarjet or bone block procedure (allograft or autograft)

→ **Key study**



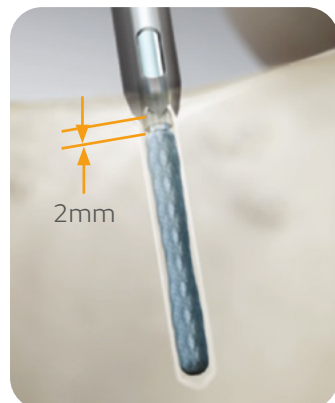
Product summary:

Q-FIX[®] All-Suture Anchors

The unique active deployment mechanism of the Q-FIX Anchor provides 360 degree radial expansion to ensure reliable purchase regardless of bone-media density.¹ In clinical studies, Q-FIX Anchors have demonstrated best in class cyclic and fixation strength, as well as a very low incidence of pullout.³

Consistent deployment

Radially expanding implant design and delivery system tensions sutures to at least 140N

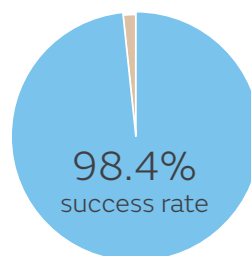


Inserter is 2mm below bone surface



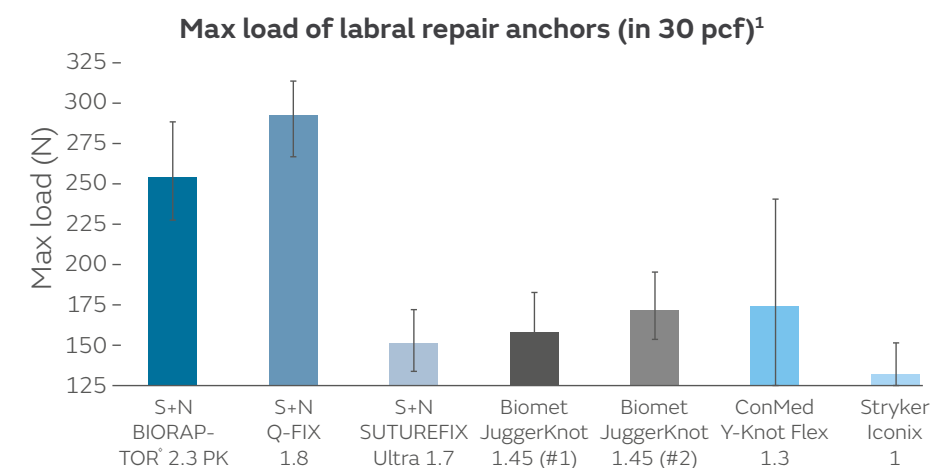
Radial expanding deployment

A clinical study, in the hip, has proven the reliability of Q-FIX Anchors³



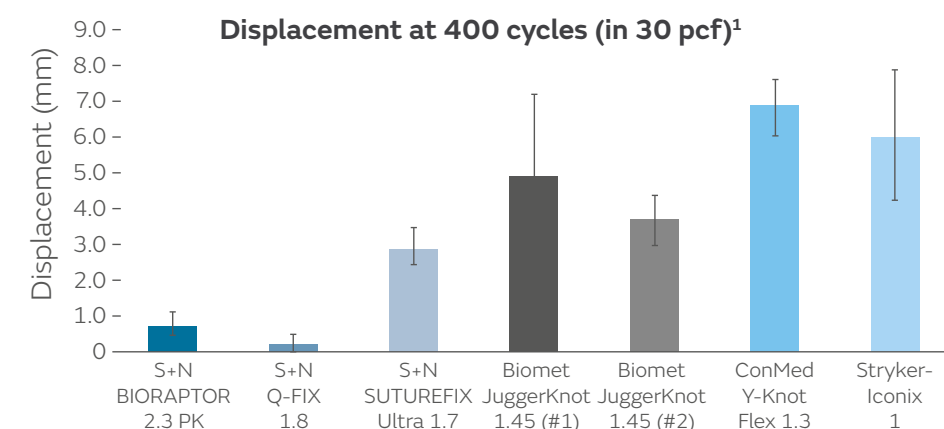
Fixation strength

Q-FIX 1.8mm Anchor shown to provide greater maximal load than other commercially available labral repair anchors in 30 pcf block*²



Low displacement/cyclic performance

Q-FIX 1.8mm Anchor shown to provide leading performance, with the lowest displacement during cyclic loading among competitor all-suture anchors^{†1,5}



*Compared to BIORAPTOR 2.3 PK, Zimmer Biomet JuggerKnot™ 1.45 (#1 and #2), Conmed Y-Knot™ Flex 1.3 and 1.8 and Stryker Iconix™ 1. †As demonstrated in benchtop testing; compared to Stryker Iconix™ 1, 2, 2.5 and 3, Parcus Medical Draw Tight™ 1.8 and 3.2, Zimmer Biomet Juggerknot™ 1.4, 1.45 (#1 and #2), 1.5 and 2.9 and Conmed Y-Knot™ Flex 1.3, 1.8 and 2.8.



Product summary:

MICRORAPTOR[®] KNOTLESS Suture Anchor

The MICRORAPTOR KNOTLESS Anchor provides access to challenging areas with off-axis insertion^{*16} and fixation performance ensures strength intraoperatively,¹⁷ while the clinically proven REGENESORB[®] Material stimulates bone healing and formation post-operatively.¹⁸⁻²⁴

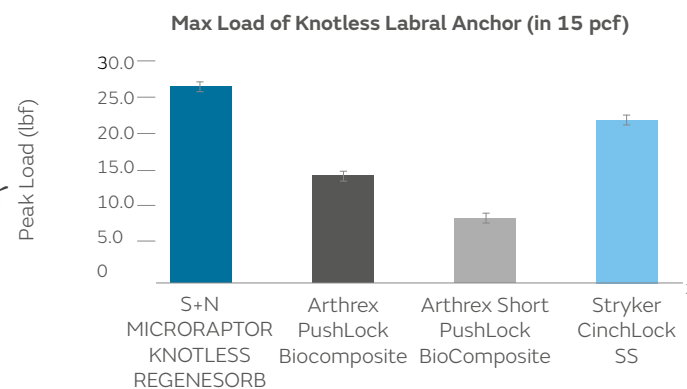
Off-axis insertion

Gain access to challenging areas with improved off-axis performance^{*16}



Fixation strength

MICRORAPTOR KNOTLESS Anchor shown to have significantly greater fixation strength compared to other commercially available knotless anchors ($p < 0.001$)^{†17}



REGENESORB Material: a unique composition of proven materials¹⁸⁻²⁴

REGENESORB Material is associated with:

Calcium sulfate:

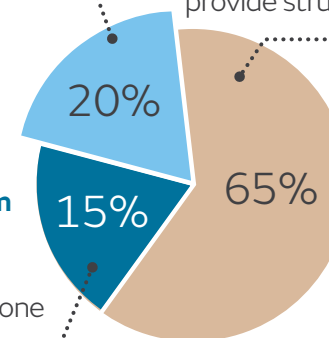
Works in early healing stages at 4–12 weeks^{20,21,24}

Poly L-lactic-co-glycolic acid (PLGA):

Comprised of natural products—lactic acid and glycolic acid^{19,23}—to provide structural integrity

β-tricalcium phosphate (β-TCP):

Sustained bone formation up to 2 years^{20,21,25}



Sustained mechanical stability²⁶⁻²⁸



Resorption and replacement by bone within 24 months^{‡26-28}



No severe osteolysis reported (one study)²⁸

^{*}As demonstrated in benchtop testing, compared to Arthrex BioComposite PushLock™ 2.9mm. [†]As demonstrated in benchtop testing; compared to Arthrex BioComposite PushLock™ 2.9mm, Arthrex BioComposite PushLock™ 2.9mm Short and Stryker CinchLock SS Knotless. [‡]As demonstrated in vivo.

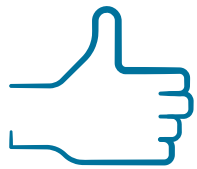


Product summary:

DOUBLE ENDOBUTTON[®] Fixation Device

Clinical evidence on the DOUBLE ENDOBUTTON Fixation Device for bone block/Latarjet procedures demonstrates low revision rates, no post-operative complications,¹¹ and accurate graft positioning;^{12,15} all of which lead to high levels of patient satisfaction^{11,12,15} and an 82.1% return to sport at pre-injury level.¹⁵

Patient satisfaction, return to sport and complications



94.1% patients were **satisfied** with the surgery at last follow-up¹⁵



At last follow-up, **82.1%** (23/28) patients **returned to sport** at pre-injury level¹¹



No neurovascular complications at the shoulder, infections or hardware failures reported at last follow-up¹¹

Graft placement and healing

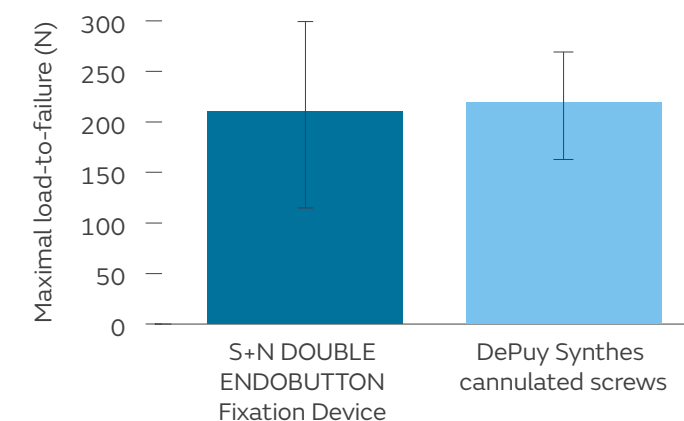


At 1-year follow-up CT scan, flush graft placement was achieved in **98.3%** (59/60; one study)¹⁵

95%

of cases demonstrated healing of the transferred coracoid process to the scapular neck (115/121; one study)¹²

Equivalent biomechanical performance with minimised graft failures¹⁴



Fewer hardware related graft failures with button versus screw fixation¹⁴



Cyclic and load to failure properties of all-suture anchors in synthetic acetabular and glenoid cancellous bone

Douglass NP, Behn AW, Safran MR. *Arthroscopy*. 2017;33(5):977–985.

Overview

Biomechanical study evaluating cyclic displacement, load-to-failure and ultimate failure mode of multiple ASAs, including:

- Q-FIX[®] 1.8mm Suture Anchor; SUTUREFIX[®] ULTRA 1.7mm Anchor; JuggerKnot[™] 1.45mm (#1 suture), 1.45mm (#2 suture), 2.9mm anchors; Y-Knot[™] Flex (ConMed Linvatec, USA) 1.3mm, 1.8mm anchors; Iconix[™] 1, 2, 2.5 and 3mm anchors and BIORAPTOR[®] PK 2.3mm Anchor was used as the control

Results

- Q-FIX 1.8mm Anchor outperformed all other anchors in displacement from cyclic loading
- Q-FIX 1.8mm Anchor also had comparable maximum failure loads to the highest values of the other tested anchors (Table)
- ASAs show better fixation (maximum load) in higher density synthetic bone

	Peak displacement at cycle 200	Peak displacement at cycle 400 and post-cyclic displacement	Maximum load and displacement at maximum load
Synthetic test block 20 pcf	Q-FIX 1.8mm Anchor showed significantly less peak displacement than all other ASAs ($p \leq 0.001$)	Q-FIX 1.8mm Anchor demonstrated significantly less peak displacement and post-cyclic displacement compared with all anchors ($p \leq 0.002$)	Q-FIX 1.8mm Anchor demonstrated significantly less peak displacement compared with all anchors ($p \leq 0.002$) Iconix [™] 2.5mm had the highest maximum load (196N)
Synthetic test block 30 pcf	Q-FIX 1.8mm Anchor had significantly less peak displacement than all other ASAs ($p \leq 0.025$)	Q-FIX 1.8mm Anchor demonstrated significantly less peak displacement ($p \leq 0.013$) and post cyclic displacement ($p \leq 0.016$) than all other ASAs except Iconix [™] 2.5mm	Q-FIX 1.8mm Anchor demonstrated significantly less displacement at maximum load ($p \leq 0.009$) than most ASAs with the exceptions of SUTUREFIX [®] ULTRA, JuggerKnot [™] and Iconix [™] 2.5mm Iconix [™] 2.5mm had the highest maximum load (307.1N)

Table. Best performing ASA with respect to displacement and ultimate failure mode

Conclusion

The distinct performance difference observed in Q-FIX Anchors may be attributed to its unique active deployment mechanism. Overall, ASA performance varies with anchor design and bone density.



Cyclic and load-to-failure properties of all-suture anchors in human cadaveric shoulder glenoid bone

Ruder JA, Dickinson EY, Peindl RD, et al. *Arthroscopy*. 2019;35(7):1954–1959.

Overview

A biomechanical study to evaluate the cyclic displacement and ultimate load-to-failure of four ASAs in human cadaveric shoulder bone (n=13). The ASAs tested were: Q-FIX[®] 1.8mm Suture Anchor; SUTUREFIX[®] ULTRA 1.7mm Anchor; JuggerKnot[™] 1.5mm anchor and Iconix[™] 1mm anchor

Results

Q-FIX Anchors outperformed all ASAs on each test:

- It achieved the lowest total failure (number of catastrophic and clinical failures) and catastrophic failure (anchor pullout prior to completion of cyclic loading) rates (both 3.85%; 1/25; Figure)
- Q-FIX Anchors were the only ASA with zero cases of clinical failure (displacement greater than 5mm; Figure)
- Q-FIX Anchors demonstrated significantly less displacement to all other anchors after both 100 and 200 cycles (mean SD: 1.40±0.97mm and 1.53±1.00mm respectively; p<0.001)
- Q-FIX Anchors showcased the highest ultimate load-to-failure (191.3±65.8N), surpassing other anchors and significantly outperforming the Iconix[™] anchor (p=0.01)
 - SUTUREFIX Anchors and JuggerKnot[™] anchors also demonstrated significantly higher ultimate load-to-failure than the Iconix[™] anchors (p=0.012 and p=0.021; respectively)

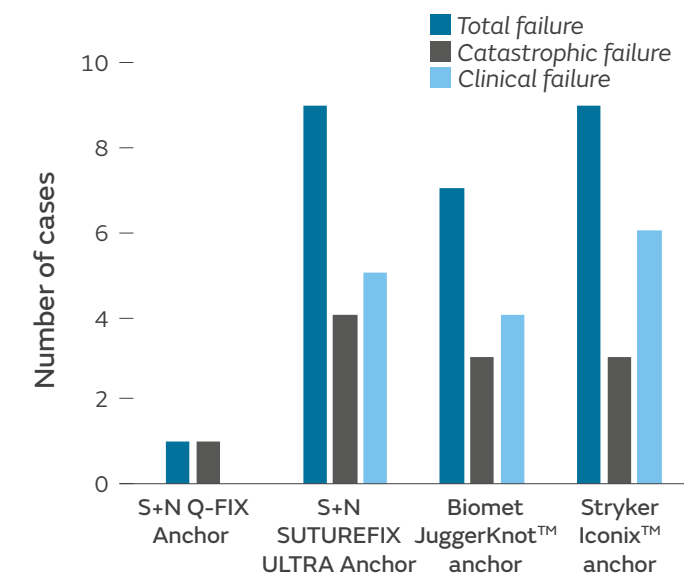


Figure. Number of failures for each anchor tested

Conclusion

Q-FIX Anchors demonstrated superior biomechanical performance out of all the ASAs tested which may be due to its unique active deployment mechanism.



Acetabular all-suture anchor for labral repair: incidence of intraoperative failure due to pull-out

Byrd JWT, Jones KS, Loring CL, Sparks SL. *Arthroscopy*. 2018;34(4):1213–1216.

Overview

Single-surgeon retrospective case series (n=434) evaluating the intraoperative failure of Q-FIX[®] 1.8mm Suture Anchor over an 18-month period in labral repair. A total of 2,007 anchors were used (average 4.6 per case) and failure was defined as any wasted anchor at time of procedure and reported at 3-month intervals

Results

- Q-FIX Anchors demonstrated a pull-out incidence rate of 1.6% (33 out of 2,007 anchors; Figure)
- Pull-out was almost exclusively linked to failure to securely embed the anchor in the bone, with an estimated incidence rate of 0.15% in properly seated implants (3 out of 2,007 anchors)
- In addition, the pull-outs were evenly distributed over 3-month intervals (4, 4, 6, 6, 5, 8), suggesting no correlation between early experience and a higher incidence of overall failures
- There was no statistical difference in average age or male-to-female ratio between those cases with and without pull-out (p=ns)



Figure. Success rate of Q-FIX 1.8mm Anchors

Conclusion

Q-FIX Anchors are exceptionally reliable, with a 98.4% success rate, in acetabular labral repair. No difference was seen in the patient demographics between those cases with or without pull-out.



The clinical and biomechanical performance of all-suture anchors: a systematic review

Ergün S, Akgün U, Barber FA, Karahan M. *Arthroscopy*. 2020;2(3):e263–e275.

Overview



16 studies:

- 3 clinical and radiological
 - 2 prospective case studies
 - 1 retrospective case study
- 13 experimental

474 patients



A systematic review and meta-analysis to clarify the relative strength and weaknesses of ASAs, including: Q-FIX[®] 1.8 and 2.8mm Suture Anchors, JuggerKnot[™] 1.4, 1.5 and 2.9mm anchors; Iconix[™] 1, 2 and 3 anchors; Y-Knot 1.3, 1.8 and 2.9mm anchors; Draw tight 1.8 and 3.2mm anchors (Parcus,* USA); SUTUREFIX[®] Ultra 1.7mm Anchor; OmegaKnot anchor (ARC, Korea)

Results

- In acetabular labral repairs (n=434), Q-FIX Anchors demonstrated a low pull-out incidence rate of 1.6%
 - This was not significantly different from the patient population with no anchor pull-out
 - The most common reason for failure was the anchor not being securely embedded into the bone
- In the biomechanical studies, Q-FIX Anchors exhibited the least displacement under cyclic loading out of all the ASAs and failure was mostly caused by suture breaking, whereas other anchors experienced pull-out
- In general, ASAs demonstrated minimal clinical failure, bone reaction or cyst formation and yielded satisfactory results and low complication rates in patients who underwent arthroscopic shoulder repair, acetabular labral repair and rotator cuff repair

Conclusion

Q-FIX Anchors demonstrated extremely reliable performance in acetabular labral repairs.

*Parcus has since been acquired by Anika.



Biomechanical comparison of a first- and a second-generation all-soft suture glenoid anchor

Erickson J, Chiarappa F, Haskel J, et al. *Orthop J Sports Med.* 2017;5(7):2325967117717010.

Overview

A biomechanical study in human cadaveric shoulder glenoid bones (n=20) to compare the load to 2mm displacement and ultimate failure in second-generation (SUTUREFIX[®] 1.7mm Anchor) and first-generation ASA (JuggerKnot[™] 1.4mm anchor) with BIORAPTOR[®] PK 2.3mm Anchor as the control

Results

- SUTUREFIX Anchors demonstrated the highest load to 2mm displacement compared with JuggerKnot[™] and BIORAPTOR PK anchors ($p < 0.01$; Figure 1)
- SUTUREFIX Anchors displayed the highest ultimate load-to-failure (182.5N; Figure 2)
 - Both SUTUREFIX and JuggerKnot[™] ASAs showed significantly higher load-to-failure than BIORAPTOR PK ($p < 0.01$)
 - No significant difference in ultimate load-to-failure between Q-FIX[®] and JuggerKnot[™] ASAs ($p = ns$)

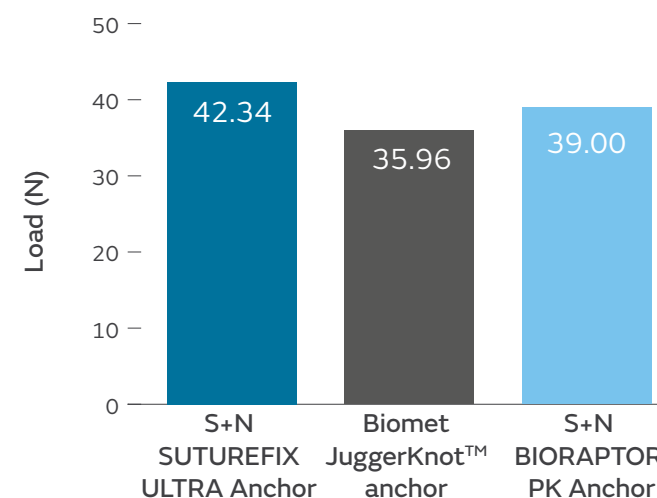


Figure 1. Load to 2mm displacement (N)

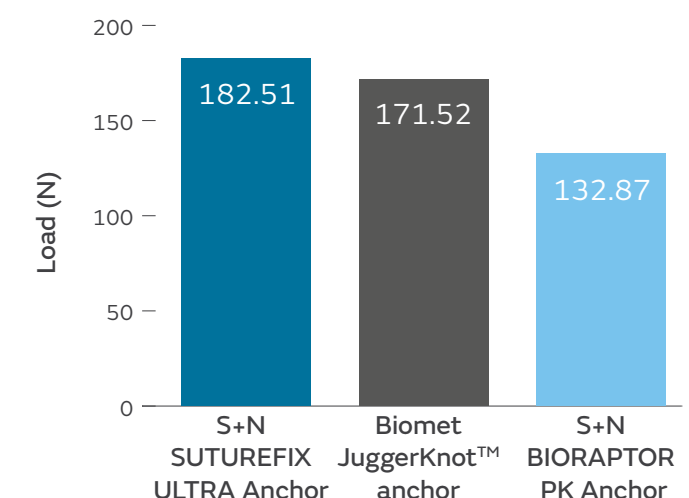


Figure 2. Ultimate load-to-failure (N)

Conclusion

The active deployment feature in SUTUREFIX Anchors (and second-generation ASAs) results in superior biomechanical properties compared with first-generation ASAs. It also appears to effectively address concerns about decreased load-to-failure observed in first-generation ASAs.



Curved-guide system is useful in achieving optimized trajectory for the most inferior suture anchor during arthroscopic Bankart repair

Liu T, Yamamoto N, Shinagawa K, Hatta T, Itoi E. *JSES*. 2019;28(9):1692–1698.

Overview

A cohort study (n=41) to compare the trajectory and position of the low anteroinferior suture anchor when using a curved-guide system (OSTEORAPTOR[®] Curved Suture Anchor) versus a conventional straight guide (GRYPHON[™] anchor; DePuy Mitek, USA) during arthroscopic Bankart repair

Results

Compared with GRYPHON[™] anchors with a convention straight guide (n=9), OSTEORAPTOR Anchors inserted with a curved guide (n=32) demonstrated:

- Significantly lower rate of opposite-cortex perforation, 11 versus 56% (1 in 9 cases and 18 in 32 cases respectively; $p=0.02$)
- Significantly shorter insertion distance ($4.0 \pm 1.6\text{mm}$ vs $7.0 \pm 2.4\text{mm}$; $p<0.01$; Figure 1)
- A higher percentage of anchors in the absolute safe zone (clock-face angle $>135^\circ$ and $<165^\circ$ and insertion angle $<100^\circ$; Figures 2 and 3)

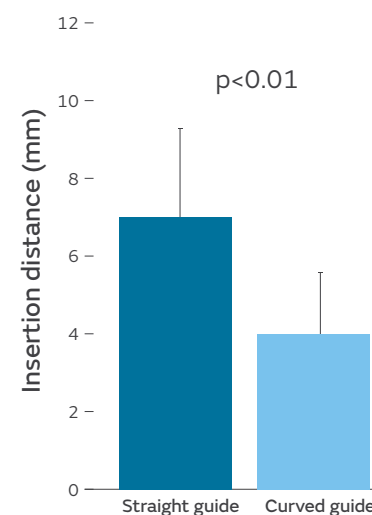


Figure 1. Comparison of anchor insertion distance (\pm standard deviation)

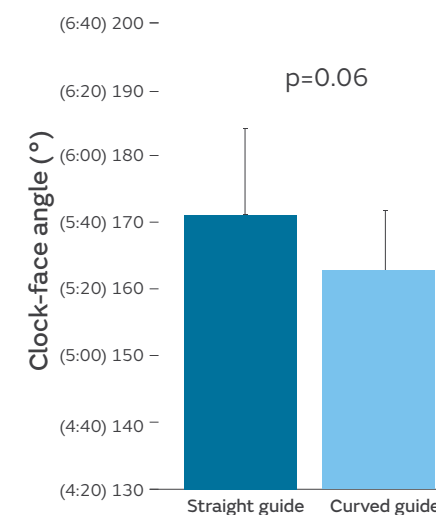


Figure 2. Comparison of clock-face angle (\pm standard deviation)

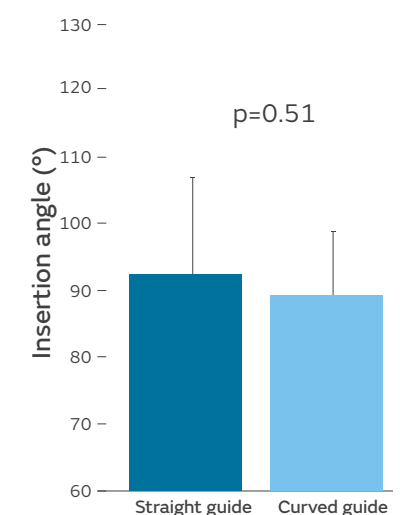


Figure 3: Comparison of insertion angle (\pm standard deviation)

Conclusion

Inserting anchors with a curved guide enables surgeons to position the most inferior anchor, during a Bankart repair, more accurately with reduced perforation risk compared to a conventional straight guide.



Assessment of Smith and Nephew Q-FIX[®] and curved SUTUREFIX[®] Anchors in arthroscopic allograft labral reconstruction of the hip

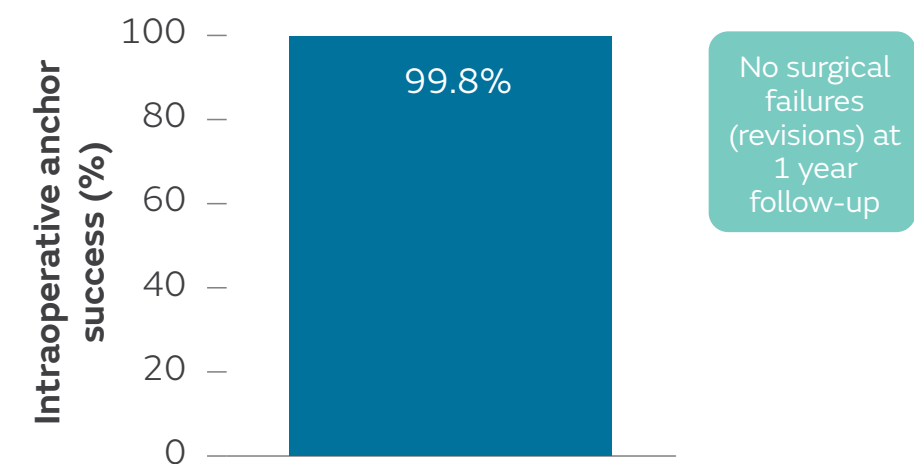
White, BJ. Poster presented at: ISHA; December 11–14 2021; Las Vegas, USA.

Overview

Retrospective case series (n=40) assessing the performance of Q-FIX 1.8mm Suture Anchor and SUTUREFIX CURVED 1.7mm Anchor in front-to-back circumferential labral reconstruction with frozen fascia lata allograft

Results

- Q-FIX and SUTUREFIX Anchors demonstrated a success (defined as anchor pull-out) rate of 99.8% (428/429; Figure)
 - Q-FIX Anchors: 1 failure
 - SUTUREFIX Anchors: 0 failures
- There were no surgical failures reported at 1-year follow-up (Figure)
- Patients reported improvements in LEFS, mHHS, and pain at 6 months compared to pre-operative levels:
 - Three-point improvement in LEFS
 - 21-point improvement in mHHS
 - Three-point improvement in pain (rest, ADL and sport)



Q-FIX and SUTUREFIX CURVED Anchors (n=429)

Figure. Percentage of Q-FIX and SUTUREFIX Anchors that did not result in intraoperative anchor pull out

Conclusion

Q-FIX and SUTUREFIX Anchors demonstrated minimal intraoperative failure, improved clinical outcomes at six months, and no surgical failures at one-year follow-up post-labral reconstruction.



Knot strength varies widely among expert arthroscopists

Hanypsiak BT, DeLong JM, Simmons L, Lowe W, Burkhart S. *Am J Sports Med.* 2014;42(8):1978–1984.

Overview

A controlled laboratory study to evaluate and compare variations in ultimate load-to-failure, 3mm displacement and knot stack height of arthroscopic suture knots tied by independent expert orthopaedic arthroscopists (n=73). Each surgeon tied five of the same type of their preferred arthroscopic knot and half-hitch locking mechanism

Results

- For an individual surgeon, the standard deviations of the five consecutive knots tied ranged from 6 to 133N
- For both ultimate and clinical load-to-failure:
 - the standard deviation for an individual surgeon was greater than 50N ($p < 0.001$)
 - surgeons with <10 years in practice were able to tie knots more consistently than surgeons with >10 years ($p = 0.018$ and $p = 0.005$ respectively; Figure 1)
 - there was no significant difference based on the number of annual cases performed by the surgeon ($p = \text{ns}$; Figure 2)
- Of the 365 knots tested, 30–40% (109–147) did not exceed the pull-out strength of the anchor

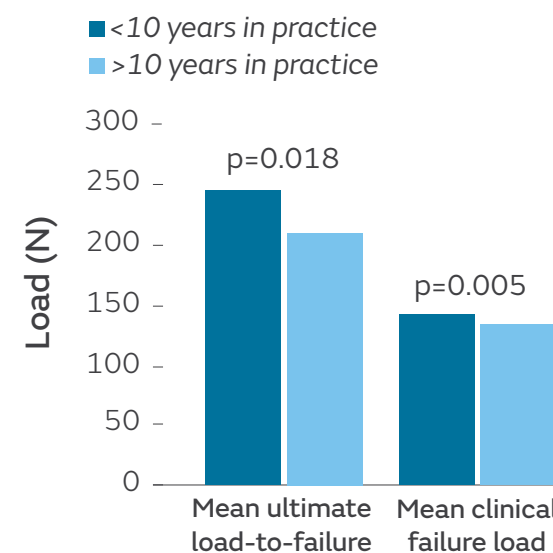


Figure 1. Ultimate load-to-failure results

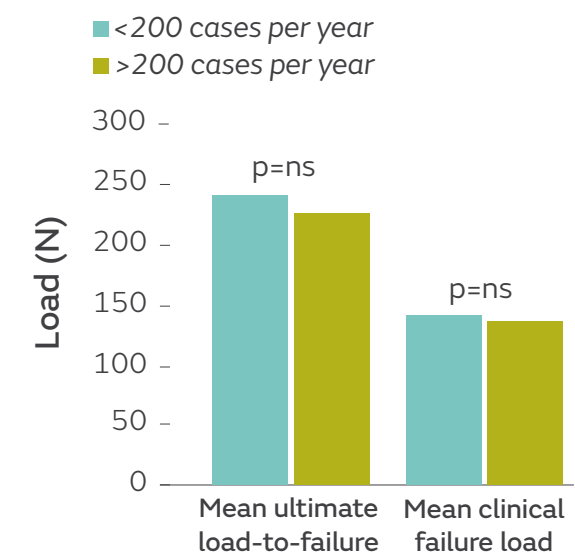


Figure 2. Clinical load-to-failure results

Conclusion

Clinicians could decrease the load variation by using a knotless construct with a similar pull-out strength to tied knots.



Movement-induced knot migration after anterior stabilization in the shoulder

Kim SH, Crater RB, Hargens AR. *Arthroscopy*. 2013;29(3):485–490.

Overview

A biomechanical study with human cadaveric shoulders (n=10) to assess the status and movement of suture knots following shoulder movement

Results

After shoulder motion:

- The length of the strand from the knot base to the anchor insertion site decreased significantly in all three locations (Figure)
 - Knots were displaced over 1mm toward the joint in every position, and the middle knot displacement was greatest, from $4.70 \pm 0.97\text{mm}$ to $3.07 \pm 0.81\text{mm}$ (Figure)
- The direction of 60% of the knots changed from facing the capsular side to pointing towards the glenoid (5/10 inferior knots; 7/10 middle knots; 6/10 superior knots)
- Loosening was also observed in the last half-hitches of 16.7% of all knots (4/10 inferior knots; 1/10 middle knots)

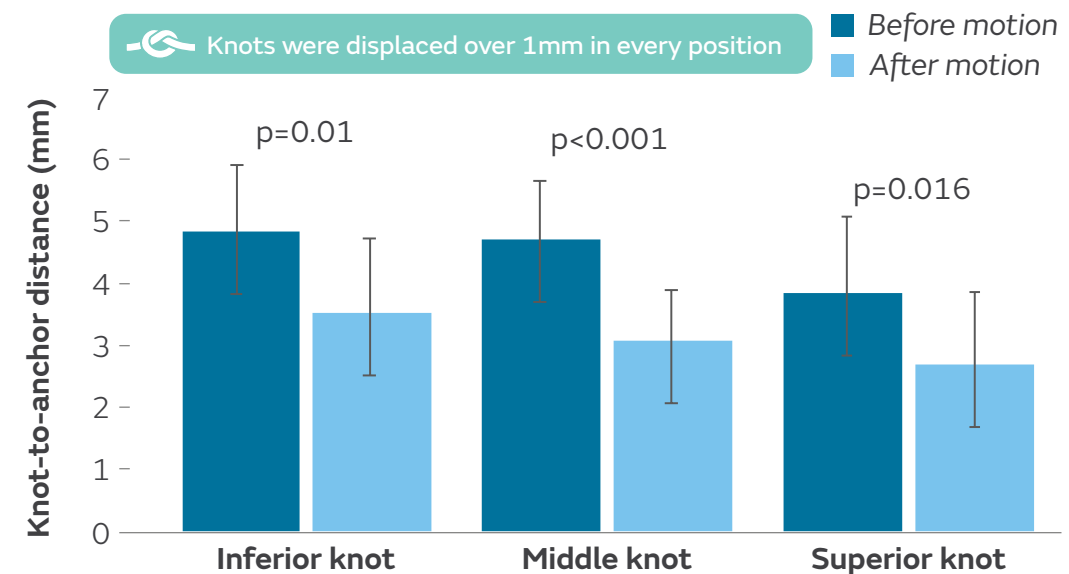


Figure. Knot-to-anchor distance change before and after motion (\pm standard deviation)

Conclusion

Shoulder movement causes significant migration of tied suture knots, posing a risk of cartilage damage. Knotless anchors may provide a potential solution to mitigate this problem.



Knotted versus knotless anchors for labral repair in the shoulder: a systematic review

Matache BA, Hurley ET, Kanakamedala AC, et al. *Arthroscopy*. 2021;37(4):1314–1321.

Overview



17 studies:
10 clinical
(overlapping cohorts)
9 biomechanical

561 patients



A systematic literature review and meta-analysis to compare biomechanical and clinical outcomes between knotless and knotted anchors in arthroscopic labral repair, specifically in Bankart repair, SLAP repair, posterior labral repair, and remplissage augmentation of Bankart repair

Results

- The clinical results show little to no differences in clinical and patient-reported outcomes between knotless and knotted anchors for labral repair in the shoulder, including Bankart repair, SLAP repair, and posterior labral repair (Figure)
 - No clinical studies looked at remplissage augmentation of Bankart repair



Bankart repair (n=295)

- No significant differences in Rowe, Constant and VAS scores and subsequent revisions (2/3 studies)
- One study showed improved VAS scores and lower recurrence and revision rates with the use of knotted anchors, but no significant difference in Rowe or Constant score
- Two studies found significantly lower operating times with knotless anchors; another study found lower surgical times that were not statistically significant



SLAP repair (n=266)

- No significant differences in return to play, ASES (4/4), VAS (3/3), and KJOC scores (1/1)
- Revision rates did not significantly differ (3/3)
- Knotless anchors outperformed knotted anchors in two studies in terms of shoulder ROM
- One study found a significant reduction in operative time with knotless anchors



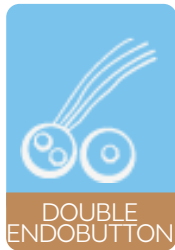
Posterior labral repair (n=295)

- No significant difference in any PROMs, including the ASES and VAS scores
- A significant reduction in operative time with knotless anchors

Figure. Results from clinical studies comparing knotless vs knotted anchors

Conclusion

Knotless anchors are a viable alternative to knotted anchors in arthroscopic shoulder surgery as there is no significant difference in outcomes between the two anchor types. One advantage with knotless anchors may be the potential to reduce operative time.



Cortical suture-button fixation for glenoid bone loss: a systematic literature review

Banffy M, Sedgwick M. Poster presented at: AANA; May 1–6, 2023; New Orleans, USA.

Overview

Systematic literature review of 10 studies (n=454) to evaluate the performance of DOUBLE ENDOBUTTON[®] Fixation Device in patients with anterior instability associated with glenoid bone loss

Results

- No subsequent subluxation or dislocation in 97.0% of patients (95% CI: 94–98%)
- No re-operation in 99.1% of patients (95% CI: 97.3–99.7%)
- No neurovascular or hardware complications in the shoulder
- Return to pre-injury level of sport in 82.1% of patients (95% CI: 69.2–90.4%; Figure)
- DOUBLE ENDOBUTTON Fixation Device was also associated with 'excellent' post-operative PROMs (Walch-Duplay and Rowe scores; Figure)

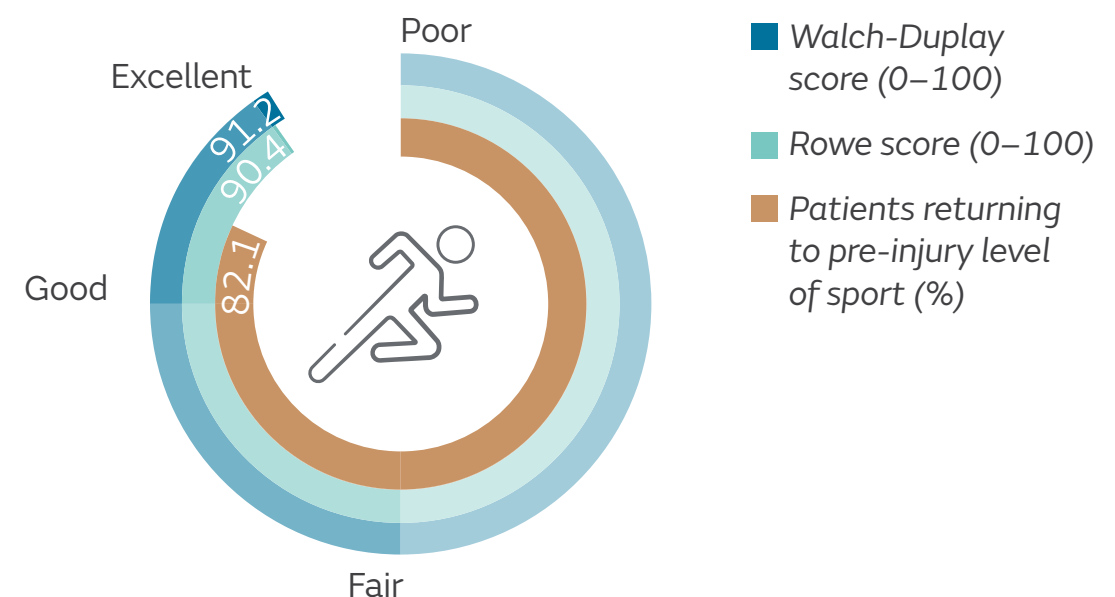
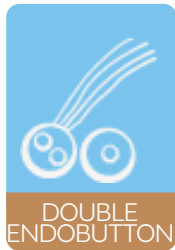


Figure. Return to pre-injury level of sport and PROMs Walch-Duplay and Rowe scores with DOUBLE ENDOBUTTON Fixation Device

Conclusion

The authors concluded that in patients with glenoid bone loss associated with anterior instability, the DOUBLE ENDOBUTTON Fixation Device demonstrated favourable clinical and patient-reported outcomes.



Arthroscopic Latarjet: suture-button fixation is a safe and reliable alternative to screw fixation

Boileau P, Saliken D, Gendre P, et al. *Arthroscopy*. 2019;35(4):1050–1061.

Overview

Single surgeon, prospective study (n=121) to assess clinical outcomes, complications, bone-block healing, and positioning with the DOUBLE ENDOBUTTON[®] Fixation Device at minimum 24 months following an arthroscopic Latarjet procedure

Results

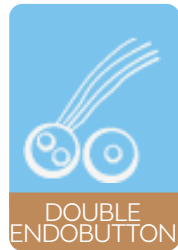
- No neurological complications, infections or hardware failures at last follow-up
- Revision rate of 2.5% at mean follow-up of 26 months
- In 95% of cases, the transferred coracoid process had healed to the scapular neck (115/121)
- Mean Rowe and Walch-Duplay scores were 'excellent' (90 and 91 respectively)
- 93% of patients (105/113) had returned to sport at last follow-up



Figure. Percentage of patients who were satisfied or very satisfied with their arthroscopic Latarjet procedure with the DOUBLE ENDOBUTTON Fixation Device (n=121)

Conclusion

The DOUBLE ENDOBUTTON Fixation Device demonstrated a low revision rate with no hardware complications and high levels of patient satisfaction.



Tensioning device increases coracoid bone block healing rates in arthroscopic Latarjet procedure with suture-button fixation

Boileau P, Gendre P, Saliken DJ, Thelu CE, Trojani C. *JSES*. 2022;31(7):1451–1462.

Overview

Prospective, single surgeon, non-randomised study (n=69) to compare clinical and PROMs between hand-tensioned and mechanically-tensioned suture-button constructs (DOUBLE ENDOBUTTON[®] Fixation Device) in coracoid bone block fixation using the arthroscopic Latarjet procedure

Results

Compared with the hand-tensioned group (n=34), the mechanically-tensioned group (n=35) demonstrated:

- Significantly higher bone block healing at 6 months (94 vs 74%; $p=0.043$; Figure)
- Fewer instances of traumatic recurrent shoulder instability episodes at last follow-up (1/35 [2.3%] vs 3/34 [8.8%])

Overall, no neurologic complications, infections, or hardware failures were recorded in either group

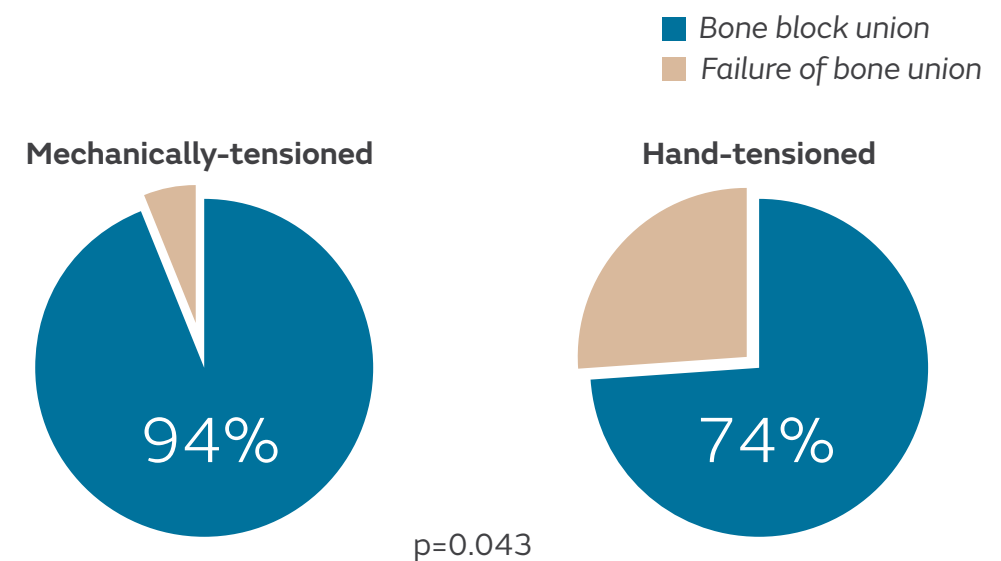


Figure. Percentage of bone block union mechanical-tensioning with the DOUBLE ENDOBUTTON Fixation Device compared with hand-tensioning

Conclusion

Compared with hand tensioning, mechanical tensioning significantly improves healing rates in arthroscopic Latarjet procedures with suture-button fixation.



Biomechanical evaluation of suture buttons versus cortical screws in the Latarjet-Bristow procedure: a fresh-frozen cadavers study

Kazum E, Chechik O, Pritsch T, et al. *Arch Orthop Trauma Surg.* 2019;139(12):1779–1783.

Overview

Biomechanical study comparing the performance of the DOUBLE ENDOBUTTON[®] Fixation Device and two cannulated screws (DePuy Synthes, Raynham, MA, USA) in coracoid fixation using the Bristol Latarjet procedure (n=9)

Results

- No significant difference in the biomechanical properties of DOUBLE ENDOBUTTON Fixation Device and screw fixation (Figures 1 and 2)
- All screw-fixed constructs (4/4) failed due to graft failure through the proximal or distal drill hole
- Failure of the DOUBLE ENDOBUTTON Fixation Device constructs were due to glenoid bone fracture (4/5) or failure at the clamp-muscle interface (1/5)

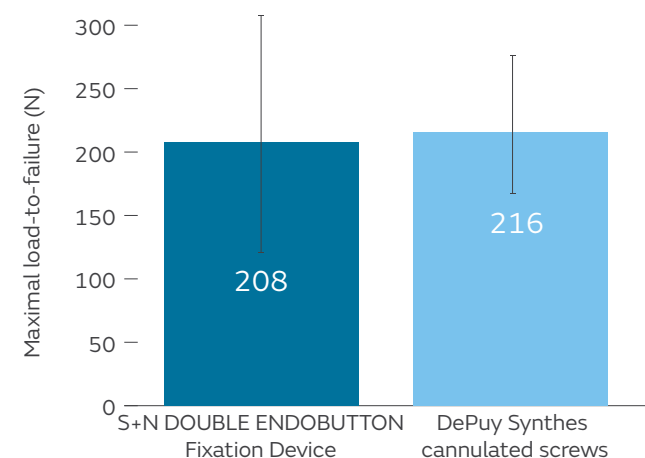


Figure 1. Average maximal load-to-failure (\pm standard deviation)

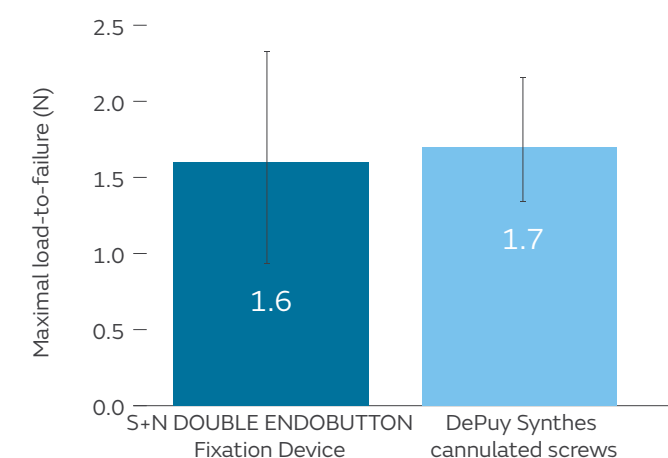
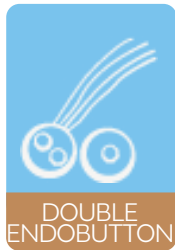


Figure 2. Average stress at maximal load (\pm standard deviation)

Conclusion

Coracoid fixation with one DOUBLE ENDOBUTTON Fixation Device in the Bristow Latarjet procedure is biomechanically comparable to fixation with two cannulated screws and presents a lower risk of graft fracture*.

*Study results should be extrapolated carefully due to the limitations of the study design, including ex-vivo only, small sample size and no measurement of coracoid dislocation after cyclic loading.



A new mini-open technique of arthroscopically assisted Latarjet

Taverna E, Longo UG, Guarrella V, et al. *BMC Musculoskelet Disord.* 2020;21(1):285.

Overview

Retrospective, consecutive case series (n=60) assessing clinical and radiological findings following an arthroscopically assisted Latarjet procedure with DOUBLE ENDOBUTTON[®] Fixation Device to treat glenoid bone loss and anterior instability of the shoulder

Results

- At 1-year follow-up CT scan, flush graft placement was achieved in 98.3% (59/60) cases
- At last follow-up (mean: 32.5 months):
 - no revisions were reported
 - 3.3% recurrence rate was reported
 - there were no neurological complications or infections
 - 94.1% patients were satisfied with the surgery
 - 'excellent' PROMs (mean Walch-Duplay, Rowe and SSV scores 92.4, 93.6 and 88.1 respectively)
 - 82.1% (23/28) patients returned to sport at pre-injury level (Figure)

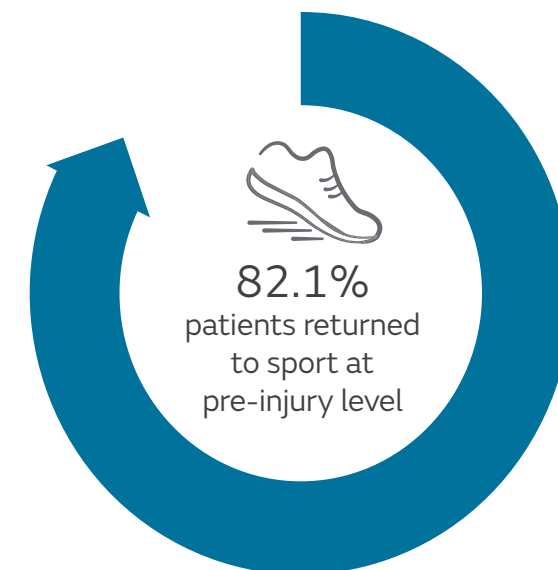


Figure. Percentage of patients that returned to sport at pre-injury level post-surgery (n=23/28)

Conclusion

An arthroscopically assisted Latarjet with DOUBLE ENDOBUTTON Fixation Device resulted in a low recurrence rate, high patient satisfaction, PROMs and return to sport, as well as accurate graft placement.

References

1. Douglass NP, Behn AW, Safran MR. Cyclic and load to failure properties of all-suture anchors in synthetic acetabular and glenoid cancellous bone. *Arthroscopy*. 2017;33:977–985.
2. Ruder JA, Dickinson EY, Peindl RD, et al. Cyclic and load-to-failure properties of all-suture anchors in human cadaveric shoulder glenoid bone. *Arthroscopy*. 2019;35(7):1954–1959.
3. Byrd JWT, Jones KS, Loring CL, Sparks SL. Acetabular all-suture anchor for labral repair: incidence of intraoperative failure due to pullout. *Arthroscopy*. 2018;34(4):1213–1216.
4. Ergün S, Akgün U, Barber FA, Karahan M. The Clinical and biomechanical performance of all-suture anchors: a systematic review. *Arthroscopy*. 2020;2(3):e263–e273.
5. Erikson J, Chiarappa F, Haskel J, et al. Biomechanical comparison of a first- and a second-generation all-soft suture glenoid anchor. *Orthop J Sports Med*. 2017;5(7):2325967117717010.
6. Liu T, Yamamoto N, Shinagawa K, Hatta T, Itoi E. Curved-guide system is useful in achieving optimized trajectory for the most inferior suture anchor during arthroscopic Bankart repair. *JSES*. 2019;28(9):1692–1698.
7. White, BJ. Assessment of Smith and Nephew Q-FIX and curved SUTUREFIX Anchors in arthroscopic allograft labral reconstruction of the hip. Poster presented at: International Society for Hip Arthroplasty; December 11–14, 2021; Las Vegas, US.
8. Hanypsiak BT, DeLong JM, Simmons L, Lowe W, Burkhart S. Knot strength varies widely among expert arthroscopists. *Am J Sports Med*. 2014;42(8):1978–1984.
9. Kim SH, Crater RB, Hargens AR. Movement-induced knot migration after anterior stabilization in the shoulder. *Arthroscopy*. 2013;29(3):485–490.
10. Matache BA, Hurley ET, Kanakamedala AC, et al. Knotted versus knotless anchors for labral repair in the shoulder: a systematic review. *Arthroscopy*. 2021;37(4):1314–1321.
11. Banffy M, Sedgwick M. Cortical suture-button fixation for glenoid bone loss: a systematic literature review. Poster presented at: Arthroscopy Association of North America (AANA); May 1–6, 2023; New Orleans, USA.
12. Boileau P, Saliken D, Gendre P, et al. Arthroscopic Latarjet: suture-button fixation is a safe and reliable alternative to screw fixation. *Arthroscopy*. 2019;35:1050–1061.
13. Boileau P, Gendre P, Saliken DJ, Thelu CE, Trojani C. Tensioning device increases coracoid bone block healing rates in arthroscopic Latarjet procedure with suture-button fixation. *JSES*. 2022;31:1451–1462.
14. Kazum E, Chechik O, Pritsch T, et al. Biomechanical evaluation of suture buttons versus cortical screws in the Latarjet–Bristow procedure: a fresh-frozen cadavers study. *Arch Orthop Trauma Surg*. 2019;139(12):1779–1783.
15. Taverna E, Longo UG, Guarrella V, et al. A new mini-open technique of arthroscopically assisted Latarjet. *BMC Musculoskelet Disord*. 2020;21:285.
16. Data on file. Smith+Nephew 2019. Internal report. 15008464.
17. Data on file. Smith+Nephew 2019. Internal report. 15008252 Rev A.
18. Arai E, Nakashima H, Tsukushi S, et al. Regenerating the fibula with beta-tricalcium phosphate minimizes morbidity after fibula resection. *Clin Orthop Relat Res*. 2005:233–237.
19. Chu C-C. Biodegradable polymeric biomaterials: an updated overview. In: Bronzino JD, ed. *The biomedical engineering handbook*. CRC Press; 1995:Section IV:44.
20. Calori GM, Mazza E, Colombo M, Ripamonti C. The use of bone-graft substitutes in large bone defects: any specific needs? *Injury*. 2011;42(SUPP 2):S56–S63.
21. Costantino PD, Friedman CD. Synthetic bone graft substitutes. *Otolaryngol Clin North Am*. 1994;27:1037–1074.
22. Gaasbeek RD, Toonen HG, van Heerwaarden RJ, Buma P. Mechanism of bone incorporation of beta-TCP bone substitute in open wedge tibial osteotomy in patients. *Biomaterials*. 2005;26:6713–6719.
23. Park K, Skidmore S, Hadar J, et al. Injectable, long-acting PLGA formulations: Analyzing PLGA and understanding microparticle formation. *J Control Release*. 2019;304:125–134.
24. Walsh WR, Morberg P, Yu Y, et al. Response of a calcium sulfate bone graft substitute in a confined cancellous defect. *Clin Orthop Relat Res*. 2003:228–236.
25. Ogose A, Hotta T, Kawashima H, et al. Comparison of hydroxyapatite and beta tricalcium phosphate as bone substitutes after excision of bone tumors. *J Biomed Mater Res B Appl Biomater*. 2005;72(1):94–101.
26. Data on file. Smith+Nephew 2010. Internal report. WRP-TE045-700-08.
27. Data on file. Smith+Nephew 2016. Internal report. NCS248.
28. Vonhoegen J, John D, Hägermann C. Osteoconductive resorption characteristics of a novel biocomposite suture anchor material in rotator cuff repair. *J Orthop Surg Res*. 2019;14:12.

Abbreviations

ADL	activities of daily living
AANA	Arthroscopy Association of North America
ASA	all-suture anchor
ASES	American Shoulder and Elbow Surgeons
ISHA	International Society for Hip Arthroscopy
KJOC	Kerlan-Jobe Orthopaedic Clinic score
LEFS	Lower Extremity Functional Scale
mHHS	Modified Harris Hip Score
N	Newton
pcf	per cubic foot
PROM	patient-reported outcome measure
Rowe score	poor 0 to 50 points; fair 51 to 74 points; good 75 to 89 points; excellent 90 to 100 points
SD	standard deviation

SLAP	Superior Labrum Anterior and Posterior
SSV	subjective shoulder value (0–100%)
Walch-Duplay score	poor 50 points or less; medium 51 to 75 points; good 76 to 90 points; excellent 91 to 100 points
VAS	Visual Analogue Scale
USA	United States of America

This material is intended for healthcare professionals. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

Smith & Nephew Pty Ltd
Australia
T +61 2 9857 3999
F +61 2 9857 3900
smith-nephew.com/en-au

Smith & Nephew Ltd
New Zealand
T +64 9 820 2840
F +64 9 820 2841
smith-nephew.com/en-nz

°Trademark of Smith+Nephew
All trademarks acknowledged
© May 2024 Smith+Nephew
40106-anz V1 05/24

**Developed by Evidence Communications,
Global Clinical & Medical Affairs**

Smith+Nephew